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Commercial Advertising of Alcohol: Using Law to Challenge Public Health Regulation

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ABSTRACT (ENGLISH)

In most countries, the alcohol industry enjoys considerable freedom to market its products. Where government regulation is proposed or enacted, the alcohol industry has often deployed legal arguments and used legal forums to challenge regulation. Governments considering marketing regulation must be cognizant of relevant legal constraints and be prepared to defend their policies against industry legal challenges.

FULL TEXT

1. Introduction

The marketing of alcoholic beverages is pervasive and problematic, yet few countries have adequately responded to this significant public health issue. Using digital media, more channels are available than ever before for the marketing of alcohol. This proliferation of alcohol promotion has occurred at the same time as knowledge has grown about the harms of alcohol consumption and the role that exposure to alcohol marketing plays in the occurrence of such harm, especially amongst young people.[1] Alcohol is commonly among the top 10 risk factors for ill-health or early death.[2] The level of harm attributable to alcohol approximately doubles when alcohol's harm to others (such as through family violence) is taken into account.[3]

The marketing of alcohol has become increasingly globalized. According to the market research firm Euromonitor, the top ten transnational alcohol corporations (TNACs) in global alcohol sales revenue sold over one-third (35.5%) of commercial alcoholic beverages in 2019, with the global market being most concentrated for beer (64.5%) and least for wine (13.8%).[4] With TNACs, an international team, combining cosmopolitan marketing expertise with knowledge of specific target cultures, often manages the promotion of an alcohol brand, in accordance with a global positioning strategy.[5]

In the face of this evidence, the World Health Organization has repeatedly called for controls on alcohol marketing to protect minors and other at-risk groups. In 2010, the WHO Global Strategy to Reduce the Harmful Use of Alcohol expressed "serious concern" about the prevalence of alcohol marketing and its impacts on young people.[6] Restrictions on alcohol marketing have been recognized by the WHO as one of the three most effective interventions for reducing alcohol-related risks.[7] In May 2022, the WHO member states, meeting as the World Health Assembly, approved an alcohol action plan for 2022–2030 which calls on member states to implement "comprehensive and robust restrictions or bans across multiple types of media."[8] The action plan also calls on relevant economic actors, such as alcohol producers, importers, and retailers, to "take concrete steps towards eliminating the marketing and advertising of alcoholic products to minors…",[9] while avoiding "the targeting of new consumer groups with alcohol marketing, advertising and promotional activities…".[10]

Our analysis reveals that industry has made use of international and domestic law in its arguments, and although rights-based arguments (human rights or constitutional rights) have been prominent, a range of areas of law have been utilised by the industry in its efforts to defeat the making or application of alcohol marketing regulation. Our

analysis also shows that legal arguments have been used against particular features of alcohol marketing regulation: restrictions on “truthful” marketing (eg, the price of the product), health claims, no or low alcohol advertising, and “lifestyle” advertising; comprehensive advertising bans; and cross-border marketing regulation.

Acting to reduce the prevalence of alcohol marketing is no small undertaking for governments. It requires regulatory astuteness, given the creativity and resources of the industry in the production of new forms of marketing. It also demands strong political commitment, in the face of certain opposition from the alcohol, media and other interested industries.[11] Legal capacity is also essential as it is not uncommon for the industry to use legal arguments and legal forums, including litigation, to oppose public health measures around alcohol that are not to the industry’s liking. This is a strategy which has been used extensively in respect of other public health regulation, including tobacco control.[12] It is, of course, important that governments act lawfully in carrying out their public health functions. However, supervising government exercises of power in the public interest is arguably not the purpose of industry litigation and legal claims against public health policy. Rather, industry is pursuing its private interests and using law as just one more tool to achieve its commercial goals. In fact, there are instances, where unmeritorious legal arguments and threats of litigation have been made against government regulation, including against the government alcohol warning label scheme in the Yukon Territories.[13] Such threats can nonetheless be a powerful influence in the policy-making process, potentially making regulators less keen to tackle the public health problem for fear that litigation, with all its attendant costs and difficulties, may ensue.[14] One of the issues is that it is always difficult to know the extent of the use of legal claims to oppose public health regulation. However, where arguments are ventilated in open legal forums, it is possible to gain some greater insight into the industry’s concerns about public health regulation and the way in which industry leverages law to resist regulation.[15]

In this article, we examine case studies from several jurisdictions where the alcohol industry has openly used law to oppose controls on alcohol marketing (Part 5). Our analysis reveals that industry has made use of international and domestic law in its arguments, and although rights-based arguments (human rights or constitutional rights) have been prominent, a range of areas of law have been utilized by the industry in its efforts to defeat the making or application of alcohol marketing regulation. Our analysis also shows that legal arguments have been used against particular features of alcohol marketing regulation: restrictions on “truthful” marketing (eg, the price of the product), health claims, no or low alcohol advertising, and “lifestyle” advertising; comprehensive advertising bans; and cross-border marketing regulation. This article places this analysis in the current context in which alcohol marketing is occurring: the marketing techniques deployed by industry interests (Part 2); the evidence of marketing’s connection to consumption and harm (Part 3); and current regulatory efforts to control alcohol marketing (Part 4). In the conclusion (Part 6), we discuss the implications for future alcohol marketing regulation.

2. Strategies for Marketing Alcohol

WHO’s Global Alcohol Strategy defines marketing as “any form of commercial communication or message that is designed to increase, or has the effect of increasing, the recognition, appeal and/or consumption of particular products and services.”[16] Traditional alcohol marketing strategies through “paid” media —such as television, radio, cinema, product placement in television and films, and print media —remain prominent and have been well-documented.[17] Sponsorships of sporting, cultural and community enterprises and individuals have long been used as marketing vehicles by the industry, providing a way to create a positive, emotional relationship between the brand and consumers.[18] Packaging and labelling of alcohol products also offer a valuable means to market the product to particular consumer segments, as they are “travel” with the product and are more visible to purchasers and consumers than any other form of marketing.

There has also been widespread uptake of the internet, and later social media, often serving to extend marketing campaigns beyond traditional media or to amplify the effect of such campaigns, for example, with sponsored events being live streamed on the internet. Social media influencer (SMI) and user-generated marketing are intrinsic to digital media.[19] The use of digital technologies has also increased the alcohol industry’s capacity to collect, store and analyze data, and has led to increasingly sophisticated and targeted alcohol marketing strategies.[20] This process of categorizing and targeting marketing is referred to as “market” or “customer” segmentation and generally involves

"segmentation" based on geographic, demographic, psychological and behavioral characteristics of sub-groups of consumers.[21] Heavy drinkers[22] and abstainers[23] (especially women[24] in new markets in low- and middle-income countries[25]) are important targets for personalized alcohol advertising. The prospect of creating these new cohorts of drinkers informs the development of new alcohol products (e.g., low calorie, and no-and low-alcohol beverages), as well as branding and promotional strategies.[26]

3. The Relationship between Alcohol Marketing, Consumption, and Harm

There is a strong evidence base suggesting that alcohol marketing exposure leads to immediate, short- and medium-term increases in alcohol consumption, particularly among adolescents.[27] For instance, Stautz and colleagues conducted a systematic review of studies concerning the impact of alcohol marketing exposure on immediate consumption, finding that viewing alcohol advertisements led to small, but significant, increases in immediate consumption.[28] Similarly, longitudinal studies examining the impact of marketing exposure on subsequent alcohol consumption have also reported significant positive associations.[29] Most of the research to date has focused on the impact of traditional marketing; however, emerging evidence regarding the impact of digital marketing also provides evidence of a significant positive association.[30] Despite evidence of a causal relation between alcohol marketing exposure and consumption, the reported effect sizes are often small.[31] A recent study examining the effect of a total ban on alcohol marketing implemented in Norway in 1975 found that the ban resulted in a 7.4% reduction in population-level consumption.[32]

Concern about alcohol marketing tends to focus on the position of minors, although they are not the only sub-group who are at particular risk from exposure to alcohol marketing. Another such group is heavy and dependent drinkers. A common research finding is that "alcohol-dependent patients report a stronger urge to drink alcohol when confronted with alcohol-related cues,"[33] such as alcohol marketing. Furthermore, the recent targeting of alcohol marketing to LMICs to build new markets raises concerns for health equity now and in the future. These countries currently have low prevalence of alcohol consumption and high abstention rates, but they also experience greater "harm per liter of alcohol" than high income countries.[34] Increased consumption resulting from increased exposure to alcohol marketing has the potential to escalate the harms already being disproportionately experienced in LMIC countries.[35]

4. Regulating Alcohol Marketing in the Public Interest

Many governments have controls on alcohol marketing, with the focus on the minimization of minors' exposure to alcohol industry marketing.[36] However, where national or subnational regulation exists, it is generally not very strong. Responses from 156 national reference points to the WHO's inquiry concerning the level of statutory regulation of alcohol marketing in 2016 found that, in half of the responses, the national level of regulation was slight (15%) or less than that (35%). The level of regulation was classified as "very" or "most" restrictive in just 24% of the national responses. In almost half the countries, there was no restriction at all on internet or social media marketing of beer.[37] A study of policies to reduce risk factors for non-communicable diseases in 151 countries found that restrictions on marketing for alcohol were among the weakest compared to restrictions for other NCD risk factors.[38]

The strong preference of industry interests, of course, is for industry self-regulation, particularly if it can take the place of an independent government regulator. Industry self-regulation of alcohol marketing is common at the international and domestic levels, despite its demonstrated ineffectiveness.[39] At the international level, the International Alliance for Responsible Drinking (IARD), with a primary membership of 12 TNACs, promotes commitments on such topics as limiting accessibility of marketing communications to children and promotion of "responsible drinking" messages.[40] At the national level, there may be self-regulation of marketing, operated by the industry or by other commercial interests, notably broadcasting companies. Or in many jurisdictions, there is a system of co-regulation, with both a government agency and representatives of the industry involved, although the former often plays a subsidiary role.[41]

Complete bans on alcohol advertising, other than in Muslim-majority countries where the sale of alcohol is also banned, have not been common. Lithuania and Norway are notable examples of complete bans. More often, there have been bans in a particular medium —for instance, television in France. Or there have been bans directed to

particular marketing content (such as advertising appealing to children)[42] or to particular times (such as bans on alcohol advertising on television until after 9.30pm) or places (such as bans on advertising on billboards near schools) at which marketing might appear. But such partial bans mean that the advertising budget for an alcohol brand is still intact and can simply be used in another medium or a different place or time. So, the effects of partial bans on alcohol consumption levels have tended to be minor,[43] as marketing shifts to the unregulated or under-regulated media.

5. Legal Strategies to Challenge Regulation of Alcohol Marketing

In this Part, we examine some examples of law being deployed against governments that have proposed to tighten their regulation of alcohol marketing or have enacted and applied regulation to alcohol advertising. We take case studies from the European Union, Lithuania, South Africa, Thailand, and the United States. These case studies are not exhaustive, but they demonstrate some of the major points of tension in alcohol marketing regulation. As would be expected, the industry opposes comprehensive bans on alcohol marketing, but it also resists bans on "truthful" marketing (such as about pricing), bans on health claims and no- and low-alcohol advertising, and bans on "lifestyle" advertising. Cross-border marketing regulation has also been a particularly vexing issue for the EU. These case studies reveal the capacity of the industry to source legal advice and representation to craft legal arguments, using a range of areas of law at the domestic and international levels, and to launch legal action to protect their interests.

A. Restrictions on "Truthful" Alcohol Advertising —United States

A complete prohibition on alcohol marketing means that consumers cannot be provided with any information about the product, except by way of the product itself and at point of sale. This form of regulation of alcohol marketing raises questions about whether at least "truthful" advertising should be allowed, such as information about the product name, type, volume, alcohol content, price, and source/country of origin. On the one hand, this information enables consumers to make informed choices about different products, but there is also an argument that this information drives harmful alcohol consumption. The banning of such information might further public health goals but sits uneasily in many legal systems where the control of consumer information is directed to protecting "rational" consumers and only ensuring they are not mislead or deceived in their purchasing decisions.

This issue has been litigated in the US. A ban on price was implemented by the Rhode Island authorities, and was subject to a constitutional challenge by the offending liquor store, 44 Liquormart. In the case of *Liquormart Inc v. Rhode Island* in 1996 ("*44 Liquormart*"),[44] the US Supreme Court found that a price ban infringed the First Amendment to the US Constitution which prohibits Congress from "abridging the freedom of speech". First Amendment protection had been extended to commercial speech in 1976 in *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council*.[45] In the *44 Liquormart case*, a liquor store had advertised alcohol, cigarettes, snacks and mixers. Specific prices were listed for all of the products, except the alcohol brands, which had the word "WOW" next to each of them. The regulator had fined 44 Liquormart $400.00 for breaching the ban on showing the price of alcohol products in its advertising.

In finding the ban to be unconstitutional, the US Supreme Court applied a more exacting standard of review —"intermediate scrutiny" —to the government's ban than it would to other forms of speech,[46] because the speech in question was "truthful" speech (ie, price information). The Supreme Court found against the ban on two bases:[47] (1) because the government did not provide sufficient evidence that the suppression of pricing information would reduce consumption;[48] and (2) there were a range of regulatory options besides a ban on speech that could have achieved the government's "temperance" goal but would have been less interfering with commercial speech, including setting taxes, limiting purchase amounts and education campaigns.

B. Restrictions on Health Claims —European Union

Related to the issue of "truthful" marketing is the use of health claims in alcohol advertising. Often these health claims appear on the product label and are repeated in the product marketing across multiple media. Information about the sugar, carbohydrate, caloric, gluten, animal content of a product is potentially useful to the consumer in their decision-making about whether to purchase or consume a particular brand. As with "truthful" marketing, health claims also raise a tension between the provision of accurate, useful information to consumers[49] *and* the way in

which this information might nonetheless drive consumption and harm. Most regulators resolve this tension by opting to stringently control the use of health claims in relation to alcohol, either prohibiting their use entirely or limiting the health claims which can be made (eg, allowing energy, carbohydrate and gluten claims only).[50]

Such a health claim was in issue in the *Deutches Weintor* case before the Court of Justice of the European Union (CJEU) in 2012. In that case, a wine label stated that the product was "easily digestible" followed by a statement about acidity levels. The relevant government authority in Rhineland-Palatinate claimed that this was a health claim, which are prohibited for alcohol products above 1.2% alcohol content under the relevant EU regulation.[51] The government authority's claim was contested by Deutches Weintor eG (the wine-growers' cooperative) and questions were referred to the CJEU about the interpretation and application of the regulation.

The CJEU found that the information that the wine was "easily digestible," followed by a statement about acidity levels, amounted to a "health claim" because it "implies the absence or reduction of effects that are adverse or harmful to health and which would otherwise accompany or follow such consumption."[52] The prohibition on such health claims were also found to be compatible with the fundamental rights found in the Lisbon Treaty of 2009 and the European Charter of Fundamental Rights, in particular the high level of protection given to human health in the EU Charter. The CJEU emphasized the "risks of addiction and abuse as well as the complex harmful effects known to be linked to the consumption of alcohol."[53] The freedom to choose an occupation and the freedom to conduct a business were found to be restricted by the prohibition on health claims, but the restrictions were directed to achieving the health objective and were not a disproportionate interference with those rights. The CJEU also found that those rights were maintained by the fact that alcohol was still able to be produced and marketed through other means.

C. Restrictions on "Lifestyle" Advertising —Thailand

Many jurisdictions have restrictions on "lifestyle" advertising. "Lifestyle" advertising is where the producer uses words, images, and other strong aesthetic design features to make connections between the product and consumers' ideas about their actual (or more often, desired) lifestyle.[54] The use of imagery of attractive people enjoying positive occasions involving alcohol are common forms of lifestyle marketing. Popular actors, sports people and other celebrities often feature in lifestyle advertising. Lifestyle advertising can operate in a subtle manner and speak to consumers' unconscious or unarticulated desires about the "good life." Most jurisdictions regulate lifestyle advertising in some manner, often through prohibitions on alcohol being marketed in connection with high-risk activities such as driving or watersports, and on claims that the consumption of alcohol brings about social, sexual, financial, professional or sporting success.[55] The industry is often able to creatively navigate its way around such restrictions on "lifestyle" advertising, but will strongly resist any attempts to completely disable its use of this highly effective form of marketing.[56]

Such industry opposition was seen in respect of Thailand's 2015 ban on certain forms of "lifestyle" marketing on the product label. The ban has a broad ambit and includes prohibitions on label promotions that use pictures of athletes, singers, movie stars or actors; that use cartoons; or that link alcohol and activities such as music, sports, contests or recreation. The ban aroused considerable opposition in the World Trade Organization Committee on Technical Barriers to Trade (TBT Committee).[57] In the Committee, member states repeatedly argued that the Thai law infringed various WTO rules, including intellectual property protections and rules prohibiting unnecessary barriers to international trade.[58] The Thai ban has not been subject to formal dispute settlement in the WTO, and Thailand has managed to resist demands in the TBT Committee for the law to be repealed. However, the pressure brought to bear in the WTO TBT Committee has resulted in some softening of the interpretation and application of the law by Thailand.[59]

D. Comprehensive Bans —South Africa

As discussed above, comprehensive bans on alcohol marketing are relatively uncommon. However, in 2013, South Africa released a new proposal for the regulation of alcohol marketing, which if it had passed, would have been one of the most comprehensive bans on alcohol marketing in the world. South Africa proposed the banning of all alcohol marketing (except for price information at point of sale), alcohol sponsorships and all gifts, competitions and

associated strategies used by alcohol companies.[60] The law has never been passed. It seems that the industry lobbied extensively against the proposal,[61] including arguing that the regulations would breach human rights by impairing rights to free expression for producers and consumers, to engage in trade and commerce, and to be treated with dignity.[62] Although international human rights law does not recognize corporations or non-natural persons to be rights-holders, the Constitution of South Africa includes a bill of rights which is extended to non-natural persons. South Africa's bill of rights has been used in the past to argue (unsuccessfully) against a ban on tobacco advertising of a similar scope to South Africa's proposed ban on alcohol advertising.[63]

In respect of the claim about freedom of expression, Bertscher, London and Röhrs argue that, drawing on the jurisprudence relating to the right as found in Article 19 of the *International Covenant on Civil and Political Rights*,[64] the proposed South African alcohol advertising law would not have violated human rights law standards. The right to free expression is clearly engaged by restrictions on alcohol marketing, which limit both a producer's right to convey information to consumers and a consumer's right to receive information about the product. However, under both international law and the South African Constitution, rights may be limited as provided by law and as necessary for a circumscribed set of purposes, such as the protection of national security or of public order (*ordre public*), or of public health or morals.[65] A strict necessity and proportionality test is applied to restrictions on the right to free expression, meaning that laws which affect free speech must be tightly drafted and must represent the least restrictive means of achieving the goal in question,[66] including where the law in question is enacted in pursuit of the realization of another human right, such as the right to health in the case of alcohol marketing.[67] As with the analysis in the US constitutional context (see above Part 5a), the compatibility of alcohol marketing restrictions with human rights will turn on (i) the extent of the contribution that the marketing restrictions make to fulfilment of the public health goal of reducing alcohol-related consumption; and (ii) the availability of any less restrictive measures. Compared to tobacco,[68] these two issues may be more difficult, but not impossible, for a government to argue in respect of alcohol, given that there is not the strongest evidence of the impacts of marketing restrictions on consumption (see above Part 4) and given that many jurisdictions have not introduced other interventions to reduce alcohol consumption.

E. Restrictions on Advertising Non-Alcoholic Beverages —Lithuania

An issue which has recently emerged is whether restrictions on alcohol marketing should apply to the marketing of non-alcoholic beverages. As discussed above, there has been a proliferation of no and low alcohol beverages into many markets. "Surrogate marketing" is common with respect to no- and low-alcohol beverages —they are generally packaged and labelled in the same livery as the alcoholic version of the product, and the marketing often adopts the same designs, colors, symbols for both products.[69] It has been argued that the packaging, labelling and marketing of non-alcoholic beverages in the same manner as alcoholic beverages serves to indirectly advertise the company's alcoholic products, with companies using the non-alcoholic beverages to evade restrictions which apply to the marketing of alcoholic beverages.[70] However, there is still work to be done to fully understand how consumers perceive and use no and low-alcohol products.[71]

The issue of how to regulate no-alcohol products has been agitated in Lithuania in two recent cases. The issue arises in the context of Lithuania having banned alcohol advertising since 2018.[72] In 2021, the Supreme Administrative Court of Lithuania upheld a decision of the Department of Drug, Tobacco and Alcohol Control that Vilnius Degtine had breached the ban on alcohol advertising by the company's marketing of its product, "epkeli" non-alcoholic cranberry soft drink. The breach arose from the company's actions in placing a product on the market with a trademark and design which was essentially identical to those used for its alcoholic bitters, and by including that trademark and design in advertising on billboards and on internet sites.[73]

However, in January 2022, the court seemed to change its position on no-alcohol marketing. The Supreme Administrative Court of Lithuania quashed a finding of the Department of Drug, Tobacco and Alcohol Control that the company, Švyturys-Utenos alus, had breached the prohibition on alcohol advertising through the company's promotion of its non-alcoholic beers, Utenos and Kronenbourg 1664.[74] The appearance of the non-alcoholic beers was essentially identical to that of the company's alcoholic beers, with the only difference being the inclusion of the

words “non-alcoholic” on the label in several places. The Supreme Court rejected the argument that the advertising of the non-alcoholic beer intended to, or did, in fact, promote the alcoholic beer. The court placed emphasis on the absence of any evidence that consumers associate or confuse non-alcoholic beverages with alcoholic beverages. There was considerable concern expressed by the court about overreach in the interpretation of the alcohol advertising prohibition, in a situation where no laws have been expressly enacted to control branding and marketing of non-alcoholic products.

F. Cross-Border Alcohol Marketing —European Union (Sweden)

The regulation of cross-border marketing (ie, marketing that is created or published in one country and that reaches audiences in another country) can be legally complex and these complexities have, on occasion, been exploited by the alcohol industry. Particular difficulties with regulating cross-border alcohol marketing have arisen in the EU context, with the application of the EU internal market law and the state of establishment principle.[75]

Sweden has encountered problems at times with both legal requirements,[76] as it has attempted for many years to place extensive restrictions on alcohol marketing.[77] In 2001, its ban on alcohol advertising in periodicals was found to “have a potential and indirect influence upon the free movement of goods and/or services”[78] and was therefore caught by the Treaty for the Functioning of the European Union and required justification.[79] The question of whether the ban was justified on public health grounds was decided by the Swedish courts which found that the ban was disproportionate and therefore unjustified.[80]

More recently, Sweden’s regulation of alcohol marketing on television has fallen foul of the state of establishment principle because of the existence of the EU’s Audiovisual Media Services Directive (“the Directive”) which sets basic standards for the regulation of alcohol marketing in audiovisual media in the EU.[81] Members are obliged to ensure “freedom of reception and shall not restrict retransmissions on their territory of audiovisual media services” from other EU members “for reasons which fall within the scope of [the] Directive” (Art 3.1). The state of establishment rule prevented Sweden from applying its stricter rules on alcohol marketing to two broadcasters who had established themselves in the United Kingdom, starting in 1987, and who broadcast in Swedish to Sweden in a manner that was inconsistent with Sweden’s alcohol advertising rules. Sweden notified the European Commission to take measures against the two broadcasters under Swedish law. In 2018, the European Commission ruled that Sweden “could not derogate from the State of Establishment principle and rejected the claim that the broadcasters had established themselves in the United Kingdom in order to circumvent the stricter Swedish alcohol advertising rules.”[82] However, when the UK left the EU in 2020, the two broadcasters returned to Sweden and again became subject to the Swedish restrictions on alcohol advertising on TV.[83]

6. Conclusion

The alcohol industry is very resistant to increased regulation of its commercial activities and prefers that interventions to address harms from alcohol focus on the duty of individuals to “drink responsibly.” The industry has made some use of legal arguments and litigation to stymie new policy proposals for alcohol marketing regulation and to limit the impacts of regulation where it exists. As our study of several jurisdictions demonstrates, some of these attempts have been successful and some have not. However, the alcohol industry is certain to continue to explore ways in which to use law to protect its interests, especially if the current momentum for alcohol policy reform at the global level flows down to regional and national contexts.[84] This likelihood points to the need for governments to carefully evaluate the legality of policy measures that they are considering and pursue measures which have a sound basis in basis in law. At the same time, governments need to be cognisant that even legally sound measures may be subject to legal challenge as part of industry’s strategy to derail new policies. This may occur where there is genuine disagreement about the legality of the measure or where the legal claim by the industry is thin. In both scenarios, governments need to resource themselves with excellent legal advice to defend such challenges. The case studies in this article also show that a further critical requirement is a solid evidence base to be able to demonstrate the problem being addressed and the capacity of the contested measure to contribute to ameliorating the problem. Finally, even with all of these material resources at its disposal, governments needs to steel themselves and support each other against attacks on public health by the alcohol industry.

DETAILS

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INTRODUCTION Commercial Speech and the Commercial Determinants of Health

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ABSTRACT (ENGLISH)

This article introduces a symposium that aims to identify and critically assess the legal strategies of the tobacco, alcohol, and food and beverage industries which rest on freedom of expression arguments.

FULL TEXT

Non-communicable diseases (NCDs), including cardiovascular diseases, cancers, chronic respiratory diseases, and diabetes, have become one of the most pressing global health concerns of the 21st century, accounting for 71% of deaths worldwide.[1] While NCDs affect individuals of all ages, gender, and socioeconomic backgrounds, they disproportionately impact those living in developing countries, and in turn, the most vulnerable groups within those countries. For instance, every year, 15 million people between the ages of 30 and 69 die from NCDs, with 86% of these premature deaths occurring in developing countries.[2] In this sense, the rapid growth of NCDs also threatens sustainable development.

Many of these diseases are attributed to four main modifiable and preventable risk factors: tobacco use, harmful consumption of alcohol, unhealthy diets, and physical inactivity.[3] As the global burden of NCDs continues to rise, the imperative to protect public health by tackling these risk factors has been highlighted by international bodies including the World Health Organization[4] and the United Nations General Assembly.[5] This understanding has also been reinforced by the recognition that NCD prevention and control is a fundamental human rights issue, connected with the right to health and other health-related rights, such as the right to information.[6] Moreover, at the domestic level, many countries have enshrined analogous rights in their constitutions,[7] while also adopting more specific NCD-related laws and policies in their legal frameworks, including pricing measures, labeling and packaging measures, and marketing and advertising restrictions.[8]

Nevertheless, progress to tackle NCD risk factors has been slow overall. Tobacco, alcohol and unhealthy foods and beverages continue to be extensively advertised or otherwise promoted by corporate actors. Taking advantage of the globalization of markets, aggressive and sophisticated marketing has spread to every part of the world,

contributing to the rise of NCD illness and deaths in Africa, Asia, and Latin America, as well as in North America and Europe.[9] Across the world, these tactics are part of deliberate “strategies and approaches to promote products and choices that are detrimental to health,”[10] which in the past years have been defined and analyzed as the commercial determinants of health.[11]

Corporate actors use a wide range of marketing strategies to increase both the exposure of consumers to marketing messages and the power of these messages, increasingly integrated, immersive, and personalized.[12] In particular, the advent of digital technologies has facilitated the profiling of consumers, and corporate actors are increasingly relying on the extraction, processing, and use of personal data for marketing purposes, raising acute privacy as well as health concerns.[13] Moreover, in the context of the COVID-19 pandemic, the alcohol and the food and beverage industries, for example, have deployed marketing strategies which have been criticized as being unethical and incurring significant health implications.[14] Overall, the marketing of tobacco, alcohol, and unhealthy food and beverages negatively influences consumer preferences, purchase, and consumption patterns[15] and is therefore an integral part of NCD-promoting environments that States must address when seeking to reduce NCDs within their jurisdiction.

Reflecting on this context, this Special Issue on Commercial Speech and Commercial Determinants of Health aims to identify and critically assess the legal strategies of the tobacco, alcohol, and food and beverage industries which rest on freedom of expression arguments. This publication will provide the first international, multidisciplinary analysis of these arguments focusing on the relationship between, on the one hand, the right to free speech often invoked by corporate actors to protect their advertising and other marketing practices from regulation, and on the other, other competing rights that require protection from harmful marketing. By delving into those questions, this Special Issue examines this contentious relationship, seeking to provide insight into whether and to what extent marketing and advertising fall within the protection afforded to the right to free speech when balanced against other rights, not the least the right to health.

However, where States around the globe have sought to implement legal and policy measures to restrict or prohibit the marketing and advertising of tobacco, alcohol, and unhealthy food and beverages, corporate actors have developed a wide range of tactics to delay and defer the creation and implementation of such measures. The more robust and effective States regulatory measures are, the more States can expect to face the vigorous opposition of the corporate actors involved in the manufacture, distribution, and promotion of these products, services, and brands.[16] Historically, tactics deployed by these industries have included legal challenges against measures that could reduce their profit margins, such as litigation grounded on creative legal arguments centered on the right to free speech (or right to freedom of expression), interpreted broadly in many jurisdictions around the world to include advertising and other forms of commercial expression.[17]

Reflecting on this context, this Special Issue on Commercial Speech and Commercial Determinants of Health aims to identify and critically assess the legal strategies of the tobacco, alcohol, and food and beverage industries which rest on freedom of expression arguments. This publication will provide the first international, multidisciplinary analysis of these arguments focusing on the relationship between, on the one hand, the right to free speech often invoked by corporate actors to protect their advertising and other marketing practices from regulation, and on the other, other competing rights that require protection from harmful marketing. By delving into those questions, this Special Issue examines this contentious relationship, seeking to provide insight into whether and to what extent marketing and advertising fall within the protection afforded to the right to free speech when balanced against other rights, not the least the right to health.

The first section introduces readers to the political, philosophical, and economic considerations associated with marketing and advertising restrictions in the context of unhealthy food. In one article, the authors examine the conceptual foundations of the restrictions to commercial speech in relation to unhealthy food, exploring the liberal and communitarian perspectives. In another, the author reviews the main normative and positive arguments that can be used in the assessment of the costs and benefits of food marketing restrictions from an economic perspective.

The second section provides a deep-dive into two other specific risk factors —tobacco use and the harmful

consumption of alcohol —, examining the marketing and advertising tactics used by the relevant corporate actors involved in the promotion of these goods, services, and brands. In particular, these articles reflect on the international instruments significant to the regulation of the relevant industries, and on how these instruments have been implemented in different jurisdictions, considering the legal challenges associated with each NCD risk factor on the grounds of freedom of commercial speech.

Building on the first two sections, the third section reflects on the development in the case law of a number of established courts around the world and examines specifically how these courts have balanced the right to health and related rights with the right to free speech. Analyzing decisions made by courts in Colombia, the United States, Canada, Europe, India, and Europe, these articles provide insight into the definition and protection of commercial speech within their respective jurisdictions, the standards of review and evidence applied, and the margin of discretion granted to governments to prevent NCDs through the regulation of marketing and advertising practices.

Finally, the last section identifies a range of notable country case studies focused on key themes relating to the relationship between commercial speech and the commercial determinants of health, including Brazil, Chile, Barbados and Jamaica, France, and South Africa. These case studies provide a picture of the complexity of marketing regulation from a legal and policy perspective.

Overall, this Special Issue is meant to serve as a reference document for a multidisciplinary, international academic audience, as well as policymakers and other public health actors involved in the adoption and implementation of measures aimed to curb the rise of NCDs around the world. It provides a systematic understanding of a central debate around the role and capabilities of States in regulating the marketing and advertising of tobacco, alcohol and unhealthy food and beverages. Taken together, the articles of this Special Issue contribute to the understanding of marketing and advertisement from a rights-based perspective, providing insight into how jurisdictions around the world have —or are beginning to —address the tension between commercial speech and the commercial determinants of health.

In an upcoming issue, we will publish an article reflecting upon the key elements distilled from the various articles included in this Special Issue, providing a coherent framework on how to address the relationship between commercial speech, on the one hand, and the marketing and advertising restrictions of different unhealthy products, on the other hand, within different contexts around the world.

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Immigration Law, Public Health, and the Future of Public Charge Policymaking

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ABSTRACT (ENGLISH)

U.S. immigration law has excluded noncitizens likely to become a “public charge” since 1882. When the Trump administration proposed a new Rule expanding the interpretation of that exclusion in 2018, over 55,000 people wrote public comments. These comments, overwhelmingly opposed to the change, are the subject of Rachel Fabi and Lauren Zahn’s insightful article in this issue of *The Journal of Law, Medicine, and Ethics*. The themes they identify resonate with the history of the public charge exclusion, which has always reflected a tension between two aims of American governance — to provide for those in need of assistance, and to shape the nation’s citizenry according to ideals of self-sufficiency.

FULL TEXT

U.S. immigration law has excluded noncitizens likely to become a “public charge” since 1882.[1] When the Trump administration proposed a new Rule expanding the interpretation of that exclusion in 2018, over 55,000 people wrote public comments.[2] These comments, overwhelmingly opposed to the change, are the subject of Rachel Fabi and Lauren Zahn’s insightful article in this issue of *The Journal of Law, Medicine, and Ethics*.[3] The themes they identify resonate with the history of the public charge exclusion, which has always reflected a tension between two aims of American governance —to provide for those in need of assistance, and to shape the nation’s citizenry according to ideals of self-sufficiency.

Fabi and Zahn’s study also offers timely lessons for the Biden administration’s effort to square the public charge exclusion with public health policy. If finalized, the Biden administration’s proposed public charge rule would return the federal interpretation of “public charge” to a more moderate position, in line with that reached under President Clinton.[4] Because the Clinton administration never finished the notice-and-comment rulemaking process, Biden’s Rule, if promulgated, would mark the first legally binding definition of “public charge” by a Democratic administration.

The History of the Public Charge Exclusion

The purpose of all three rulemaking efforts —Clinton’s nonbinding guidance, Trump’s now-halted expansion, and Biden’s proposed return to the Clinton-era policy —has been to fill gaps in federal immigration law. The Immigration and Nationality Act does not define “public charge,” and Congress left few details on how to enforce the exclusion in individual cases. While there is general agreement that the term refers to someone reliant on public assistance, enforcing the exclusion has proven complicated in practice. As immigration increased in the early 1900s, immigration officers applied the exclusion inconsistently, and federal courts failed to cohere around a workable definition of “public charge.”[5] The phrase’s meaning warped further over the 20th century, as the federal government took a central role in addressing public welfare.[6] Is someone a “public charge” if they receive Social Security? Food Stamps? Medicaid? The language of the law predates the existence of these programs.

The function of the exclusion is to prevent certain noncitizens from entering the country or gaining lawful permanent residency. But since the 1990s, policymakers and advocates have increasingly identified another, indirect consequence —to dissuade noncitizens living in the U.S. from participating in public programs such as Medicaid.[7] Despite the fact that very few noncitizens eligible for federal benefits are subject to the exclusion, fear and confusion over losing their chance at lawful status lead many to forgo benefits to which they are lawfully entitled.[8] This “chilling effect” thus creates a conflict between the goals of immigration enforcement and the public policy aims of benefits programs.[9] Indeed, when the Trump administration proposed to consider participation in Medicaid and the Supplemental Nutrition Assistance Program, it was followed by a decrease in low-income child enrollment in those programs.[10]

Trump’s Rule was not the first time the public charge exclusion has weakened public health policy. Aggressive enforcement of the exclusion in the 1990s led public health officials, governors, and members of Congress to urge

the Clinton administration to clarify its stance on public charge.[11] In letters to the administration, they described how federal immigration agencies were interfering with public health aims by chilling participation in public benefits programs like Medicaid. This public pressure led to a years-long interagency negotiation, in which the Clinton White House brokered a compromise between the Immigration and Naturalization Service (DHS's predecessor) and the Department of Health and Human Services. The result was the nonbinding Interim Guidance document that set federal public charge policy until the Trump Rule went into effect in 2019.

In the long term, the public charge exclusion's incompatibility with public welfare policies warrants its repeal by Congress. But policymakers in the Biden administration face a more immediate challenge: crafting a notice-and-comment rule that can encourage the use of needed services *and* survive legal challenges. Navigating this process, in particular responding to public comments, will require thoughtful engagement with the themes identified by Fabi and Zahn —belonging, deservingness, justice, and compassion.

Public Comments in Federal Rulemaking

When federal law leaves gaps, such as how to define and enforce "public charge," the Administrative Procedure Act provides a pathway for agencies to fill them in: notice-and-comment rulemaking.[12] This process requires agencies to provide a meaningful opportunity for public comment on proposed rules, and to address those comments in final rules.[13] The effect of public comments in shaping final rules is debated by scholars.[14] Fabi and Zahn note that although more than 96% of comments to the 2018 proposed rule opposed it, the Rule went into effect without substantial change, and although DHS duly catalogued the commenter's objections as required by law, its responses were analytically inadequate.[15]

But, as Fabi and Zahn observe, public comments also serve a legal function. Comments become part of the administrative record, which is relevant for legal challenges to determine whether the agency's rule was properly considered.[16] Litigation against the 2019 Rule on this basis resulted in multiple federal courts blocking the rule.[17] Before the litigation could resolve however, the Biden administration took office and abandoned the Rule, as promised during Biden's campaign. In response, a group of states with Republican attorneys general sought to defend it. In February of 2022, the Supreme Court heard oral argument in *Arizona v. City and County of San Francisco*, on the question of whether the states may defend the 2019 Rule notwithstanding the Biden administration's refusal to defend it.[18] But the Court reversed course in June by dismissing the case without a decision.[19] As a consequence, the 1999 Guidance remains in effect as litigation on the 2019 Rule continues in the lower courts.

The Future of Public Charge

The outcome of the litigation may not ultimately matter to policymakers and immigrants, because a new rulemaking process is already underway. Days before the Court heard oral arguments in *Arizona*, DHS published a Notice of Proposed Rulemaking that contrasts starkly with its predecessor. It defines "public charge" as the Clinton Administration did, as someone "likely to become primarily dependent on the government for subsistence."[20] Although DHS likely could and should prohibit the consideration of all lawfully received public benefits in public charge determinations, the return to the 1999 Guidance's focus on "cash" benefits signals a re-prioritization of public health.[21]

In the long term, the public charge exclusion's incompatibility with public welfare policies warrants its repeal by Congress. But policymakers in the Biden administration face a more immediate challenge: crafting a notice-and-comment rule that can encourage the use of needed services *and* survive legal challenges. Navigating this process, in particular responding to public comments, will require thoughtful engagement with the themes identified by Fabi and Zahn —belonging, deservingness, justice, and compassion.

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Letter From The Editor

Hutchinson, Ted

FULL TEXT

In this issue, we continue the celebration around the *Journal of Law, Medicine &Ethics'* 50th anniversary with the publication of the symposium "Commercial Speech and Commercial Determinants of Health," guest-edited by Amandine Garde and Oscar A. Cabrera. In this collection, the editors make the case that while "states around the globe have sought to implement legal and policy measures to restrict or prohibit the marketing and advertising of tobacco, alcohol, and unhealthy food and beverages, corporate actors have developed a wide range of tactics to delay and defer the creation and implementation of such measures." In other words, the editors and their team of international authors, spanning a wide array of nations, nationalities, and backgrounds, explore the tensions between creating a healthy society and issues around freedom of expression and speech. The findings are fascinating. We hope our readers and members enjoy the collection, along with our usual independent articles, commentaries, columns, and a separate supplementary symposium, "Financing and Delivering Pre-Exposure Prophylaxis (PrEP) to End the HIV Epidemic," guest edited by Jeremiah Johnson, Amy Killelea, Derek T. Dangerfield II, Chris Beyrer, and Joshua M. Sharfstein. At the very least, we are satisfied we have given our readers enough to read for the next few months.

This anniversary also gives us a moment to reflect on some of the most important contributors to *JLME*'s history. In this letter we would like to take a moment to thank the many great scholars who have served as Editors-in-Chief of the *Journal*, a long and distinguished list that includes some of the finest minds in health law, medicine, and ethics. Our Editors-in-Chief over the last fifty years include George Annas, Edward Doudera, Miles Zaremski, Barry Furrow, Larry Gostin, Steven Miles, Karen Rothenberg, Ellen Wright Clayton, Bernard Lo, Kathleen Boozang, Sandra Johnson, Ana Iltis, Kevin Outerson, and our current EIC, the peerless Aaron Kesselheim. Each of our Editors-in-Chief share many traits, including intellectual curiosity, a desire to serve their academic field, and above all a deep commitment to publishing and disseminating important academic work. Their steady leadership has provided the *Journal* with a sense of direction and purpose over the last fifty years, as we continually use our publications as a tool to ask new questions of new scholars. *The Journal of Law, Medicine &Ethics* would not be the preeminent publication it is without the hard work and dedication of the many great Editors-in-Chief who have served for over half a century, and we thank each and everyone of them for their work, their service, and their commitment to making the world a little bit of a better place.

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United States: Protecting Commercial Speech under the First Amendment

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ABSTRACT (ENGLISH)

The First Amendment to the US Constitution protects commercial speech from government interference. Commercial speech has been defined by the US Supreme Court as speech that proposes a commercial transaction, such as marketing and labeling. Companies that produce products associated with public health harms, such as alcohol, tobacco, and food, thus have a constitutional right to market these products to consumers. This article will examine the evolution of US law related to the protection of commercial speech, often at the expense of public health. It will then identify outstanding questions related to the commercial speech doctrine and the few remaining avenues available in the United States to regulate commercial speech including the use of government speech and addressing deceptive and misleading commercial speech.

FULL TEXT

Introduction

The United States is an outlier internationally because US law unquestionably protects commercial speech at the expense of public health. Unlike constitutions of other countries, the US Constitution does not protect social rights, such as the right to health, housing, or food, so there is no legally recognized right to health enforceable against the government. Moreover, the United States rarely ratifies international treaties that set forth human rights protections so international law does not provide an alternative avenue to enforce human rights in the country.[1] Yet, US law recognizes corporations as entities akin to individuals in terms of the “negative rights”[2] the Constitution does protect, such as the freedom of speech and to practice religion without government interference. Over the last two decades, the US Supreme Court has expanded the breadth of protections for both, corporations as akin to individuals and corporations’ right to free speech.[3] As a result, under the US Constitution, industries that produce harmful products have a constitutional right to market these products that far surpasses any right US citizens have to attain health.

In terms of speech in particular, the US Supreme Court has now interpreted the First Amendment to the US Constitution to protect commercial entities’ right to engage in both political speech and commercial speech the First Amendment to the US Constitution to protect commercial entities’ right to engage in both political speech and commercial speech. A major shift occurred in 2010 based on the decision in *Citizens United v. FEC*, under which the Supreme Court essentially held that corporations have equal political speech rights as individuals.[4] This decision is concerning from a public health perspective because multinational corporations have the financial ability to engage in speech to influence election outcomes and financially support candidates who support corporate objectives over public health. Under the First Amendment, commercial speech is protected to a lesser degree than political speech. However, because the freedom of expression is broadly guaranteed for corporate entities in the United States, it has become nearly impossible to restrict commercial speech, including the marketing of products associated with noncommunicable disease.

This article will examine the evolution of US law related to commercial speech for products associated with public health harms such as alcohol, tobacco, and food. It will then identify the few remaining avenues available in the

United States to regulate commercial speech for products associated with noncommunicable disease.

An interesting example of the US framework is the fact that the United States is one of very few countries in the world that has not signed on the International Code of Marketing of Breast-Milk Substitutes; nor has it specifically implemented the Code's provisions into law.[5] As a result, within the United States, the breastmilk substitute industry engages in advertising, labeling, and other marketing practices that violate the Code (and would violate the laws of most countries with respect to infant formula marketing).[6] Because of the Supreme Court's interpretation of the First Amendment, however, it would be constitutionally difficult to restrict most marketing and labeling practices covered by the Code. Thus, even though the US Surgeon General called on companies to abide by the Code within the United States, there is no threat of US enforcement to encourage manufacturers to do so.

This article will examine the evolution of US law related to commercial speech for products associated with public health harms such as alcohol, tobacco, and food. It will then identify the few remaining avenues available in the United States to regulate commercial speech for products associated with noncommunicable disease.

Framework for Analyzing Government Regulation of Speech

The US Constitution established the structure and framework for the US government. The Bill of Rights is the first ten amendments to the Constitution and defines citizens' rights and liberties in relationship to the government. The US Supreme Court established three levels of scrutiny along with corresponding tests to determine if government regulations that impinge on these rights are consistent with the Constitution.

The most difficult test to pass is strict scrutiny and applies to what the Court has deemed to be most strongly held constitutional values (e.g., classifications based on race, the right to travel across the states). This test is applied to restrictions and compulsions of fully protected expression, such as political and religious speech. The mid-level test is generally called intermediate scrutiny and applies to constitutional values that receive a mid-level of protection (e.g., classifications based on sex). This test is relevant to commercial speech. The easiest test for the government to pass is generally called the rational basis test —under which the government needs only a rational basis for the regulation. Most public health regulations that do not implicate constitutionally protect rights receive rational basis review (e.g., vaccine requirements). This test is relevant to disclosure requirements in the commercial context.

The First Amendment to the US Constitution states that, "Congress shall make no law …abridging the freedom of speech." This protects against the federal government's interference with the freedom of speech; the same prohibition applies to the states (and localities) through the Fourteenth Amendment. The original rationale behind this clause was to protect the free exchange of ideas to enable participation in a representative democracy. This type of "political speech" is considered fully protected speech and both government restrictions and compulsions of political speech are subject to strict scrutiny and, as a result, are almost always found to be unconstitutional. Within the context of fully protect speech, regulation based on the time, place or manner of speech are permitted if they are content-neutral, meaning they are justified without reference to the content of the speech. For example, a community can require parade organizers to obtain a permit and require the parade to take place on certain days, during specific times, and in specific locations.

Commercial speech is subject to different constitutional considerations. As such, the next section will trace the origins of the commercial speech doctrine including the different constitutional framework established for restrictions on commercial speech as opposed to disclosure requirements in the commercial context. The sections following will describe how these tests evolved to ultimately render a variety of speech regulations not legally feasible in the United States.

Origin of the Commercial Speech DoctrineRestrictions on Commercial Speech

It was not until the 1970s that the Supreme Court decided that the First Amendment protects commercial speech. The first two cases were considered positive from a public health perspective. In *Bigelow v. Commonwealth of Virginia*, a newspaper editor had been convicted of violating a Virginia law that made it a misdemeanor to publish an advertisement for abortion services (even though the advertisement in question was for services available in New York State). The Supreme Court overturned the conviction. In doing so, the Court for the first time moved away from its earlier statement that, "the Constitution imposes no such restraint on government as respects purely commercial

advertising."[7] In *Bigelow*, the Court found that the fact that newspaper advertisements had commercial aspects or reflected advertisers' commercial interests, "did not negate all First Amendment guarantees."[8]

One year later, in *VA State Pharmacy v. VA Citizens Consumer Council*, the Supreme Court confirmed that commercial speech, which it described as speech that "does no more than propose a commercial transaction," was protected under the First Amendment.[9] In that case, a licensed pharmacist had been found guilty of unprofessional conduct in Virginia for advertising prescription drug prices. The Court established the beginning of the commercial speech doctrine and held that the Virginia law violated the First Amendment. In doing so, it explained that, a "consumer's interest in the free flow of commercial information …may be as keen, if not keener by far, than his interest in the day's most urgent political debate."[10] The Court determined that false commercial speech would not be protected (unlike false political speech which is protected) and that the government can still regulate deceptive or misleading commercial speech to ensure "that the stream of commercial information flow cleanly as well as freely."[11]

Over the years, the Court has explained that commercial speech includes all forms of marketing, such as advertising,[12] labeling,[13] and price information.[14] In the 1980 case, *Central Hudson Gas &Electric Corp. v. Public Service Commission,* the Supreme Court established the *Central Hudson* test that at the time was considered an intermediate level test to determine if government restrictions on commercial speech are constitutional.[15] Under this test, courts first determine (1) whether the expression is protected by the First Amendment, meaning that it must relate to a lawful activity and not be false, deceptive, or misleading. If it is found to be protected, the court must ask whether (2) the government asserted a substantial interest to be achieved by restricting commercial speech; (3) the regulation directly advances this interest; and (4) the restriction is not more extensive than necessary to serve this interest.[16]

Compulsions of Speech in the Commercial Context

In the context of most consumer products, government frequently requires the disclosure of factual information on product labels (and sometimes on advertisements). Such disclosures can take the form of purely factual data to provide consumers with clear information about the products for sale (e.g., the information panel on food packaging which includes the Nutrition Facts label, ingredient list, and common food allergens). A second type of disclosure includes warnings about products, for example, warnings on tobacco and alcohol labels about potential health and safety concerns associated with consumption. As opposed to restrictions on commercial speech, the Supreme Court found that compulsions of factual information in the commercial context were subject to a different test and level of scrutiny.

In 1985, the Court established the test to determine whether government requirements to disclose factual information in the commercial context were constitutional. In *Zauderer v. Office of Disciplinary Counsel*, the Court held that disclosure requirements, including warnings and disclaimers, are constitutional if they are "reasonably related" to the "government's interest in preventing deception of consumers," they are "purely factual and uncontroversial," and not "unjustified or unduly burdensome."[17] This is called the *Zauderer* test and was considered akin to a rational basis test. In *Zauderer* itself, the Court did not provide any type of explanation of the requirements of the test.

The Supreme Court expounded on the last clause of the *Zauderer* test in a subsequent 1994 case, *Ibanez v. Florida Dept. of Business &Professional Regulation*. In this case, the government had tried to require a professional's business cards to include a long disclaimer that would essentially make using a business card prohibitive. First, the Court stated that to justify a disclosure requirement, the government needed evidence to show that the harm it seeks to address "is potentially real," and "not purely hypothetical."[18] The Court found that the disclosure requirement at issue was "unduly burdensome" because it was so long and detailed that it effectively drowned or ruled out the commercial communication in the first place.[19] Despite this case, courts still struggled to determine what constituted a burdensome requirement, often focusing on font size.[20] The burdensome requirement therefore developed into somewhat of a subjective test.

Lower court seeking to apply *Zauderer* generally expect the government to amass evidence to support its requirement.[21] But a lack of clarity remained about the rest of the test. Courts generally concluded that the

"uncontroversial" language in *Zauderer* referred to uncontroversial facts (e.g., a product either contains mercury or it does not[22]). And that the government's interest in "preventing deception of consumers" was a description of the government's interest in the *Zauderer* case itself, rather than the sole governmental interest that could be used to justify disclosure and warning requirements. For decades courts determined that that government could require factual disclosures and warnings based on government interests beyond preventing deception of consumers, including health, safety, and the environment.[23] (But they did find that an interest in satisfying consumer curiosity was not enough.[24]) Thus, lower courts generally upheld disclosure requirements passed to protect public health.

Summary

Thus, the Supreme Court initially seemed to establish three levels of scrutiny for speech regulations. Strict scrutiny has always applied to restrictions and compulsions of fully protected expression such as political speech, protests, religious speech, and artistic expression. The *Central Hudson* test, which evaluates restrictions on truthful commercial speech was deemed an intermediate test. And for factual disclosure requirements in the commercial context (including both warnings and factual information), the Court initially established the "reasonable basis" test, which was deemed to be akin to rational basis in other constitutional contexts.

However, both the *Central Hudson* and *Zauderer* tests have been interpreted with increasingly "stricter" scrutiny and thus, more difficult for the government to pass than perhaps was originally envisioned.[25] No commercial speech restriction has passed the *Central Hudson* test in decades, and it is now unclear whether a restriction on non-deceptive commercial speech can ever pass this test. Further, a recent case that was not necessarily a commercial speech case altered courts' interpretation of the *Zauderer* test.

Evolution of the Commercial Speech DoctrineCommercial Speech Restrictions

Several cases decided under *Central Hudson* that directly relate to products associated with public health harm reveal that no matter how strong the government interest, how much evidence it amassed that the product harms health or that restricting speech is a method to address potential health harms, the government cannot restrict non-deceptive commercial speech about products legally for sale in the marketplace. In the context of alcohol, in *Rubin v. Coors Brewing Company*, the Supreme Court struck down a federal law that prohibited beer labels from displaying alcohol content to prevent "strength wars" among manufacturers competing on the basis of high potent alcoholic beverages.[26] Although the Court agreed the government's interest was "substantial," it held that the law unconstitutionally restricted truthful speech and thus failed the *Central Hudson* test. This holding is not entirely surprising because it is contrary to First Amendment values for the government to prohibit the disclosure of factual data about a product for sale. But the opinion is important for how it helped usher in the ultimate trajectory of First Amendment analysis under the Central Hudson test.

Writing for the majority, Justice Thomas explained that to pass the "last two steps of the *Central Hudson*," there must be a "'fit' between the legislature's ends and the means chosen to accomplish those ends."[27] This statement was originally part of a broader statement in a previous case that had a liberal meaning: "a fit that is not necessarily perfect, but reasonable; that represents not necessarily the single best disposition but one whose scope is 'in proportion to the interests served.'"[28] Nonetheless, the second part of this statement has now become something repeated by dissenting opinions when the majority finds the fit to be improper. The "fit" requirement means that the government must show that its interest is proportionate to the burden placed on speech;[29] however, given the increased protection for commercial speech, the governments is not able to meet this burden. Thus, the question over fit has ultimately become a signal that a speech restriction cannot meet both parts three and four of *Central Hudson* simultaneously.

The majority in *Rubin v. Coors Brewing* also questioned whether the ban on alcohol content would directly advance the government's interest (and noted that the rest of the regulatory scheme was irrational because it also applied to wine and spirits and had exceptions for state laws). Importantly, the Court then pointed to alternatives to meet federal goals without burdening speech, including directly limiting the alcohol content of beers. This signaled that regulated entities may need to only come up with alternative methods to address the government's concern without implicating speech, and this would show the speech restriction was not proportionate to the government's interest.

One year later in 1996, the Court struck down a state law banning the advertisement of alcohol prices. The Court explained that "bans against truthful, nonmisleading commercial speech …usually rest solely on the offensive assumption that the public will respond 'irrationally' to the truth."[30] It also confirmed there is no "vice" exception to the commercial speech doctrine for products that pose a threat to public health.[31]

In 2001, the Court went a step beyond previous decisions to strike down Massachusetts' regulations that aimed to protect children —who cannot legally purchase tobacco products —from seeing tobacco advertisements.[32] In *Lorillard v. Reilly*, the Court first found that the state had amassed adequate evidence to further its "substantial" and perhaps "even compelling" interest in preventing tobacco use by minors.[33] Nonetheless, the Court found the regulation prohibiting tobacco advertising within a 1,000-foot radius of a school or playground violated the fourth part of *Central Hudson*. It explained that in some areas in Massachusetts, this restriction would constitute "nearly a complete ban on the communication of truthful information" about tobacco products to adult consumers. This, the Court found, would violate the First Amendment interests of "tobacco retailers and manufacturers [who] have an interest in conveying truthful information about their products to adults," and adults who "have a corresponding interest in receiving truthful information about tobacco products."[34]

In *Lorillard v. Reilly*, the Supreme Court characterized the *Central Hudson* test as "a framework for analyzing regulations of commercial speech that is 'substantially similar' to the test for time, place, and manner restrictions." Nonetheless, it did not flesh out this conceptual overlap.[35]

The Court also started to take more seriously industry arguments to apply strict scrutiny to commercial speech restrictions.[36] Justice Thomas wrote a concurring opinion, in which he reiterated his argument in the *Rubin v. Coors Brewing Company*, that the government should consider alternatives to limiting speech:

[T]he State should have examined ways of advancing its interest that do not require limiting speech at all…. Massachusetts already prohibits the sale of tobacco to minors, but it could take steps to enforce that prohibition more vigorously. It also could enact laws prohibiting the purchase, possession, or use of tobacco by minors. And, if its concern is that tobacco advertising communicates a message with which it disagrees, it could seek to counteract that message with 'more speech'[37]

These specific suggestions are especially intriguing because they are not evidence-based and in fact are contrary to the public health evidence on punishing minors for tobacco use. This underscores the reality in the US court system that social science evidence is given little weight in First Amendment cases.

In his concurring opinion, Justice Thomas also explicitly stated that he would subject advertising restrictions to strict scrutiny and weaved into his argument the idea of "content-based" restrictions which was historically only discussed in the context of fully protected speech.[38] He questioned whether it was even possible to draw a "coherent distinction between commercial and noncommercial speech." Justice Thomas argued that since the regulations sought to suppress speech about tobacco because the state objected to the "content of that speech," they were content-based regulations of speech which should be subject to strict scrutiny.[39] This perspective is concerning because all commercial speech restrictions are "content-based." Nonetheless, less than two decades later, the Supreme Court seems to have embraced Justice Thomas' views on commercial speech.

In 2011[40] and 2020,[41] the Court analyzed two regulations under the First Amendment that the government argued were economic regulations that happen to have a speech component, but where the majority found the regulation imposed "content-based" burdens on speech and struck them down. In *Sorrell v. IMS Health Inc.*, a Vermont law restricted the sale, disclosure, and use of pharmacy records that revealed prescriber-identifying information.[42] The Court found the law imposed content-based and speaker-based burdens on protected expression, finding that "heightened judicial scrutiny" was warranted.[43] It relied on cases in the commercial speech context *and* in the context of fully protected speech and did not explain exactly what "heightened" scrutiny meant. The Court stated that under either test (intermediate or strict scrutiny) the regulation violated the First Amendment.[44]

At this point, although the Supreme Court had not expressly stated it, the majority opinions have evidenced a departure from the origins of the commercial speech doctrine.

Importantly, the dissent considered the Vermont law to be an economic regulation that should have been subjected

to, and pass, rational basis review. The dissent explained the significance of this case and highlighted a changing tide for First Amendment jurisprudence:

[N]either of these categories —'content-based' nor 'speaker-based' —has ever before justified greater scrutiny when regulatory activity affects commercial speech… Regulatory programs necessarily draw distinctions on the basis of content… Nor, in the context of a regulatory program, is it unusual for particular rules to be "speaker-based."[45]

In 2020, the Court issued a similar decision on the topic of cell phone-based robocalls, again with the majority finding the regulation was content-based and subject to strict scrutiny, under which it failed.[46] The dissent again argued that applying the strictest level of scrutiny to an "ordinary commercial regulation" was "divorced from First Amendment values" as it had "next to nothing" to do with the marketplace of ideas.[47] At this point, although the Supreme Court had not expressly stated it, the majority opinions have evidenced a departure from the origins of the commercial speech doctrine.

Commercial Disclosure Requirements

While the Supreme Court has pioneered First Amendment jurisprudence with respect to commercial speech restrictions (and thus analysis of the *Central Hudson* test), federal appellate courts have generally interpreted *Zauderer* without Supreme Court guidance for decades. This changed with a 2018 Supreme Court decision, discussed below. Before this decision, lower courts upheld commercial disclosure requirements in the context of environmental regulations (e.g., to require the disclosure of mercury in products to aid with proper disposal[48]), tobacco (e.g., textual health warnings for tobacco products[49]), nutrition (e.g., calorie[50] and sodium[51] warning labels on restaurant menus), and radio-frequency radiation exposure notices at the point of sale.[52]

Lower courts did strike down disclosure requirements that were not based on evidence (i.e., "unjustified") or that were non-factual (e.g., finding there was no factual definition of "conflict- free" minerals[53]). Perhaps the most important case from an international perspective was the case where a federal appellate court struck down graphic warning requirements for tobacco products, a labeling strategy widely accepted in countries world-wide.[54] In 2012, the DC Circuit found the FDA's proposed graphic tobacco warning labels were unconstitutional, stating:

[M]any of the images do not convey any warning information at all, much less make an 'accurate statement' about cigarettes. For example, the images of a woman crying, a small child, and the man wearing a T-shirt emblazoned with the words 'I QUIT' do not offer any information about the health effects of smoking.[55]

Moreover, the court questioned the government's ability to make "every single pack of cigarettes in the country a mini billboard for the government's anti-smoking message."[56] The FDA has since created new graphic warning labels and has been sued by two tobacco manufacturers. The cases are pending in federal court as of the time of this writing.

The Supreme Court took on *Zauderer* in the 2018 case, *Nat'l Inst. of Family &Life Advocates (NIFLA) v. Becerra*.[57] Rather than clarify the test, the case created upheaval in how to interpret the government's ability to require disclosures or warnings in the commercial context. This case stemmed from California's disclosure requirements for clinics that serve pregnant women. It is unclear to some extent whether this case should be interpreted as a speech case about abortion, a case about fully protected speech, or a case about commercial speech.[58] In *NIFLA*, the Court examined two notice disclosure requirements which it characterized as "content-based" and "speaker-based." It struck down the two requirements as violating the First Amendment and seemed to clarify parts of the *Zauderer* test in the opposite direction than lower courts had taken it. It is important to note that Justice Thomas authored the *NIFLA* opinion; he had previously stated that he is "skeptical of the premise on which *Zauderer* rests —that, in the commercial-speech context, 'the First Amendment interests implicated by disclosure requirements are substantially weaker than those at stake when speech is actually suppressed.'"[59]

First, the Supreme Court explained that *Zauderer* only applies to disclosure requirements that are purely factual and uncontroversial. In interpreting the term "uncontroversial," the majority found that the disclosure requirement at issue was not subject to *Zauderer* because it mentioned abortion which is "anything but an 'uncontroversial' topic."[60] However, abortion is a politically controversial topic; the existence of the medical procedure of abortion is not. This is contrary to how lower courts have analyzed the "uncontroversial" requirement. Moreover, since companies have

equal political speech rights as individuals,[61] a finding that a disclosure requirement related to abortion is controversial for First Amendment purposes is a deeply concerning interpretation of the First Amendment. Most public health regulations are controversial because they evoke competing values of community health versus individual or business interests. Further, companies that produce harmful products have the First Amendment right to create political controversy over any topic at any time.

Second, the Court disapproved of the fact that the disclosure at issue was "government-scripted." (This is reminiscent one of Justice Thomas's previous opinions where he stated: "even under *Zauderer*, we 'have not presumptively endorsed' laws requiring the use of 'government-scripted disclaimers' in commercial advertising."[62]) Yet, essentially all warning requirements are government scripted (e.g., "WARNING: Cigarettes cause cancer"). Ostensibly understanding the difficulty that government will have drafting, and courts will have evaluating disclosure requirements based on this decision, the majority added: "we do not question the legality of health and safety warnings long considered permissible, or purely factual and uncontroversial disclosures about commercial products." [63] However, it did not flesh out which disclosures and warnings fall under this category.

The Court did not decide whether other interests besides "preventing deception of consumers" can support disclosures or warnings; and only stated that the notice requirement was "wholly disconnected from California's informational interest."[64] The Court also found that the state did not amass evidence that pregnant women did not already know the information sought to be disclosed, and therefore the notice requirement was "unjustified." This was a confusing finding because all health and safety warnings provide information about which certain consumers may already be familiar. In fact, Congress requires a health and safety warning on alcoholic beverage labels for the exact purpose of providing "a clear, nonconfusing reminder of such hazards" to the American public. Lastly, the Court found that the requirement to disclose the notice in up to 13 languages —which California envisioned would be tailored to the particular community —was unduly burdensome. Although it is clear that requiring a disclosure in 13 languages at once is burdensome under *Ibanez* given the amount of space it would require, it is unclear how many languages at once would not be burdensome.

In *NIFLA*, the majority used similar language as in the *IMS Health*, stating that one notice requirement imposed a "speaker-based disclosure requirement,"[65] while the second notice was a "content-based regulation of speech" that compelled the regulated entity "to speak a particular message."[66] This latter statement captures every single disclosure and warning requirement currently in place in the US commercial marketplace. Moreover, writing for the majority, Justice Thomas made clear that California should have found an alternative to regulating speech; the opinion suggested that California "could inform the women itself with a public-information campaign" or by using public property to convey its message.[67]

Reminiscent of the dissent in *Sorrell v. IMS Health*, the dissent in *NIFLA* similarly warned about the repercussions of striking down disclosure requirements aimed at supporting informed consumer decision-making:

Because much, perhaps most, human behavior takes place through speech and because much, perhaps most, law regulates that speech in terms of its content, the majority's approach at the least threatens considerable litigation over the constitutional validity of much, perhaps most, government regulation. Virtually every disclosure law could be considered 'content based,' for virtually every disclosure law requires individuals 'to speak a particular message.' Thus, the majority's view, if taken literally, could radically change prior law, perhaps placing much securities law or consumer protection law at constitutional risk, depending on how broadly its exceptions are interpreted.[68]

A subsequent Ninth Circuit case highlights judges' difficulty in evaluating warning or disclosure requirements post-*NIFLA*. In 2019, the Ninth Circuit analyzed San Francisco's requirement that outdoor advertising for sugary beverages must include a warning on 20% of the advertisement that stated: "WARNING: Drinking beverages with added sugar(s) contributes to obesity, diabetes, and tooth decay. This is a message from the City and County of San Francisco."[69] The Ninth Circuit struck down the law under *Zauderer*.[70] The majority found the 20% size requirement to be unduly burdensome because the state did not show that it would not "drown out" the advertiser's message, which would "effectively rule out the possibility" of advertisements in the first place.[71] The court acknowledged that the Sixth Circuit previously upheld a similar requirement in the context of tobacco

advertisements, but pointed to a study in the context of sugary beverages found that warnings that were half the size would be similarly effective.[72] The court went on to say that it was not holding that a warning that was 10% of the size of the advertisement would be constitutional, further confirming the lack of an objective requirement for this part of the *Zauderer* test.

The concurring opinions revealed much conflict over how to interpret *NIFLA*. One concurring opinion stated that only "health and safety warnings [that] date back to [the year] 1791" would qualify as "long considered permissible" under the *NIFLA* standard.[73] This is an untenable position given that all current warnings have been created since 1791 and the government could not address newly invented threats (e.g., toddler milks, electronic cigarettes) or products for which the science has evolved (e.g., sugar-sweetened beverages).[74] Another concurring opinion argued that the proposed warning language was factually inaccurate because the FDA previously declared added sugars as "generally recognized as safe," and stated that they "can be a part of a healthy dietary pattern" when not consumed in excess.[75] Another concurring opinion questioned the application of *Zauderer* at all, stating they "disagreed with applying *Zauderer* outside the context of false and misleading speech."[76]

Directions for the Future

As the US Supreme Court has moved toward granting increased protections to corporations, including their right to communicate through political and commercial expression, one can only expect it to continue in this direction given the make-up of the Court in 2022. It would take a constitutional amendment to pull back on the speech rights of corporations; however, this is not politically likely.

Although of unclear efficacy, as noted in previous cases, government can use its own speech —government speech —to communicate with the public. Although the government cannot afford to fund counter-marketing campaigns that match even one company's marketing campaign, it can engage in public service campaigns to dissuade consumption of harmful products. At present, outside of tobacco control, this is generally rare in the United States. Another avenue available to government is for it to proscribe speech in its own buildings (e.g., office buildings, schools) and public transportation.[77] As long as it uses viewpoint neutral guidelines (i.e., does not choose among similar types of expression based on the viewpoint expressed), it can restrict commercial speech across government venues. These efforts, of course, will have a limited reach but are legally feasible.

So, what is left for marketing of products that cause public health harm? Despite the progression of increased protection for commercial speech and decreased ability for government to regulate it under both *Central Hudson* and *Zauderer,* false, deceptive, and misleading speech in the commercial context remains subject to government regulation. The ability to address false and deceptive commercial speech underlies much of the consumer protection authority of the Federal Trade Commission (FTC) and state attorneys general. Moreover, in the case law, evidence of deception is more compelling than social science evidence for speech regulations.[78] The outcome of First Amendment cases in the context of both commercial and fully protected speech has never been contingent on the amount or strength of social science evidence presented even when the government amasses an enormous amount of evidence of the public health repercussion of speech.[79] However, evidence of deception does influence the outcome of First Amendment cases.[82]

In both *Central Hudson*[83] and *Zauderer*[84], the Court indicated that deceptive speech is subject to regulation. At this point, the Court has not overruled this area of First Amendment jurisprudence. The dissent in *IMS Health* noted the same, stating that, "the Court normally exempts the regulation of 'misleading' and 'deceptive' information even from the rigors of its 'intermediate' commercial speech scrutiny."[83] Nonetheless, the Court has not analyzed a case directly on this point in decades. In fact, *NIFLA* could have been a case about deceptive speech by clinics that serve pregnant women but the State did not present it this way.[84] The state could have argued that the unlicensed clinic disclosure requirement was necessary to prevent deception because the state legislature explicitly had found that these clinics engaged in "intentionally deceptive advertising and counseling practices [that] often confuse, misinform, and even intimidate women from making fully informed, time-sensitive decisions about critical health care."[85] The majority in *NIFLA* went so far as to cut off phrases from *Zauderer* to avoid discussing deceptive speech.[86] Had they done so, they would have had to highlight a potential avenue for government to require such disclosures: curing

deception.[87]

Decades-old case law indicates that there are three types of misleading commercial speech: potentially, inherently, and actually misleading commercial speech.The Supreme Court previously held that potentially misleading commercial speech (i.e., speech that is capable of being presented in a way that is not deceptive) is protected by the First Amendment. However, inherently and actually misleading speech are amenable to regulation.

This case law is not well fleshed out as there are very few cases in this area. The few cases that do exist indicate that inherently misleading speech is speech that is "incapable of being presented in a way that is not deceptive."[88] This has been found when advertising terms have no inherent meaning (e.g., the use of a trade name for optometrists;[89] the term "invoice" in car ads[90]). Nonetheless, courts have only rarely found speech to be inherently misleading. Actually misleading speech is speech for which there is "evidence of deception" which the Court only explained as evidence that consumers are misled.[91] Decades ago, the Court stated that the government "may impose appropriate restrictions" on inherently and actually misleading commercial speech.[92] However, it is not clear this is actually feasible in terms of direct regulation. In *Zauderer* itself (and a subsequent case almost identical to it, *Milavetz*) the Court upheld a disclosure requirement to cure inherently misleading speech.[93] In the context of deceptive advertising, the FTC and state attorneys general bring cases against ad campaigns deemed deceptive; the settlements include agreements by advertisers to cease using such deceptive claims in future advertising.[94] Expanding these types of cases is a viable option to address deceptive marketing practices and an area ripe for FTC and state attorney general action.[95]

As governments consider policy going forward, it should gather evidence of deception. FTC cases sometimes include review of actual evidence of deception in the form of consumer surveys.[96] Moreover, courts would look for evidence of deception to support commercial speech restrictions or disclosures. Social scientists have a role to play to reveal and amass evidence on how modern marketing practices for products that harm health, deceive consumers.[97]

Conclusion

Many outstanding questions remain about the commercial speech doctrine. It is now not fully known the extent a commercial speech restriction can ever survive First Amendment scrutiny under *Central Hudson* or if the Court will apply strict scrutiny to commercial speech restrictions in the future. It is also unknown the extent the government should consider and apply time, place, and manner restrictions on commercial speech. Future cases are needed to determine how courts will continue to flesh out *Zauderer* in light of *NIFLA*. Cases currently pending in federal court will provide additional insight on whether graphic warning labels can ever survive First Amendment scrutiny.

The Supreme Court's interpretation of the freedom of speech over the last two decades has fundamentally changed First Amendment jurisprudence, protecting corporate expression in all meaningful ways and at the expense of other values, including health. It is thus not surprising that little regulation of commercial speech has taken place in the United States. At a minimum, US law serves as a cautionary tale to other countries, but it also functions to support corporations in a global marketplace with digital expression that transverses country lines. Absent constitutional amendments, Americans may expect an expansion of the commercial speech doctrine, few rights related to attaining health, and an escalation of noncommunicable disease as a result of this market-driven framework.

DETAILS

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Voluntary Registries: Filling the Critical Information Gap in First Response to Mental Health Crises

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ABSTRACT (ENGLISH)

We argue that voluntary mental health registries integrated into the 9-1-1 system, where patients and caregivers can establish a repository of this information, will help fill this information gap by enabling first responders to quickly understand the context of a call for service with a mental health component, and to make better informed decisions. Despite valid concerns about privacy, stigma, and the potential misuse of protected health information, such registries, if carefully designed and administered, can improve the health outcomes of 9-1-1 calls for service involving mental health-related crises.

FULL TEXT

The 9-1-1 Information Gap

In the United States —and large parts of the world —the 9-1-1 system is the principal way public safety and medical resources are deployed in response to emergencies, including mental and behavioral health crises. The system evolved at the confluence of three technological developments that rapidly spread in the wake of World War II: the omnipresence of the telephone, the widespread use of the automobile, and the availability of wireless radios. The latter, which had gotten much smaller and more powerful during and after the war, could thus be used to dispatch roving police units to citizens' calls for service. In 1967, the President's Commission on Law Enforcement and Administration of Justice recommended a single phone number be used across jurisdictions for this purpose.[1] The 9-1-1 system was born.

Behind the modern 9-1-1 system's computer-aided dispatch lies a vast electronic records management network with federal, state, and local databases that not only record data about incidents as they unfold, and house the resulting reports, but provide access to the information necessary for a safe and effective first response. This includes information about past incidents at a location, who may be wanted for a crime, and people wanted for questioning. This knowledge can be used to help assess the risks of response to an incident and assist in investigations, but it provides little by way of helping police and other first responders react quickly and effectively to mental and behavioral health emergencies. In their paper in this issue of *Journal of Law, Medicine &Ethics*, Heather M. Ross, Diana M. Bowman, and Jessica M. Wani make the case that these systems can be linked to a voluntary registry to provide police with critical information about people with dementia.[2] Should they wander and become lost, for example, police can gain immediate access to their physical description, diagnosis, habits, historical routes of travel, and locations where caregivers have found them in the past. They would be better equipped to find the person,

safely engage them, and quickly link them to care. Such registries could potentially fill critical gaps in the nation's 9-1-1 system, and for that reason they are overdue.

Voluntary Registries: The Right Information at the Right Time

The 9-1-1 system delivers speed and efficiency, but with it comes some limitations: police and paramedics are by nature generalists, emergencies can be complex and evolving events, and both callers and call-takers are imperfect at identifying all relevant particulars of a crisis and bringing the most relevant information to the fore. In the event of mental health crises, the results of an information gap can have profound consequences when police attempt to intervene. The result can be an arrest when linkage to treatment would be more effective at both protecting health and preventing repeat occurrences. It could also mean mistaking the temporary effects of a crisis for resistance, obstruction, or a deliberate intention to cause harm, resulting in use of force rather than containment and de-escalation. In the case of an Alzheimer's patient gone missing, as discussed in Ross et al.'s piece, delaying a properly focused search directly contributes to their risk of death.

In response to the legitimate desire to protect the widespread disclosure of a patient's health information, Ross et al. make an important point, one that we feel is worth emphasizing: HIPAA privacy laws don't apply to voluntary registries maintained by police, and the common belief that they do is a misunderstanding.

Voluntary registries can help fill these information gaps if they are implemented with an eye toward privacy, professionalism, and equity. One of the authors of this commentary (MTC) is conducting a trial in Georgia in which individuals with serious mental illnesses can opt into a database that links police to mental health clinicians by phone.[3] When officers encounter someone at the scene of an incident, pull someone over, or simply happen upon someone during routine patrol, and query their name —a nearly universal step in police procedure —they are prompted to make the call. This practice, which provides police with real-time insights about the person's condition, and the mental health diagnoses that may explain their behavior, is being tested in terms of effectiveness at linking these patients to care in the context of a police contact, while reducing the risk of arrest for minor charges. Police have broad discretion in making arrests versus referrals for a wide range of situations,[4] and the information officers receive from clinicians can help them distinguish between criminally destructive or disruptive behaviors and the results of a mental health condition or crisis (or psychosocial need) that would benefit from reconnection to care rather than criminal legal system entanglement. Complementing such a system with a dementia registry would be the beginning of a continuum of improved mental health first response by providing timely and accurate information about an incident's underlying origins and the most appropriate courses of action.

Privacy, Confidentiality, and Stigma

There is a tension inherent in voluntary registries that seek to put sensitive medical information into the hands of police and other first responders, however. On one side is the value proposition that it reduces the 9-1-1 system's information gap when time is of the essence, speeding a decisive response when units arrive and begin their investigation. On the other is the worry that law enforcement will fail to safeguard or will otherwise misuse information about a person's mental or behavioral health condition. Acknowledging one's status as a person with a mental illness is stigmatizing, and law enforcement officers may lack the skills and procedures to make the best use of the information. These concerns must be addressed for registries of various types to succeed.

In response to the legitimate desire to protect the widespread disclosure of a patient's health information, Ross et al. make an important point, one that we feel is worth emphasizing: HIPAA privacy laws don't apply to voluntary registries maintained by police, and the common belief that they do is a misunderstanding. Police routinely collect information about people that pertains to their health, from reports of overdose and the outcomes of mental health crises to the injuries sustained during motor vehicle crashes and other routine accidents that require a preliminary investigation. Indeed, when a person with dementia goes missing, the ensuing police reports are bound to contain detailed clinical information that would be HIPAA protected if it were in an electronic health record. But as data not held by health care providers, it is not governed by HIPAA, and neither would data voluntarily provided by people with dementia in advance of a missing person incident. In jurisdictions without registries, when a person with dementia goes missing more than once, it is past reports that can provide officers the information necessary for a

fast, effective response. This is a legitimate use of the patient's health information, regardless of how it was initially obtained by police.

Compromise of this information is another concern, but police trade in sensitive information by the nature of their work, and have constructed their systems accordingly. One answer lies in utilizing the safeguards already in place for housing sensitive information in police facilities. The FBI requires municipal police departments to comply with its Criminal Justice Information Service security requirements,[5] which restrict who can access information and what it can be used for, and requires an audit trail for all transactions. It also spells out the physical and cyber security standards for the servers and other hardware that maintain and provide access to sensitive criminal justice information. Applying this standard to personal health information (PHI) as well, such as the information contained in voluntary registries, would provide the level of security otherwise reserved for data used in highly sensitive criminal investigations. Not only would this in effect render the data secure, but would demonstrate an agency's practical commitment to protecting the privacy and the dignity of people who entrust their information to the police in order to improve the 9-1-1 response to mental health crises.

At the same time, stigma toward people with mental health conditions is real, dementia is not an exception,[6] and distrust of the police by vulnerable populations subjected to a history of discrimination and racism cannot be ignored. One response proposes to therefore see the police out of these situations altogether, and replace them with clinicians who specialize in mental health crisis response. It is important to consider, however, that the information contained in these registries is agnostic regarding its user. Anybody responding to a person in need would benefit from it, police or otherwise. As alternative responders, however, people specifically acting as health care providers (i.e., "covered entities") may ironically trigger HIPAA protections that would impede the transfer of critical information between actors *unless* it was obtained from a voluntary registry that waived the corresponding protections. As it stands now, police, who are not covered entities, can share PHI without prior permission, as needed or as an incident unfolds.

There are also practical concerns about diminishing the police role in certain incidents. In the case of a registry for people with dementia, where one of the primary purposes is quickly returning lost people to their caregivers, it is unlikely that even the most reform-minded communities will develop an effective alternative to police investigations and searches. The use of aviation, canines, sensors, and a fleet of vehicles, among other tools and technologies,[7] provide police with the specialized equipment and staffing necessary to conduct fast and thorough searches more so than any other agency or group, and it all comes at great expense. So long as first responders are dispatched to crises when people call, registries will benefit any responder regardless of their role, and it is unlikely that police will be replaced when the response is to emergencies that have an element of actual physical danger or call for resource-intensive searches or containment practices.

The First Steps Toward Comprehensive Reform

The introduction of voluntary registries to enhance emergency response to patients with Alzheimer's disease and other forms of dementia may prove to be a valuable test case, and a stepping stone for the expanded use of this proactive approach. People with dementia are perceived to be acutely vulnerable, and unlikely to be aggressive, dangerous, or involved in activities that could be considered crimes. Their condition is stigmatized, but their advanced age most often inspires compassion. If anything, they are stereotyped as being helpless but largely harmless. This suggests that their presence in a registry is unlikely to evoke stereotypes in first responders that put them at an elevated risk of arrest or subject to a forceful response. As the ethics of privacy and the need for information security are addressed, registries for this population seem to have little downside, and can reduce the considerable burdens faced by their caregivers.

One critical observation is that information alone only goes so far. It needs to be accompanied by the resources, training, and procedures to make the best use of it. In the case of registries for dementia, it needs to be accompanied by the resources necessary to make the response to a missing person decisive and more likely to succeed. It will require planning and coordination between patrol and investigative units, with the need to codify these arrangements in standing procedures. In the case of the clinical trial being conducted by one of the authors

here, knowledge about the link between mental health and behavior is critical for understanding why connections to care are preferable to arrest. For mental health crises where a person's behavior can be unpredictable or aggressive, Crisis Intervention Team training and competence in the type of effective de-escalation found in the Police Executive Research Forum's Integrating Communications, Assessment and Tactics curriculum[8] should be the minimum standard for a safe and compassionate response. It has been shown that officers who report self-efficacy when it comes to de-escalation and referrals to treatment are more likely to exercise these preferred options.[9] It is critical, however, that policy, leadership, and oversight ensures they are exercised equitably in terms of race and other sociodemographic factors. Too often, improvements in access to care disproportionately accrue to more affluent, white communities.

Despite these needs, however, voluntary registries are a promising sign, because they acknowledge the need to take mental and behavioral health crises seriously as a distinct type of incident. They may hold promise for a more tailored, well-informed response, rather than the prevailing practice of collecting basic information through the 9-1-1 system and figuring out the rest upon arrival. In the case of people with dementia, the latter can result in wasted time, when time is truly of the essence. In the case of mental health crises, the result may not only be an unnecessary arrest, but an avoidable use of force. In both cases, the problem is a 9-1-1 information gap, one which voluntary registries may be poised to fill.

DETAILS

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Right to Commercial Speech in India: Construing Constitutional Provisions Harmoniously in Favor of Public Health

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ABSTRACT (ENGLISH)

This article examines the right to commercial speech that has been read into the right to freedom of speech and expression under Article 19(1)(a) of the Constitution of India. Restrictions on this right are only permitted if they come within the ambit of the exhaustive list of reasonable restrictions under Article 19(2), under which public health is notably absent. Nevertheless, through the doctrine of harmonious construction, the Indian judiciary have adopted a purposive interpretation to circumvent the omission of public health by carving up freedom of commercial speech into two parts: protected speech which furthers public interest and unprotected speech which is purely commercial. Moreover, the Indian courts have construed these provisions in light of the right to life under Article 21 and the health-related Directive Principles of State Policy under Part IV of the Constitution. This article concludes that judicial creativity in India has consistently been used in favor of protecting public health.

FULL TEXT

1. Introduction

The scale of India's epidemiological transition was highlighted in a comprehensive study which found that, between 1996-2016, non-communicable diseases (NCDs) contributed to 62% of total deaths, of which 48% were premature.[1] In particular, the rate of overweight and obesity is increasing faster than world average, and the prevalence of overweight and obesity amongst 20–69 year olds is forecast to double and triple respectively between 2010-2040.[2] Despite alcohol prohibition in some states,[3] the per capita consumption in India is expected to increase from 5.7 in 2016 to 7.9 litres in 2025.[4] Though India has one of the highest tobacco consumption levels in absolute numbers globally, the latest national survey indicates a slight decline in tobacco consumption across most states over the last fifteen years.[5] An improvement is also seen in the figures for exclusive breastfeeding for infants under 6 months from 55% in 2015-16 to 64% in 2019-21.[6]

India has enacted various rules to prohibit or restrict advertisements that promote unhealthy commodities, including on social and digital media. The Cable Television Networks Rules 1994, for instance, prohibit direct and indirect advertisements that promote "infant milk substitutes, feeding bottle or infant food" and "cigarettes, tobacco products, wine, alcohol, liquor and other intoxicants."[7] In 2020, regulations were introduced to prohibit advertisements of unhealthy food products in and near school premises,[8] and consumer protection rules were strengthened to restrict surrogate or indirect advertisements for products whose advertising have previously been restricted or prohibited.[9]

This article examines how the judiciary has excluded the protection of certain types of commercial speech that are not in the public interest. By resorting to the doctrine of harmonious construction, that adopts a purposive approach to achieve public health, the Indian judiciary has been able to circumvent the omission of "public health" as a reasonable restriction under Article 19(2) and achieve public health objectives.

It is within this context that this article examines the right to commercial speech that has been read into the ambit of Article 19(1)(a) of the Constitution of India, which guarantees the right to freedom of speech and expression.[10] Though public health is not a ground in the strictly exhaustive list of reasonable restrictions permitted by Article 19(2),[11] this article examines how the judiciary has excluded the protection of certain types of commercial speech that are not in the public interest.[12] By resorting to the doctrine of harmonious construction, that adopts a purposive approach to achieve public health, the Indian judiciary has been able to circumvent the omission of "public health" as a reasonable restriction under Article 19(2) and achieve public health objectives.

Section II examines the protection granted to commercial speech within Article 19(1)(a). It explores the case law within the High Courts and the Supreme Court of India, specifically in cases of advertisements promoting unhealthy commodities, to highlight the nuances used by the judiciary to limit commercial speech protection to certain types of commercial speech that are in public interest. Section III examines how the judiciary has harmoniously construed the provisions under Article 19(1)(a) with Article 21 (right to life) and certain public-health related provisions of the Directive Principles of State Policy provided under Article 47, Article 39(e) and Article 39(f) of the Constitution. In conclusion, the article argues that the Indian judiciary's penchant for "judicial creativity," "hyper-activism" and "judicial over-reach" appear to be consistently used in favour of protecting public health.[13]

2. Constitutional Protection of Commercial Speech that is *Only* in the Public Interest

2.1 Commercial Speech Initially Not Protected

The Supreme Court of India considered the right to commercial speech for the first time in 1959 in *Hamdard Dawakhana,* where advertisers had challenged the constitutionality of the Drugs and Medical Remedies Act 1954 that aimed to prevent misleading advertisements for products claiming "magical" medical remedies.[14] The court noted that advertising "is no doubt a form of speech, but…when it takes the form of a commercial advertisement which has an element of trade or commerce, it no longer falls within the concept of freedom of speech for the object is not propagation of ideas —social, political or economic or furtherance of literature or human thought."[15] Hence, the right to commercial advertisements cannot fall within the parameters of Article 19(1)(a) if they are "part of a business" as they do not fall within the realms of "essential concept of the freedom of speech," thereby treating commercial speech as "a classic example of… 'low-value' speech."[16]

2.2 Commercial Speech Begins to be Protected

The position taken in *Hamdard Dawakhan* was limited in *Indian Express Newspapers*, where the imposition of levies compelled reduction of the area of newspapers used for advertisements.[17] The loss in advertisement revenue was found to be in contravention of Article 19(1)(a) on the basis that curtailment of newspaper circulation impacted on the ability of the "democratic electorate…to make responsible judgements" as the "purpose of the press is to advance public interests."[18]

Interestingly, *Indian Express Newspapers* observed that the Parliament *intended* to exclude "a clause enabling the imposition of reasonable restrictions in the public interest" whilst amending the provisions of Article 19(2) under the Constitution (First Amendment) Act 1951.[19] This did not prevent *Indian Express Newspapers* to make an expansive reading of Article 19(1)(a) to recognize freedom of press based on the principle of public interest. *Indian Express Newspapers* found *Hamdard Dawakhana's* observations on "*all* commercial speech" to be "too broadly stated," given that the latter had only aimed to curtail a specific "type" of misleading advertisement. Thus, commercial speech per se should not be denied the protection of Article 19(1)(a) "*merely* because they are issued by businessmen."[20]

2.3 Protection is Limited to Specific Instances Where it is in the Public Interest

The protection of commercial speech was echoed by *Tata Press*[21] in a case involving the publication and circulation of "Tata Press Yellow Pages," where a buyer's guide comprising of advertisements from traders was in dispute. *Tata Press* limited *Hamdard Dawakhana* to advertisements that are "deceptive, unfair, misleading and untruthful" and noted that commercial speech *per se* should not be denied Article 19(1)(a) protection merely because they are issued by business people. What is interesting to note is that the rationale to protect advertisements under Article 19(1)(a) was articulated primarily on public interest grounds and also on the public's right to receive such commercial speech. The court found that commercial advertisements benefit the public as they help disseminate information in "a democratic economy" and could be of "much more importance to general public than to the advertiser who may be having purely a trade consideration."[22] In other words, the expansive reading of Article 19(1)(a) was specifically to protect the interests of the public as opposed to corporate interests, which were arguably treated as incidental in comparison to the objective of public interest protection.

Tata Press also failed to specify the specific restriction under Article 19(2) that would come into play whilst excluding commercial advertisements that are deceptive, unfair, misleading and untruthful.[23] A similar issue can be seen in *KVHS* where the court did not specify the restriction under Article 19(2) that would come into play whilst preventing tobacco advertisements used in the film industry and once again articulated its finding on the basis of public interest.[24] This use of the principle of public interest to read commercial speech into Article 19(1)(a) is not unusual in that this principle has been used consistently to expand the boundaries of the right to freedom of speech and expression.[25] Such expansive understanding of free speech was based on instrumental principles whereby free speech aims to secure or promote broader values such as democracy[26] rather than being protected for its own intrinsic value.[27] Such an interpretation led courts into reading two different types of commercial interests —one that promotes public interest and one that was solely in corporate interests.

In *Mahesh Bhatt,* the petition challenged the constitutionality of legislation prohibiting advertisements of tobacco products on the basis that the list of reasonable restrictions under Article 19(2) does not include "public health."[28] Where an advertisement has the *mere* object of furthering business, the Delhi High Court found that such commercial speech did not fall strictly within the ambit of Article 19(1)(a) which protects free speech *only* where it has the objective to propagate ideas that are social, political, economic or furthers literature or human thought.[29] Moreover, the Delhi High Court observed that "commercial speech can be restricted more easily as compared to political or social speeches" when and if there is substantial justification, as Article 19(1) ought to be read in a manner that includes the principle of the larger public interest.[30] On this basis, the court upheld the ban on tobacco advertisements and declared that, in cases of commercial speech where "the purpose is to merely earn profits by selling products/services," it does not receive the protection of Article 19(1)(a) as there is "*hardly any element of free speech*…involved."[31]

In *Telecom Watchdog,* the Delhi High Court makes a distinction between "purely commercial advertisement," the

purpose of which is to further trade and commerce —thus placing it "outside the concept of freedom of speech and expression" and those types of commercial speech whose purpose is the propagation of ideas —social, political or economic, or ideas in furtherance of literature or human thought."[32] Such limitation on the scope of commercial speech can be noted from *Suresh*, where the Supreme Court held that in cases where "freedom of speech gets intertwined with business it undergoes a fundamental change and its exercise has to be balanced against societal interest."[33]

3. Construing Constitutional Provisions Harmoniously to Prioritise Public Health

The judiciary has used the principle of harmonious interpretation to give substance to the notion that certain types of commercial speech do not fall within the protection of free speech guaranteed by Article 19(1)(a).[34] As the Supreme Court recognised in the seminal case of *Maneka Gandhi,* different fundamental rights within Part III of the Constitution "do not represent separate streams of rights…they are all parts of an integrated scheme" such that "the isolation of various aspects of human freedom, for purposes of their protection, is neither realistic nor beneficial but would defeat the very objects of such protection."[35]

3.1 Article 21 Right to Life

Over the years, the right to life under Article 21 has been interpreted in the widest and most liberal manner with a view to "anticipate and take account of changing conditions and purposes so that the Constitutional provision does not get atrophied or fossilized but remains flexible enough to meet the newly emerging problems and challenges…"[36] As such, the right to life has been expanded to include the right to health.[37] This broad reading of Article 21 is made clear in *Peerless General Finance*, where the Supreme Court observed that the right to life includes the right to live with basic dignity "with necessities of life such as nutrition, clothing, food, shelter over the head, facilities for cultural and [the] socio-economic wellbeing of every individual."[38]

This raises the question as to how two provisions of the constitution, such as Article 19(1)(a) that have been broadly interpreted to include commercial speech and Article 21 which has been broadly interpreted to include the right to health, can be reconciled with one another. In early cases such as *Sankari Prasad,* the Supreme Court observed that harmonious construction requires one right to be read as controlled and qualified by the other.[39] This view has since been refined on the basis that the framers of the Constitution had not intended "conflict or repugnancy" between various provisions and if they "appear to be in conflict with each other, these provisions should be interpreted as to give effect to a reconciliation between them, so that, if possible, effect could be given to all."[40]

In *Mahesh Bhatt,* though the laws restricting advertisements of tobacco "strictly do not fall within the ambit of Article 19(2)", they were held to be "intra vires and valid", as freedom of speech and expression guaranteed under Article 19(1)(a) and the right to life guaranteed under Article 21 have to be "harmoniously construed to advance interest of general public".[41] Similarly, in *Struggle Against Pain*, the restrictions on advertising of harmful products was found to be "reasonable and justified" these are in the "larger public interest" and promotes the right to life under Article 21."[42]

The harmonious alignment of Article 19(1)(a) right to speech with Article 21 right to life is achieved where, for instance, in *Mahesh Bhatt*, Article 19(1)(a) protections are carved away and removed from "purely commercial speech" as it encourages use of tobacco leading to disease and health problems,[43] as these are not in public interest.

3.2 Directive Principles of State Policy

The Directive Principles of State Policy (Part IV of the Constitution) perform an "expressive function" wherein a directive's endorsement of an agenda, such as public health, "bestows upon it a degree of symbolic constitutional legitimacy."[44] Unlike provisions relating to the fundamental rights that are guaranteed by the Constitution, the directive principles are not enforceable even though they are recognised as setting out the "programme and the mechanics…to attain the constitutional goals set out in the Preamble."[45] The directive principles are "fundamental in the governance of the country," and it shall be the duty of the state to apply these principles in making law.[46] It is important to note that the mere lack of justiciability should not be a ground for discrediting the importance of the directive principles vis-à-vis the fundamental rights.[47]

In the seminal case of *Kesavananda Bharati*, the Supreme Court declared both directive principles and fundamental

rights to represent the “conscience of the Constitution” and found it necessary to harmonise them to achieve “the dignity of the individual.”[48] Holding that the makers of the Constitution “did not contemplate any disharmony between the fundamental rights and directive principles,” as they “were meant to supplement one another,”[49] *Kesavananda Bharti* put forth the notion that it “can be said that the directive principles prescribed the goal to be attained and the fundamental rights laid down the means by which that goal was to be achieved.”[50] In *Minerva Mills*[51] the Supreme Court noted that the directive principles and fundamental rights “are like two wheels of a chariot, one no less important than the other.”[52]

The directive principles under Article 47, especially since it refers to issues arising from intoxicating drinks, have been used by the courts in alcohol control cases.[53] The Supreme Court broadly interpreted public health on the basis that a “true interpretation” of the term “public health” includes several aspects that promote healthy living since “public health refers to both a goal for the health of a population and to professional practices aimed at its attainment.”[54] In *MC Mehta,*[55] the Supreme Court prioritised concerns for public health by reducing air pollution and observed that “to allow industries to benefit at the expense of public health” is a violation of the directive principles, including Article 39(e) and Article 47. Allowing a public interest petition filed by the *Centre for Public Interest Litigation*, that sought to protect children from the harmful effects of soft drinks arising from misleading advertisements, the Supreme Court observed that it is the paramount duty cast on a state to achieve “an appropriate level of protection to human life and health” from any food article that is “hazardous or injurious to public health” by reading Article 21 with Article 47.”[56]

The directive principles under Article 39(e) provides that the state shall direct its policy towards securing “the health and strength of workers” and Article 39(f) provides for opportunities and facilities to be given for the development and growth of children in conditions of freedom and dignity. A harmonious construction of Article 19(1)(a), Article 21, Articles 47, 39(e) and (f) can thus allow for the protection of public health when placed alongside Article 19(1)(a) that protects commercial speech only in cases of public interest.

Conclusion

India has a well-developed public interest litigation system, which has allowed individuals and civil society bodies to approach the Supreme Court directly on behalf of others or specific social causes, through a broad construction of locus standi.[57] Most public health and NCD-related cases are filed as public interest litigation petition with one of the earliest order relating to public smoking ban being ruled by the Kerala High Court in 1999, followed by a nation-wide ban order ruled by the Supreme Court in 2001 on the basis of indirect violation of the right to life of non-smokers.[58] The expansion of Article 21 right to life to include right to education, health, to live with dignity, right to shelter, right to food security, right to life in healthy environment etc were all issued as part of public interest litigation. The zealousness of the judiciary to engage in “social revolution”[59] has come at a price.[60] The Supreme Court of India has been accused of “deciding cases based on a certain conception of its own role —whether as a social transformer, sentinel of democracy or protector of the market economy” and this “unique decision-making process has side-lined reason-giving in preference to arriving at outcomes that match the Court’s perception” to the extent that the decisions can sometimes be “detached from precedent, doctrine, and established interpretive methods.”[61]

This explains why the judiciary has not sufficiently explored reasonableness of the restrictions available under Article 19(2) to limit commercial speech.[62] Instead, to circumvent the omission of “public health” in Article 19(2), the judiciary has resorted to riving up freedom of commercial speech into two parts —one that furthers public interest and those that are primarily based on purely commercial interest - to rule that whilst commercial advertisers may have rights guaranteed under Article 19(1)(a), they are protected only where they are in the interests of the public. Left without an identifiable test that can determine the distinction, the judiciary has relied on the doctrine of harmonious construction to engage in a purposive interpretation of various constitutional provisions that can be linked to the issue of public health in order to arrive at findings that promote public health.

As highlighted in this paper, emerging jurisprudence indicates that it has become increasingly difficult for industry to judicially challenge rules and regulations that prohibit or restrict advertisements of unhealthy commodities. This position is further entrenched against advertisers of unhealthy commodities intending to challenge legislation

protecting public health as they need to cross the hurdle of presumption in favour of the constitutionality of such enactments as provided by Article 13 of the Constitution.[63] Even so, such rulings have not always translated into effective compliance.[64] Over the last decade, the food lobby has successfully delayed the introduction of a comprehensive and clear food-labelling system to warn consumers about harmful levels of fat, salt and sugar in processed food. A harmonious interpretation of the little referred to statement in *Tata Press* to the second facet of freedom of expression —the consumer's "right to receive" information —may provide future opportunities to move beyond restrictions on commercial speech to granting consumers the protection to become informed about known harms of products.[65]

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The OSHA COVID-19 Case and the Scope of the Occupational Safety and Health Act

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ABSTRACT (ENGLISH)

The Occupational Safety and Health Administration (OSHA) issued an emergency temporary standard (ETS) for COVID-19 applicable to private sector employers with 100 or more employees. Among other things, the ETS required employers either to mandate employee vaccination or weekly testing and wearing masks.

FULL TEXT

The pandemic of COVID-19 raged largely out of control in the United States for much of 2020.[1] The Food and Drug Administration (FDA) emergency use authorization for (and later approval of) extremely safe and highly effective vaccines was not greeted with the widespread acceptance that many researchers, clinicians, public health experts, and government officials expected. For various personal, social, and political reasons a vocal minority of the population expressed extreme skepticism, indifference, or antipathy to the new vaccines.[2] As a result, vaccination rates in the United States lagged other high-income countries and were inadequate to meet the challenge of even less infectious and milder variants of SARS-CoV-2.[3] The Biden Administration, which took office on January 20, 2021, was determined to increase vaccination rates. Unfortunately, exhortation, encouragement, inducements, and other measures in the private and public sectors had only limited success.[4] Public health and bioethics experts asserted it was necessary and appropriate to mandate vaccination in various settings, including workplaces,[5] but the

legal basis for doing so was unclear.

Tracing the constitutional origins of governmental authority to regulate public health requires a brief foray into American legal history. During the colonial period, public health laws in each colony predated the federal Constitution and helps to explain why public health was not one of the enumerated powers granted to the federal government in the Constitution.[6] Pursuant to the Tenth Amendment,[7] the "police power" to safeguard the health, safety, and morals of the community was vested in the states.[8] Consequently, states and their political subdivisions retain the primary responsibility for vaccination, quarantine, isolation, and other public health measures.[9] The federal government has limited constitutional authority for public health, mainly under the commerce clause, but it is limited to international and interstate threats to public health.[10]

Some states enacted laws mandating vaccination or frequent testing of some or all state employees or health care workers against COVID-19.[11] Other states, by legislation or executive order, prohibited vaccination mandates for state or local government employees, health care workers, or all private sector employees.[12] In short, the nation's response to COVID-19, including in the workplace, has been inconsistent and insufficient to prevent the deaths of over 900,000 Americans; and tragically, most of these deaths were preventable.[13]

The federal government, without constitutional authority to impose a population-wide vaccination mandate,[14] in 2021 issued regulations and executive orders to require vaccination for five categories of workers subject to federal regulation: (1) federal government employees;[15] (2) employees, contractors, and volunteers in the federally-funded Head Start program;[16] (3) employees of federal government contractors and subcontractors;[17] (4) employees of health care employers participating in the Medicare and Medicaid programs;[18] and (5) employees of employers subject to the Occupational Safety and Health Act (OSH Act).[19] Each of these federal vaccination mandates has been challenged in court, but this article focuses on the challenge to the OSH Act emergency temporary standard (ETS) decided by the Supreme Court on January 13, 2022. The article begins by considering the OSH Act's provision for issuing an ETS, followed by a discussion of the ETS for COVID-19, the *OSHA COVID-19 Case*, the major questions doctrine, Congressional Review Act, and the implications of judicial entry into major economic and political questions.

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Emergency Temporary Standards

The procedure for promulgating new occupational safety and health standards under the OSH Act[20] is arduous, resource intensive, and excruciatingly slow.[21] The OSH Act contains a provision to expedite this process in extraordinary situations. If the Secretary of Labor determines that employees are "exposed to grave danger from exposure to substances or agents determined to be toxic or physically harmful or from new hazards" an ETS may be issued.[22] The standard becomes effective immediately upon publication in the *Federal Register* without further rulemaking. An ETS may remain in effect for only six months, and then the OSH Act's detailed rulemaking process must be followed to promulgate a permanent standard.

As with all OSHA standards, an ETS is subject to judicial review,[23] and the courts of appeals have struck down five of the six original ETS's challenged in court.[24] In *Asbestos Information Association / North America v. OSHA*,[25] the Fifth Circuit invalidated an ETS for asbestos. The court held that in weighing the risks and benefits of a proposed ETS, OSHA may consider only the benefits of the ETS during the six-month period in which it would be in effect. At the same time, the court said it was troubled by the possible inaccuracy of using risk assessments for such a short period of time.[26] The court concluded that OSHA failed to prove that an ETS, the "most dramatic weapon in its enforcement arsenal," was necessary to achieve the projected benefits.[27]

After the *Asbestos* case imposed a heavy burden on the Secretary of Labor to establish the validity of an ETS, OSHA did not issue an ETS for nearly 40 years —until 2021.[28] In his first day on the job, President Biden pledged

that OSHA would issue an ETS to address the workplace hazards of COVID-19, especially as they pertained to "essential workers," such as health care workers, meat and poultry workers, and transportation workers.[29] The delay in researching, drafting, and issuing the ETS,[30] until June 21, 2021, appeared to lessen the need for a comprehensive measure. By then, the first two vaccines received emergency use authorization from the FDA, people were being vaccinated, and the number of cases, hospitalizations, and fatalities were declining.[31] Consequently, the Secretary issued a limited ETS applicable only to health care employers. Along with requirements to use personal protective equipment and implement hazard controls, the ETS merely "encouraged" vaccination of workers. The ETS was not challenged in court, and it expired at the end of six months, on December 21, 2021.

The *OSHA COVID-19 Case*

The optimism of the spring of 2021 was short lived, and it ended in the summer when the United States was overwhelmed by the more transmissible and lethal Delta variant and the resulting resurgence of cases, hospitalizations, and fatalities. At the same time, opposition to vaccine mandates was hardening. On September 9, 2021, President Biden announced plans to require vaccination of five categories of workers subject to federal regulation,[32] and he announced that an OSHA ETS would be forthcoming.

On November 5, 2021, OSHA issued an ETS for COVID-19,[33] applicable to employers with 100 or more employees, including part-time employees and those who worked at all locations across the country.[34] The requirements did not apply to employees who worked at home or other locations where others are not present, or to employees who worked exclusively outdoors.[35] The ETS did not apply to employees of the federal government, federal contractors, or health care workers, who were subject to a separate ETS or executive order.[36] OSHA estimated that the ETS applied to 84.2 million employees.[37]

Covered employers were required to establish and enforce a policy that was either (1) a written, mandatory vaccination policy requiring vaccination for current and new employees, unless they were entitled to a reasonable accommodation under the Americans with Disabilities Act[38] (based on a medical reason for not being vaccinated) or Title VII of the Civil Rights Act of 1964[39] (based on a sincerely held religious belief, practice, or observance); or (2) a written policy allowing employees, in lieu of vaccination, to provide proof of a negative COVID-19 test at least every seven days and wearing a face mask while at the workplace.[40] Employers also were required to adopt policies to determine the vaccination status of employees, provide paid time off for vaccination and any vaccine side effects, enforce face mask requirements, and provide information to employees about vaccinations and relevant laws regarding anti-retaliation protections and providing false information.[41]

The OSHA ETS explicitly preempted any contrary state laws, including legislation or executive orders prohibiting vaccination mandates. State plan states were required to implement the new federal ETS or promulgate their own comparable ETS "at least as effective" as the federal OSHA ETS.[42] As with any ETS, it was to remain in effect only for six months.

The ETS was challenged in 34 cases, with at least one case filed in every circuit. A lottery, pursuant to federal law,[43] placed the consolidated case in the Sixth Circuit. The court's first order of business was to consider the government's motion to dissolve a stay issued by the Fifth Circuit, which had decided the case on an emergency basis and held that the petitioners challenging the ETS were likely to succeed on the merits.[44]

A Sixth Circuit panel dissolved the stay and held that OSHA had explicit statutory authority under the OSH Act to regulate health risks in the workplace, which Congress reaffirmed in the Needlestick Safety and Prevention Act[45] and the American Rescue Plan.[46] Judge Stranch's majority opinion stated that OSHA's finding of a "grave danger" was heightened by the emergence of the Delta variant. "Fundamentally, the ETS is an important step in curtailing the transmission of a deadly virus that has killed over 800,000 people in the United States, brought our healthcare system to its knees, forced businesses to shut down for months on end, and cost hundreds of thousands of workers their jobs."[47] Judge Larsen's dissent asserted that OSHA exceeded its statutory authority in promulgating the ETS. [48]

The Supreme Court granted emergency review to consider whether the Sixth Circuit erred in dissolving the stay imposed by the Fifth Circuit. In *National Federation of Independent Business v. Department of Labor*,[49] the Supreme Court stayed the ETS pending a decision on the merits by the Sixth Circuit. The Court's rationale for reimposing the

stay, the challengers' likelihood of success on the merits, was a *de facto* invalidation of the ETS.

The *per curiam* opinion of six justices stated that the Secretary of Labor lacked statutory authority to issue such a sweeping standard in the absence of an explicit congressional directive. "It is telling that OSHA, in its half century of existence, has never before adopted a broad public health regulation of this kind —addressing a threat that is untethered, in any casual sense, from the workplace."[50]

In articulating this narrow view of the permissible scope of OSHA's authority to regulate workplace hazards, the Court's rhetoric and reasoning may be questioned. First, the opinion asserted that "[t]he Act empowers the Secretary to set *workplace* safety standards, not broad public health measures."[51] The OSH Act not only empowers the Secretary to set "workplace safety standards," it authorizes the Secretary to set workplace safety *and health* standards. After all, it is the Occupational Safety *and Health* Act, and the legislative history of the OSH Act clearly indicates that occupational illness was a major concern of Congress in enacting the OSH Act.[52] The statute also created the National Institute for Occupational Safety and Health in the Department of Health and Human Services to conduct research on occupational health hazards such as asbestosis, byssinosis, lead, and pesticides.[53]

Second, the opinion used and repeated an oversimplified characterization of the ETS as a "vaccine mandate." Although vaccination was its most controversial element, the ETS contained many other measures designed to protect workers, such as personal protective equipment and testing. Vaccination was the preferred option of the ETS, but as an alternative to vaccination, employers could implement a policy of allowing employees to have weekly testing and wear a face mask while at the workplace.

Third, the opinion stated that OSHA is limited to regulating hazards unique to or at least especially problematic in the workplace. "Although COVID-19 is a risk that occurs in many workplaces, it is not an *occupational* hazard in most. COVID-19 can and does spread at home, in schools, during sporting events, and everywhere else that people gather."[54] This assertion overlooks the fact that OSHA regulates many safety and health hazards that exist both in and beyond the workplace, including fire, noise, asbestos, lead, and toxic chemicals. Furthermore, in the "Rationale for the ETS" section of its *Federal Register* filing, OSHA described the particular workplace risks of transmission. "Workplace factors that exacerbate the risk of transmission of SARS-CoV-2 include working in indoor settings, working in poorly-ventilated areas, and spending hours in close proximity with others."[55] The background text of the ETS discussed several workplace-based COVD-19 disease clusters documented in various industries and in multiple states, including the heightened risks posed by the Delta variant.[56]

The opinion added that where the virus "poses a "special danger because of the particular features of an employee's job or workplace, targeted regulations are plainly permissible."[57] This statement aligns the OSHA case with the Court's decision upholding the healthcare workplace regulation of COVID-19 issued by the Centers for Medicare and Medicaid Services and decided by the Supreme Court the same day.[58]

Justice Gorsuch (joined by Justices Thomas and Alito) wrote a concurring opinion that emphasized the role of the major questions doctrine in determining whether the ETS was beyond the scope of authority delegated by Congress. "The question before us is not how to respond to the pandemic, but who holds the power to do so. The answer is clear: Under the law as it stands today, that power rests with the States and Congress, not OSHA."[59] That conclusion is based on the major questions doctrine. "We expect Congress to speak clearly when authorizing an agency to exercise powers of vast economic and political significance."[60]

Justice Breyer (joined by Justices Sotomayor and Kagan) dissented, writing that OSHA demonstrated in "meticulous detail" that close contact between infected and uninfected individuals spreads disease and shared indoor workplaces present "heightened dangers."[61] Responding to the majority's assertion that OSHA lacked the authority to impose a broad standard regulating a health threat that exists widely beyond workplaces, Justice Breyer stated that "[t]he statute does not require that employees are exposed to those dangers only while on the workplace clock."[62] Finally, the dissent used the majority's argument that OSHA acted beyond its authority to assert that it was the Supreme Court that was acting beyond its authority in striking down the ETS.[63]

Major Questions Doctrine

Several of the judicial opinions holding or advocating for a narrow view of OSHA's statutory authority rely on the

major questions doctrine.[64] However, this is a relatively recent, ill-defined, and largely unexamined judicial canon with major implications. The origins of the doctrine go back to *Chevron, U.S.A., Inc. v. Natural Resources Defense Council,*[65] in which the Supreme Court held that unless Congress has said otherwise, the courts should defer to administrative agencies if the agency's interpretation of the enabling legislation is not unreasonable. The major questions doctrine emerged as a way to limit deference to administrative agencies. Thus, in two subsequent cases the Court said that in extraordinary cases agency interpretations carry little weight and are not entitled to *Chevron* deference.[66] Then, in *King v. Burwell*,[67] in upholding the constitutionality of the Affordable Care Act, the Supreme Court relied on the major questions doctrine to hold that *Chevron* deference did not apply. Nevertheless, the Court did its own statutory analysis and reached the same result as the agency.

In its two most recent applications of the major questions doctrine, both dealing with COVID-19, the Court extended the doctrine beyond the issue of whether deference should be afforded to the agency to ruling on whether the agency action was beyond the scope of its statutory authority. In *Alabama Association of Realtors v. Department of Health and Human Services*,[68] the Supreme Court applied the major questions doctrine to invalidate a nationwide moratorium on evictions in counties with high levels of COVID-19 transmission. The Court held that there was no evidence that Congress intended for a vague section of the Public Health Service Act to authorize the Centers for Disease Control and Prevention to regulate landlord-tenant relations, a traditional domain of state law. Then, in applying the doctrine to strike down the OSHA COVID-19 ETS, the Court expanded the doctrine to strike down a workplace safety and health regulation imposed by an agency explicitly created by Congress to regulate workplace safety and health.[69]

There are two main problems with the expansive major questions doctrine. First, it is not clear what a major question is.[70] As Judge Stranch wrote in her majority opinion for the Sixth Circuit panel, "The doctrine itself is hardly a model of clarity, and its precise contours —specifically, what constitutes a question concerning deep economic and political significance —remain undefined."[71] Furthermore, using the number of public comments submitted as a metric for "political significance" is an invitation to mass, fraudulent, and computer-generated comments.[72]

Second, the major questions doctrine represents an extraordinary level of judicial activism that undermines fundamental aspects of the separation of powers. "The doctrine has nothing to do with preserving self-government and everything to do with increasing the reach of the juristocracy."[73] In the *OSHA COVID-19 Case*, the Supreme Court attacked the fundamental principle that Congress establishes federal administrative agencies with the expertise to design and implement specific measures to complete a regulatory picture only sketched by Congress. There are vast implications for health policy of this unconstrained constitutional doctrine. "By limiting the federal government's ability to flexibly protect public health, the justices gave themselves an outsize role in formulating health policy, with significant ramifications that will remain long after the pandemic ends."[74]

Congressional Review Act

The Supreme Court's *per curiam* opinion asserted that Congress never authorized OSHA to issue such a broad and far-ranging standard. "In fact, the most noteworthy action concerning the vaccine mandate by either House of Congress has been a majority vote of the Senate disapproving the regulation on December 8, 2021. S.J. Res. 29, 117th Cong., 1st Sess. 2021)."[75] The Court's reference to a vote under the Congressional Review Act[76] as evidence of congressional sentiment appears to vary from the legislative intent.

The Congressional Review Act of 1996 provides a mechanism for Congress to consider, and then approve or disapprove, major federal regulations. The first use of the law was in 2001 when President Bush signed a congressional resolution of disapproval of the OSHA ergonomics standard.[77] In 2017, President Trump signed a joint resolution revoking the OSHA recordkeeping rule finalized in the last days of the Obama Administration.[78] The language and legislative history of the Congressional Review Act make it clear that "courts were not to intervene during the legislative process or assume congressional intent from failing to adopt a resolution of disapproval."[79] According to the Senate sponsors of the law: "Subsection 801(g) prohibits a court or agency from inferring any intent of the Congress only when 'Congress does not enact a joint resolution of disapproval' or by implication, when it has not yet done so."[80] Similarly, passage of a resolution by one chamber of Congress does not support an inference of

congressional sentiment.

Conclusion

The *per curiam* opinion in the *OSHA COVID-19 Case* stated that the COVID-19 ETS was unprecedented. “This ‘lack of historical precedent,’ coupled with the breadth of authority that the Secretary now claims, is a ‘telling indication’ that the mandate extends beyond the agency’s legitimate reach.”[81] The Court did not mention that in the last century the United States has never faced such a dire threat to public health, one in which deaths directly attributable to COVID-19 in the United States could reach one million. Nor did the Court mention that many —if not most —of the fatalities could have been prevented if millions more Americans were vaccinated, including with booster shots, at no cost to them and using vaccines with an unprecedented level of safety and efficacy.[82] The Court also was unpersuaded by evidence that the workplace played a significant role in the transmission of COVID-19.[83]

The essence of public health is balancing the interests of the public and the individual. With the extraordinary severity of the pandemic self-evident, judicial decisions opposing vaccination requirements have emphasized the supposed burdens of vaccination. A Sixth Circuit opinion characterized vaccination as “permanent and physically intrusive” and asserted that a “vaccine may not be taken off when the workday ends.”[84] According to the Fifth Circuit, “the Mandate threatens to substantially burden the liberty interests of reluctant individual recipients put to a choice between their job(s) and their jab(s).”[85]

The reasonable liberty interests of individuals deserve protection in the workplace and beyond, but they do not trump the interests of the population. As Justice John Marshall Harlan wrote, “There are manifold restraints to which every person is necessarily subject for the common good of its members. On any other basis, organized society could not exist with safety to its members.”[86]

The immediate implication of the *OSHA COVID-19 Case* is to prohibit OSHA from comprehensive regulation of working conditions that contribute to transmission of COVID-19. But the repercussions extend beyond this case. The Supreme Court has unabashedly entered the realm of politics and embraced a doctrine that ostensibly shifts power from federal agencies to Congress and the states. In reality, at least for the foreseeable future, instead of a shift in regulatory responsibility there will be a void in essential public health protections.

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About This Column

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Commercial Speech and Unhealthy Food Products: Conceptual Foundations

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ABSTRACT (ENGLISH)

This article provides a critical and philosophical assessment of arguments invoked for and against the constitutional protection of commercial expression and the regulation of commercial speech with a focus on the commercialization of unhealthy food products.

FULL TEXT

Debates over the role of commercial speech and the permissibility of restrictions to commercial speech have long taken place in academic and non-academic settings. Scholars and caselaw have often claimed that commercial speech plays a vital role in the economic and social fabric. Commercial speech allows individuals to access valuable information to make personal decisions. Advertising provides useful information for making informed choices relevant to us and our close ones;thus, promoting individual self-government.[1] In addition, commercial speech allows the economy to thrive by creating bonds and relationships between producers and consumers.[2] This translates into profits, and ultimately national revenue; and, on the part of the consumer, the fulfilment of their needs. Proponents of robust protection of commercial speech have argued that it is a form of free speech (a cornerstone of liberal democracy), claiming that bans on advertising, promotion, and sponsorship violate their rights to freedom of commerce and freedom of expression. In their view, commercial speech is essential for producers and sellers to communicate information about their products and services. Thus, the restriction of commercial speech could restrain competition and favor some producers and sellers over others.[3] Consequently, the role of commercial speech is arguably vital both to individuals and society.

In recent years, and based on emerging evidence of the impact of marketing and advertising in increasing the consumption of unhealthy products, various governments have adopted measures to restrict commercial speech when it promotes unhealthy food products.[4] For instance, some countries have regulated the marketing of unhealthy food products to minors. Others have adopted regulations requiring the inclusion of front-of-package labels to help consumers make informed purchase and consumer choices.[5] A global controversy has arisen about whether ultra-processed foods and beverages companies should or should not sponsor the Olympic Games or other major sports events.[6] On the one hand, governments have justified these restrictions as a matter of public health policy on the evidence that marketing of unhealthy food products leads to decisions that can be detrimental to health.[7] On the other hand, the corporate world has frequently questioned and denied such evidence.[8]

In light of these controversies, this piece explores the conceptual foundations of restrictions to commercial speech when it comes to the promotion of unhealthy food products. Firstly, we explore whether commercial speech can be restricted to promote personal autonomy, a fundamental value of liberal democracy, and explain why protecting autonomy requires restricting commercial speech, especially when aimed at children. Secondly, we suggest that, considering the evidence showing bounded rationality, autonomy may require restrictions on unhealthy food products even if not aimed at children. In this sense, we tackle objections that commercial speech restrictions entail impermissible paternalism. Thirdly, we explore why the public health and communitarian perspectives require regulating commercial speech, while addressing the objection that commercial speech regulation would be an impermissible perfectionist measure. The last section concludes.

This piece explores the conceptual foundations of restrictions to commercial speech when it comes to the promotion of unhealthy food products. Firstly, we explore whether commercial speech can be restricted to promote personal autonomy, a fundamental value of liberal democracy, and explain why protecting autonomy requires restricting

commercial speech, especially when aimed at children. Secondly, we suggest that, considering the evidence showing bounded rationality, autonomy may require restrictions on unhealthy food products even if not aimed at children.

Commercial Speech and Autonomy

In the classic liberal account of autonomy, the commitment of our societies to personal autonomy entails respect for our life plans, regardless of how others see their value. As the liberal philosopher John Stuart Mill famously put it, "[o]ver himself, over his own body and mind, the individual is sovereign."[9] Economists have developed a similar idea under the concept of the "homo economicus," a hypothetical, perfectly rational individual with complete information about their options and perfect foresight of consequences who makes choices to promote their preferences.[10] To exercise their autonomy, individuals require freedom from external interference by others, including the State; they also need information. In this view, provided that individuals have access to information, they are the best judges of the value of their decisions and governments should remain neutral as to the value of individuals' life plans. Therefore, the only acceptable justification for interference is to prevent harm to others —this is Mill's famous "harm principle," a cornerstone of liberal political philosophy. Of course, defining "harm to others" is not an easy task —it has been argued that "risk" is not a value-neutral concept and that the level of risk each individual is ready to accept is not obvious.[11]

In light of the harm principle, given the absence of potential harm to others and the relevance of information for individual decision-making, restrictions on commercial speech would not be justified, as a rule, in the classic liberal view. Nevertheless, the protection of autonomy may provide reasons to justify the government's legal right to regulate commercial speech when it is misleading or deceptive. In certain cases, governments may even be required to compel speech —for instance, when mandating disclosure requirements —to prevent harm to or exploitation of the otherwise uninformed consumer.[12]

Now, in addition to freedom from external interference, the exercise of autonomy requires an internal capacity for deliberative action.[13] Individuals with insufficient understanding to make informed choices to deliberate and act based on their desires and preferences are usually protected by legal systems from decisions that may harm them. This is clear, for instance, in the case of children. Under the assumption that children are not in the best position to judge which courses of action promote their own good, or that they are more likely to make poor choices, legal systems usually protect them from making decisions on their own. That is, they interfere with children's will to advance their good. This interference is often regarded as a form of acceptable paternalism.[14] When acting on behalf of children, adults have a duty to promote childrens' "best interests."[15] This duty usually involves preventing children from exposure to certain risks which, in many countries, has included the requirement for broadcasting companies to establish child protection hours in order to prevent exposure to certain contents.[16]

The duty to promote children's best interests may justify restricting commercial speech that targets them. Although as children grow older, their deliberative capacity becomes stronger and they start to understand the nutritional dimension of food, studies have shown that advertising and marketing continue to affect children's preferences for unhealthy food products. This, in turn, impacts their body weight development and, thus, their health.[17] As a response to the global concern for childhood obesity, countries like Chile, South Korea, the U.K., and Argentina have adopted regulations to reduce children's exposure to the marketing of unhealthy food products —including prohibitions of marketing of unhealthy products in schools, or using fictional characters, like cartoons, to encourage consumption.[18] This shows that, under the liberal framework, the autonomy-defense of commercial speech does not apply to children. The duty to promote children's best interests actually requires governments to restrict commercial speech in these cases.[19]

In contrast, as we have already mentioned, in the liberal framework, given the commitment to neutrality and deference to the individual as the best judge of their interests, overriding a competent adult's preferences for the sake of preventing harm to themselves is a controversial measure.[20] Nevertheless, autonomy could still provide an argument to restrict commercial speech even if not aimed at children.

In our societies, we often accept paternalistic measures for risk regulation, such as the mandating of motorcycle

helmets and seat belts or the fluoridation of drinking waters. Other more socially controversial measures, such as taxes on unhealthy products, like cigarettes, are paternalistic because they aim to disincentivize harmful conducts.[21] These measures and regulations acknowledge the centrality of personal autonomy, but recognize the fact that personal behavior is not merely an issue of free will, and that both internal and external constraints also shape it.[22] This is relevant in the context of unhealthy food products particularly due to the way in which these products are purposely engineered to trigger neurotransmitters and manipulate addictive-inducing sensations, as well as practices designed to target mental and emotional processing, such as, for instance, neuromarketing techniques.[23] Accordingly, it can be argued that human beings actually lack complete information and foresight when it comes to harmful products like unhealthy foods, as well as logical and practical omniscience: we cannot have complete knowledge of all that logically and practically follows from our current actions and commitments. Moreover, we may lack the ability to fully understand risks. This is known as "bounded rationality."[24]

Considering the evidence showing people's bounded rationality, autonomy could actually provide reasons in favor of a restriction of commercial speech. Access to appropriate information is a necessary condition to make informed choices and assume risks, but commercial marketing and advertising can skew information consumers receive and heavily influence consumer purchase and consumption choices.[25] In some cases, marketing tactics from the food and beverage industry portray consumption of unhealthy food products as "cool" or use popular fictional characters to associate the products with social recognition and professional success.[26]

It is not possible to speak of full rationality when the marketing and advertising of unhealthy products operate at the most primitive level of our brains, influencing our decision-making processes and, thus, undermining the detailed scrutiny of the advantages and disadvantages of their consumption. Marketing and advertising techniques generate an impulse to consume these unhealthy food products.[27] Thus, measures to restrict commercial speech would be justified in cases in which regulation is intended to neutralize the effects that marketing and advertising have on the consumption of products harmful to health in the face of a rationality deficit.[28]

Commercial Speech, Community, and Perfectionism

Another dimension of the commercial speech restriction debate comes from the communitarian perspective that strives to answer the question of what type of community we want to live in and what kind of relationships we want to foster. Communitarians argue that social institutions must promote social and communal values, which build our identity. Of course, individual autonomy and self-fulfillment matters, but they are not the main and only values for life in society.[29] In this view, our societies are not merely a collection of strangers with duties to respect the legal rights of one another arising from a "social contract"; our respect for others is that we owe each other as fellow members of a community. Public health matters because it "encourages connectedness to the community… viewing health risks as common to the group, rather than specific to individuals, helps foster a collective responsibility for well-being."[30] As Dan Beauchamp explained in his seminal article, public health is "communal in nature, and concerned with the well-being of community as a whole and not just the well-being of any particular person. Policy, and here public health paternalism, operates at the level of practices and not at the level of individual behavior."[31] As such, regulators must use the law as a tool for creating conditions for a type of society where individuals can lead healthy and meaningful lives in their communities. According to this view, public health regulations, such as those involving restrictions to the marketing or advertising of unhealthy food products, aim at achieving community well-being. Accordingly, from a communitarian perspective, commercial speech restrictions would be justified as they aim to promote a community where people can lead healthy lives.

It may be argued, however, that communitarian public health measures restricting commercial speech incur in perfectionism. By dictating and promoting certain ideals of human excellence. Perfectionists accept restrictions to autonomy to promote those ideals of excellence. This is a stronger thesis than paternalism because it disregards the agent's interests and only seeks to adjust the agent's behavior to a particular ideal. In that sense, perfectionism is objectionable because it disrespects individuals in a particularly profound way: it does not set precise limits for its demands, and its goals do not have to be shared by its recipients.[32]

However, the perfectionist accusation does not seem to apply to commercial speech restrictions, as these

restrictions do not impose, nor aim to impose, an ideal of excellence or a lifestyle. On the contrary, they contribute to promoting an environment in which people can enjoy greater freedom to carry out their life plans by making informed choices or avoiding uninformed ones within their communities. Were the State not to intervene, it would deprive people of real opportunities to choose a healthy way of life. State intervention aims at creating environments that ensure healthy options do not go unnoticed or require a significant investment of time, money, and willpower that few people have. In such contexts, the State could effectively promote life plans that it considers valuable, as long as it does not coercively impose the way of life that it considers correct.[33]

Conclusion

In this article, we have shown that the discussion about regulation of commercial speech, when it comes to the commercialization of unhealthy food products, should not be limited to whether the government interferes with free speech, but should rather consider the government's role in creating conditions for people to pursue their life plans, and ultimately promote their autonomy. We have also discussed a communitarian approach, which leads to public health regulations that invoke societal values.

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COVID-19 Law Lab: Building Strong Legal Evidence

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ABSTRACT (ENGLISH)

The COVID-19 Law Lab platform enables quantitative representation of epidemic law and policies in a given country for multiple years, enabling governments and researchers to compare countries, and learn about the impacts and drivers of policy choices. The Law Lab initiative is designed to address the urgent need for quality legal information to support the study of how law and policy can be used to effectively manage this, and future, pandemic(s).

FULL TEXT

Law has been at the center of the public health response adopted to address the COVID-19 pandemic, ranging from mandates on individuals, businesses, schools, religious organizations, and government offices; interventions ranging from less intrusive (e.g., social distancing) to more (e.g., vaccination requirements); and empowering a wide range of social actors for enforcement. Law has the potential to be a powerful tool for public health as laws and regulations

can regulate and alter the behaviors of large segments of the population. These behavior changes can lead to reduced exposure to risk factors and subsequently to lower transmission rates. Until vaccines received widespread regulatory approval and became widely available (in wealthier countries), law was the only tool to fight for public health. The COVID-19 pandemic has demonstrated a critical need for these legal measures to be evidence driven and shaped by community interests. Throughout the course of the COVID-19 pandemic, however, it has become clear that the global legal and scientific communities lack a robust body of evidence on which to base these kinds of decisions, and ensure effective implementation through law.

The COVID-19 Law Lab initiative, launched in summer 2020, aggregates legal and policy documents from nearly every country in the world. A joint project of the World Health Organization (WHO), United Nations Development Programme (UNDP), the Joint United Nations Programme on HIV/AIDS (UNAIDS), Inter-Parliamentary Union (IPU) the O'Neill Institute for National and Global Health Law, and the Georgetown University, and supported by universities, and individual researchers worldwide, the COVID-19 Law Lab contributes to filling the knowledge gap identified above. The Law Lab provides an open-access database that governments, international organizations, practitioners, researchers, policymakers, civil society, and others can use to better understand and evaluate the COVID-19-related legal and policy environment within and across countries.

Building Legal Capacity

When drafted properly laws can provide the foundation that brings clarity to complexity, embrace nuance, and identify gaps of uncertainty, some of the critical aspects of ensuring that epidemic or pandemic diseases do not disproportionately burden racial, ethnic, and religious minorities or that public health measures do not exacerbate exclusion or marginalization. School closures over the course of COVID-19, for example, have disproportionately affected women workers and the move to virtual education has privileged populations with access to computers and high-speed broadband.[1] Having a solid evidentiary base of legal information can promote the understanding of what works well, when, and where, and it can drive resources and action to where they are needed most.

The Law Lab provides an open-access database that governments, international organizations, practitioners, researchers, policymakers, civil society, and others can use to better understand and evaluate the COVID-19-related legal and policy environment within and across countries.

With COVID-19, countries have responded differently to the same threat, creating a wealth of evidence that can be analyzed by adopting a number of variables. For example, New Zealand was one of the last countries to implement a mask mandate (cases per 100,000: 117)[2] whereas Mongolia was one of the first to do so (cases per 100,000: 10,871).[3] Masking has been recommended by the WHO since June of 2020. South Korea adopted an early and comprehensive testing, tracing, and isolation system. It also incorporated contact tracing apps and individual surveillance for isolated individuals that other countries did not deploy because of applicable confidentiality and privacy law.[4] Sweden broadly adopted a controlled herd natural immunity approach, but also adopted restrictions on large gatherings and moved secondary schools and universities to online platforms.[5] Japanese authorities at the national level possessed no legal basis to "lockdown" or restrict movement or gatherings but did communicate those requests as a voluntary matter.[6]

When we begin to emerge from the COVID-19 pandemic, it will be critical to provide policymakers with guidance on what laws or policies were effective at responding to disease outbreaks, and what measures should be put in place to be able to quickly respond to future disease outbreaks. We know that legal mechanisms can enable nations to reduce inequities and prepare for emerging threats, like novel pathogens that result in deadly disease outbreaks or antibiotic resistance.[7] The collection and analysis of data on these legal mechanisms is a critical step towards ensuring that legal interventions and legal landscapes are effectively incorporated into more traditional kinds of health science data analyses. The data housed in the COVID-19 Law Lab is a unique opportunity to collect and analyze this kind of non-traditional data to inform policy using laws and policies from across the globe, and across diseases. This global view is critical to assessing the efficacy of policies in a wide range of cultural, economic, and demographic circumstances.

COVID-19 has demonstrated that we also have much to learn from other outbreak responses, such as the HIV/AIDS

response around the world. By examining data from policy responses to different disease outbreaks in a cross-cutting and innovative way, we hope to surface common mistakes, lessons learned, and ways in which effective policies can be leveraged across diseases to facilitate more effective and just legal responses.

Need for Stronger Data

Well-designed laws and policies, based on evidence and shaped by individual and community rights, can help build strong health systems, implement necessary measures to combat viral transmission, enforce actions that promote public health and safety for everyone, and on the individual level have a direct impact on health outcomes. Poorly designed laws and policies, on the other hand, can fail to achieve the intended results and/or obstruct the realization of fundamental human rights, further disease spread, or cause unintended collateral harm.

For a public health law or policy to be effective, well-designed evidence-based implementation strategies are necessary to ensure that the policies further the intended objectives. In the past, policies have been implemented based upon limited data. For example, school closures adopted after the declaration of the H1N1 pandemic in 2009 were shown to have little basis in evidence and no clear correlation with reduced transmission or individual outcomes.[8] Relatedly, the importance of access to schools for other social determinants of health requires that the evidentiary basis for restriction and limitation be robust. What evidence has been available has been largely anecdotal and idiosyncratic to country or disease. In other cases, a concerted effort to collect specific data on the efficacy of health policies has demonstrated the specific impacts of these policies, and has helped to inform expansion of those policies, or changes to make them more effective.

Data has been used to show that the following health policy interventions have concretely impacted health outcomes, either negatively or positively. For example, evidence has shown that the support from the polio program infrastructure, particularly the coordination mechanism adopted, the availability of skilled personnel in the polio program, and the lessons learned from managing the polio eradication program greatly contributed to the speedy containment of the 2014 Ebola outbreak in Nigeria.[9] The national emergency response infrastructure in the Democratic Republic of Congo for Ebola has managed to allow it to relatively quickly address outbreaks, especially since 2017.[10] Additionally, in Angola, Nigeria and Ethiopia, many disease epidemics including Marburg Hemorrhagic Fever, Dengue fever, Ebola Virus Disease, Measles, Anthrax and Shigella have been controlled using existing polio eradication initiative resources. Polio staff are deployed on occasions to support outbreak response activities (coordination, surveillance, contact tracing, case investigation, finance, data management). Many polio tools including micro planning, dashboard, guidelines, standard operating procedures (SOPs) on preparedness and response have also benefited other epidemic-prone diseases.[11] A second example of legal interventions having direct impacts on public health can be seen in the case of China. When China relaxed its one-child policy, maternal mortality stemming from illegal pregnancies declined.[12] Thirdly, a decrease in alcohol consumption in Halls Creek, a remote town in Western Australia, was attributed to the restriction on trading hours when “takeaway” alcohol was available.[13] Finally, showing a negative health outcome in the US, maternal mortality rates have increased when Planned Parenthood clinics were closed, increasing mortality by 6%-15% across racial/ethnic groups.[14]

These examples show the critical importance of investing in the development of systems for both collecting and analyzing data on health policy, including legal measures. Not only do these kinds of data help law and policymakers to create the most effective policies and monitor their efficacy, but they also allow policymakers to be constantly amending and tailoring these policies in response to emerging evidence. In addition to informing decision-makers, and empowering policymakers to develop evidence-based and effective measures, stronger data can play a critical role in developing public health communication strategies and fostering public trust in institutions. This can be especially helpful when promoting buy-in from citizens if they know that a policy is put in place for a specific purpose. Data on the efficacy of public health measures enables policymakers to indicate to the public which interventions have been successful, and to assure the public that those measures that are ineffective are not being applied indiscriminately or in contradiction of the available evidence. This can lead to increased compliance with public health measures, and increased community buy-in.

Law must not be static, particularly in times of crisis. Strong and reliable data can allow policies to be both

responsive and dynamic, to become more refined, less restrictive on businesses and individuals, and more narrowly tailored to focus on the components of the policy with the most beneficial impact. While it's not practical or plausible for governments to respond to every new byte of data; more accessible and reliable information can help them to respond to both existing public health crises and emerging crises such as the spread of novel pathogens.

The Database

In response to a pandemic, governments devote considerable resources to developing and/or procuring medical countermeasures including vaccines and therapeutics. Despite these clinical efforts, medical interventions may be insufficient to impede the spread of infection. At times vaccines and medical treatments may be ineffective or unavailable, and medical supplies may become scarce. Even with the development and deployment of medical countermeasures, they still need other public health interventions that are grounded in law and policy. During such unavailability or inadequacy of pharmaceutical interventions, governments adopted public health interventions that are particularly important in the response to infectious disease emergencies: isolation of persons known to be infectious; quarantine of asymptomatic persons who have been exposed (or potentially exposed); specific measures to protect vulnerable groups; surveillance and contact tracing; international and domestic travel restrictions; lockdowns and stay-home orders; and social distancing measures. National response during a public health emergency is often contingent on specific legal declarations such as the state of emergency declaration.

Based on these public health emergency response strategies, the COVID-19 Law Lab has identified seven categories of laws and policies as the key areas in the COVID-19 response [Table 1]. These seven types of laws and policies represent the core legal public health response strategies, and raise vital social, political, cultural, and constitutional questions as they implicate several other fundamental rights and freedoms, including association, travel[15], privacy[16], education[17], freedom from violence[18], and access to courts and tribunals.[19] These measures are tagged [Table 2] by keyword so that users can see which laws and policies implicate certain measures.

The Law Lab has identified number of objectives with respect to facilitating stakeholder use and analysis of evidence-based legal interventions. The first goal of the Lab is to gather as complete a set of legal texts and policies as possible across jurisdictions and key areas. To date, the COVID-19 Law Lab has collected over 7,000 legal and policy documents issued by governments or their public health authorities. This new and evolving effort harnesses efforts by academic, civil society, and international organization networks including UNDP, UNAIDS, WHO and IPU, and universities to collect legal and policy documents. If these primary sources are not available, official government press releases are gathered.

The text of laws and policies are categorized and tagged in using a 'directed content analysis' approach and using native speakers as the primary coders for the majority of texts.[20] The focus while categorizing and tagging is on the content of the law and policy in a country —not on how, or to what degree, that policy has been implemented, or enforced. The dataset is publicly available and encourages public participation. The Lab invites stakeholders, users, and supporters around the world to contribute legal and policy documents. All data on the site are available to search, filter, and download.

Conclusion

The COVID-19 Law Lab is not just a collection of legal and policy texts relating to the COVID-19 pandemic; it is a dataset of concise and actionable legal information that can be used by health researchers, social scientists, academics, human rights advocates, lawyers, and policymakers, governments, and others for cross-disciplinary quantitative and qualitative analysis to identify best practices from this outbreak, and previous ones, to be better prepared for potential future public health events. It presents evidence for a more effective public health response for future outbreaks.

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About This Column

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Collaborating Center on National and Global Health Law. Professor Meier is a Professor of Global Health Policy at the University of North Carolina at Chapel Hill and a Scholar at the O'Neill Institute for National and Global Health Law. This column will feature timely analyses and perspectives on law, policy, and justice in global health.

DETAILS

Subject:	Human immunodeficiency virus--HIV; COVID-19; Regulatory approval; Pandemics; Empowerment; Epidemics; Contact tracing; Public health; International organizations; Ebola virus; Law; Acquired immune deficiency syndrome--AIDS; Dengue fever; Surveillance; Maternal mortality; Poliomyelitis; Civil society; Disease transmission
Business indexing term:	Subject: Regulatory approval
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Company / organization:	Name: United Nations Development Programme; NAICS: 928120
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The Influence of the Commercial Speech Doctrine on the Development of Tobacco Control Measures

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ABSTRACT (ENGLISH)

Among the attempts to oppose tobacco control legislation, the tobacco industry has alleged violations of its right to commercial speech. While the disputes that took place in some jurisdictions like the United States (US), Canada, or the European Union (EU) have been already analyzed, much less is known about how, globally, this doctrine has influenced the adoption of tobacco control measures. This article contributes to filling this gap by illustrating how the commercial speech doctrine influenced the negotiations of the Framework Convention on Tobacco Control (FCTC). Moreover, using the Tobacco Control Database of Campaign for Tobacco-Free Kids, it shows that arguments on commercial speech have been used to challenge tobacco control measures in an increasing number of countries.

FULL TEXT

1. Introduction

Tobacco advertising has a long and dark history. For great part of the 20th century, tobacco manufacturers have freely employed virtually every possible advertising tool to market their deadly products: billboards, radio, television, cinema, comics, and even skywriting.[1] Not only did tobacco companies hide the dangers of smoking, they also actively tried to dispel fears by promoting allegedly safer cigarettes and recruiting doctors.[2] Marketing of cigarettes is a powerful tool for recruiting smokers, and the tobacco industry has used it to expand the market to specific groups of users, particularly teenagers,[3] minorities,[4] and women.[5]

As the late tobacco control advocate Ruth Roemer argued, restrictions on tobacco advertising are needed

for the same reasons that the tobacco industry spends vast amounts of money on it —because advertising increases sales and consumption of tobacco, encourages smokers to continue, induces young people to start smoking, and creates an atmosphere in which smoking is viewed as socially acceptable.[6]

The first comprehensive restrictions on tobacco advertising were enacted in the 1970s by Finland, Iceland, and Norway.[7] The experience of these pioneer countries and those that followed has allowed researchers to conclude that restrictions on advertising are among the most effective tobacco control measures.[8] Nonetheless, enacting, implementing, and enforcing restrictions on advertising for tobacco products has encountered fierce resistance by the tobacco industry. According to the most recent report of the World Health Organization (WHO), only 21% of the world population is covered by an effective ban on advertising, promotion, and sponsorship of tobacco products.[9]

There are several difficulties that explain why it is so hard adopt effective restrictions on advertising for tobacco products, including the multitude of channels and forms in which direct and indirect advertising can take place. The rapid growth of internet platforms and social media, for example, has certainly created loopholes and difficulties in enforcement of old regulations.[10]

It is incontrovertible, however, that one of the hardest challenges in adopting restrictions on advertising is the interference by the tobacco industry. Over the last 70+ years, the tobacco industry has developed a considerable amount of tactics to influence policy-making.[11] Aggressive litigation and threats of litigation are among them. When it comes to restrictions on advertising, one of the tobacco industry's core arguments has been that these restrictions would violate their freedom of commercial speech.[12] As explained in the introduction to this special issue, freedom of commercial speech is the application of freedom of expression in the context of messages and advertising by private companies. Since the doctrine of commercial speech was developed by United States (US) courts in the 1970s, it has received considerable attention.[13] The tobacco industry has used this doctrine to challenge (or threaten to challenge) restrictions on advertising.[14]

While the disputes that took place in some jurisdictions like the US as well as Canada and the European Union (EU) have been already analyzed, much less is known about how, globally, the commercial speech doctrine has influenced the development of tobacco control measures. This article contributes to filling this gap.

While the disputes that took place in some jurisdictions like the US as well as Canada and the European Union (EU) have been already analyzed,[15] much less is known about how, globally, the commercial speech doctrine has influenced the development of tobacco control measures. This article contributes to filling this gap. Section 2 starts the analysis by illustrating how the commercial speech doctrine influenced the negotiations of the treaty on tobacco, the Framework Convention on Tobacco Control (FCTC). Section 3 proceeds to examine the impact of commercial speech in litigation. Using the Tobacco Control Database of Campaign for Tobacco-Free Kids, this section shows that arguments on commercial speech have been used to challenge tobacco control measures in an increasing number of countries. However, they have mostly been unsuccessful. Finally, Section 4 shows that, although with different approaches, all the judgements examined have adopted an interpretation of commercial speech and of the applicable proportionality test that represents a valuable precedent. In spite of the tobacco industry's attempts, this trend dims the hope that commercial speech can be successfully used against tobacco control regulations outside of the US.

2. Using Commercial Speech to Oppose Strong Language in the Framework Convention on Tobacco Control

By the time the negotiations of the FCTC started in 2000, it was already demonstrated that restrictions on advertising were among the most effective measures to curb tobacco consumption.[16] However, there is a catch. Restrictions on advertising are effective "only if they are comprehensive, covering all media and all uses of brand names and logos."[17] The basic idea is that restricting advertising only, for example, in television would be not a very effective measure because the tobacco industry would simply move to invest more resources in newspaper advertisement or in other promotional activities like smoking in movies and sport sponsorship. To avoid this "leaking," policy-makers must adopt restrictions that cover all possible channels and forms of advertisement of tobacco products.

However, the proponents of a ban on advertising of tobacco products encountered strong resistance among the

negotiating States. One of the most repeated arguments against such a measure was that a comprehensive ban would infringe their constitutional rights and particularly freedom of commercial speech. The opposition of Germany is well documented.[18] Moreover, from the official records of the negotiations, we can see that the list of countries invoking constitutional limits against a comprehensive ban on advertising includes countries like Brazil,[19] Argentina,[20] Japan,[21] and the United States.[22] It is hard to know exactly what led these countries to raise the concern regarding commercial speech doctrine. What we can say, however, is that raising constitutional arguments in an international negotiations can be a powerful strategy. In a context where the effectiveness of a measure has already been demonstrated, there is little room for a debate on its merits and potential pitfalls of a measure. Instead, invoking a constitutional argument draws a red line that can be hardly confuted by the other negotiating parties.

Eventually, this opposition led the negotiating parties to agree to a less stringent wording on tobacco advertising than originally proposed. The final text of the FCTC thus represents an intricate compromise between recognizing that a total ban would be most effective, and acknowledging that some States' constitutions may prevent them from adopting a total ban. The article on advertising restrictions begins by "recogniz[ing] that a comprehensive ban on advertising, promotion and sponsorship would reduce the consumption of tobacco products."[23] The obligation to adopt such a measure, however, is softened by the caveat that this should be done "in accordance with [the] constitution or constitutional principles,"[24] For this reason, it is foreseen that if a party "is not in a position to undertake a comprehensive ban due to its constitution or constitutional principles [it] shall apply restrictions on all tobacco advertising, promotion and sponsorship."[25] To avoid the risk of an excessively narrow interpretation of this provision, the article clarifies that "[a]s a minimum" the FCTC parties must adopt some measures such as prohibition of "false, misleading or deceptive" advertising, health warnings, and restrictions on advertising in media and international sport events.[26]

To the best of my knowledge, since the adoption of the FCTC in 2003, no party to the FCTC or other actor has tried to challenge, or even simply debate, the idea that the commercial speech doctrine could prevent the adoption of restrictions on advertising in the context of tobacco control. The Guidelines to Article 13 of the FCTC, adopted in 2008, clarify the scope of application of the prohibition on advertising and give some guidance to States on how to adopt it.[27] However, they do not discuss any development on the issue of commercial speech. This seems to confirm that tackling constitutional debates in an international forum like the FCTC is considered very hard or, perhaps, even inappropriate.

In order to understand how the doctrine of commercial speech has impacted tobacco control after the conclusion of the FCTC, hence, we should focus our attention to domestic courts.

3. Using Commercial Speech to Oppose Tobacco Control via Judiciary Action

As noted in the introduction, US courts have been the first to develop the doctrine of commercial speech, and the first where commercial speech has been used to oppose restrictions to tobacco advertising. In this regard, it is worth recalling that, in principle, US case-law recognizes that tobacco advertising can be restricted to protect public health. However, the legality of advertising restrictions is subject to a proportionality-like test.[28] In assessing whether the challenged measures were more extensive than necessary, US courts have in some notable instances struck down restrictions on tobacco advertising.[29]

Outside of the US, the best place where to look for the impact of the commercial speech doctrine on the case-law on tobacco control measures is a website called Tobacco Control Laws. This is a database of laws and judgements about tobacco control measures managed by the nongovernmental organization Campaign for Tobacco-Free Kids.[30] At the time of writing, its database of judicial decisions contains more than 1000 entries, both from countries that have ratified the FCTC and from those who have not.[31] Of these decisions, 33 are relevant for this discussion as they are actions against government policies or regulations concerning advertising, and contain arguments on freedom of expression and commercial speech.[32] Most likely, these decisions do not represent the entirety of all decisions on commercial speech. However, they offer a sizeable sample to understand how the doctrine of commercial speech has been used to oppose tobacco control regulations on advertising around the world.

An analysis of the relevant decisions shows that, outside of the US, the doctrine of commercial speech has been

used to oppose tobacco control measures in many different countries with different legal traditions, including India, South Africa, Argentina, Canada, Costa Rica, Colombia, the EU, and Sri Lanka. Second, with respect to historical trends, the first cases on commercial speech outside of the US reported in the database date back to 2006, but cases have increased in the most recent years. Commercial speech, hence, appears to be increasingly used to oppose tobacco control legislation, in terms of both the number of countries and the number of cases concerned.
The most important fact that these judgements reveal, however, is that in the vast majority of the cases the restrictions on tobacco advertising have been upheld, and the courts have ruled that the protection of public health overrides any right to freedom of expression of the tobacco companies.
Among the non-US courts, only two courts appear to have invalidated tobacco control regulations on the ground that they would violate freedom of expression: the Supreme Court of Canada,[33] and the High Court of Delhi in India.[34] In both cases, however, the context of the decisions is critical to understanding the ruling. In the case of Canada, the ruling is from 1994, before the FCTC negotiations even took place and consensus on the effectiveness of a comprehensive ban was crystallized. The court held that a complete ban on advertising would be unconstitutional because it was not proportional. Among the reasons it gave, it noted that the Canadian government had not demonstrated that a total ban would be more effective than "a less invasive ban."[35] The court, thus, did not rule that tobacco advertisement could not be lawfully restricted, and did not even rule out the legality of a comprehensive ban, but only held that, in that specific case, there was no evidence supporting it.
In the case of India, understanding the dispute is more complex because it concerns film production, a specific sector where commercial speech is inextricably linked with freedom of speech in creative arts.[36] The dispute was brought by a film director, who challenged a rule that prohibited display of tobacco products in new Indian movies. Interestingly, the court held that the doctrine of commercial speech should be applied only "when a manufacturer places the product in the film for an economic purpose and not a mere exposure of the brand name in a film."[37] Since the rule prohibited *any* display of tobacco products, and not only those that are placed in films for economic purposes, the court found that the rule was in violation of freedom of expression. Although the provision was struck down, hence, the Indian case can be interpreted as recognizing that commercial speech can be lawfully restricted, while a higher threshold is needed for freedom of speech in the context of creative arts.
Overall, the rulings from Canada and India seem both to be the result of the circumstances of the specific cases than rulings affirming a strong stance in favor of protecting commercial speech in the context of tobacco. Therefore, at least as far as the Tobacco Control Laws database allows us to see, the US appears to be an outlier. In the rest of the world, arguments on commercial speech seem to have mostly failed in opposing tobacco advertising restrictions.
This finding, however, should be interpreted carefully. The fact that lawsuits based on commercial speech arguments have been largely unsuccessful outside of the US does not mean that the doctrine does not bear influence. Commercial speech may be working in a prior step, preventing regulations from being adopted at all. The tobacco industry is well-known for using the threat of litigation to dissuade governments from adopting tobacco control measures.[38] The disputes where commercial speech has been invoked, thus, may well represent the proverbial tip of the iceberg.

4. Different Approaches to the Interpretation of Commercial Speech in the Context of Tobacco Advertisement

Another reason why it is important to go beyond a simple analysis of the numbers of successful cases is that even disputes that look favorable (i.e., that have upheld restrictions on tobacco advertising) may have adopted an expansive interpretation of commercial speech that creates a potentially dangerous precedent for future disputes. For this reason, examining how courts have interpreted commercial speech is key to understanding the long-term implications of these judgements.
In this regard, the first thing that should be noted is that, since a claim of violation of the commercial speech doctrine typically requires an assessment of a proportionality or proportionality-like test, courts can apply various degrees of scrutiny in balancing the protection of public health and commercial speech. Depending on the circumstances of the case, US courts have applied three different forms of scrutiny in the tobacco control disputes: a rational basis scrutiny, an intermediate scrutiny, and a strict scrutiny.[39] Although there is some variability in how the tests are

employed by different courts, the Supreme Court has usually adopted the looser scrutiny (the rational basis), when the advertising is potentially misleading; the strictest scrutiny when the government mandates a specific form of commercial speech, like in the case of graphic warnings; and the intermediate scrutiny in all the other cases.[40]
While it is hard to fully compare the case-law from the different jurisdictions, it is possible to review the relevant judgements to understand which levels of scrutiny have been applied by the courts outside of the US. Some courts ruled that freedom of expression would guarantee only a very narrow protection to advertising, or could not be applied at all —hence rebuffing the application of the doctrine of commercial speech. For example, in upholding a provincial law prohibiting advertising and sponsorship of tobacco products, the Supreme Court of Argentina recognized that a loose scrutiny would apply to a claim of violation of freedom of speech that "does not bear a close relationship with the functioning of the republic and democratic system," but rather merely protects economic interests.[41] Even more vehemently, the Supreme Court of Sri Lanka held that advertising did not fall within the scope of the protected right to freedom of speech because it is not intended "to safeguard the natural right of an organized freedom loving society to impart and acquire information about a matter of common interest."[42]
Other courts recognized that commercial speech could be considered a protected right, but allowed an ample leeway to limit it in the public interest. The Supreme Court of Panama, for example, upheld the measures on tobacco advertising by simply noting that the protection of public health justified a restriction to the freedom of expression. The Court held that "[w]hen the social interest (collective wellbeing) is invoked and pursued, the adoption of a particular decision or act on the part of State authorities is justified."[43] Similarly, the EU Court of Justice held that "human health protection —in an area characterised by the proven harmfulness of tobacco consumption, by the addictive effects of tobacco and by the incidence of serious diseases …—outweighs the interests put forward by the claimants in the main proceedings."[44] In both these cases the courts seem to have applied a loose scrutiny, similar to the rational basis test employed by US courts. The mere existence of a public health interest, in fact, seems sufficient to justify the restriction of the tobacco companies' freedom of expression.
A third category of judgements, very relevant for this article, provided an interpretation of commercial speech specific to tobacco advertising —thus recognizing the exceptional history and characteristic of tobacco products. This was the case of the Supreme Court of Canada and of the Supreme Court of Appeal of South Africa. These courts recognized that the plaintiffs' claims could not be successful because "[w]hen commercial expression is used, as alleged here, for the purposes of inducing people to engage in harmful and addictive behaviour, its value becomes tenuous."[45] The issue, hence, is not that commercial speech cannot be protected, but that it cannot be protected in the case of a harmful and addictive product. Another very interesting judgement is represented by a ruling of the Constitutional Court of Colombia, which examined the double nature of commercial speech: as a protection of economic interest and as a protection of consumers' right to be informed.[46] The Constitutional Court started by engaging in an analysis of the reasons underlying the choice to protect commercial speech. It held that by its nature "commercial advertising" contains two forms of expression: an "informative" one and a "persuasive" one.[47] While the former is protected because it "ties to the protection of consumer rights," the latter "is exclusively an expression of economic freedoms," and for this reason it can be "limited, even quite stringently."[48] Accepting this understanding of commercial speech, the Constitutional Court went on to explain that restrictions on advertisement of "intrinsically hazardous" products like tobacco products do not impinge upon the "informative aspect" of commercial speech, but only its persuasive one —which, as stated above, is only expression of economic freedoms.[49] Accordingly, it found, the plaintiffs' claim could not be accepted as it did not encroach the constitutionally protected form of commercial speech.[50] This ruling represents a strong precedent to oppose possible future claims of violation of freedom of speech by the tobacco industry or similar industries. By holding that commercial speech by tobacco companies does not meet the requirements of constitutionally protected commercial speech, the Constitutional Court of Colombia basically barred any future claims on the constitutionality of restrictions on advertisement of tobacco products. In this view, restrictions on advertising of products like tobacco would be always lawful insofar as those forms of advertising does not serve the purpose of providing meaningful information to consumers.
Overall, the review of the cases above shows that the case-law on commercial speech and tobacco products around

the globe is replete with favorable precedents. Although with different approaches, all the judgements examined have rejected the possibility of protecting commercial speech rights of tobacco companies. Not only did these judgements reject claims of violation of commercial speech, but they did so adopting an interpretation of commercial speech (or of how commercial speech protection applies to tobacco products) that would make it harder for future similar cases to be successful.

5. Conclusions

This article has analyzed how the commercial speech doctrine has been used to oppose restrictions on advertising of tobacco products outside the US. First, Section 2 has illustrated how potential violations of commercial speech were used by several delegations to influence the negotiations of the FCTC. This argument was one of the main reasons why the text of Article 13 of the FCTC acknowledged the need of a total ban on tobacco advertisement, promotion and sponsorship, but stopped short from recommending it. Section 3 has continued the inquiry by reviewing how commercial speech has been used in litigation. Using the database of Campaign for Tobacco-Free Kids, it has shown that commercial speech has been used to oppose restrictions on tobacco advertising in a number of different jurisdictions, including India, South Africa, Argentina, Canada, Costa Rica, Colombia, the EU, and Sri Lanka. The number of cases in the past few years seems to have increased. Although only very few of these legal challenges have been successful, this article has cautioned against quickly declaring that the commercial speech doctrine has not influenced policy-making. The tobacco industry is known to use threats of litigation to prevent the adoption of tobacco control measures. Thus, commercial speech may have been used as an argument to oppose the very adoption of restrictions on advertising.

This analysis reveals that, despite the tobacco industry's attempts to use commercial speech to oppose restrictions on tobacco advertising around the globe, the US remains an outlier in terms of protecting the commercial speech of the tobacco industry. The other judgements examined in this article show that, although with different approaches, other courts tend to reject the idea that commercial speech can receive any protection at all or a strong protection. Not only commercial speech arguments have not been successful so far, but there is also little possibility that possible future disputes opposing restrictions on tobacco advertising on these grounds could be successful. Bearing these considerations in mind, it is fundamental that any policy-makers consider carefully any attempt by the tobacco industry to use commercial speech to hinder the advancement of tobacco control.

Finally, Section 4 has examined how the courts adopt different approaches in assessing the balance between public health and commercial speech rights. US courts have applied different tests for cases of commercial speech and tobacco products, resulting in a mix of looser or more stringent scrutiny according to the circumstances of the case. Conversely, all of the other jurisdictions examined seem to have adopted a favorable precedent. Some courts like the Supreme Court of Argentina and the Supreme Court of Sri Lanka have rejected the notion that commercial speech, generally, could receive a broad protection, or some protection at all. Others, like the Supreme Court of Panama and the EU Court of Justice have recognized that such protection exists but they have allowed for it to be limited when public health is at stake. Arguably, the most interesting rulings have been issued by the Supreme Court of Canada, the Supreme Court of Appeal of South Africa, and the Constitutional Court of Colombia. These courts, in fact, have decided that, although commercial speech is generally protected, it is less so in the specific case of tobacco products, for they are hazardous, harmful, and addictive products.

This analysis reveals that, despite the tobacco industry's attempts to use commercial speech to oppose restrictions on tobacco advertising around the globe, the US remains an outlier in terms of protecting the commercial speech of the tobacco industry. The other judgements examined in this article show that, although with different approaches, other courts tend to reject the idea that commercial speech can receive any protection at all or a strong protection. Not only commercial speech arguments have not been successful so far, but there is also little possibility that possible future disputes opposing restrictions on tobacco advertising on these grounds could be successful. Bearing these considerations in mind, it is fundamental that any policy-makers consider carefully any attempt by the tobacco industry to use commercial speech to hinder the advancement of tobacco control.

DETAILS

Subject:	Bans; Advertising restrictions; Smoking; Constitutional law; Tobacco; Speech; Negotiations; Tobacco industry; Commercial speech; Litigation; Legislation
Business indexing term:	Subject: Advertising restrictions Tobacco industry Commercial speech
Location:	United States--US; Canada
Company / organization:	Name: European Union; NAICS: 926110, 928120
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Public Reason, Public Comments, and Public Charge: A Case Study in Moral &Practical Reasoning in Federal Rulemaking

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ABSTRACT (ENGLISH)

The “public charge” rule is a long-standing immigration policy that seeks to determine the likelihood that a prospective immigrant will become dependent on the government for subsistence. When the Trump administration sought to expand the criteria that would count against an applicant for permanent residency to include public benefits historically excluded from the calculation, thousands of commenters wrote to oppose or support the proposed changes. This paper explores the moral and practical reasons commenters provided for their position on the public charge rule and considers the value of the public comment process for immigration, health, and social policy.

FULL TEXT

In October 2018, the Trump administration’s Department of Homeland Security (DHS) published a notice of proposed rulemaking (NPRM) in the *Federal Register*. This NPRM requested public comments on its proposal to change what is known as the “public charge” rule. The comments received by DHS, and the agency’s response to those comments in the August 2019 publication of the final rule, are the focus of this analysis. We review a sample of the public comments on the proposed changes to the public charge rule to identify the moral and practical reasons that commenters used to support or oppose the proposed rule. We explore the themes that emerge from the comments in the context of the government’s response in the finalized public charge rule from August 2019, subsequent court challenges to the rule, and the COVID-19 pandemic. Finally, we consider the value of public comments on proposed regulations related to immigration and immigrant health more generally.

Policy Background

According to the U.S. Citizenship and Immigration Services, a *public charge* is someone who is likely to become “primarily dependent on the government for subsistence.”[1] The “public charge rule” finds its roots in the Immigration Act of 1882, which denied admission to any “convict, lunatic, idiot or any person unable to take care of him or herself without becoming a public charge.”[2] The stated goal of restricting immigration in this way is to place limits on benefit use and prevent dependence on the government in order to reduce government spending. The rule uses a

screening test to determine if an applicant is likely to become a public charge. Groups that fall under the purview of the rule are: (1) legal immigrants applying for adjustment of status (that is, applying for permanent residency, or a "green card") and (2) immigrants applying for visas to gain admission into the United States. The public charge test does not apply to all immigrants; humanitarian immigrants, such as refugees and victims of trafficking, as well as Lawful Permanent Residents (LPRs) applying for citizenship, are not impacted by the rule.[3]

Historically, the United States has considered the use of two public benefits when making a public charge determination in the context of an applicant's "totality of circumstances": (1) receipt of cash assistance for income maintenance, and (2) institutionalization for long-term care at government expense.[4] Under the rule proposed by the Trump administration in 2018, the public charge test would have considered additional factors in this determination. Although the totality of circumstances test is not new, having been in place since the now-defunct Immigration and Naturalization Service (INS) issued the "Field Guidance on Deportability and Inadmissibility on Public Charge Grounds" in 1999, the proposed rule would have changed what factors were given weight in the assessment. Determinations under the proposed rule would have been reached through a calculation that considered age, health, family status, assets, resources, financial status, education, and skill. For example, age would be a "positive factor" in the case of the 30-year old applicant, but enrollment in Medicaid would weigh more heavily in the determination. In this regard, the "totality" calculation involves a balancing of "positive" and "negative" factors. The public benefits included in the new calculation would also have been expanded; whereas previously the government only counted receipt of cash benefits and long-term institutionalization against an applicant, the proposed rule included other benefits like Medicaid, SNAP, and housing programs. The proposed rule also sought comment on whether to include the Children's Health Insurance Program (CHIP), but as will be discussed below, this program was ultimately not included in the final rule.

We review a sample of the public comments on the proposed changes to the public charge rule to identify the moral and practical reasons that commenters used to support or oppose the proposed rule. We explore the themes that emerge from the comments in the context of the government's response in the finalized public charge rule from August 2019, subsequent court challenges to the rule, and the COVID-19 pandemic. Finally, we consider the value of public comments on proposed regulations related to immigration and immigrant health more generally.

In its proposed rule, DHS anticipated the total new costs imposed on applicants would range from approximately $453,134,220 to $1,295,968,450 over the course of the first 10 years.[5] They also noted in the proposed rule that the added complexity of the public charge test would place a "time-burden" on applicants and officials.[6] Under the proposed rule, those seeking legal permanent residency would be required to provide more extensive documentation, particularly regarding the benefits they receive and other considerations. Officials would face "familiarization costs" associated with the proposed rule; "reading the details of [the] rule to understand its changes" will in itself "cost" time. In terms of savings, DHS estimates the "total reduction in transfer payments from the federal and state governments would be approximately $2.27 billion."[7] This estimate reflects money saved from both disenrollment and "forgone enrollment," which is money saved from "individuals that forego enrollment due to concern about the consequences to that person receiving public benefits and being found to be likely to become a public charge." DHS acknowledged the high likelihood of this "chilling effect."

Public Comment Process and Value

When an executive agency like DHS seeks to create new regulations or substantially revise existing ones, they must follow a prescribed process for doing so. This process, laid out in the 1946 Administrative Procedure Act (APA), involves the publication of a Notice of Proposed Rulemaking (NPRM) in the *Federal Register*, a set period during which the public may submit comments on the proposed rule, and the publication of a final rule along with a summary of the comments received and the agency's response to those comments. Regulatory officials are expected to enter the rulemaking process without an "unalterably closed mind on matters critical to the disposition" of the issue at hand, such that comments submitted by the public may lead to substantive changes in the proposed rules.[8] This "unalterably closed mind" standard is meant to ensure that public comments present a meaningful way for the public to participate in rulemaking, rather than civic engagement window dressing that gives agencies cover

to proceed with whatever rulemaking they would have pursued regardless of public input. Although the standard is notoriously difficult to prove, requiring “clear and convincing” evidence of an unalterably closed mind, it suggests that the public comment process should be a valuable part of federal rulemaking.

A rich literature has examined the extent to which public comments are, in fact, valuable to the rulemaking process. Just as it is difficult to produce evidence of the open or closed nature of a regulator’s mind, it is also challenging to measure the effect that public comments have on final rules promulgated by executive agencies. There is something approaching a consensus around the idea that not all comments submitted are equally valuable. Scholars of administrative law often argue that “rulemaking is not and should not be a plebiscite,” in that comments are not merely “votes” for or against a proposed rule.[9] In their paper “Rulemaking vs. Democracy: Judging and Nudging Public Participation That Counts,” Cynthia Farina et al. argue that “participation that counts requires reason-giving, and this will inevitably privilege some types of preferences over others.”[10]

Farina et al. identify the types of preferences expressed in comments as *spontaneous preferences*, which are “rapid, low-thought extrapolations from the individual’s general knowledge, underlying value system, and worldview”; *group-framed preferences*, such as those that might be shaped by advocacy groups via mass-mailing campaigns; *informed preferences*, which reflect “exposure to, and consideration of, reasonably full and accurate factual information about the issue”; and *adaptive* preferences, which are “informed preferences modified by an assessment of the larger socio-political environment.”[11] Perhaps unsurprisingly, executive agencies engaged in rulemaking often place more value on the latter two types of preferences. Additionally, Farina’s work distinguishes between comments made by rulemaking “insiders” and “outsiders.”[12] Insiders, like advocacy groups, industry, and trade associations, tend to rely on “empirical ‘objective’ evidence in the form of quantitative data and premise-argument-conclusion analytical reasoning,” while outsiders often provide “situated knowledge,” which is “highly contextualized, experiential information, often communicated in the form of personal stories.”[13] Although less value is placed on comments that impart situated knowledge, Farina et al. argue that it can supplement the expertise of regulatory insiders by providing information about the potential impacts, problems, enforceability, contributory causes, and unintended consequences of propose rules.[14]

Given the various advantages of different sorts of comments, and especially those that provide situated knowledge, we believe that public notice and comment represents an important form of public engagement with the regulatory process. It is a way to “take the temperature” of the segment of the public that has an interest and the know-how to share their opinions. While of course the comment process cannot capture the full range of views, it does offer valuable insight into the moral and practical reasons that engaged members of the public find convincing. In this paper we analyze those reasons to identify the themes and subthemes that emerge from a critical reading of the comments in relation to moral principles and practical considerations that bear on an immigration policy that would likely chill the use of public benefits by immigrants.

MethodsData Collection

All public comments submitted on the proposed changes to the public charge rule are available on the website www.regulations.gov under the docket number for the proposed rule (USCIS-2010-0012). The comment period lasted from October 10, 2018 to December 10, 2018, but submitted comments received within that window were continuously reviewed and posted for months following the close date for the comment period. In order to determine the sampling frame for the comments eligible for inclusion in the analysis, a cut-off date of February 10, 2019 was chosen.

Comments that were posted to www.regulations.gov after February 10, 2019 were excluded from the sampling frame; these comments may have differed from earlier comments in terms of the mode of submission, as comments submitted by mail or fax can take longer to process. The regulations.gov site excluded duplicates and near-duplicates from the public repository (i.e. only one comment from each mass-mailing campaign was posted). The sampling frame for data collection therefore included all unique comments posted between October 10, 2018 and February 10, 2019, a total of 55,074 unique comments.

In order to obtain a random sample of those 55,074 comments, StataSE was used to generate a list of 200 random

integers between 1 and 55,074.[15] The random integers were then appended to the regulations.gov docket number for the NPRM (e.g. USCIS-2010-0012-19544) to identify comments for inclusion. The text of each comment was then retrieved from regulations.gov and copied into an Excel spreadsheet, along with the signed name of the commenter, the posted and received date of the comment, and the organization the commenter claimed to represent, if any.

Data Analysis

Comments were analyzed using an iterative emergent thematic coding and constant comparison approach.[16] This involved several stages, including data review, coding, and memo-writing. Prior to data review and throughout analysis, both team members wrote reflexive memos exploring their positionality, expectations, and beliefs with regard to the research topic to identify how their personal lens may influence their interpretation of data.[17] Comments were then analyzed using Dupli Checker determine whether they included language found on the internet or in other comments.[18] Next, all comments were imported into NVivo 12 for Mac OS to facilitate qualitative analysis.[19] Team members reviewed the comments for whether they generally indicated support for or opposition to the proposed rule, which was coded as a binary variable. This was followed by the development of an initial hierarchical codebook using inductive open coding to identify themes and subthemes. Coders independently reviewed and coded sets of 10 comments using inductive thematic coding, with intercoder discussions, coding comparisons, and code reconciliation after each set to refine the codebook. Following 5 rounds of independent coding comparison, a hierarchical codebook was finalized and applied to all 200 comments in the sample, with new codes added and iteratively applied as appropriate following intercoder consultation. The coded data was then analyzed using coding matrices and data visualization for pattern matching, and team members wrote analytic memos summarizing the key elements of and relationships between each theme and subtheme.

Findings

The reasons commenters provided for supporting or opposing the proposed changes to the public charge rule generally fell into two overarching categories: moral reasons and practical reasons. Moral reasons are those reasons that appeal to ethical values or obligations derived from a conception of right or wrong action (e.g. “justice” or “human rights”). Practical reasons are those reasons that appeal to the interests of citizens and legal residents (e.g., “public health” or “economics”).[20] Within each of those categories, we identified three major themes, some of which had identifiable subthemes. We now review the themes and subthemes that we identified in the public comments on the NPRM.

Moral ReasonsTheme 1: American Identity

Many commenters discussed the concept of American Identity and the importance of upholding the values it encompasses. Comments that fell under this theme often reflected a shared understanding of what and who America is, and many commenters drew from the country’s history in shaping that understanding. The subthemes included (1a) appeals to the U.S.’s history as a *country of immigrants*; (1b) appeals to the concept of the *American Dream*; and (1c) appeals to a wide range of *American values*.

Subtheme 1a: “Country of Immigrants”

Within the broader theme of American Identity, one frequent subtheme was that of America as a “country of immigrants,” which commenters used to argue that the U.S. has a moral obligation to treat new immigrants with compassion. One commenter observed that “I learned in my American history courses in high school and college, and I was taught by my parents, that we are a nation proud of its immigrant background… This proposed change will eliminate from potential legal permanent status many immigrants who have much to contribute to the on-going story of America” (29210). Other commenters echoed the language about America’s reputation as an immigrant country, in several instances referring to the Statue of Liberty and the Emma Lazarus poem inscribed on its pedestal as emblematic of the nation’s historic commitment to immigration: “The inscription on the Statue of Liberty says: With silent lips. Give me your tired, your poor, Your huddled masses yearning to breathe free, The wretched refuse of your teeming shore. Send these, the homeless, tempest-tossed to me, I lift my lamp beside the golden door! Don’t those words represent America, itself, anymore?” (47419). The significance of this quotation, and its August 2019

revision by a senior Trump administration official, will be further examined in the discussion section. Overall, however, it is important to note that many commenters emphasized the historically-grounded immigrant identity of the United States, frequently mentioning their own family's immigrant background.

Subtheme 1b: "American Dream"

Another frequently mentioned subtheme within American Identity was the notion of the "American Dream," which was explicitly named or implied by over 20% of commenters. Many commenters argued that the rule places the American Dream of creating a better life for one's family, through hard work and ingenuity, beyond the reach of many immigrants. As one commenter put it, "like generations of immigrants, the new immigrants come with the ambition to achieve their 'American Dream,' which requires hard work. But they need that little push to make the transformative jump" (41905). Another commenter observed that the immigrants who are most likely to pursue and achieve the American Dream are "not the already wealthy immigrants …but those who desperately want to create a better life for themselves and their children. They are the most innovative, determined, and courageous of their previous homelands" (41927). Commenters who mentioned the American Dream felt that the proposed rule directly contradicted America's implicit promise that anyone, regardless of their socioeconomic status, could achieve a better life through hard work.

Subtheme 1c: American Values

The third subtheme within American Identity were appeals to American values, which commenters defined in a variety of ways, while others declined to specify at all, instead appealing to the concept in a general way. This theme was common among both supporters and opponents of the proposed changes to the public charge rule. One supporter of the rule stated "I believe we should exclude people who have no skills and no work ethic. I want only those who value the American values, Declaration of Independence and want to bring value to our country. I do want people who are waving other flags, or speaking other languages unless they learn English, want to assimilate into our country and bring value to it [sic]" (50012). For this commenter, American values appear to include a work ethic and English speaking, but this view was not shared by most commenters. Nevetherless, some commenters agreed that hard work is an American value, but felt that the public charge rule would benefit people who did not uphold that value: "[the proposed rule] would keep out hardworking people without wealth, who may go on to contribute greatly to our society, while privileging other types like non-working wealthy [immigrants]. Not a good trade, in my opinion; hard work is a part of American values" (48162). Some appeals to American values included the suggestion that diversity was a core American value. One commenter noted that "The proposed regulation violates the spirit of our country …Our country was built on diversity, and this is what has made us a great and productive nation" (42252). Although this commenter appeals to the vague notion of the "spirit of American values," they end with an appeal to diversity as a driver of American greatness and productivity. Some others did not specify the content of American values, letting the concept speak for itself: "These extremist, cruel and anti-immigrant measures betray our fundamental values" (11468).

Theme 2: Autonomy/Respect for Persons

The second major theme that emerged from the analysis of the moral reasons for supporting or opposing the new public charge rule was that the rule infringed on a moral obligation to respect the autonomy of individuals to pursue the life goals they deem important. The subthemes included (2a) distinguishing between dependence and assistance, (2b) forcing a choice between permanent residency and meeting basic human needs, and (2c) the inherent dignity and value of human beings.

Subtheme 2a: Dependence vs. Assistance

Several commenters emphasized the distinction between dependence and assistance, arguing that the rule fails to recognized the difference between the two. Based on the criteria of the proposed rule, a person's use of public assistance programs is viewed as a sign of dependence. As one commenter notes, "public charge" is synonymous with "dependence" (6704). Under the rule, people who rely on the help of public assistance programs are deemed dependent. Any help, be it in the form of food, shelter, or health care, falls under the heading of dependence and counts against the applicant. Some commenters argued that all people, no matter the circumstance, need help at

some point it their life. Those just getting on their feet, such as new immigrants, are in particular need of assistance. In the words of one commenter, however, the rule conflates assistance with dependence, and as a result, deprives immigrants of "that little push to make the transformative jump" (41905).

Commenters also called attention to the assumptions and biases built into the concept of public charge. One commenter who works with immigrants countered the image of the immigrant as a drain to society, describing how his clients "grudgingly accept public benefits because they come to the US with big dreams. They take them only when it is necessary. No sooner than they become self-sufficient do they end it" (41905). This story emphasizes that assistance is often temporary, which is at odds with the definition and purpose of public charge. Several commenters also cited their own family history as illustrative of the rise to self-sufficiency with a "little push" of assistance, countering the core claim of the public charge rule. They argue that autonomy and independence are in fact facilitated by government assistance. Losing Medicaid, SNAP benefits, and other assistance programs undermines a person's ability to achieve the goal of autonomy: the rule's public charge definition impinges upon this moral right.

Subtheme 2b: Forced Choice

Several commenters expressed doubt regarding the stated goal of the rule of bolstering autonomy by "better ensur[ing] that aliens subject to the public charge inadmissibility ground are self-sufficient, i.e., do not depend on public resources to meet their needs, butmrather rely on their own capabilities."[21] These commenters argued that the rule actually violates the requirements of the principle of autonomy by forcing immigrants to make an "impossible" (54253) choice: either (1) stop receiving benefits from services that provide resources essential to life, health, and well-being, or (2) risk the loss of future permanent residency and, for families, face the possibility of separation. Commenters warned of the dangerous consequences of forcing vulnerable groups to make such a choice. In the words of one respondent, "No human being should have to decide, in a free country, between keeping all their family members together and receiving basic needs like food" (38807). Forcing immigrant families to choose would lead to sacrifice and risk regardless of the choice. Autonomy, these commenters argued, would be weakened by the restrictive choice set and its future-limiting impact.

Subtheme 2c: Inherent Dignity and Value

Commenters argued that the rule fails to uphold the inherent value and dignity of all persons. Under the rule, the degree to which an individual is (or is not) deserving of residency is determined by a consideration of a "totality of circumstances." Some commenters felt that this determination was unethical because it defines deservingness in terms of external factors like "health, age, education, family, and English proficiency…in a way that treats them [as] less than human" (41667). The public charge rule, according to these commenters, violates a moral obligation to uphold the dignity and value of all persons, including those who use public benefits. They argued that human dignity transcends national, racial, socioeconomic, and other situated boundaries. As one commenter put it, "I believe in human dignity and the value of all persons, regardless of where they come from or how much money they have in their pockets" (6387).

Theme 3: Deservingness

The third major theme, deservingness, captures moral reasons relating to the characteristics that make an individual more or less deserving of access to public resources and benefits. The three primary subthemes that emerged are the various deservingness-determining characteristics of populations that would be affected by the revised public charge rule. These subthemes are (3a) contribution to society, (3b) immigration/citizenship status, and (3c) vulnerability.

Subtheme 3a. Social/Economic Contributions and Deservingness

Many commenters argued that immigrants deserve access to public resources and benefits because they contribute to and enrich the society that produces those benefits through hard work and social connections. One commenter wrote, "Immigrants come to this country to seek better opportunities. They are the hardest of workers and contribute to the patriotism and the energy of this country…Those coming to this country are looking to better their lives and their families'. While moving up in society, they help our economy as well!" (34483). Other commenters shared this

view, often drawing on their family's immigrant history to illustrate the potential contributions of immigrants: "All of my aunts and uncles have used public assistance when they first arrived in the US. Now over 40 members of my cousins, nieces, and nephews have graduated from college. As dentists, doctors, pharmacists, professors, computer scientists, accountants, nurses and business owners, we are adding to the financial and cultural vitality of America" (41667). These commenters share an implicit belief that current or future contributions to American society entitle immigrant individuals and families to the same benefits available to American citizens.

In addition to emphasizing the societal contributions of immigrants, many commenters argued that economic contributions of immigrants created reciprocity obligations. However, a few commenters in support of the change argued the converse: that immigrants do not contribute and therefore they do not deserve public resources. It should be noted that most of these commenters did not recognize that the rule only applies to legally present immigrants, and instead, directed their deservingness arguments against undocumented immigrants. One such commenter wrote that "I support the implementation of all methods that stop the flow of illegal aliens who are not [sic] going to abuse and use resources they did not contribute to, or by citizenship, be entitled to" (10080). This commenter was one of several in our sample who supported the rule but believed that its purpose was to restrict the use of federal benefits by undocumented immigrants, a restriction already in place. This relates directly to the "immigration status" subtheme within the overarching "deservingness" theme.

Subtheme 3b: Immigration Status and Deservingness

As mentioned above, most supporters of the rule believed that it targeted the use of benefits by undocumented immigrants (for example, one commenter simply wrote "No more free rides for illegals who take our jobs as well. Deport them they are here as CRIMINALS" (48877). Indeed, of the 18 comments in our sample supporting the proposed rule change, 13 indicated that they supported it because they opposed "illegal" immigration, and only two of the other five provided reasons for their position. The vast majority of commenters opposed the rule change, and a substantial portion of commenters argued that the legal status of the affected population mattered morally. Specifically, the arguments about legal status from the opposing commenters were often that the affected immigrants were legally present, and therefore were deserving of public resources and benefits. One commenter expressed this view, observing that "while [the] U.S. government rationale for current policies has focused on legalities of unauthorized immigration status, changes in [the] public charge rule would punish families who are 'following the rules'" (48677). This appeal to rule-following highlights the justice-based nature of the deservingness argument, which is essentially that those who "follow the rules" should be treated similarly to others who also follow the rules.

Subtheme 3c: Vulnerability and Deservingness

The deservingness theme also includes a "needs-based" argument that vulnerable people deserve help by virtue of their vulnerability. One commenter linked this obligation to foundational values, saying "As a nation founded on Judeo-Christian values and humanist principles, we are called to protect families, children, and the vulnerable" (6387). Another described how the rule requires us to "turn our back against those who need our help the most: the sick, the young, the old, and the poor" (36672). This commenter suggests that conditions that put a person or group in a vulnerable position in the social landscape, such as age, poverty, poor health, or discrimination at large, deserve assistance, and that to do deny them assistance is to "turn our back against them."

Under the proposed rule, however, deservingness takes these factors into account in a negative way. Deservingness of public benefits is determined by weighing an applicant's "totality of circumstances," with certain factors counting for and against the applicant, such as medical status, age, financial conditions, and number of dependents. Essentially, those characteristics that commenters suggest contribute to vulnerability, such as medical need, advanced age, low socioeconomic status, and disability are counted against an immigrant's case for permanent residency. "This rule," in the words of one commenter, "will disproportionately harm the most vulnerable in our society, including children, pregnant women, older adults, and families living paycheck to paycheck" (1600). Commenters expressed dismay at this reversal of the link between vulnerability and deservingness, arguing that those who need help are fundamentally deserving of such help, not despite their vulnerability, but precisely because

of it. They should be given that help; not doing so, according to some commenters, is a moral failure.

Practical Reasons

Unlike moral reasons provided by commenters, which focus on values and ethical obligations towards immigrants derived from various conceptions of right and wrong, practical reasons focus instead on those reasons that promote the relevant but not intrinsically moral interests of citizens and immigrants.[22] The reasons for supporting or opposing the changes to the public charge rule that can most accurately be described as "practical" include the major themes of *health-related* reasons and *economic* reasons. Each of these categories of practical reasons contained multiple subthemes, described below.

Theme 4: Health-Related Reasons

Many commenters emphasized the deleterious effects the public charge rule would have on health. These arguments emphasized that the public charge rule would have a (1) chilling effect on immigrants' use of health care, which would ultimately be harmful their health, and which in turn would have (2) negative effects on citizen health.

Subtheme 4a. Chilling Effect and Immigrant Health

Many commenters argued that the public charge rule would have a "chilling effect" on immigrants' use of health care services, meaning that even if it didn't directly affect their eligibility for insurance or services, it would affect their willingness to enroll in or use insurance to obtain health care and other necessary social services. As one commenter wrote, "This policy will devastate all our communities by making immigrants and their family members afraid to access essential health, nutrition and shelter programs. Immigrant communities, will now live in fear of seeking supports they need —regardless of whether they are actually subject to the public charge test" (15547). The concern that the chilling effect would extend beyond the population directly affected by public charge determinations to include all immigrant populations, including those not subject to public charge, was widespread. One commenter who cited literature argued that the effect would be "particularly stark for children …As the American Academy of Pediatrics [AAP] notes, many families applying for green cards would choose not to seek essential benefits. The Fiscal Policy Institute estimates that 'chilling effect' [of] these rules would cause would extend to 24 million people in the United States, including 9 million children" (17625). This is dramatically different from the proposed rule's estimates that only 324,438 people would forego or disenroll from public benefits.[23]

Of course, many commenters who did not offer statistics on the chilling effect nevertheless felt it was a dangerous move that would have far-reaching health consequences, as many illustrated with personal anecdotes and experiences. One commenter wrote, "I am a Patient Navigator and work closely with immigrant families to ensure that they are accessing their necessary medical care. Without these resources, my clients will not be able to afford services such as primary care visits, surgeries, and prenatal care" (39017). Another commenter described a patient whose health would be harmed by the public charge rule, saying "I think of 'S,' a young immigrant woman who is currently receiving chemotherapy for cancer… She is a straight-A student. She has dreams for her future. I would hate for her family to have to stop her treatment or to even have the weight of that decision. It would be cruel to deny her care" (48677). Personal anecdotes like these were extremely common in the comments; the value of lived experience in public comments is considered in the discussion section.

4b. Effects on Citizen Health

In addition to detailing the potential effects of the new public charge rule for immigrants, many commenters also described the potential harms to citizen health that could result from the policy. These arguments often relied on the communicable nature of health and disease. As one commenter wrote, "[The rule] would increase the incidence of childhood diseases like chickenpox, measles, mumps and rubella and deter parents from vaccinating their children. This is dangerous not only to individuals but to communities as a whole" (12906). That immigrants live in deeply intertwined communities with non-immigrants and that their health prospects cannot be disentangled from those of their neighbors was a common argument, and often included concern about both communicable and non-communicable health statuses. Another commenter who shared this view wrote "Research suggests that the proposed rule would lead to worse health outcomes and widening health inequities related to issues such as prevalence of communicable diseases, rates of poverty and housing instability, and educational attainment.

Furthermore, immigrants avoiding health care as a result of this change may lead them to forgo services such as immunizations, which could increase the chance of future disease outbreaks" (9395). This comment seems particularly prescient in a post-COVID-19 world, when anecdotal evidence suggests that the public charge rule may have had exactly this effect on the outbreak.[24]

Another way in which the public charge rule could harm citizen health, according to some commenters, is through the effect it could have on immigrant health workers. One commenter addresses this issue explicitly, saying:

Immigrants comprise 1 in 6 American workers, and are crucial to meeting the demand for low to middle skill positions in nursing homes, such as certified nurse aides (CNA) or personal care aides (PCA). These essential care workers have median wages close to or below the poverty threshold. Programs like SNAP, CHIP, and Medicaid are designed to help these lower-income individuals meet their families' basic needs to keep them healthy and safe. [The policy] will have a downstream effect on care to seniors and residents of these nursing facilities that rely on immigrant workers to fill CNA and PCA positions. (50136)

This specific example of the harms that public charge might cause for immigrant health workers who take care of older adults in the U.S. illustrates the broader effect that the rule might have in other areas of the health work force, including immigrant physicians, PAs, and nurses who may also have families who use some public programs or use public programs themselves. The harms to the health care workforce, commenters suggested, could have far-reaching consequences for Americans in need of health care.

Theme 5: Economic Reasons

Economic reasons are those reasons rooted in costs, savings, and economic well-being for individuals and for American society at large. The subthemes within this category include arguments regarding (4a) immigrant contributions to the economy and (4b) the policy's effect on health care costs.

Subtheme 5a: Immigrant Contributions to the Economy

Many people who submitted comments opposing the proposed changes to the public charge rule argued that the rule was ill-considered because immigrants contribute to the economy. For some commenters, this was a moral "deservingness" argument, as described above, but for many others, the fact that immigrants contribute to the economy was a practical concern. This argument hinged on the concern that public charge would cause immigrants to retreat from the economy; as one commenter put it, the public charge rule change would be "an economy-killer: chasing away many millions of productive people, hard-working people, doing the dirty work of American society… [Immigration] builds and grows an economy, not weakens it" (31097). Another commenter was more specific about the possible economic harms of the change, noting that:

The economic loss to communities would be great. Loss of property taxes from housing, sales taxes, federal and state income and Medicare taxes from employment, as well as many other sources of revenue to public and nonprofit entities will be lost. Banks will lose accrued interest on investments, loan interest from business loans, and investment from immigrant savers and borrowers. Mortgage lenders will be affected just as banks (51703).

Arguments like these, which suggested that immigration is a "net plus" (14951) to the economy, and that the public charge rule would harm the economy, were common.

Subtheme 5b: The Policy's Effect on Health Care Costs

Not all practical economic arguments were grounded in the big picture of the American economy. Instead, some focused on the economic impact solely of the anticipated increase in health care costs that might be associated with a decrease in immigrant access to health care. One commenter representing a civil society organization wrote that "Delayed care or care administered in inappropriate settings, such as hospital emergency rooms for non-emergency situations, leads to increased costs to communities and places an unnecessary burden on safety-net facilities, already operating on tight budgets, to provide even more uncompensated care" (50136). Commenters who wrote about the effect of the public charge rule on health care costs often made the logical connection from less access to insurance to less access to preventive care, which can result in an increased need for higher costs over the long term. One pediatrician commenter wrote:

Good preventative medicine allows us to identify health conditions early, on allowing for better control and less

overall cost to the medical system. We also are able to emphasize healthy behaviors relating to eating, substance use and safety. All of these interventions have been shown to reduce future healthcare costs in multiple different studies. (0554)

Another pediatrician shared an anecdote about a child whose parents' fear of the immigration implications of seeking care kept her away from seeing a doctor until her condition had worsened. This pediatrician wrote that "If her family had felt safe bringing her to the doctor earlier she could have avoided hospitalization all together. Clearly this hospitalization was much more costly than a simple prescription for oral antibiotics" (7501). This theme, about the economic implications of discouraging immigrants from obtaining primary care by limiting access to public insurance, was quite common, and often paired with other themes related to the health effects of the public charge rule discussed above.

Discussion

The wide range of practical and moral reasons provided by commenters on the public charge rule illustrates the diversity of justifications that enter into the public dialog around immigration-related public policy. And yet, despite the fact that over 96% of commenters in our sample opposed the changes to the public charge rule, the Department of Homeland Security ultimately promulgated a final rule that imposed a significant burden on legally-residing immigrants who use public benefits. How are we to understand the relationship between the reasons given against the rule by an overwhelming majority of commenters and the finalized rule? And given that the final rule did not significantly change to reflect the arguments made by commenters, what is the value of the public comment process for regulations that affect immigrant health? And finally, what lessons can we take from the ongoing legal challenges to the public charge rule in light of the COVID-19 pandemic and the Biden administration's decision to stop defending the rule? In this section, we discuss the questions and suggest several policy implications for future immigrant health and social policy.

The Final Rule

When DHS issued the final rule on August 14, 2019, it included several notable changes from the proposed rule. The NPRM had specifically requested input from the public on whether CHIP should be included in the set of public benefits that bear on an immigrant's "totality of circumstances." As the findings above indicate, DHS received a flood of responses arguing that the use of public benefits by children, including CHIP, should not be considered in a public charge determination. In the final rule, DHS excluded the use of CHIP or Medicaid by immigrants under the age of 21, as well was the use of these benefits by pregnant people. Additionally, DHS decided to exclude Medicare Part D Low-Income Subsidies (LIS) in response to comments that pointed out the extensive work requirements that determine eligibility for Medicare Part D LIS.[25] Although these changes were responsive to the comments DHS received, the majority of the proposed rule remained intact.

DHS is legally required to summarize and respond to every comment they receive, either individually or by grouping together comments with similar themes, much like the analysis performed in this manuscript. A comparison of DHS's summary with the analysis could therefore provide insight into the value DHS placed on the various moral and practical reasons commenters provided, although a thorough comparison might merit a separate publication altogether. The agency's summary can be distilled to its main themes by examining the subheadings in the table of contents of the final rule under the heading "Comments Expressing General Opposition to the NPRM," which include, among others:

- Purpose of the Rule and Self-Sufficiency
- Discrimination and Disparate Impact
- Potential Disenrollment Impacts
- Choice Between Public Benefits and Immigration Status

•General Assertions as to Effects

•Housing Benefit-Related Effects

•Food and Nutrition Benefit-Related Effects

•Health Benefit-Related Effects

•Effects on Vulnerable Populations

•Effects on U.S. Citizens

•Increased Costs to Health Care Providers, States, and Localities

•Inconsistent with American Values and Historic Commitment to Immigrants

•Contributions to American Society and Consideration of Self-Sufficiency[26]

Many of these themes match exactly the themes identified by our analysis.

The Department's response to the comments in each theme, however, was nearly uniform rejection of either the premise or the importance of the points raised by commenters, coupled with an assertion about the importance of self-sufficient. For instance, in response to the many comments that the proposed changes were un-American and/or unethical, DHS responded:

While immigration and diversity have strengthened the United States, DHS strongly disagrees that this rule is motivated by fear or greed, or is un-American or immoral. DHS does not seek to frustrate the United States' long-standing commitment to family unity, humanitarian relief, and religious liberty through this rule. DHS also disagrees that this rule re-shapes, penalizes, or impedes the overall flow of legal immigration, and disagrees that the rule puts lawful permanent resident status beyond the reach of working-class and poor immigrant families …Through this final rule, DHS seeks to better ensure that applicants are self-sufficient.[27]

Rather than substantively engaging with the points raised by the hundreds of thousands of commenters who opposed the rule for the reasons summarized here, DHS simply rejected the premise.

Throughout the response, DHS acknowledged that the proposed rule would likely have negative effects in many of these areas. The agency reiterated again and again, however, that the purpose of the rule was to increase self-sufficiency among immigrants living in the United States, and asserted that "DHS disagrees with the commenters that ensuring the self-sufficiency of immigrants is unnecessary, or that a lack of self-sufficiency is a non-existent problem… [S]elf-sufficiency has been a basic principle of United States immigration law since this country's earliest immigration statutes and [it] should continue to be a governing principle in the United States."[28] Despite the overwhelming evidence that commenters disagreed that self-sufficiency should be the driving factor in determining whether an immigrant should receive legal permanent residency, DHS and the Trump administration pushed forward with the rule. In a widely reported interview about the publication of the final rule, acting director of U.S. Citizenship and Immigration Services (USCIS) Ken Cuccinelli misquoted the poem inscribed on the Statue of Liberty, saying "Give me your tired and your poor who can stand on their own two feet and who will not become a public charge."[29] Cuccinelli's intentional misquotation stands in stark contrast to the many commenters who correctly quoted the poem in their response to the NPRM as evidence of the rule's violation of fundamental American values. In our sample, four commenters quoted the original poem, suggesting that the poem represents core values and that the administration's position is at odds with those values.

This analysis does not claim to yield definitive answers as to the “correct” reasons for supporting or opposing a policy. Indeed, it does not even go so far as to suggest which reasons are most convincing, or which may be the most effective in the crafting of future immigration and social welfare policy. Such conclusions would be impossible to draw from public comment data, which is inherently biased by the engagement necessary to submit a public comment to an executive agency, let alone the tenuous connection between empirical bioethics data and normative truth. Instead, what this analysis of public comments yields is a trove of information on the wide range of views politically engaged U.S. residents hold on immigration policy as it relates to immigrant health. Describing and examining these views can be used to frame discussions of the moral and practical challenges that flow from enacting policies that treat immigrants differently from other U.S. residents.

Value of Public Comments

Given the obvious disconnect between the moral and practical reasons given by commenters for opposing the NPRM and the reasons for finalizing the rule given by DHS, it would be reasonable to ask what value, if any, derives from the public comment process. Aside from the exclusion of CHIP and Medicaid for children and pregnant women from the list of programs included in a public charge determination at the urging of commenters, we argue that these comments serve several other important purposes. These include providing valuable information about message-framing that could be useful for policymakers hoping to pursue immigrant-friendly policy in the future, as well as providing reasoning and data that can be used in legal challenges to the rule itself.

Earlier we discussed Farina et al.’s work on the categorization of types of public comments and the preferences they express, including spontaneous preferences, group-framed preferences, informed preferences, and adaptive preferences.[30] Although this paper does not seek to categorize the types of comments received by DHS on the proposed changes to the public charge rule, the comments we analyzed here cover the range of types, from spontaneous to adaptive, and included views from both regulatory insiders and outsiders. We do not distinguish between these types in our analysis, but would note that all types of comments are a valuable source of information on the reasons that are convincing to stakeholders, including those directly affected by the proposed rule change and those indirectly affected as community members and fellow U.S. residents.

We also do not explicitly note when comments are clearly low-information, as evidenced by their inclusion of false statements or beliefs, but we feel that these types of comments also provide useful information on the perception of a policy, regardless of whether that perception is correct. For example, many of the supporters of the proposed rule change argued that it should be enacted because it would stop undocumented immigrants from accessing public benefits. This belief is false, but its persistence among proponents of the policy change suggests that their opposition to the policy may be rooted in a more general anti-immigrant animus. On the other hand, comments from opponents of the policy change were often grounded in appeals to their situated knowledge: pediatricians described the negative impact the proposed rule would have on their patients, while citizens with immigrant family histories discussed the ways access to public benefits helped them pursue the “American Dream.” These types of comments, some of which may be expressing spontaneous preferences, are nonetheless useful for understanding the types of moral and practical reasons motivating commenters to engage on a question of public policy.

This analysis does not claim to yield definitive answers as to the “correct” reasons for supporting or opposing a policy. Indeed, it does not even go so far as to suggest which reasons are most convincing, or which may be the most effective in the crafting of future immigration and social welfare policy. Such conclusions would be impossible to draw from public comment data, which is inherently biased by the engagement necessary to submit a public comment to an executive agency, let alone the tenuous connection between empirical bioethics data and normative truth. Instead, what this analysis of public comments yields is a trove of information on the wide range of views

politically engaged U.S. residents hold on immigration policy as it relates to immigrant health. Describing and examining these views can be used to frame discussions of the moral and practical challenges that flow from enacting policies that treat immigrants differently from other U.S. residents.

Aside from this somewhat intangible value of public comments and their analysis, the comments are also useful for establishing that the government failed in its regulatory duties when promulgating a rule. Although a full accounting of the many legal challenges to the final rule is beyond the scope of this paper, we briefly consider one injunction to the rule issued in October 2019, and the 2020 decision that vacated the rule nationwide, to illustrate how public comments can affect legal challenges to regulations.

In the preliminary injunction issued by the United State District Court in the Northern District of California, the court considered several challenges to the final rule, including a consideration of whether the rule was "arbitrary and capricious," a standard under the APA that "focuses on the reasonableness of an agency's decision-making processes."[31] Under this standard, "agency action is invalid if the agency fails to give adequate reasons for its decisions, fails to examine the relevant data, or offers no 'rational connection between the facts found and the choice made.'"[32] In issuing its injunction, the court found that DHS failed to adequately consider and respond to comments that documented the costs and benefits of the change to the rule. These costs and benefits aligned with many of the practical reasons commenters provided for opposing the rule change, including economic and public health arguments. With regard to the government's response to comments on the costs and benefits of the rule change, the court states:

[E]ven under the deferential APA analysis, DHS appears to have wholly failed to engage with this entire category of comments. DHS failed to grapple with the Rule's predictable effects on local governments, and instead concluded that the harms —whatever they may be —are an acceptable price to pay. At minimum, the APA requires more than reading public comments and responding with a general statement that, however correct the comments may be, the agency declines to consider the issues and costs identified because doing so would contravene the government's favored policy.[33]

The court enumerated several other types of comments that DHS failed to engage with and found that the plaintiffs (the state of California, several counties within California, and several immigrant health organizations) were likely to succeed on the merits of an "arbitrary and capricious" claim.

In parallel litigation, the Northern District of Illinois issued an opinion on November 2, 2020 that vacated the public charge rule. That decision quoted the Seventh Circuit, which held:

Even assuming that the term "public charge" is ambiguous and thus might encompass more than institutionalization or primary, long-term dependence on cash benefits, it does violence to the English language and the statutory context to say that it covers a person who receives only *de minimis* benefits for a *de minimis* period of time. There is a floor inherent in the words "public charge," backed up by the weight of history. The term requires a degree of dependence that goes beyond temporary receipt of supplemental in-kind benefits from any type of public agency.[34]

The Seventh Circuit also noted that DHS "did not acknowledge or address the significant, predictable collateral consequences of the Rule," much of which was described in the comments DHS received. Thus, the District Court decision, which applied nationwide, held that the Trump administration's public charge rule was "substantively and procedurally invalid under the APA."[35] Although this decision was stayed the next day, the Biden administration ultimately withdrew its defense of the Trump-era public charge rule, making the District Court's decision final and leading USCIS to revert to the 1999 Interim Field Guidance for determining public charge.[36] Speaking about the choice to withdraw from defending the rule, DHS Secretary Alejandro N. Mayorkas noted that "The 2019 public charge rule was not in keeping with our nation's values. It penalized those who access health benefits and other

government services available to them."[37] Although there is no explicit indication that Secretary Mayorkas read the public comments, these sentiments clearly reflect the same views expressed by the many commenters who opposed the proposed changes to the public charge rule.

Conclusion

In addition to several injunctions delaying the start of the public charge rule change, parts of the final rule's implementation were effectively postponed by DHS itself in response to the start of the COVID-19 pandemic in early 2020 (before, as noted above, being effectively withdrawn by the Biden administration). The rule went into effect in most of the country on February 24, 2020, mere weeks before the country began to shut down in response to the growing number of cases. DHS quickly issued guidance stating:

To address the possibility that some aliens impacted by COVID-19 may be hesitant to seek necessary medical treatment or preventive services, USCIS will neither consider testing, treatment, nor preventative care (including vaccines, if a vaccine becomes available) related to COVID-19 as part of a public charge inadmissibility determination.[38]

In issuing this guidance, DHS essentially acknowledged that the arguments of many commenters who opposed the rule were correct: the public charge rule would result in a chilling effect that discouraged immigrants from seeking care for communicable diseases, and that communicable diseases do not care about citizenship status. This was echoed by yet another nationwide injunction against the new public charge rule issued by the U.S. District Court for the Southern District of New York (SDNY) in July 2020 that enjoined the rule from going into effect during a declared national health emergency (like COVID-19), although this injunction was ultimately removed by the Second Circuit.[39] Nonetheless, the obvious public health risks presented by a policy that discourages immigrants from seeking health care in the middle of a global pandemic underscore the relevance of the moral and practical reasons commenters provided for opposing the rule change.

This paper has examined the moral and practical reasons that commenters provided for supporting or opposing the proposed changes to the public charge rule. This analysis draws on comments submitted by motivated and engaged members of U.S. society during the public notice-and-comment period, which limits the transferability of these findings to the general population. Additionally, this analysis cannot (and does not seek to) determine the morally "correct" reasons for supporting or opposing a policy that affect immigrant health, but rather catalogs the sorts of reasons that engaged people found important enough to write to the federal government about. The descriptive nature of this project is thus both a limitation and a strength, as it limits the implications of the findings to the political, rather than the normative. Nonetheless, as the discussion has shown, the identification of compelling reasons can be useful for policymakers seeking to frame their support for immigrant-friendly health policies that they believe are morally correct.

Although the Trump administration's public charge rule is no longer in effect, the comments on the rule offer valuable insight into the reasons that can frame pro-immigrant immigration, health, and social policy. Future research in this area should measure the framing effects of the moral and practical reasons that this exploratory qualitative study identified as anchoring immigrant-friendly policy positions. Survey work that draws on the findings of this paper could ascertain which moral and practical frames are the most effective at garnering political support for a policy, especially among politically engaged people who have the motivation to comment on proposed policy. Such information could be useful for policymakers and advocacy groups as they attempt to promote more just health policy. Although there is much more work to be done, both in promoting immigrant health through policy and in understanding the value of public comments to the regulatory process, this exploration of the public charge rule serves as an illuminating case study in both.

DETAILS

Subject:	Government agencies; Institutionalization; Medicaid; National security; Immigrants; Pandemics; Immigration policy; Citizenship; Cost control; Coronaviruses; Social policy; Immigration; COVID-19
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Location:	United States--US
Company / organization:	Name: Federal Register; NAICS: 513120
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Optimizing Ethics Engagement in Research: Learning from the Ethical Complexities of Studying Opioid Use in Pregnancy

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ABSTRACT (ENGLISH)

Research on opioid use in pregnancy is critically important to understand how the opioid epidemic has affected a generation of children, but also raises significant ethical and legal challenges. Embedded ethicists can help to fill the gaps in ethics oversight for such research, but further guidance is needed to help strike the balance between integration and independence.

FULL TEXT

Introduction

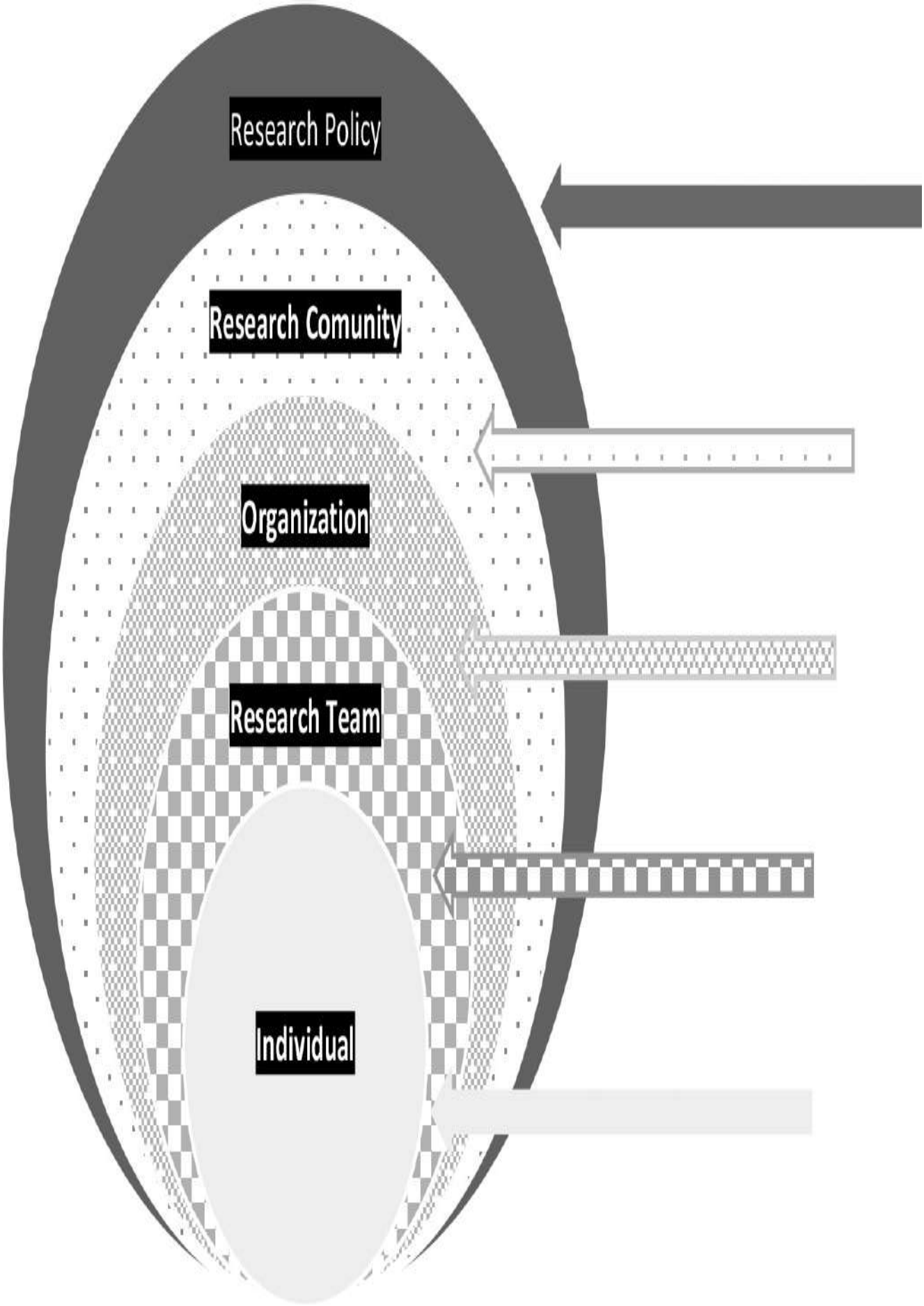
Conducting research on substance use disorder is ethically challenging,[1] particularly when studying the effects of substance use during pregnancy on neonatal and childhood development. As part of a broader effort to address the opioid epidemic, the National Institutes of Health (NIH) funded a network of researchers through the Helping to End Addition Long-term (HEAL) initiative's HEALthy Brain and Child Development (HBCD) Study. This study examines early neurological development after prenatal exposure to maternal substance use (including opioids). The NIH also encouraged examination of the attendant ethical and legal considerations for this controversial research.[2] State laws sometimes criminalize substance use in pregnancy or consider it a form of child abuse. Additionally, there is considerable stigma associated with opioid use.[3] In this context, there are psychosocial, economic, reputational, and legal risks to participants that are not straightforward to address. Including ethicists during study design and implementation was therefore recommended in the request for applications to plan the longitudinal research. HBCD

research teams across the US have subsequently involved ethicists, albeit in different ways.[4] Notably, encouraging ethicist involvement in requests for applications is one of several different approaches to fostering ethics engagement in NIH-supported research. NIH has also promoted ethics engagement by providing supplemental bioethics research funding and earmarking funding dedicated to a particular scientific area for ethics research.[5] The nationwide attention to intentional, prospective ethics engagement across projects facing similar ethical issues presents an opportunity to build upon what is known about ethics engagement. There is limited guidance for how best to engage ethicists in research projects. While research ethics consultation services are available at many institutions and have received some scholarly attention,[6] the many other ways ethicists can engage with research teams are less well-studied.[7] In this paper, we draw from the approaches developed across the country for the HBCD study to better conceptualize the practice of ethics engagement and provide recommendations for how it can be done effectively. We first contextualize and define ethics engagement in research. Next, we provide examples from the HBCD network gathered from the request for applications, network meetings, our experiences, and an informal, exempt survey of engaged ethicists. Throughout the paper, we supplement what we learned from the HBCD network by using examples from existing literature to illustrate a broad spectrum of engagement approaches. Finally, we consider how to balance a fundamental tension in ethics engagement —the value of maintaining independence and objectivity versus the benefits of integration within a larger research team to understand the scientific and cultural context. We conclude by discussing relative strengths and weaknesses of different forms of ethics engagement.

In this paper, we draw from the approaches developed across the country for the HBCD study to better conceptualize the practice of ethics engagement and provide recommendations for how it can be done effectively. We first contextualize and define ethics engagement in research. Next, we provide examples from the HBCD network gathered from the request for applications, network meetings, our experiences, and an informal, exempt survey of engaged ethicists. Throughout the paper, we supplement what we learned from the HBCD network by using examples from existing literature to illustrate a broad spectrum of engagement approaches. Finally, we consider how to balance a fundamental tension in ethics engagement —the value of maintaining independence and objectivity versus the benefits of integration within a larger research team to understand the scientific and cultural context. We conclude by discussing relative strengths and weaknesses of different forms of ethics engagement.

Defining Ethics Engagement in Research

The ethical conduct of research involves applying moral principles, frameworks, and regulations along with awareness of the norms, conventions, and standards of different disciplines. The study and practice of research ethics has emerged in large part due to egregious acts of misconduct within biomedical research.[8] Ethics engagement can now involve research ethicists working across many different levels (Figure 1). Research must comply with the U.S. federal regulations when funded by the U.S. federal government, or if the researchers work at an institution that receives some U.S. federal government funding and has entered into an agreement to conduct all of its research under the same rules.[9] Human subjects research regulations promulgated by the Department of Health and Human Services are designed to protect research participants and ensure research has sufficient potential benefit to justify the risks. Regulations provide extra protections for groups identified as vulnerable. Enforcement of these regulations is often accomplished through institutional review boards and committees (e.g., Institutional Review Boards,[10] Conflict of Interest Committees, Institutional Biosafety Committees,[11] etc.). Educational programs for researchers are also often required to provide those on the research team with the knowledge and skills needed to carry out the proposed work in accordance with the ethical guidelines and standards (e.g., trainings in human research protections and managing conflicts of interest).[12] Yet there are many gaps within this system.



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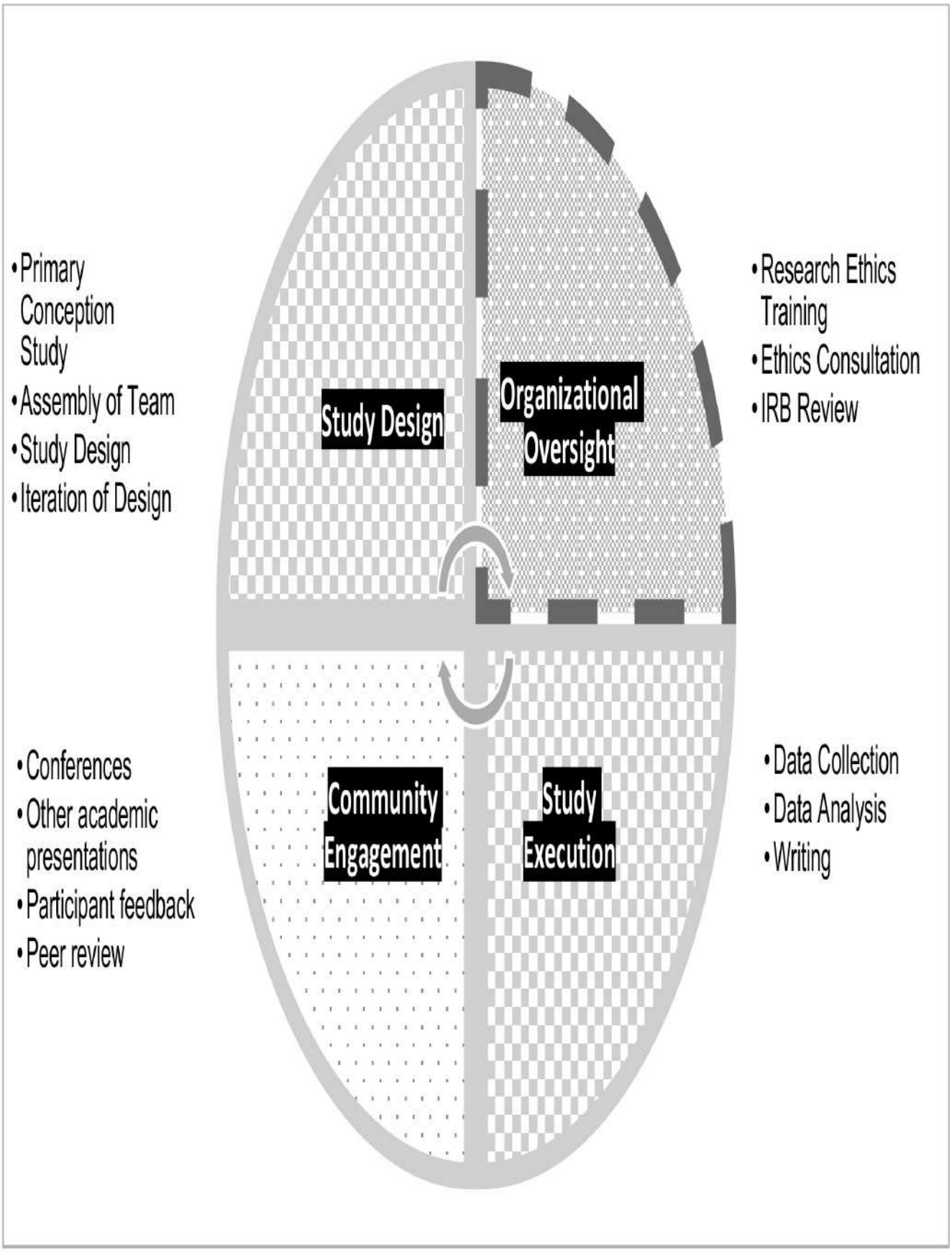
Perhaps more importantly, mere compliance with regulations is not sufficient to ensure research is conducted ethically. The current system of ethical oversight in the U.S. was vividly described by Carol Levine as “born in

scandal, reared in protectionism."[13] In other words, research ethics has historically taken a reactive, rather than proactive, stance. When new scientific advances emerge, existing regulations designed to respond to past misconduct may not provide the right guidance for the future. More generally, regulations can be slow to adapt to technological advancements, and Institutional Review Boards may lack the training or authority to go beyond existing regulations. Furthermore, some ethical issues may arise after regulatory approval. Although there are some structures to review the evolving social value and risks associated with ongoing research, such as Data and Safety Monitoring Boards, guidance for ethical issues that arise as trials are ongoing is limited.[14] Other important ethical issues are not covered by regulations, such as how to address risks to third parties not enrolled in research.[15] Finally, legal and moral obligations may sometimes conflict.[16]

To address these issues may require the additional expertise held by scholars specializing in research ethics. Research ethics involves application of moral principles to the domain and practice of research. Direct engagement between ethicists and research teams can help improve the quality and relevance of the research as well as the ethical work connected with it. To do this work, "one needs to become part of the very processes one studies."[17] The degree to which one becomes part of a team, however, can vary. Importantly, ethics engagement is different from ensuring compliance with policies or regulations. Compliance involves setting a "floor" for research activity —ensuring that a study does what is minimally required to be responsive to regulations. By contrast, engaged ethicists focus on what *should* be done within the range of what is legally permitted. In collaboration with legal experts, they can also recommend how to interpret ambiguous regulations when there are different principles to balance. Ethicists can even make recommendations about how to resolve potential conflicts between regulations or laws and ethical principles.[18]

Some forms of engagement, including research ethics consultation (Figure 1), are limited in time and scope. For example, periodic consultation offers a less expensive and accessible option for research teams seeking guidance. Some research teams may welcome ethics involvement to improve the responsible conduct of their own research, but face disincentives due to increased costs or time. The consultation option can also help ethicists gain entry into projects that may need significant attention. When appropriate, an ethicist could make a case for greater engagement over time.

On the other hand, ethicists who are directly engaged in research as a member of research teams might conduct "research on research."[19] Ethicists who engage with teams without conducting research of their own may do so in one of three main ways (Figure 2). First, some ethicists provide expertise, such as by helping identify ethical problems based on understanding of regulations and ethical principles, framing discussions, and finding defensible solutions. Ideally, ethicists functioning at this level can serve as critics lending an analytical eye to projects with an insider's view and raise ethical concerns to help the researcher avoid ethical dilemmas and address challenges that arise. Some issues are trickier than others to address. For example, ethicists may have fundamental concerns that call into question whether the research should be done at all or introduce substantial costs or delays to address. This may be especially difficult to address for ethicists also funded by the research, as we will discuss further below.



**Patterns correspond to levels of ethicist involvement depicted in Figure 1

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Second, ethicists might help with capacity building. Ethicists can train scientists in ethics to enable self-regulation. For example, one ethicist within the HBCD network contributed to writing guidance to be applied across a 5-site

consortium on: a) recruitment, enrollment, and retention; b) training for core staff; and c) innovative consent processes. This guidance could then be used by other members of the research team to guide ethical and responsible practices. Third, ethicists can perform community or public outreach by helping to bridge researchers and communities, communicating about the research with the public, and shaping the process and content of obtaining community input.[20]

Ethicists who conduct research of their own (sometimes referred to as “research on research”) may focus on either normative or empirical analysis. Normative (or “conceptual”) research does not require collecting data, but rather applying principles, analytical reasoning, and examples to reach conclusions about the ethical dimensions of an issue. This could involve determining which decisions or approaches are ethically defensible or providing a framework to guide action. Legal analysis is a related type of research that requires applying principles of legal reasoning to interpret existing laws. Policy research can involve building on legal analysis by recommending ways to develop or reform laws, as well as studying their application and interpretation. For example, one ethicist contributed to the national Ethics and Law Working Group by conducting normative analysis on the use of wearable technologies that passively record potentially sensitive biological, behavioral and environmental data about participants and, potentially bystanders. Another ethicist conducted an in-depth 50-state survey of laws governing substance use in pregnancy and postpartum to better understand the potential risks to HBCD participants.[21]

By contrast, empirical research refers to research that involves the collection and/or analysis of data. Methodological approaches that are commonly used by ethicists are used by social scientists generally; approaches can be divided further into qualitative or quantitative methods. One example of *qualitative* empirical research in the HBCD involves conducting interviews with both pregnant women and researchers to identify barriers and best practices for studying infant development in the context of laws penalizing substance use in pregnancy. Interviews also explored what forms of recruitment are more or less acceptable to participants. An example of quantitative empirical research involved a national survey of obstetricians to learn how laws penalizing substance use in pregnancy affect the care they provide for pregnant patients, what barriers prevent them from referring patients to research, and how the COVID-19 epidemic has affected their ability to screen patients for substance use and refer them to medically assisted treatment.

Fundamental Tension in Ethics Engagement

Perhaps the fundamental challenge with ethics engagement is that a significant conflict of interest is built into the role of an ethicist directly engaged with a research team. Part of an ethicist’s job is to engage in critical reflection on controversial issues that may slow down or prevent certain research from proceeding. Ethicists who are fully integrated into teams may be dependent on that team for salary and other support, particularly in an environment where grant funding is required. This embeddedness may lead ethicists to assume the biases of the research team (See Figure 1). If an ethicist uncovers controversial issues that would be costly or time consuming to address, or otherwise counter to the objectives of the research team, they may be disincentivized to raise these issues. Additionally, some teams may not permit publication of analyses of ethical issues that were addressed (or potential harms avoided) if it could bring negative attention to the research or the institution. Some degree of independence can be important. Independence may give ethicists greater ability to provide genuine reflective critique and raise issues that may be uncomfortable or unwelcome, but important.

On the other hand, as previously mentioned, entirely independent ethicists may lack knowledge of the relevant science or technology or the culture within the field. Additionally, the nature of the interaction between the field and the community they serve may be hard to understand from the outside. Thus, closer engagement may be necessary to provide nuanced, practical, and actionable recommendations regarding research practices and methods. For example, an ethicist without context or experience may not appreciate the importance of providing a non-judgmental environment for the care of pregnant individuals with substance use that addresses their fears related to privacy and negative consequences. Research teams that fail to provide a non-judgmental setting could drive individuals away from engaging in research that is ethically informed. Many ethical challenges are simply not visible without a deep understanding of the subject under investigation. Aditionally, limited ethics engagement may not be sufficient to

address all ethical concerns, but the fact that ethics engagement has occurred may give the appearance that a project is ethically sound, even if it raises serious concerns. Such a phenomenon has been described in the context of artificial intelligence as “ethics washing,”[22] referring to situations where an ethicist is involved with a project in a superficial, distant way (perhaps with limited time funded or expected to be spent on the project) in order to reassure outsiders about the ethics of the project, and there is limited interest in having an ethicist involved to uncover and address ethical issues.[23]

Closer engagement can also be important for building mutual trust. As Ashby and Morrell argue, “the process of understanding may require a relationship with the subject and its researchers, whereby the bioethicist becomes embedded in the area and indeed may achieve, or strive for, credibility and perhaps respect from the practitioners concerned and within the scientific community.”[24] Researchers who believe that ethicists are acting with integrity, with a good understanding of both the subject-matter and the importance of conducting the research, will be more willing to listen to ethical critiques and collaborate to address them. Alternatively, clinicians or researchers could themselves obtain in-depth bioethics training so they are able to see ethical issues with greater acuity. It is unclear, however, how many researchers have the time and desire to obtain rigorous ethics training and remain up-to-date in both their home discipline and the field of bioethics.

Finally, ethics engagement can also be beneficial for ethicists. Ethicists who work closely with research teams may learn more about the practice of research and the reasons for particular approaches. This knowledge can enable the ethicist to distinguish true ethical concerns from approaches unfamiliar to the ethicist that, nevertheless, could be appropriate under the right circumstances if adequate protections are in place. For example, an ethicist who was unfamiliar with human challenge trials, or studies that involve deliberately exposing participants to diseases, might assume these studies are always unethical without realizing there are ethical frameworks for conducting them responsibly.[25] Ethicists who engage with research teams can also obtain a better appreciation of the gap between principles and their application.[26] Ethicists may also learn from the experience in ways that can improve their own analytical abilities for future challenges. Moreover, some practices that have become normalized may be ethically problematic, and ethicists able to engage deeply may be better able to bring attention to this type of problem. Ethicists may need time with the research team to understand the science involved for these benefits of engagement to manifest. On the other hand, it is possible that greater objectivity will make it easier to identify practices that are problematic but, common and normalized within the field.

Striking the Balance Between Integration and Independence

Planning engagement that strikes the right balance between independence and integration is difficult. It may be easier for ethicists to manage conflicts of interest when there is external scrutiny to hold investigators accountable. For example, some have compared bioethics engagement to journalism. Journalists must maintain some degree of independence to retain credibility but can learn great deal from being embedded within the object of their study. In some cases, embedded reporting may even be necessary to do meaningful work.[27] Although journalists may face pressure from the objects of study to withhold important information, journalists have editorial staff to report to, fact-checkers reviewing their work, and ultimately must account to the public. Another discipline that faces similar pressures is biostatistics.[28] Biostatisticians who are employed by researchers may face pressure to massage findings, deviate from pre-planned analyses, or display results in a more positive light. Requirements to preregister hypotheses, set up ongoing review by data and safety monitoring boards that include statisticians, and submit results for peer review that includes independent evaluation of data are important checks and balances that can help maintain research integrity. The approaches of disciplines like journalism and biostatistics therefore suggest that it is important for ethics engagement to include transparency and accountability to individuals and communities other than the embedded ethicist herself.

Some teams may not need external accountability and are committed to conducting research with integrity even if it comes at a cost. For reaserch teams that need convincing, ethicists can appeal to external authorities who can impose consequences for research that is not ethically appropriate, such as Institutional Review Boards/Research Ethics Committees, journals that may not agree to publish ethically problematic articles, and future public scrutiny to

explain the importance of their work. Ethicists may also benefit from being able to present their work at bioethics conferences and use colleagues as sounding boards. Engaging with colleagues from the field of bioethics can serve to reinforce the importance of existing norms and share strategies for withstanding external pressure.

One way to strengthen ethics engagement to counter the above challenges is to consider funding mechanisms such as those employed in HBCD. Yet, in the literature, there is limited discussion of whether ethicists are adequately funded for their work. One strength of the HBCD approach is that it provided a “carrot” for researchers to work with ethicists by making it clear applications including ethisists would be reviewed favorably for it. However, it can be difficult to anticipate what amount of an ethicist’s time will be required for a given study. For example, normative work that primarily involves engagement and learning, followed by providing expertise and guidance, is essential but easily undervalued —especially if not connected to specific research deliverables. Moreover, plans for how much time and resources will be devoted to ethics engagement in a funded study are typically developed before the ethical issues become clear. This suggests studies may budget much more or much less time than is required to do the work. During the planning phase of the HBCD, many ethicists acknowledged being un- or under-funded.

Some countries, such as Canada, explicitly make it a condition of funding genomic research that the project includes embedded research on ethical, economic, or environmental implications.[29] This is distinct from the HBCD approach because ethics engagement is explicitly required for genomic research to be funded, rather than merely being encouraged. However, engagement under the Canadian approach to funding genomic research can involve economic or environmental analysis; this could mean that some studies that could benefit from ethics engagement still do not have it. From the perspective of research ethicists, this requirement for engagement on the social implications of a research project from the start makes it easier for ethicists to have a steady portfolio of funding. On the other hand, Canadian research funds do not typically allow ethicists to be principal investigators on standalone ethics-focused projects. One upside of this financial security is that ethicists are more likely to be able to raise critiques or challenges that the research team may not welcome. Yet ethicists may have less autonomy to run independent research labs to conduct normative and empirical research and bioethics work. This in turn may limit their ability to develop a robust theory of how a particular type of research ought to be done. Indeed, the Canadian Institute of Health Research has faced criticism for its approach to incorporating ethics into its leadership structure and now consults with a Standing Committee on Ethics to improve its approach.[30]

In the U.S., public research funding supports the creation of centers or large collaborations focused on ethics in particular areas, such as genetics.[31] Ethics engagement in most other scientific areas is not routinely written into funding applications except in discrete scientific areas, such as artificial intelligence or neurological research.[32] Funding dedicated to ethics work beyond these areas typically requires administrative supplements, and these only apply when ethics research is being performed as part of the engagement of an ethicist.[33] Ethicists can more readily serve as independent investigators proposing their own projects, which could lead to larger ethics projects being conducted in the U.S. as compared with Canada, but also more uncertainty for ethicists reliant on research funding for their salaries. Mindful of the trade-offs involved, some recommend more guaranteed ethics support for projects that are truly independent. Arnason argues that, “[r]ather than embedding ethicists in scientific research projects, it would be preferable to support independent ethics projects through, for example, national research councils or the European Union funding bodies in Europe.”[34] Per Arnason, the independence of ethicists is more essential to their value than the benefits that come from integration.

Recommendations for Optimizing Ethics Engagement Based on the HBCD Experience

It is important to strike the right balance between independence and integration in ethics engagement, particularly when resources are constrained, to ensure ethical analyses and critiques are as rigorous as possible. Returning to the example of the HBCD network’s approach to ethics engagement, some strengths of the approach taken are clear. For example, in the request for applications, “creative designs and innovative solutions” were considered important in three main areas, with legal and ethical considerations mentioned before scientific questions.[35] Researchers were prompted to seek outside expertise. Network meetings also consistently featured presentations by ethicists. After funding was awarded, the network created a separate working group composed of ethics and legal

experts who served the purpose of sharing ideas, writing manuscripts, and providing opportunities for feedback on ongoing work. In phase II, the project's program announcement indicate that the administrative core for the larger network would need to provide "dedicated expertise" and plans for addressing ethical issues, including those associated with participant risk and incidental findings.

In reflecting on the HBCD planning phase experience, several recommendations for future research emerged. We organize our recommendations based on the relevant stakeholders to whom they apply: sponsors, professional societies, research teams, and ethicists (Table 4). First, sponsors should invest in early and robust ethics engagement. The NIH highlighted the importance of ethics engagement starting with early planning meetings and extending to the request for applications. Perhaps most importantly, the NIH ultimately funded several applications that included ethics-related research projects. Second, the NIH created an inter-network Ethics and Law Working Group, providing ethicists with an opportunity to collaborate to identify, discuss and potentially resolve issues with a goal of strengthening the second phase of the HBCD study. Nevertheless, ethicists were generally underfunded with respect to the workload. Moreover, some ethicists may have been willing to take on less funding than necessary, with an eye towards being able to secure more funding in the second phase of the project. As well-intentioned as these ethicists might be, they may also be in conflict and incentivized not to raise significant ethical challenges that could derail the future project. This suggests that funders should evaluate expectations of those who are identified as the "ethics" experts on planning grants. Funders should then allocate sufficient funding and instruct reviewers to evaluate whether ethics engagement is appropriately funded to do the needed work.

Second, professional societies should help educate the public and researchers about the added value of ethics engagement in research. For example, the American Association for the Advancement of Science (AAAS) is a science advocacy organization with a mission to "advance science, engineering, and innovation throughout the world for the benefit of all people."[36] In this role, AAAS could function as a hub to reach and educate scientific and engineering professional organizations about the distinctions between ethics, law, and societal dimensions of biomedical, bioengineering, engineering, and behavioral research, and the importance of early engagement with ethicists. Professional ethics societies like the American Society for Bioethics and Humanities and the World Congress of Bioethics could play complementary roles.

Third, research teams should recognize the importance of ethics engagement and independence. While some research teams have great sensitivity to ethical issues and less rigid hierarchies, others may be less amenable to critique and collaboration. Reform of the culture of research to foster cultivation of teams and investigators who endorse the importance of ethics[37] may be one of the most important, longer-term solutions to support the use of ethics engagement to ensure the ethical conduct of research. Helping researchers value ethics in and of itself, however, can be difficult in a culture that prioritizes initial scientific discoveries over slower contributions to scientific knowledge. Research teams could also use both ethics consultations and embedded ethics work for their studies. External ethics consultation could help address potential bias by adding a more objective, second opinion on challenging and controversial issues.

Finally, individual ethicists can also advocate for the value added through ethics engagement and the importance of independence. Ethicists should evaluate prospective work and avoid ethics engagement in name only. Ethicists should endeavor to engage with teams that have a commitment to prospectively addressing ethical issues arising in the research, even if those issues may prove to be difficult to surmount. Ethicists can explain that their critiques can be opportunities for improvement that anticipate challenges in a way that could prevent projects from being derailed down the road. When it is done well, ethics engagement across the planning, conduct, and dissemination of research can enhance both integrity and trustworthiness.

DETAILS

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High-Priced Sickle Cell Gene Therapies Threaten to Exacerbate US Health Disparities and Establish New Pricing Precedents for Molecular Medicine

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ABSTRACT (ENGLISH)

Gene therapies to treat sickle cell disease are in development and are expected to have high costs. The large eligible population size — by far, the largest for a gene therapy — poses daunting budget challenges and threatens to exacerbate health disparities for Black patients, who make up the vast majority of American sickle cell patients.

FULL TEXT

Important medical advances are emerging for the treatment of sickle cell disease (SCD). In November 2019, the US Food and Drug Administration (FDA) approved crizanlizumab-tmca (Adakveo), a once-monthly medication proven to reduce the number of sickle cell pain crises, and voxelotor (Oxbryta), which inhibits the sickling and destruction of red blood cells, improving hemoglobin levels for patients.[1] Allogeneic bone and marrow transplantation has also emerged as a promising SCD therapy but is limited by the availability of matched related donors. Other transformative treatments are on the horizon. Several companies are developing gene therapies that would insert a functional copy of the beta-globin gene into the blood-producing hematopoietic stem cells of patients with SCD using viral vectors and gene editors like CRISPR.[2] These alterations have the potential to prevent erythropoietic sickling and to eliminate pain crises and their sequelae.[3]

Although the science and therapeutic benefit of such treatments are promising, the economic realities of paying for such drugs are troubling. In the US, crizanlizumab-tmca and voxelotor cost about $100,000 per year, and the price of sickle cell gene therapies may far surpass this at an expected cost of over $1 million for one-time treatment.[4] Similar prices are expected for gene therapies to treat hemophilia and beta-thalassemia. In Europe, a beta-thalassemia gene therapy, betibeglogene autotemcel (Zynteglo), already sells for $1.8 million.[5]

Such prices have been justified on the basis of long-term savings to the health care system from reduced disease management costs.[6] However, payment models for gene therapies may not be scalable for commonly occurring ailments like SCD. For example, the roughly 100,000 US patients with SCD is far larger than any other eligible populations for FDA-approved gene therapies.[7] Although the patient population is very large by gene therapy

standards, it would qualify SCD therapies for special status under the US Orphan Drug Act, which may explain, in part, their high prices. Recently, rare disease drug prices have been rising.[8] However, even for a rare disease drug, the price of SCD therapies at $1 million or more would be astronomically high: the average annual cost for rare disease drugs was $138,919 from 2008 to 2017.[9]

Payers have struggled with the budget impact of expensive drugs for both small numbers of patients, even when these drugs are extremely effective.[10] After the 2013 approval of sofosbuvir (Sovaldi) —a curative treatment for hepatitis C virus infection that was initially priced at $84,000 for a course of treatment —many states restricted its access to otherwise eligible Medicaid patients and those in the prison population.[11] Private payers also struggled to afford sofosbuvir.[12] Moderate price reductions from competition due to comparable products made by other manufacturers have since allowed greater access to products treating hepatitis C virus, but public insurers are still spending substantial sums on these drugs. The number of patients with SCD combined with the expected drug prices will have a similarly significant budget impact for payers, which will, in turn, likely restrict drug access to patients.

The cost of SCD therapies will likely be a major barrier in accessing care, and may, because of the demographics of SCD patients in the US, also exacerbate existing racial health disparities experienced by Black Americans. The vast majority of US patients with SCD are Black —an estimated 1 in 365 Black Americans have the disease as compared to roughly 1 in 93,000 White Americans.[13] Additionally, 1 in 13 Black Americans are carriers of sickle cell trait —a milder, related condition that increases risk of chronic kidney disease and venous thromboembolism —and may one day also be treated with gene therapies.[14]

US gene therapy prices have recently reached from $475,000 to over $2 million for one-time use. But the case of SCD therapies brings an additional consideration into the drug pricing ecosystem: how should health equity be incorporated into pricing? Should manufacturers have the unilateral power to set an unfettered price for a treatment benefiting a population with historical health disparities whose medical needs have been long under-researched and under-funded? The emergence of high-priced SCD treatments also raises the question of how the US federal government’s contribution to SCD gene therapy development should impact its price.

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Price-Setting Considerations for Expensive Sickle Cell Disease Treatments

The classic justification for drugmakers being able to set their own prices in the US has been the high cost of research and development, but pharmaceutical manufacturers —influenced by existing market incentives —have long under-invested in SCD research and development. Indeed, over the past two decades, SCD has been under-researched and under-funded compared to other diseases with similar or lower incidence in the US, even though the average life expectancy of people with the disease is just 54 years.[16] Compounding this problem, historical under-investment is often used to justify higher prices. Since a drug treats a population with a health disparity, the argument goes, manufacturers should be better rewarded for developing a drug to treat the population. But why should systematic biases against certain populations be later weaponized to cost those patients more?

While the private market has not provided much funding for SCD research, the US government does appear to have played a substantial role in funding SCD gene therapy development via the National Institutes of Health (NIH). Viral vector technology, designed for use in SCD gene therapy, was developed, in part, at the NIH through its intramural research program.[17] In 2019, the NIH announced plans to invest an additional $100 million into the development of SCD gene therapies.[18] CRISPR technology, a therapeutic treatment modality for SCD therapy, was developed at academic institutions with extensive NIH support.[19] Also, ongoing clinical trials to study the effects of SCD gene therapies received funding from the NIH, with some studies using NIH facilities in Bethesda, Maryland as a trial site.

Manufacturers producing the gene therapy may contend that a $1 million or more price tag is justified because treatment at such a price offers value to the health care system, which would be expected to pay slightly more than this amount in costs to treat a SCD patient over a lifetime. But this reasoning is concerning in several ways. First, since even a fraction of this price would be difficult for nearly any American to pay out-of-pocket, access to the drug would be limited to patients with insurance. However, it has historically been the case that Black Americans have had lower rates of health insurance and underinsurance of coverage as compared to non-Hispanic White Americans across all age groups, increasing the risk of exposure to high out-of-pocket costs.[21] As such, it would be difficult to achieve “pharmacoequity” —fair access to prescription drugs regardless of race or socioeconomic background —an issue bearing special attention in the wake of protests to bring greater racial equity to the US health care system.[22]
For SCD patients with health insurance, coverage decisions —especially by government insurers —may also lead to unethical outcomes. Medicaid is now the largest insurer of SCD patients —over 55,000 out of the roughly 100,000 SCD patients in the US were insured through the program in June 2019.[23] To pay for 55,000 sickle cell gene therapies at a price of $1 million per dose, Medicaid would have to pay $55 billion, over 85% of Medicaid’s national spend for outpatient drugs in 2017. By contrast, the hepatitis C virus treatments sofosbuvir (Sovaldi) and ledipasvir/sofosbuvir (Harvoni) cost Medicaid about $2.8 billion in 2015.[24]
For individual state Medicaid programs, paying for SCD gene therapies would consume disproportionate percentages of their budgets. In the state of Illinois, for example, 2020 Medicaid spending allocated to “prescribed drugs” was $872 million.[25] There are an estimated 3,500 patients in Illinois with SCD.[26] If about 55% of these patients were on Medicaid —the average percentage nationally —and SCD gene therapy cost $1 million, then it would cost $1.925 billion, about 2.2 times the amount needed to cover *all* Medicaid outpatient drugs in a state with a population of over 12.5 million people. Even if only 875 out of the estimated 1,925 Medicaid-covered SCD patients in Illinois—about 45% of this population—received SCD gene therapy, the total spending on 875 patients would still exceed Illinois Medicaid spending for all outpatient drugs in the state. Thus, SCD gene therapy’s expected price-point would severely challenge government budgets, potentially limiting Medicaid’s ability to pay for its current drugs and services.

Alternative Pricing Options for Sickle Cell Disease Therapies

In light of the US federal government’s contribution to SCD gene therapy development and the impending effect that its price may have in exacerbating health care disparities, there is a strong case that legislative bodies should prospectively address SCD gene therapy prices. In a June 2019 opinion piece, US Senator Bill Cassidy (R-LA) hinted at the possibility of bipartisan-supported payment strategies to make SCD gene therapies more affordable.[27] He suggested that payors could use a subscription model of payment, in which a lump sum was paid by each state’s Medicaid office to cover all SCD patients —a strategy that was previously used by Louisiana to purchase hepatitis C virus treatments like sofosbuvir for its Medicaid patients.[28] Cassidy also suggested the creation of a payor collaboration for a curative gene therapy fund, into which Medicaid and private insurers would make contributions. This fund would be used to pay for all SCD gene therapies. Since payment for therapies would be carved out of premiums, all insurers and users of the gene treatment would get the same price.[29]
Cassidy additionally suggested that gene therapies could be priced in a prorated fashion that incorporates the cost of past treatment care and future life expectancy. For example, a 30-year-old sickle cell disease patient with a current life expectancy of 54 years might not pay $1 million for treatment, but rather $1 million divided by 54, about $18,500 per year for nearly a quarter of a century.[30] However, this payment strategy would have important problems. First, it would subject patients to crippling debt sustained over decades, which may exacerbate low socioeconomic conditions for Medicaid eligible patients. Additionally, issues of insurance coverage could further complicate the plan. What would happen if a patient changed insurance? In the installments plan, private insurers would likely have strong incentives to delay treatment in the hopes that patients would switch to another third-party payor. Nevertheless, payment strategies that extend the length of payments may play a role in paying for SCD gene therapies. In devising such reforms, officials should not take as a starting point the price tag set by the manufacturer

without the input of payers. The price of the therapy should be negotiated by government based on its clinical benefits as well as the government's support for the development of technology, patients' ability to afford the medication, and health equity concerns. For drug products like SCD gene therapies with significant development support from US federal funding, there have been previous calls to mandate reasonable pricing as a condition of transferring relevant intellectual property rights to manufacturers and calls to leverage federal support of drug development in price negotiations by federal payers.[31] This latter strategy might be applied by Medicaid and the Children's Health Insurance Program to bring to manufacturers' attention the NIH's federal support of SCD therapy development. Federal payers could thus avoid having the government "pay-twice" for drugs —once for development, again for purchase.

Another related policy proposal would be the enactment of a federal review board, charged with determining the equitability of pricing for products costing more than $500,000 for one-time use (perhaps in conjunction with existing organizations that evaluate the appropriateness of pharmaceutical pricing). Such a board could be encouraged not to use equity considerations as a way to increase the price of a drug (as a recent health technology assessment did),[32] but rather, as a way to offer greater social value —reducing the budget burden on state Medicaid offices, which could use millions of dollars in savings to reinvest in underserved communities. Such pricing would faithfully acknowledge the original intent of publicly funding sickle cell research —to improve disparities by designing new therapies, not exacerbate them by setting prices that gatekeep patients from these medicines.

Conclusion

In today's drug development system in which companies have sole authority to set price in the US market, important factors like equity and public funding contribution to drug development are unlikely to be factored into pricing. As SCD therapies are developed and brought to market, it will be critical to think of strategies that price sickle cell agents in ways that fairly reward manufacturers for any risky private investments they made in paradigm-shifting medications with federal support and also make medications available to those who stand to benefit from the treatment.

All solutions to this problem must begin with acknowledgement that in today's drug development system there are misaligned incentives that allow for the inequitable pricing and production of pharmaceuticals. In 2022, the pricing of drugs already exacerbates health and socioeconomic inequities, which are not factored into drug pricing policy decision-making. With the emergence of gene therapies, this trend will only become worse.

In a system in which drug companies have sole authority to set price, important factors like equity and public funding contribution to drug development will be unlikely to be factored into pricing. There needs to be a re-alignment of market incentives that encourages development of fairly-priced treatments for populations with historical health disparity to help patients who have been underserved by medicine in the past and should not be again.

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About This Column

Aaron Kesselheim serves as the editor for Health Policy Portal. Dr. Kesselheim is the JLME editor-in-chief and director of the Program On Regulation, Therapeutics, And Law at Brigham and Women's Hospital/Harvard Medical School. This column features timely analyses and perspectives on issues at the intersection of medicine, law, and health policy that are directly relevant to patient care. If you would like to submit to this section of JLME, please contact Dr. Kesselheim at akesselheim@bwh.harvard.edu.

DETAILS

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For the Common Good: Philosophical Foundations of Research Ethics by Alex John London

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ABSTRACT (ENGLISH)

Written in response to what he recognizes as the problematic philosophical underpinnings of "orthodox research ethics," Alex John London's For the Common Good reimagines what is called for in any effort to create a better system of oversight and regulation in biomedical research. London weaves a common thread — justice — through this historical and critical account of the practice of research ethics and its organization of stakeholders, institutions and regulations. By introducing the idea of "a common good" London reframes the narrative and responsibilities of the research ethics field to demonstrate that scientific research and regard for the rights and welfare of individuals are not mutually exclusive. This impressive monograph encourages its readers to push past the limitations of traditional research ethics to consider the context in which the discipline is embedded. That is, rather than settling for analysis at the level of researchers and research participants alone, London encourages us to expand our inquiry to encompass a wider array of stakeholders who co-labor in the social undertaking of biomedical knowledge production. London accomplishes the difficult task of upstream analysis — turning his attention to the conditions and assumptions which create ethical dilemmas rather than applying a retrospective ethical salve to injuries near-guaranteed by a broken system. As opposed to the limited domain of orthodox research ethics (researchers, participants, and the institutional bodies which regulate interaction between the two) London also considers the role and contributions of affected communities, pharmaceutical firms, philanthropic organizations, and journal editors among others.

FULL TEXT

Written in response to what he recognizes as the problematic philosophical underpinnings of "orthodox research ethics," Alex John London's *For the Common Good* reimagines what is called for in any effort to create a better system of oversight and regulation in biomedical research. London weaves a common thread —justice —through this historical and critical account of the practice of research ethics and its organization of stakeholders, institutions and regulations. By introducing the idea of "a common good" London reframes the narrative and responsibilities of the research ethics field to demonstrate that scientific research and regard for the rights and welfare of individuals are not mutually exclusive. This impressive monograph encourages its readers to push past the limitations of traditional research ethics to consider the context in which the discipline is embedded. That is, rather than settling for analysis at the level of researchers and research participants alone, London encourages us to expand our inquiry to encompass a wider array of stakeholders who co-labor in the social undertaking of biomedical knowledge production. London accomplishes the difficult task of upstream analysis —turning his attention to the conditions and assumptions which *create* ethical dilemmas rather than applying a retrospective ethical salve to injuries near-

guaranteed by a broken system. As opposed to the limited domain of orthodox research ethics (researchers, participants, and the institutional bodies which regulate interaction between the two) London also considers the role and contributions of affected communities, pharmaceutical firms, philanthropic organizations, and journal editors among others. London organizes the book into three parts —focusing first on the flawed foundation of research ethics, then homing in on the ethical nuances of domestic and international research. *For the Common Good* reads as simultaneously an indictment of orthodox research ethics and an invitation to consider an alternate framework. According to London, the aim of orthodox research ethics is to safeguard research participants from excess harms at the hands of researchers, generally through regulation of study protocols by Institutional Review Boards (IRBs). London refers to this arrangement as the "IRB triangle." Orthodox research ethics locates the "moral epicenter of research" at the center of this triangle, drastically limiting the scope of the field and dismissing broader questions and other stakeholders as outside the purview of the field. While certainly an important safeguarding practice, orthodox research ethics as it stands lacks any mechanism with which it could ask questions such as: Will this research produce knowledge that is socially valuable? Who is it meant to benefit? Who could it harm? And, perhaps most damningly, how should it be funded?

In failing to ask these essential questions, research ethics finds itself in the role of putting out fires that could have been avoided if the collective imagination surrounding biomedical research were more truly informed by philosophically robust ideals of justice. Research ethics has, since its inception, been somewhat of a reactionary enterprise. That is, often, if not always, research ethics is moderating and legislating around harms to research subjects by researchers. The field's foundational codes, declarations, and trials were a direct response to crimes committed by Nazi experimenters, and the field has continued to develop against the backdrop of public outcry against ethical breaches: the Jewish Chronic Disease Hospital study, in which researchers injected cancer cells into geriatric patients who did not previously have cancer; the publication of Henry Beecher's "Ethics and Clinical Research," which highlighted 22 examples of what Beecher saw as ethics violations in research; and the Tuskegee Syphilis Study, in which the National Public Health Service studied the progression of syphilis in Black men in Tuskegee, Alabama. This fraught history and the never-ending battle to contain harms while maximizing scientific gains has at times seemed to pit biomedical research against the welfare of research participants. However, London argues that this does not have to be the case, as it is not human participation in research that is inherently problematic, but rather the regrettable severance of research from broader social aims. Drawing on Rawls, London distinguishes between a philosophical *concept* of justice and differing *conceptions* of justice, positing that despite diversity in substantive values, life goals, and how to facilitate their attainment, "every person can recognize themselves as sharing a more basic or generic interest in being able to form, pursue and revise a life plan of their own" (London, 15). In this way, London claims that there are universalizable social aims that can and should undergird both research aims and their oversight.

London's project hinges on the idea that "the same concern for the common good that grounds an imperative to conduct scientifically sound research in the face of uncertainty and conflicting judgment grounds an equally strong imperative to ensure that this undertaking is organized on terms that respect its various stakeholders' claim to be treated as free and equal persons" (London, xvi). While we generally agree with the aims of the project, it remains unclear how, even under perfect circumstances, the philosophical framework London proposes would translate into material reform. In a practical sense, the text calls for more than intervention at the level of reforming processes, such as altering the ways in which studies ensure their participants' informed consent. Instead, London pushes us to reimagine relationships between stakeholders in shared knowledge production, including a more expansive understanding of who the stakeholders are, so that the fundamentals of a practical research ethics can shift toward common goals. London admits, and we concur, that this book is not a set of directions for spot treating every individual issue in research ethics, but rather a philosophical framework which allows us to transcend our currently imagined restraints to formulate a new perspective on the problems in research ethics. We find London's approach to disentangling the philosophical from the bureaucratic intriguing, and remain wary of reform to structures which are currently far from what would be required to facilitate London's proposed framework. While conflicts on the ground

frequently *do* so pit the aims of research against participant welfare, and it remains unclear how to get from where we are to where we need to be in order for London's scaffolding to be set into place, *For the Common Good* shows that research ethics need not continue to be a reactionary enterprise.

DETAILS

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Chile: Front-of-Package Warning Labels and Food Marketing

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ABSTRACT (ENGLISH)

This Article aims to show how the food industry has instrumentalized the right to freedom of expression to oppose innovative laws in Chile aimed at creating healthier food environments.

FULL TEXT

According to Chile's National Statistics Institute, the country's three main causes of death are cancers (26%), cardiovascular diseases (25.6%), and respiratory diseases (12.6%).[1] A major contributing factor to such non-communicable diseases (NCDs) are overweight and obesity,[2] which affects 74.2% of Chile's population.[3] Moreover, people in lower socioeconomic groups suffer from higher rates of obesity, and women are more obese and morbidly obese than men.[4] Overweight and obesity are fundamentally caused by an energy imbalance between calories consumed and calories expended, making dietary habits and physical inactivity key risk factors. In this regard, it is not surprising that Chileans suffer from high rates of overweight and obesity and diet-related NCDs: they are large consumers of sugary drinks, averaging 190 calories per person per day,[5] and buy on average 201.9 kg of ultra-processed foods and beverages per person per year.[6] As regards physical activity, 86.7% of Chileans lead sedentary lifestyles, exercising less than three times a week.[7]

It is against this background that the Act on the Nutritional Composition of Food Products and their Advertising (the Food Act) entered into force in 2016.[8] The goal of this ambitious act was to promote healthier diets by introducing a mandatory front-of-package warning label (FOPL) for foods high in fats, sodium, sugar, or calories (HFSS foods), strict marketing and advertising restrictions of HFSS foods to children, and a sales ban of HFSS foods in schools, among other measures. Crucially, the Food Act is at the heart of a comprehensive, multi-sectoral nutrition policy aimed at curbing obesity and diet-related diseases, which includes an 18% excise duty on sugary drinks,[9] the promotion of breastfeeding,[10] and a prohibition to use nutrition and health claims on HFSS foods and food supplements.[11]

From the outset of the parliamentary discussions of Chile's proposed Food Act, national and multinational food companies expressed their discontent, advocating for an approach based on voluntary self-regulation and public-private partnerships instead.[12] In opposing the Food Act and its related regulations, the industry used all available means to try to influence the outcome of the legislative and regulatory processes and the perceived legality of these regulatory actions.

Illustrative are the international economic law concerns raised by corporations and industry associations in stakeholder submissions during public consultations related to Chile's subsequent regulations implementing the Food Act, as well as their extensive coordination with their government representatives to raise similar concerns in diplomatic government-to-government exchanges, particularly at the World Trade Organization's Technical Barriers to Trade Committee.[13] Moreover, the food industry expressed concerns under national law grounds in several parliamentary hearings and stakeholder submissions. These legal concerns were primarily based on constitutional rights, including the right to freedom of commercial expression and the right to property.

Taking these arguments as a starting point, this contribution shows how the industry relied heavily on the right to freedom of commercial expression during parliamentary hearings and stakeholder submissions to oppose Chile's advertising and marketing restrictions, but later on relied primarily on the right to property to build their arguments in formal legal challenges. It is argued that this practice reflects an instrumentalization of legal rights, and is part and parcel of the industry's legal strategies to oppose state regulation more generally.

Taking these national law challenges as a starting point, the goal how the industry relied heavily on the right to freedom of commercial expression during parliamentary hearings and stakeholder submissions to oppose Chile's advertising and marketing restrictions, but later on relied primarily on the right to property to build their arguments in formal legal challenges. It is argued that this practice reflects an instrumentalization of certain legal rights, and is part and parcel of the industry's legal strategies to oppose state regulation more generally.

After briefly describing the most contested measures introduced by the Food Act and its related regulations, I consider more fully specific arguments raised by multinational food companies in challenging some of these measures, and explore possible explanations as to why arguments alleging breaches of freedom of commercial expression were not included in subsequent formal legal challenges. Finally, I offer brief concluding remarks.

Chile's Strengthened Food and Nutrition Policy

The Chilean Food Act became fully operational on 27 June 2016, when its implementing decree entered into force.[14] The Food Act contains *inter alia* provisions regulating food labelling and food information, food sales of foods in schools, and food marketing and advertising. Additionally, regulations concerning health and nutrition claims were adopted separately by Chile's Ministry of Health to bring relevant rules in compliance with the newly adopted Food Act.

Front-of-Package Warning Labels

The Food Act's mandatory FOPL scheme mandates that food products that exceed certain nutrient thresholds for sodium, sugar, fats and calories be marked with black octagonal warning signs (resembling traffic STOP signs) on the front of their packaging.[15] Written on these signs is the warning "High in…" for each nutrient exceeding the legal thresholds (e.g. "High in sugar"). Thus, a product may may have to display up to four "High in…" warnings, occupying significant space from the front face of a product's packaging. The nutrient thresholds set by the Ministry of Health are also particularly strict if compared with the voluntary FOPL schemes introduced in other countries, like the United Kingdom or Australia for example.[16] However, they have been applied gradually to allow sufficient time for the industry to adapt. The strictest thresholds entered into force on June 27, 2019 and the FOPL scheme will be mandatory for smaller businesses as of June 27, 2022.

Marketing and Advertising Restrictions

Strict marketing and advertising restrictions were included in the Food Act to protect children from pervasive and ubiquitous exposure to unhealthy food marketing.[17] In particular, HFSS foods can no longer be advertised to children under 14 years of age,[18] and cannot appear on TV or in cinemas between 6 am and 10 pm.[19] Crucially, the advertising ban to children has been interpreted by health authorities as prohibiting also the use of cartoons and other child-attractive figures on the packaging of HFSS foods, affecting brand equity characters such as Tony the Tiger and Cheetos' Chester Cheetah.[20] Finally, marketing restrictions have banned the use of "commercial hooks" unrelated to the product itself (e.g. toys, contests, raffles, stickers, games, etc.), banning products like Ferrero's Kinder Surprise eggs from the Chilean market.[21]

Prohibition of Using Nutrition and Health Claims

The use of voluntary nutrition and health claims such as “sugars-free” on HFSS foods has also been prohibited, primarily on the basis that they could mislead consumers.[22] Moreover, the use of such claims has been banned from certain food products regardless of their nutritional composition because they do not align with the varied and balanced diet that Chile is seeking to promote according to its dietary guidelines and national nutrition policy. Such products include food supplements, sports foods, and infant formulas.[23]

Legal Arguments Raised by the Food Industry

In addition to arguments based on international economic law, the food industry has also raised several objections based on Chilean constitutional law in their attempt to oppose the Food Act and its related regulations, and in particular arguments pertaining to the right to freedom of expression and the right to property.

The Right to Freedom of Commercial Expression

Concerns related to the right to freedom of commercial expression were first raised during parliamentary hearings discussing the Food Act bill. In particular, the National Advertisers Association (NAA), whose list of members includes multinational food companies such as Coca-Cola, Unilever, and Nestlé,[24] stressed that the restrictions included in the bill would infringe Article 19(12) of the Chilean Constitution, which protects the “freedom to express opinions and to inform, without previous censorship, in any form and by any means.”[25] The interpretation advanced by the NAA also claimed that freedom of commercial expression was as “indispensable” as any other form of expression or communication (e.g. artistic, political and journalistic), and thus protected to the same degree.[26]

It is worth noting that such an interpretation was very expansive considering that commercial speech has traditionally been excluded from discussions concerning freedom of expression in Chile. The concept itself was not mentioned by the Chilean constituents mentioned when discussing the inclusion of freedom of expression in the Chilean Constitution, and is normally not included in leading academic works on the topic.[27] Moreover, the interpretation advanced by the industry did not consider that the advertising restrictions only apply to a subset of products, i.e. HFFS foods, and only when directed at children. Neither did it consider that the right to health is also protected by the Chilean Constitution. These are all important factors to consider, as the Constitutional Court of Chile has explicitly acknowledged that freedom of expression is not an absolute right and can and should be subject to legitimate restrictions in a democratic society to protect other rights and values, including public health.[28] Taking into account the widespread use of a proportionality test to strike a fair balance between competing interests,[29] one would have expected considerations relevant to such test to have been included in the NAA’s arguments relating to commercial speech or freedom of commercial expression. As discussed below, a better understanding of the industry’s arguments based on commercial speech reflect an instrumentalization of certain legal rights to oppose food marketing and advertising restrictions, rather than genuine concerns based on their understanding of their legal entitlements.

Similarly, concerns related to commercial speech were raised by the Latin American Alliance for Responsible Nutrition (ALANUR) —an association that represents producers of food supplements in Latin America —albeit in relation to proposals to ban the use of nutrition and health claims on food supplements and sports foods. These concerns were raised in stakeholder submissions during public consultations, where the industry claimed that the right of business operators to inform consumers about the science-based health benefits of their food products was also protected under Article 19(12) of the Chilean Constitution.[30] By anchoring their arguments on the scientific accuracy of the nutrition and health claims —rather than on commercial speech more generally —the industry was also able to invoke Articles 29 and 33 of the Chilean Consumer Protection Act, which permits the dissemination of accurate and truthful product information. The Ministry of Health responded stressing that the industry’s right to inform was already guaranteed by the possibility to provide relevant information to consumers in the ingredients list and nutrition declaration of their food products. It further argued that using nutrition and health claims could not be permitted taking into account Chile’s nutrition policy, which seeks to promote a varied and balanced diet.

The Right to Property

The right to property has been at the center of formal legal challenges against the Food Act and its related regulations. The food industry has primarily challenged the prohibition to use child-attractive trademarks on the

packaging of their food products, claiming that such prohibition constitutes a “regulatory taking” of their intellectual property. Lawsuits were filed by multinational companies including Kellogg’s,[31] PepsiCo,[32] and Carozzi.[33] Whilst most cases have been dismissed, one major case is still pending.[34]

In their claims, the industry relied on Article 19(24) of the Chilean Constitution, which protects the right to property and states that “[o]nly the law may establish the form of acquiring, using, enjoying, and disposing of property.” Since the Food Act and its related regulations do not include trademarks in their definition of advertising, the industry claimed that health authorities’ prohibition to use child-attractive trademarks on the packaging of HFSS foods was illegal and expropriatory, demanding adequate and effective compensation.[35]

Thus far, courts have ruled against the food industry, stating that trademarks fall within the scope of the Food Act and its related regulations,[36] which means that resulting use-restrictions do not constitute a deprivation of the companies’ intellectual property rights.[37] Courts have also weighed the right to property against the right to health, ruling that public health concerns justify Chile’s advertising restrictions.[38] Overall, the advertising restrictions have been found to be lawful under Chilean law, and health authorities have been given a wide margin of discretion to implement the Food Act and its related regulations.[39]

Remarks on the Food Industry’s Legal Strategies

It is interesting to note that not all legal arguments raised prior to the adoption of the Chilean Food Act and its related regulations have reached national courts. Although legal arguments raised in formal legal challenges are largely dependent on the factual circumstances of the case —which in Chile have primarily concerned decisions of health authorities prohibiting the use of trademarks —two factors may explain why the food industry has not invoked the right to commercial speech in formal litigation.

Firstly, by contesting primarily the trademark restrictions read into the Chilean Food Act and its related regulations —and linking this to the constitutional protection of the right to property —the food industry has sought to center the courts’ attention on questions concerning the scope of application of the Food Act and on the alleged lack of powers of health authorities, thus avoiding questions of proportionality. This strategy is further confirmed by the large amount of evidence submitted to demonstrate that the use of trademarks on the packaging of food products should not be considered to be a form of advertising.[40]

Secondly, by relying on the high level of protection afforded to the right to property by the Chilean Constitution and traditionally by the Chilean judiciary, the industry confidently put forward the interpretation that intellectual property was protected under the Constitution to the same degree as normal property. Such interpretation was likely reinforced by concordant opinions of prominent Chilean constitutional and intellectual property lawyers, some of whom submitted legal expert opinions supporting the industry’s case.[41]

Had the industry advanced alternative or complementary arguments based on the right to freedom of commercial expression, it would have had to overcome several legal hurdles, such as convincing the courts that the right to freedom of expression covers commercial speech and also protects it to the same degree as other forms of expression (e.g. artistic, political and journalistic). Moreover, the industry would also have had to make a *prima facie* case that the restrictions on commercial speech were disproportionate in the context of Chile’s obesity epidemic. These difficulties could explain why there has been no lawsuits to date challenging other aspects of the strict marketing and advertising restrictions introduced by Chile, as well as the prohibition to use nutrition and health claims to promote certain products, despite their being strongly resisted during parliamentary hearings and public consultation procedures.

Conclusion

Consistent with research demonstrating the relevance of interpretive contests between regulators and corporations over the legality of specific regulatory measures,[42] this contribution has shown that the food industry put forward very expansive interpretations of the right to freedom of expression during parliamentary hearings and public consultation submissions to protect their advertising and marketing practices from State regulations in Chile. However, once adopted, arguments on the right to freedom of expression were not included in formal legal challenges, suggesting that industries’ pre-regulatory interpretive practices do not necessarily correspond to their actual understanding of

their legal entitlements, but are rather part of their overall legal strategies to do away with or diminish the effect of unwanted State regulations. The fact that no other lawsuits have been filed against unparalleled strict advertising restrictions of food products introduced by Chile, as well as prohibitions to use science-based nutrition and health claims on certain food products, further reinforces this conclusion.

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Voluntary Registries to Support Improved Interaction Between Police and People Living with Dementia

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ABSTRACT (ENGLISH)

This paper provides an overview of the societal impact of a rising dementia population and examines the legal and ethical implications posed by voluntary registries as a community-oriented solution to improve interactions between law enforcement and individuals with dementia. It provides a survey of active voluntary registries across the United States, with a focus on Arizona, which has the highest projected growth for individuals living with dementia in the country.

FULL TEXT

DETAILS

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Freedom of Commercial Expression and Public Health Protection at the European Court of Human Rights

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ABSTRACT (ENGLISH)

This contribution considers the case law of European Court of Human Rights (ECtHR) and focuses on the extent to which the Contracting Parties to the European Convention on Human Rights (ECHR) can regulate the tobacco, alcohol, and food industries in a manner compatible with their ECHR obligations. After briefly presenting the two key cases dealing specifically with tobacco advertising, this contribution considers the main factors that the ECtHR takes into account when balancing competing concerns, and in particular freedom of commercial expression and public health protection. It concludes that none of these factors is absolute, as the Court considers the strength of each one of them on the facts of each case. Nevertheless, it is clear from its case law that States have a wide margin of appreciation to regulate marketing practices that are inimical to public health and the prevention of non-communicable diseases more specifically, to the extent that even extensive advertising restrictions can be compatible with Article 10 of the ECHR.

FULL TEXT

Introduction

In a suite of cases, the European Court of Human Rights (the ECtHR or the Court) has established that the protection granted to freedom of expression under Article 10 of the European Convention on Human Rights (ECHR or the Convention) extends to commercial expression. However, the Court has also made it clear that such expression can be significantly restricted by States pursuing various public interest objectives, including the protection of public health. This short contribution considers the case law of ECtHR, focusing on the extent to which the Contracting Parties to the ECHR can regulate the tobacco, alcohol, and food industries in a manner compatible with their ECHR obligations. After briefly presenting the two key cases dealing specifically with tobacco advertising (1), this contribution considers the main factors that the ECtHR takes into account when balancing competing interests, and in particular freedom of commercial expression and public health protection (2).

The ECHR was adopted within the Council of Europe and all Member States of the Council of Europe are also parties to the ECHR. Readers who are not familiar with the Council of Europe should bear in mind that it is distinct from the European Union (EU). If all EU Member States are members of the Council of Europe, not all Council of Europe Member States are EU Member States.[1] However, as this short contribution shows, there are close links between the case law of the Court of Justice of the European Union (CJEU) and the case law of the ECtHR, particularly in relation to the balancing of public health and freedom of expression considerations. Therefore, even if this contribution does not, as such, purport to present the case law of the CJEU,[2] it does refer to it.

This short contribution considers the case law of ECtHR, focusing on the extent to which the Contracting Parties to the ECHR can regulate the tobacco, alcohol, and food industries in a manner compatible with their ECHR obligations. After briefly presenting the two key cases dealing specifically with tobacco advertising, this contribution considers the main factors that the ECtHR takes into account when balancing competing concerns, and in particular freedom of commercial expression and public health protection

1. The two judgments of the Court addressing specifically the compatibility of national tobacco advertising restrictions with the ECHR

In 2009, the ECtHR was called upon to rule in two similar cases on the compatibility of the French Loi Evin with Article 10 ECHR.[3] The Loi Evin is an Act of Parliament that was adopted in 1991 to protect public health and amended the Public Health Code by introducing measures prohibiting tobacco advertising and significantly restricting the advertising of alcoholic beverages.[4]

In 2002, the applicants (two companies and their publishing directors) published monthly magazines featuring the photographs of the Formula One driver Michael Schumacher with the sporting logos of the Marlboro cigarette brand. The accompanying article identified him as the highest paid sports personality in the world, indicating that he earned EUR 65 million a year: EUR 34 million as salary and the rest as sponsorship agreements. After ruling that such photographs infringed the Loi Evin, the French courts fined the applicant companies and ordered them to pay damages to the national anti-tobacco committee[5] for unlawful tobacco advertising. The French courts pointed out, among other things, the danger of displaying cigarette brands in a sports-related environment that attracted the attention of the general public and young people in particular. The applicants' appeals were dismissed domestically. They lodged separate applications to the ECtHR in 2005.

Bearing in mind the similarities between these two cases, the ECtHR delivered its judgments on the same day in June 2009 and held unanimously that there had been no violation of Article 10 of the ECHR.

Article 10(1) ECHR provides that "[e]veryone has the right to freedom of expression. This right shall include freedom to hold opinions and to receive and impart information and ideas without interference by public authority and regardless of frontiers." As discussed more fully below, the ECtHR adopts a broad interpretation of the notion of "expression" to include within its scope commercial speech which consists in the provision of information, expression of ideas or communication of images as part of the promotion of a commercial activity and the concomitant right to receive such communications.[6] Therefore, after determining that the Loi Evin interfered with the applicants' right to freedom of expression, the ECtHR assessed whether this interference was justified.

Establishing that a particular activity falls within the ambit of Article 10 does not mean that the Court will necessarily prohibit any type of state interference. Some forms of interferences are legal and justifiable under the Convention as interpreted by the Court. Article 10 itself recognizes that the right to freedom of expression is not absolute. States can restrict this right in order to achieve various legitimate aims. As Article 10(2) ECHR states,

The exercise of [the freedoms to hold opinions and to receive and impart information and ideas], since it carries with it duties and responsibilities, may be subject to such formalities, conditions, restrictions or penalties as are prescribed by law and are necessary in a democratic society, in the interests of national security, territorial integrity or public safety, for the prevention of disorder or crime, for *the protection of health* or morals, for the protection of the reputation or rights of others, for preventing the disclosure of information received in confidence, or for maintaining the authority and impartiality of the judiciary.[7]

This provision specifically identifies public health protection as one of the legitimate aims justifying that some limits may be set by law on the right to freedom of expression. Such restrictions must, however, be proportionate.

In order to determine the compatibility of the specific restriction under review with the ECHR, the ECtHR established a proportionality test:

- The Court first considers whether there is an interference with the right to freedom of expression and if so whether such interference complies with national law. This requirement did not raise any difficulty in the two tobacco cases, bearing in mind the contentious measure under review was an Act of Parliament.

- The Court then determines whether there is a legitimate aim for the restriction. The protection of public health clearly constitutes a legitimate aim that France was entitled to pursue, not least as the Court characterized smoking as "a social evil" for the public as a whole and young people in particular. Interestingly, the ECtHR noted in one of its two tobacco judgments that the Magazine *Entrevue* was the most read magazine by young men aged between

15 to 24 years of age.[8]

- Finally, and most importantly, the Court considers whether the measures adopted to achieve the legitimate aim are not excessive. In other words, the ECtHR determines whether less intrusive measures could have achieved the same aim. In the two tobacco cases under review, the Court considered what interests were at stake and whether these interests had been properly balanced against each other by the French authorities. In particular, the Court relied on the importance of public health protection as a legitimate aim, the existence of smoking as a social evil, the imperative to fight against it, as well as the existence of a European consensus on the need to ban tobacco advertising, to conclude that the sanctions imposed on the applicants were proportionate and that the extensive prohibition on tobacco advertising French law imposed did not infringe Article 10 ECHR on the facts.[9]

These two cases illustrate that, even though the right to freedom of commercial expression is protected by the ECHR, such protection is not absolute. States can interfere with this right provided that this interference is "necessary in a democratic society," namely that it is legal and proportionate. In their assessment of proportionality, the ECtHR recognizes that States have some discretion in assessing the situation and how they can best address it. The Court will intervene only when States overstep the boundaries of their discretion. In other words, the Court defers to the State's decision unless these decisions cannot be justified from the perspective of the Convention. The scope of this deference is traditionally labelled by the Court as the margin of appreciation.[10]

2. The Factors Determining the Margin of appreciation of States to Regulate the Tobacco, Alcohol and Food Industries to Protect Public Health

The following discussion identifies the key factors that the Court considers when assessing the proportionality of the interference and the margin of appreciation that States have in given circumstances. It is important to note from the outset that none of these factors is absolute. The Court considers the strength of each one of them on the facts of each case. Moreover, the list provided here does not purport to be exhaustive. However, it identifies the factors that often guide the Court's decision-making and are particularly relevant when considering the compatibility of advertising restrictions with the ECHR when such restrictions pursue public health interests.

The Type of Speech

The ECtHR has defined the notion of "expression" broadly, to include political speech,[11] artistic performances,[12] publication of photos,[13] statements on the Internet,[14] and commercial advertising.[15] The fact that the Court considers a particular activity as expression is a value neutral statement. The Court repeated on a number of occasions that Article 10

is applicable not only to 'information' or 'ideas' that are favourably received or regarded as inoffensive or as a matter of indifference, but also to those that offend, shock or disturb. Such are the demands of pluralism, tolerance and broadmindedness without which there is no 'democratic society.'[16]

Whether commercial expression should fall within the ambit of protection of Article 10 was specifically discussed in *Casado Coca v. Spain* where the respondent state argued that commercial advertisement did not fall within the definition of expression as it "did not serve the public interest but the private interests of the individuals concerned."[17] However, the ECtHR rejected this argument, noting that Article 10 guaranteed freedom of expression to "everyone," without drawing any distinction according to whether the type of speech or the aim it pursued was motivated by making a profit or not.[18] The structure of Article 10 ECHR itself does not require the Court to provide any specific reason to protect freedom of expression: as soon as the ECtHR establishes that a particular action is expression, the protection follows almost[19] automatically.[20]

Commercial expression is the least protected type of expression,[21] particularly when compared to political or artistic

expression. Therefore, States enjoy a broader margin of appreciation in how they can interfere with commercial expression than with other types of expression. Such difference in protection is based on the value of expression for democracy: the ECtHR has recognized that freedom of political debate "form[s] the bedrock of any democratic system."[22] At the opposite end of the spectrum, commercial expression is considered the furthest from the core aim of the Convention and therefore is the least protected, even if it recognized as a form of expression. In advertising cases, Contracting Parties therefore have a very broad margin of appreciation.[23] In the Court's eyes the importance of a particular form of expression for the public debate determines its value. Since the key aim of commercial expression is not to initiate a public debate but to promote a particular product, service or brand, its value is not considered as particularly high. Another factor that might broaden the margin of appreciation vis-à-vis commercial expression is its complexity. In *Markt Intern Verlag GmbH and Klaus Beermann v. Germany*, the Court stated that "margin of appreciation is essential in commercial matters and, in particular, in an area as complex and fluctuating as that of unfair competition."[24]

The scope of the margin of appreciation seems to become even broader when commercial speech is deemed offensive. The Court summarized its approach in its 2018 judgment in *Sekmadienis LTD v. Lithuania* dealing with the use of religious symbols in commercial advertising, which some Lithuanians found offensive:

… there is little scope under Article 10(2) of the Convention for restrictions on political speech or on debate on matters of public interest. However, a wider margin of appreciation is generally available to the Contracting States when regulating freedom of expression in relation to matters liable to offend intimate personal convictions within the sphere of morals or, especially, religion. Similarly, States have a broad margin of appreciation in the regulation of speech in commercial matters or advertising.[25]

Even though this classification system seems relatively straightforward, it is often very difficult in practice to identify a precise type of expression. Cases will often involve "mixed speech." Artistic expression can have a commercial component to it, while commercial publications can raise issues of public interest and therefore contribute to public debate. For example, in *Hertel v. Switzerland*, the applicants published a scientific article suggested that the food cooked in microwave ovens was unsafe. The Swiss courts

prohibited… [him] from stating that food prepared in microwave ovens is a danger to health and leads to changes in the blood of those who consume it that indicate a pathological disorder and present a pattern that could be seen as the beginning of a carcinogenic process, and from using, in publications and public speeches on microwave ovens, the image of death.[26]

The argument of the Swiss government that the applicant's article was in effect commercial speech that created unfair competition and therefore enjoyed a lesser degree of protection was rejected by the Court which concluded that the expression was not purely commercial. Consequently, the Court ruled that the State's margin of appreciation should be reduced and the Court's scrutiny of the proportionality of the restriction correspondingly heightened

When what is at stake is not a given individual's purely "commercial" statements, but his participation in a debate affecting the general interest, for example, over public health; in the instant case, it cannot be denied that such a debate existed.[27]

Similarly, in the above mentioned case of *Société de conception de presse et d'édition and Ponson v. France* the image containing the cigarette brand was published as a part of the news article intended to inform the public on the salaries of sports people. The ECtHR noted that it had consistently highlighted the existence of a right for the public to receive information and concluded, on this basis, that the expression at stake in this case was not "strictly" commercial and that the margin of appreciation of the State was consequently more limited.[28]

Thus, the type of expression does affect the Court's balancing exercise, even though it may often be difficult to

clearly distinguish between different types.

The Nature of the Legitimate Aims Pursued

Even if the ECHR does not as such contain a specific provision dedicated to the right to health, the ECtHR has recognized the importance of protecting the health of the public. States can therefore legitimately endeavour to protect public health.[29] This is explicit in Article 10(2) itself. Public health imperatives can be of such importance that the ECtHR has granted States a broad margin of appreciation in determining how far they intend to protect health and the means they intend to deploy to this effect.

Article 10(2) therefore provides for the possibility for States to limit freedom of expression on public health grounds. In such cases, the Court considers the connection between the expression and the degree to which the expression offends the protected interest. In particular, the Court has been clear that States can adopt wide ranging restrictions on tobacco advertising due to the serious public health implications smoking entails:

The Court is of the opinion… that the restriction of advertising of tobacco and tobacco products constitutes an essential axis of a more global strategy on the fight against the social evil of smoking. This policy raises the sustained interest of the public and public authorities. Thus, overriding public health considerations… may take precedence over economic imperatives, and even certain fundamental rights such as freedom of expression.[30]

In other words, the Court decided that the State's interference with the freedom of expression pursued a legitimate aim and, since this aim was of such importance to society, then even a significant interference with such freedom could be justified. The ECtHR specifically noted, as the French courts had observed, that the magazines in question were aimed at the general public, and in particular young people, who were more vulnerable. It was therefore necessary to consider the impact of the cigarette logos on those readers, who were particularly attentive to success in sports or finance.

Very importantly too, the ECtHR upheld the stance taken by the French courts that it was not necessary to take account of the actual impact of an advertising ban on tobacco consumption to determine whether the ban may be justified. The fact that the publications in question were regarded as capable of inciting people to consume such products was, for the Court, a "relevant" and "sufficient" reason to justify the interference.[31] This is welcome bearing in mind the complexity of NCDs and the fact that only comprehensive, coordinated, multi-sectoral strategies can effectively prevent and control NCDs. More specifically, as the impact of advertising of tobacco, alcohol or unhealthy food on public health is unavoidably difficult to quantify, the Court should indeed ensure that it does not substitute its assessment to that of legislative authorities without good reasons.[32]

The Existence of a European Consensus

The concept of European consensus determines the scope of the margin of appreciation in that it lays down a rebuttable presumption in favour of the solution adopted by the majority of the Contracting Parties to the ECHR.[33] The state has a narrower margin of appreciation in relation to issues where a European consensus exists,[34] whilst in the absence of such consensus, this margin is broader. Even though European Consensus is not a decisive argument, the presumption it establishes is not easily rebutted.

The Court did invoke the existence of European consensus in the two tobacco advertising cases discussed above. The Court's deployment of consensus is somewhat unusual in these cases. Normally, the Court uses consensus when the regulation in question falls outside of such consensus. However, in *Société de conception de presse et d'édition and Ponson v. France*, the Court highlighted that the measures adopted by the respondent state were part of a European consensus confirming the appropriateness of such actions. The Court stated:

There is in fact European consensus in favour of strict regulation of the advertising of tobacco products… In addition, the Court observes that a general trend towards regulation is now displayed at the global level.[35]

In the two tobacco cases decided in 2009, the ECtHR assessed the French Loi Evin considering the broader context in which it was challenged, and it relied extensively on a range of European and international sources to identify a European consensus on the imperative to restrict tobacco advertising. Firstly, it noted that EU Member States were all bound by the directive prohibiting the cross-border advertising and sponsorship of tobacco products,[36] whose validity was upheld by the CJEU in 2006.[37] In its decision, the CJEU was called upon to consider whether a complete EU-wide ban on tobacco cross-border advertising infringed Article 10 of the ECHR. It noted that commercial expression was a lesser form of expression and could, as such, be restricted significantly on public health grounds. In particular, relying on its earlier ruling in the *Karner* case, the CJEU noted that it would be reluctant to intervene with the margin of discretion left to competent authorities in relation to the commercial use of freedom of expression, particularly "in a field as complex and fluctuating as advertising."[38] On this basis, it concluded by upholding the compatibility of the 2003 EU Tobacco Advertising Directive with the EU Treaties:

In the present case, even assuming that the measures laid down in Articles 3 and 4 of the Directive prohibiting advertising and sponsorship have the effect of weakening freedom of expression indirectly, journalistic freedom of expression, as such, remains unimpaired and the editorial contributions of journalists are therefore not affected.

It must therefore be found that the [EU] legislature did not, by adopting such measures, exceed the limits of the discretion which it is expressly accorded.

It follows that those measures cannot be regarded as disproportionate.[39]

Drawing on this case law, the ECtHR concluded that the EU legislature had "reasonable grounds" to consider that an extensive prohibition of tobacco advertising and sponsorship at EU level could lead to a significant reduction in the levels of tobacco consumption and could therefore protect public health. After also referring to the works of the Council of Europe, and in particular a resolution of the Parliamentary Assembly of the Council of Europe of 2002,[40] the Court noted that the general trend towards increasing tobacco advertising regulation had now become global. It mentioned specifically the Framework Convention on Tobacco Control (FCTC), which was adopted in 2003 and entered into force in 2005. In particular, the ECtHR noted that France was one of the (then) 150 signatories and referred to the specific provision of the FCTC calling on States to prohibit all forms of advertising, promotion, and sponsorship for tobacco products.[41]

The existence of a European consensus was one of the reasons why the Court found that there had been no violation in this case despite the existence of significant restrictions on the freedom to advertise tobacco products. However, as pointed out above the Court rarely establishes that the regulation in question is part of a European consensus and finds no violation as a result. More commonly, the Court finds no violation in the absence of a European consensus, allowing a broad margin of appreciation to the respondent state. In *Animal Defenders International v. the United Kingdom*, the Court established the absence of a European consensus before concluding that there had been no violation of Article 10 ECHR. The ECtHR stated:

there is no European consensus between Contracting States on how to regulate paid political advertising in broadcasting… It is recalled that a lack of a relevant consensus amongst Contracting States could speak in favour of allowing a somewhat wider margin of appreciation than that normally afforded to restrictions on expression on matters of public interest… [W]hile there may be a trend away from broad prohibitions, it remains clear that there is a substantial variety of means employed by the Contracting States to regulate such advertising, reflecting the wealth of differences in historical development, cultural diversity, political thought and, consequently, democratic vision of those States.[42]

Thus, the Court considers the state of European consensus in determining the scope of margin of appreciation in freedom of expression cases. The Court is more likely to find no violation if the disputed interference is either part of

European consensus or when there is no European consensus.

The Decision-Making Process Adopted by the State

Another important factor that the Court considers is the process by which national authorities came up with the rule or decision in question. The proceduralization of human rights is a growing issue in European Human Rights Law.[43] It means that the ECtHR pays more attention to how the decision has been reached rather than what the actual decision is.

In *Animal Defenders International v. the United Kingdom*, the Court acknowledged that the national decision-maker carefully considered the positive and negative aspects of a ban on paid political advertisement. The Court stated:

The Court… attaches considerable weight to …exacting and pertinent reviews, by both parliamentary and judicial bodies, of the complex regulatory regime governing political broadcasting in the United Kingdom and to their view that the general measure was necessary to prevent the distortion of crucial public interest debates and, thereby, the undermining of the democratic process.[44]

Importantly, none of the factors we have identified above in our review of ECtHR case law is absolute. The Court considers the strength of each one of them on the facts of each case. Nevertheless, it is clear from the case law that States have a wide margin of appreciation to regulate marketing practices that are inimical to public health and the prevention of non-communicable diseases more specifically, to the extent that even extensive advertising restrictions can be compatible with Article 10 of the ECHR.

As a result, the Court found no violation in this case. By contrast, in *Sekmadienis LTD v. Lithuania*, the Court determined that the Lithuanian decision to ban an advertising campaign on public morality grounds violated Article 10 ECHR. In this case, the applicant was a clothing company that released the advertisement campaign using references to “Jesus” and “Mary” that some religious people in Lithuania found offensive. The ECtHR considered the reasoning of national courts and decided that, by placing “absolute primacy to protecting the feelings of religious people,” the Lithuanian courts had not struck a proper balance. The government therefore failed to persuade the Court that the interference was proportionate. The Court’s disapproval of the reasoning adopted by the Lithuanian courts was vividly expressed:

The wording of [the national courts’] decisions —such as “in this case the game has gone too far”, “the basic respect for spirituality is disappearing”, “inappropriate use [of religious symbols] demeans them [and] is contrary to universally accepted moral and ethical norms” and “religious people react very sensitively to any use of religious symbols or religious persons in advertising” —demonstrates that the authorities gave absolute primacy to protecting the feelings of religious people, without adequately taking into account the applicant company’s right to freedom of expression.[45]

The Court was much more sympathetic in *PETA Deutschland v. Germany*. Even though this case did not involve commercial speech, it concerned social advertising and contains interesting reasoning of the Court that could similarly apply in a commercial advertising context. The applicant started an advertising campaign which aimed at drawing attention to animal suffering. To this effect, they produced posters which depicted animals in cages in the top section of the posters and Holocaust victims in the bottom section. These posters were banned from circulation by German authorities, a decision which was challenged before the ECtHR. In its ruling, the Court paid particular attention to the decision-making of national authorities to conclude that there was no ECHR violation. In particular, the Court stated that

the domestic courts adjudicating the applicant’s case carefully examined whether the issue of the requested civil injunction would violate the applicant association’s right to freedom of expression. In doing so, the domestic courts applied the standards developed by the Court…[46]

The Extent to which the Penalty Imposed is Commensurate with the Legitimate Aim Pursued

The severity of the sanctions applied is also subject to the review of the ECtHR. More severe sanctions require convincing justifications, while lighter ones might fall within the margin of appreciation of the respondent State. The Court assesses whether the sanctions can be seen as producing a “chilling effect” on public debate[47] and if so, concludes that they might be deemed disproportionate. Although the Court considers the seriousness of a given punishment, the “chilling effect” is much more difficult to rely upon in commercial speech cases. In *Perrin v. the United Kingdom*, the Court assessed an application of the owner of the website that was selling obscene images, who was sanctioned to a prison term and argued that this sentence was disproportionate. The ECtHR disagreed: the purpose of the present expression was purely commercial and there is no suggestion that it contributed to any public debate on a matter of public interest or that it was of any artistic merit: the applicant’s conviction cannot therefore be said to engender any obviously detrimental chilling effect. Moreover, given that the applicant stood to gain financially by putting obscene photographs on his preview page, it was reasonable for the domestic authorities to consider that a purely financial penalty would not have constituted sufficient punishment or deterrent.[48]

In the two tobacco cases discussed above, the applicants challenged the penalties imposed on them as unduly burdensome. The French courts had imposed fines of EUR 30,000 and EUR 20,000 and ordered the two companies to pay EUR 10,000 each in damages to the national anti-tobacco committee. When asked to review these sanctions, the Court concluded in both cases that the amounts were certainly not negligible, but that in assessing whether they were unduly harsh they had to be assessed in light of the revenue and the high circulation of the magazines in which the two contested adverts appeared.

It is important to reiterate here that none of the factors we have identified above in our review of ECtHR case law is absolute. The Court considers the strength of each one of them on the facts of each case. Nevertheless, it is clear from the case law that States have a wide margin of appreciation to regulate marketing practices that are inimical to public health and the prevention of non-communicable diseases more specifically, to the extent that even extensive advertising restrictions can be compatible with Article 10 of the ECHR.

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Economic Perspectives on Food Choices, Marketing, and Consumer Welfare

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ABSTRACT (ENGLISH)

This contribution reviews the main normative and positive arguments that can used in the assessment of the costs and benefits of food marketing restrictions, focusing specifically on theoretical and empirical developments in the economics of advertising, consumer behaviour and industrial organization since the 70s.

FULL TEXT

Introduction

Theoretical and empirical insights from economics have been much less influential in the design of nutrition policies than in competition or trade policies. One explanation is that nutrition policies have not been until now an area of great litigation processes. This is changing, as public health authorities, and national or international bodies push for more stringent regulation of the nutritional quality, the price, and the marketing of food products (see, e.g., the investigation into the Nutri-Score food labelling system launched by the Italian antitrust authority in January 2022). As adversarial processes between legislators or regulators and the food industry become more frequent, it is important to present the perspectives that economists can provide to both sides, and to discuss their empirical validity. I focus specifically on normative and positive arguments that may be used in the assessment of the costs and benefits of marketing restrictions.

Cost-benefit analysis has become central in the discussion of public policies. It allows to select the “best” policy option (ex-ante) and evaluate their effectiveness (ex-post) when stakeholders’ interests diverge. Governments and supra-national institutions have increasingly relied on cost-benefit money metrics in the construction of standards and laws.[1] Yet, it is crucial to understand that these costs and benefits are valid money metric equivalent only under precise sets of methodological assumptions that are required to value consumer welfare. These are the questions of what costs and benefits should be counted, and how to measure them. Answering these questions raises in turn two critical issues. First, what assumptions do we make regarding consumer preferences and rationality? Second, even when consumer sovereignty does not hold, can the regulation of marketing practices make them worse off, through indirect unintended effects such as a decrease in price competition?

I start by reviewing the neo-classical approach to consumer choices, markets and marketing. Starting in the 1970s, it has had a great influence in the construction of the legal framework binding regulation.[2] It is characterized by a strong emphasis on the autonomy and rationality of a consumer endowed with stable preferences. Therefore, marketing does not *a priori* affect consumer choices by influencing their preferences. Marketing is viewed as providing information about products, or as a complementary product characteristic that is intrinsically valued by consumers. It has a strategic role in the competition between firms. “Good” marketing will often increase consumer welfare, while “bad” marketing (deceptive advertising) should disappear, thanks to competition and market efficiency. As such, marketing restrictions will likely make consumers worse off. Prior to the neo-classical perspective, economists made a distinction between informative and persuasive marketing. I discuss why the view that marketing can alter consumer preferences by persuading them poses difficulties to the standard economic analysis of the welfare effects of marketing.

The second section discusses the validity of the neo-classical approach by reviewing the empirical evidence about the effect of marketing on consumer decisions and markets. Ingenious studies in behavioral economics and experimental marketing have clearly shown that marketing actions can distort consumers’ decision making, and thus hurt consumer sovereignty.

The second section discusses the validity of the neo-classical approach by reviewing the empirical evidence about the effect of marketing on consumer decisions and markets. Ingenious studies in behavioral economics and experimental marketing have clearly shown that marketing actions can distort consumers’ decision making,[3] and

thus hurt consumer sovereignty. There is a fundamental asymmetry between firms and consumers, because the former are fully able to develop an economic rationality while the latter have limited abilities in terms of perception and cognition, and emotion-control. Yet, these experimental studies have limited external validity. Observational studies of markets suggest that marketing has small and rather pro-competitive effects,[4] a result that is more consistent with the "informative" perspective on advertising than with the "persuasive" one. However, the internal validity of these observational studies most often relies on the same rationality assumptions that ground the neo-classical model of consumer choices. Finally, I discuss recent theoretical results in the Economics of Industrial Organization suggesting that firms can durably exploit consumers' behavioral biases to decrease competition, thus harming consumer welfare.[5] One straightforward consequence is that more stringent marketing regulations may increase consumer welfare, by "debiasing" people's choices and align them with their long-term interest. In addition, both theoretical and empirical studies provide results showing that firms generally spend too much on marketing.[6] Hence, marketing restrictions may actually increase the profitability of firms in addition to their potential benefits in terms of consumer welfare and protection.

The Neo-Classical Approach to Consumer Choices, Health, and Marketing

The economic analysis of marketing has historically focused on advertising or Promotion, one of the four Ps involved in food marketing, along with the Price, the Product (seen as a bundle of attributes including its taste, its composition, its packaging and so on), and the Place (where it is marketed). From the massification of advertising between the two world wars to the 1970s, the idea that advertising intends to influence consumer preferences and can "make demand" was not uncommon among economists.[7] From the 1970s onwards, three hypotheses have structured the research. First, advertising can inform consumers about the existence of products or certain objective attributes of products, including their prices. Second, advertising can persuade well-informed consumers that a product they know well is more desirable than they think. Third, advertising can be seen as a good that is complementary to the product in producing a subjective consumption experience. This research has been deeply shaped by the neo-classical economic approach to markets, whose key peculiarity is that it provides both a toolbox for understanding consumer behavior and a reference normative standard for assessing the relevance of market regulation policies in terms of economic efficiency.[8] I start by introducing the neo-classical approach to consumer choices and markets. I then expose the three alternative views on the impact of advertising on consumer demand.

The Neo-Classical Approach to Consumer Choices

In the neoclassical approach to consumption and health, consumers make trade-offs between maximizing the immediate pleasure of eating and preserving future health or body shape. Their decisions are constrained by their available time and budget. The future costs and benefits of consumption are weighted against immediate ones by a discount factor that expresses their subjective preference for the present, and their choices are supposed to be temporally consistent. The temporal consistency of choices implies that consumers do not change their consumption plans when their food environment is unchanged. They are therefore able to regulate their food intakes over time in order to achieve long-term goals that may or may not be in line with public health recommendations: being obese can be the outcome of perfectly rational food choices.[9] Indeed, the neo-classical *homo oeconomicus* is not a *homo medicus*, in the sense that they have no normative reasons to wish maximizing their health.[10] Their decisions merely reveal their preferences.

In this theoretical framework, consumers are *a priori* held responsible for the consequences of their decisions, and nutritional health is private issues. If they have an unbalanced diet, gain weight, and develop illnesses, they will start valuing healthy behaviors, and this will increase their demand for healthier foods or for physical activity. The market should *a priori* provide them efficiently with what they need to achieve their desired level of health. A normative consequence is that public policies ought to respect the axiom of consumer sovereignty. Nutritional health policies, especially market regulations, can only be justified by market failures, in particular the existence of externalities or imperfect information.[11]

Food markets generate externalities in terms of losses of economic productivity and direct health-care costs, especially in countries where a large proportion of health expenditure is covered by public insurance. For instance,

the current trends in obesity and diet-related noncommunicable diseases might account for 8.4% of total health care expenditure in the next decades in countries member of the Organisation for Economic Co-operation and Development.[12] These externalities may justify the implementation of corrective taxes, also called Pigouvian taxes, the optimal design of which is the subject of abundant literature.[13] Such taxes restore the truth of prices, in the sense that the latter must convey correct information about the value of products. As analyzed by Michel Foucault in the late 1970s, the truth of prices is an essential condition for the governmentality of behavior in neo-liberal economies.[14] Consumers can adopt behaviors that deviate from public health recommendations as long as they pay the price that internalizes the externality that they create.

Consumers are in a situation of imperfect information when they have little knowledge of the health impacts of their eating behaviors, or when producers do not disclose some characteristics of the products they offer. In the first case, generic information can be provided by public authorities (e.g. health education campaigns) or, sometimes, by a collective actor (e.g. the union of Fruits and Vegetable producers in France), because it is rarely in the interest of a specific company to make the effort of providing information that could also be to the benefit of its competitors, except if the company wants to show a form of social responsibility. In the second case, the nutritional labeling of products or menus offered in restaurants can fill the information gap.

Advertising as Information

Advertising is said to be informative when it informs consumers about product availability, product characteristics or product prices.[15] In that case, it enhances consumer welfare as it lowers the costs of searching for information and it reduces information asymmetry between sellers and consumers.

Consumers are rarely aware of all the consumption opportunities offered by markets. Acquiring information is costly, as finding good information takes time, and the time spend with information search represents foregone opportunities to undertake more pleasurable activities or to work and earn money. Hence, consumers are better-off when information is provided freely by sellers. The welfare gains may be unequally distributed, depending on the value of time for individuals. High-income consumers have a higher value of time and therefore higher search costs. They have therefore less incentives to search for good prices or products and, perhaps counter-intuitively, they may benefit more from informative advertising. Yet, low-income consumers may also benefit from informative advertising, as they have overall less income to devote to information search. Informative advertising also raises consumer welfare by increasing their responsiveness to price changes, or their ability to switch to alternative products that will better satisfy their preferences. It can therefore increase competition on consumer markets, thus limiting the market power of firms, and leading to lower prices.

Beyond providing information on prices and available products, advertising may provide information on product quality, and therefore help solve issues of imperfect information about quality. Some attributes of food are difficult to verify by inspecting or experiencing products. We often do not know the possible health impacts of innovative ingredients, the environmental cost of the product, or whether it has been produced under socially fair conditions for workers. These product characteristics are credence attributes, because consumers cannot check their presence on the point of purchase, unlike search attributes (e.g. the product price), nor experience them during consumption (e.g. a particular flavor). The presence or absence of these credence attributes is associated with higher production costs and, at the same time, a higher average willingness-to-pay of consumers. This raises a problem of information asymmetry known as adverse selection:[16] if consumers could not ascertain product quality, then firms would have little incentive to make efforts to produce high-quality products, and markets would end offering only low-quality products. Here, advertising (if not deceptive) can help restore a good functioning of the market. For this to hold, one must have a market with a sufficiently large proportion of low-quality products. Then high-quality sellers have an incentive to advertise the quality of their products because they can take advantage of vertical differentiation in quality to sell at higher prices.

Interestingly, some economists have used this argument to recommend that nutrition labelling should not be made mandatory. Indeed, if consumers value the nutritional quality of products, then producers of healthy foods have an incentive to signal that their products are the best in order to gain market share. The combination of incentives and

competition may then be sufficient to provide nutritional information to those consumers who have a real preference for healthy foods.[17] From this perspective, food markets are segmented according to consumer preferences, and there is no justification for the introduction of mandatory nutrition labelling.[18] Advertising, marketing claims and labels are treated similarly, as information.

A pending issue is how to ensure that advertising provides correct information. Deceptive advertising is less an issue for experience or search attributes than for credence attributes. If consumers can experience an attribute, only firms that sell high-quality products have incentives to advertise their quality, in order to attract first-time buyers or retain consumers.[19] The idea here is that high-quality firms use advertising expenditures as a signaling device. By engaging in such expenditures, they signal that, over the long-term, they can commit to substantial expenses because they expect to durably offer high-quality products at a high price. Here, advertising is useful, not only because advertising messages may convey new information, but also because the practice of advertising allows consumers to discriminate high-quality products from low-quality ones. This reasoning relies on the questionable assumption that consumers fully realize that low-quality firms have less incentives to engage in advertising expenditures.

Third-part certification might be a solution for credence attributes, hence the emergence of labels for guaranteeing the origin of products, or that they are organic or a result of fair-trade. However, in many cases, it is difficult to resort to third-party certification. Alternatively, some public regulation body may control whether information is deceptive or not. If companies risk being fined for deceptive advertising, then low-quality firms will not engage in it. In practice, such control-and-check approach often fails, either because financial and material resources for the task are limited, or because it is difficult to provide firm evidence that marketing claims are fraudulent. The protection of commercial freedom and free speech also constrains the activity of regulatory bodies.

Last, industrial economists have devoted much energy to identifying the role played by informative advertising in market competition, especially whether it is pro-competitive and whether advertising expenditures are not too excessive. Excessive advertising efforts can result from the potential intensification of competition between firms which are trapped in a non-cooperative equilibrium, whereby each firm has to raise its effort at the level of its rivals to avoid losing market shares.[20] Hence, the race for informative advertising may reduce company profits.

Advertising as Persuasion: A Good or a Bad?

Advertising has changed over the last century. Nowadays, advertisements and marketing campaigns are often designed to convey narratives telling consumers why they must buy a product and not what this product is or costs. Stories are constructed around products, or products are derived from stories. These stories appeal to emotions, implicit associations and cognitive schemes such as the need of belonging to a community of consumers.[21] When advertising is not informative, it may be said to be persuasive, in the sense that it would alter consumer tastes.[22]

Persuasive advertising can have two effects on consumer demand for a product.[23] First, it can expand the demand for the product, either by taking market shares from rival products or by increasing the size of the market. Such distinction is important because one widespread argument against regulating the advertisement of unhealthy goods is that this *does not* expand the market size by increasing purchase volumes by habitual consumers, but just play a role in the competition for market shares.[24] Note that showing that advertising expands the market size by attracting new consumers does not prove that it is persuasive, as new consumers might have just been previously uniformed of the existence of the product.[25] Second, persuasive advertising can alter consumer responsiveness to price changes. For instance, creating a strong brand identity is a means of lowering consumer price responsiveness, so that consumers will be less sensitive to increases in own-price or to decreases in the price of rival brands. Incumbent firms may also use it to create barriers to market entry, as new entrants will have to spend important resources in marketing efforts. In these cases, persuasive advertising would harm consumer welfare by increasing total demand so that consumers buy too much of the product, and by lowering market competition. Yet, the anti-competitive effect may not be observed if all firms simultaneously increase their advertising efforts, in a strategic attempt to best reply to their competitors. In addition, some firms may also reply by lowering their prices if possible. A cost-benefit analysis may therefore conclude that prohibiting persuasive advertising is not beneficial to the

consumer if beneficial pro-competitive effects offset the harmful taste-shifting effects.

In addition, there is a practical difficulty in assessing welfare losses due to taste-shifting. If the consumer does not have the same preferences before and after an advertising campaign, then what are the preferences that should be taken into consideration for assessing the welfare impacts of advertising? If prior preferences, then one implicitly assumes the normative position that preferences should remain unaltered. But then why would it be more legitimate to try changing consumer preferences through public health information campaigns? If posterior preferences —because consumer preferences have been irremediably altered —, then prohibiting advertising can only stand on the basis that it is a proportioned means of avoiding potential welfare consequences that the consumer or the market would not have internalized, such as health or environmental damages. It should be proportioned in the sense that the problem of externalities cannot be solved *more efficiently* by some standard Pigouvian tax. The economists' preference for a tax rather than a ban is illustrated, for instance, by Shiman,[26] who studies the opportunity of a tax to regulate excess direct marketing to consumers.

Dixit and Norman[27] propose a middle way to inform the welfare consequences of persuasive advertising: comparing the changes in consumer welfare calculated under prior and under posterior preferences. They show that, in general, the *marginal* effect of persuasive advertising is to increase firm profits by a first-order of magnitude and to decrease consumer welfare (under prior preferences) by a second-order of magnitude. Hence, from a marginalist point of view, this small welfare loss for consumers is not sufficient to decide that persuasive advertising should be prohibited.[28] However, even if advertising has small short-run effects, its long-run effects appear to be important when we compare the consumer now and the consumer a decade ago. In that case, we are back to the situation of having to decide which preferences to consider. There is one case, however, where Dixit and Norman reach the conclusion that persuasive advertising is welfare damaging: when it raises the price of products. In that case, the producer increases its profit at the expense of consumer welfare even from the perspective of posterior preferences. There is a transfer of surplus from the consumer to the firm, and the firm has bad incentives to increase its advertising expenditures. Once again, competition between firms may increase, so that firms may end over-investing in advertising.

As refined as it looks, the Dixit and Norman's approach has not been successful in economic analysis. This is essentially because, in the 1980s, the triumphant view was that one must assume *a priori* that consumer preferences are stable, and that economists should not try to explain markets and social facts by relying on ad hoc assumptions regarding changes in consumer tastes. Stigler and Becker wrote in 1978 a key article of the neo-classical pantheon - "De Gustibus Non Est Disputandum" —, in which they argued that apparent changes in preferences could indeed be understood as being produced by stable "meta-preferences."[29] They reframed the development of a preference for music or for junk-food as the *intentional and consequentialist* accumulation of a "stock" of consumption experience. With perfect anticipation of how this stock of consumption accumulates, and how it affects the pleasure of listening to music or eating junk-food, consumers *choose* to fulfil their desire in all their sovereignty. Consumption is not just the use of a product or a service, but an experience that is produced by the subject via the combination of past experiences (and knowledges, memories of emotions, skills etc.) and current purchases.

Following this line of thought, advertising is seen as a good providing additional characteristics to the product (like a cloth dressing a character). Becker and Murphy[30] indeed defended the view that advertising creates narratives that consumers demand and like. These narratives would not alter consumer taste because the consumption experience is not made up only of the product, but also of the emotions that make it more or less enjoyable. Eating a cake can be associated with memories of childhood, and some effective marketing may reactivate this memory. Advertising is thus seen as a good that is complementary to the product in the production of a consumption experience. Of course, this subtle way of reframing the perspective on non-informative advertising has powerful normative implications for regulation: advertising builds value for the consumer. In that case, even if it raises prices, this is not bad for consumers, as this rise in price corresponds merely to an increase in consumer willingness-to-pay for the consumption experience but not to a change in preferences. The creation of value comes at the expense of firms'

profits, as advertising is costly and intensifies competition. Hence, firms prefer to limit advertising and, perhaps surprisingly, they may even *undersupply* advertising as compared to what would maximize consumer welfare.
The neo-classical approach to consumer choice leaves little room for regulation of advertising. Informative or complementary advertising tends to increase consumer welfare, while persuasive marketing can decrease it if it reduces competition between firms. However, economists are reluctant to consider that marketing is persuasive, notably because it raises the issue of the observability of consumer "true" preferences. Then, advertising regulation can only be based on evidence that it is deceptive or that it generates externalities, for example, in terms of health or environmental costs. In the latter case, the question for public authorities is whether restrictions and bans are the most appropriate tools for reducing externalities, or whether a Pigouvian tax —which is simpler to implement —would be more effective. These conclusions apply more generally to many aspects of marketing activities, such as packaging design, sponsorship of sports events or product placement in video games.

Consumer Behavioral Failures and their Exploitation

The neo-classical approach is based on the key assumption that consumer choices are the expression of stable and consistent preferences under time and money constraints. Expanding the diversity of consumption experiences (complementary advertising) or making more information available (informative advertising) is welfare-enhancing. In addition, the consumer has the cognitive and knowledge capacities to understand and outsmart firms' strategies, so that competition would solve most regulatory issues at low costs. Naturally, the validity of this approach depends on how well this assumption, or the predictions it generates, is supported by empirical evidence. I first start reviewing experimental evidence showing that consumer decisions are biased by the interplay of environmental factors, and perceptual or cognitive factors. I then present observational evidence from empirical studies of existing markets. They rather support the "informative" view of advertising, but they often implicitly rely on rationality assumptions that are consistent with the neo-classical approach. Finally, I present some recent theoretical advances of a recent research field —"behavioral industrial organization" —that tries to think about the implications of consumer behavioral failures for market regulation as rational firms can strategically exploit these failures to increase their profits or strengthen their market positions.

Experimental Evidence on Marketing and Food Choices

The standard economic approach ignores the variety of perceptual, affective, and cognitive mechanisms that determine what individuals decide to purchase and to eat along both the quantity and quality dimensions. Experimental studies in economics, marketing, and psychology have provided extensive evidence that these mechanisms play a significant and *systematic* role in food choices.[31] This implies that the food environment is a key determinant of consumer behavior, in addition to their preferences and the time and income constraints they face.
Marketing often plays with perceptual cues that affect consumer-revealed preferences. For instance, exposure to palatable food cues reduces the ability of dieters to substitute healthy food for unhealthy one, because they interfere with the cognitive processing of comparison between the weight control goal and short-term pleasure.[32] The shape of packaging also has an impact on consumer perception of overall volumes, in such a way that doubling all sizes of a product package makes it appear only 50% bigger.[33] As consumers tend to rely on portion size to regulate their intake, the underestimation of increasing volumes when packaging sizes increase causes individuals to eat more.[34]
Beyond product-specific perceptual cues, environmental cues act as distractors that alter the perception of hunger and satiety. Experiments have shown that listening to music, watching a movie or even a soft light tend to increase food intake at eating occasions.[35]
Marketing also uses framing techniques to alter consumer valuation of the choice options. For instance, adding extra-large options in a menu shifts upward the preferences of consumers who did not choose the previously largest option.[36] Here, framing plays with consumer aversion for extreme options in a choice set. This renders options with less extreme attributes more salient. Consumer evaluation of products can also be affected by halo effects that are obtained by associating the (unhealthy) product with elements that evoke healthiness. For instance, consumers evaluate a meal as less caloric when healthy food is added to unhealthy food as compared to when unhealthy food is presented alone.[37] Marketing a brand as "healthy" affects people's perceptions of its nutritional and calorie

content.[38]

Finally, several experimental studies have also analyzed the impact of exposure to advertising on brand recognition, liking and eating in children and in adults. In particular, Connell et al.[39] show that exposure to advertising in childhood generates positive affects for the advertised brand in adulthood, independently from the fact that subjects may also have consumed the product. Harris et al.[40] provide evidence that exposure to food advertising during TV viewing tends to trigger snacking in children and in adults as compared to exposure to non-food advertising. This shows that food advertising could increase food demand, beyond some impacts on market shares and competition.

The neo-classical approach is based on the key assumption that consumer choices are the expression of stable and consistent preferences under time and money constraints. Expanding the diversity of consumption experiences (complementary advertising) or making more information available (informative advertising) is welfare-enhancing. In addition, the consumer has the cognitive and knowledge capacities to understand and outsmart firms' strategies, so that competition would solve most regulatory issues at low costs. Naturally, the validity of this approach depends on how well this assumption, or the predictions it generates, is supported by empirical evidence.

As compelling as they are, these results are not sufficient to conclude that marketing has persuasive effects. First, the "complementary view" argument may apply "in real life" to some of the choice situations that demonstrate "in lab" the consumer sensitivity to environmental cues. For instance, eating with friends or family, or the sounds and lighting of the eating environment, tend to increase food intake. However, having a dinner with one's partner at a romantic restaurant is a consumption experience that is made up of food, the partner, candles, and the jazzy music. Second, it may be possible that people are subject to all sort of biases, but that they are still able to maintain the stability of their food intake (at least in terms of calories) by engaging homeostatic responses that modulate hunger and satiety and correct for past errors. Studies in neurobiology have demonstrated how the functioning of some of the neural systems and pathways driving food decisions can be altered by the perceptual cues, framing effects and other environmental "pressure" discussed above.[41] Yet, to the best of my knowledge, we lack long-term cohort studies showing that these alterations translate permanently and over the long-term into a change in food preferences. Such long-term studies would be useful because, if consumers are prone to systematic errors that do not cancel over time, then their food choices are no longer consistent over time. They are not able to stick to pre-determined consumption plans that would be optimal over the long-term, and the argument of consumer sovereignty collapses. Public health authorities then have an additional reason for regulating marketing practices: the burden of "internalities" that current consumers generate for their future selves.[42] Taxes may directly increase consumer welfare by helping them to adopt behaviors that would be more consistent with their long-term "true" preferences. In that case, the optimal tax level is to be calculated so as to cover both the externalities of consumption and the internalities, but we are back to the difficult task of defining what consumer "true" preferences are.

Observational Evidence on Marketing and Food Choices

Collecting observational evidence on the impact of food marketing is interesting for two reasons. First, although laboratory experiments are useful to highlight the mechanisms through which food marketing can alter choices, they may be criticized for their lack of external validity. The effects found in the lab often magnify the reality of the field. More importantly, even if in-lab marketing manipulations lead subjects to eat more unhealthy food, the same subjects may immediately offset these excess intakes in the days following the experiment. Second, field data can be used to test some of the theoretical predictions of the standard economic approach. For instance, if advertising has persuasive effects, then it may increase brand fidelity and the volumes purchased by habitual consumers. If it has informative effects, then it should increase consumer price responsiveness and brand-switching. Importantly, all empirical studies cited below focus on advertising as it is the marketing variable that is the easiest to measure.

Empirical studies of market data tend to conclude that advertising often increases the brand market share in the short-term, but not necessarily in the long-term, that it generally has a negative effect on rivals' market shares ("combative" advertising), and that it tends to increase price elasticity. Deighton et al.[43] studying the Ketchup market and Ackerberg[44] studying the Yogurt market find that advertising is effective at attracting new consumers but not at retaining them. It has no effect on the purchases of those consumers who already have experienced the product.

Shum[45] finds similarly for the breakfast-cereal market evidence that advertising encourages consumers to substitute for less familiar brands. Ippolito and Mathios[46] show that allowing firms to use health claims on breakfast-cereal packages increased the consumption of brands displaying such claims. Rao and Wang[47] analyze the impact of the termination of claims following charges by the U.S Federal Trade Commission. They document a significant decline in demand that is mainly explained by a loss in ability to attract new consumers. These results are consistent with informative rather than persuasive or complementary advertising.[48]

If advertising is informative and only serves to attract new consumers, then it is *a priori* welfare-enhancing. However, consumers develop some brand-loyalty over time, a fact that is well-documented. It is explained by purchase routines that may reflect various behavioral mechanisms, such as loss aversion (psychological attachment to the brand), default option bias, or aversion to the risk of trying a new product.[49] If new consumers do not anticipate well the stickiness of their choice over the long-term, then even informative advertising may have negative consequences for their long-term welfare.

In addition to these market studies, applied economists have uncovered evidence of a small positive impact of advertising on quantity outcomes beyond the effect on brand market shares. They apply quasi-experimental design to exploit spatial variations across regions that differ in the intensity of their exposure to advertising. This is not an easy task as food companies are likely to concentrate their efforts on regions where the demand is large enough and more responsive to marketing. Some studies have tried to use the price of advertisement and the number of households with a television in the area as exogenous source of variation for advertising exposure. They find small but significant correlations between fast-food and soft-drink advertising and consumption.[50] Another set of studies has exploited the ban on advertising targeting children on Quebec TV stations. As English-speaking children living in Quebec continued to be exposed to border TV stations in English, it is possible to compare the consumption trends between French-speaking and English-speaking children. Dhar and Baylis[51] find that the ban has decreased fast-food consumption at the extensive margin (the number of purchase occasions), while Goldberg[52] reports a decrease in cereals purchase in French-speaking households.

To summarize, empirical evidence from existing observational studies lend support to both the informative view on advertising and to the idea that advertising efforts can increase the overall quantities sold on market. The view that advertising has a persuasive effect seems to be rejected. However, it is important to note that the existing studies use data collected on “mature” markets in high-income countries. We lack evidence from emerging economies and middle-income countries, while we know that they suffer more and more from the burden of food-related chronic diseases.

These market studies are based on empirical techniques that rely implicitly on specific assumptions regarding consumer choices.[53] More precisely, consumers are supposed to maximize a utility function over a set of alternative products. They are supposed to consider all the products that are offered by the market, to have no bias in their perceptions of the product attributes, and to be able to choose the option that maximizes their utility. The experimental evidence briefly reviewed above and the observation of consumer decision process in the real world show that these assumptions are unlikely to hold. Consumers exhibit restricted consideration sets.[54] They misperceive certain attributes. They are not consistent utility-maximizers when environmental or internal cues make them succumb to impulse buying and forget the health consequences of their decisions. While experimental studies lack external validity, observational studies lack internal validity.

The Commercial Exploitation of Behavioral Biases

Advertising and other marketing techniques play with consumer difficulties to make unbiased value comparisons between products. Advertising renders more salient certain choice options, which may then enter into the consumer consideration set.[55] It also changes the perception of product attributes.[56] It may cause impulse buying as is the case with the placement of sweet products in cashier zones or end-of-aisles.[57] In that case, consumer behavioral failures generate internalities because the utility experienced by consumers differ from the utility they expected at the moment of purchase. This loss corresponds to a transfer of welfare surplus from the consumer to the firm.

A policy-maker who wishes to impose more stringent regulation on marketing could use empirical evidence showing

that it is detrimental to consumer welfare. Bhargava and Loewenstein have argued that behavioral sciences provide evidence for protecting more aggressively consumers from “behavioral exploitation by firms,” through taxation and regulation of the choice context. However, the economic literature does not provide unambiguous results regarding the welfare-damaging of advertising. Experimental evidence showing that marketing techniques do bias consumer decisions are somewhat at odds with results inferred from market data.

A growing theoretical literature tries to understand the implication of the commercial exploitation of behavioral biases for markets.[58] They focus on obfuscation strategies that aim at “shrouding” specific attributes, or at making them more or less salient to focus the attention of consumers in the process of product evaluation.[59] In particular, one issue is whether biased consumers, in addition to suffering from health-damaging internalities, also suffer from a loss of price competition.

One important result is that rational firms may use marketing as an obfuscation strategy to increase choice complexity so as *to decrease* competition, thus lowering its benefits for consumer welfare.[60] A second important result is that firms may end up under-investing on product quality, if advertising is used as a means of rendering product differentiation more salient, or of focusing consumer attention.[61] If consumers over-value the differences in quality between products relatively to the difference in price, or if marketing restricts the consideration set of consumers, then firms producing high-quality products have less incentives to invest in quality, for instance to formulate food with healthier but more expensive ingredients. They may prefer investing more in adding cartoon characters on the packaging. Finally, firms face a trade-off between “educating” consumers and using obfuscation strategies. A firm can educate consumers by choosing transparency, e.g., displaying a clear front-of-pack nutritional label on the packaging. The results are not unambiguous, as their strategies will depend on the intensity of competition and the relative costs of education and obfuscation that can be both achieved through marketing. For instance, when obfuscation is cheap and competition is intense (as is likely the case for food markets), obfuscation will be used as a means of maintaining cost-price margins. But this result may change if obfuscation is costly.[62]

Conclusion

A policy-maker who wishes to impose more stringent regulation on marketing could use empirical evidence showing that it is detrimental to consumer welfare. Bhargava and Loewenstein[63] have argued that behavioral sciences provide evidence for protecting more aggressively consumers from “behavioral exploitation by firms,” through taxation and regulation of the choice context. However, the economic literature does not provide unambiguous results regarding the welfare-damaging of advertising. Experimental evidence showing that marketing techniques do bias consumer decisions are somewhat at odds with results inferred from market data.

Experimental studies tend by design to produce results that have large “effect sizes” and thus lack external validity. Existing observational evidence has been produced by using econometric methods that ignore consumer biases and thus lack internal validity. In addition, the welfare losses produced by persuasive marketing and the commercial exploitation of behavioral biases depend on the discrepancy between the preferences revealed by consumers through their choices and some “true” preferences. The latter are by essence very difficult to identify with observational data, if we do not have additional information on the extent of consumer bias.[64] In (quasi-)experimental settings, one may sometime back out the individual “true” preferences from the comparison of the choices made by individuals in an environment conducive to biases to those made in a context known to remove biases. For instance, Allcott et al.[65] examines the pattern of soft-drink purchases by households depending on whether they have accurate nutritional knowledge and declare to have problems controlling their consumption. They use this information to calculate the soft-drink tax that would be optimal to make biased consumers as well-off as unbiased consumers. Collecting more compelling observational evidence thus requires more precise data. With the rise of digital marketing, access to data on online purchases may help to make progress in that direction. Finally, it is important to note that existing studies have generally focused on one specific marketing technique (e.g TV advertising, price promotions), while marketing campaigns are multi-channeled. The economics of advertising has little to say about the effect of massive change in the environment, perhaps because the field is structured around the idea that only precise causal effects are worthy of scientific interest.

Economists have also been interested in knowing whether firms spend too much in marketing and advertising. Competition here plays a key role, whether advertising be informative, persuasive or complementary. The literature uncovers empirical evidence of negative return on investments in advertising for many important brands (see the evidence in Shapiro et al.[66] for the U.S.). This is explained by the “non-cooperative” aspect of advertising. Firms are trapped in an inefficient strategic equilibrium where they cannot cut on their advertising expenditures without seeing their market shares stolen by rivals. This implies that restricting marketing efforts could actually be beneficial to both firms and consumers, at least in high-income countries and for mature markets.[67] This efficiency argument may eventually help to reframe marketing restrictions as a win-win policy.

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Regressive Federalism, Rights Reversals, and the Public's Health

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ABSTRACT (ENGLISH)

As the United States emerges from the worst public health threat it has ever experienced, the Supreme Court is poised to reconsider constitutional principles from bygone eras. Judicial proposals to roll back rights under a federalism infrastructure grounded in states' interests threaten the nation's legal fabric at a precarious time. This column explores judicial shifts in 3 key public health contexts — reproductive rights, vaccinations, and national security — and their repercussions.

FULL TEXT

Deconstruction of constitutional norms at the hands of an overly conservative Supreme Court (and corresponding lower-level tribunals) is emerging as a dominant legal trend in the 21st century. Revived assessments of the scope of federalism as a structural foundation are lending to re-examinations of governmental authorities and constitutional rights. Some courts are taking "new federalism" beyond its original moors in the 1990s[1] to a foregone era when states' traditional powers served as definitive boundaries against federal intrusions and supremacy.[2]

Even as some Justices struggle with limits of their own roles under principles of separation of powers,[3] the Supreme Court is poised to roll back rights it previously bestowed, exemplified by its ongoing reassessment of abortion and other reproductive rights. Against decades of precedents, the Court is considering limiting abortion rights at the behest of politicized legislative acts in Mississippi,[4] Texas,[5] and other states. If abortion is ripe for constitutional reconsideration, other civil rights —to marry, to intimacy, to privacy, to parent, to travel —may also be subject to

reversals.[6]

The emergence of "regressive federalism"[7] carries additional consequences. Prioritizing traditional police and *parens patriae* powers via the Tenth Amendment enhances states' authorities in definitive areas of public health policy. Resulting limits on federal incursions into such realms, such as vaccinations, alter modern efforts to craft national policies at a precipitous time. Millions of Americans are resisting vaccines due to misinformation, misperception of risks, government distrust, or outright refusal to observe civic responsibilities.[8] Multiple states actively promote liberty interests over COVID-19 vaccine mandates despite Americans' heightened risk of COVID-19 infection and deaths.[9] While the Court has allowed state-based vaccine mandates to continue largely unabated,[10] its jurisprudence dispelling federal vaccine requirements affecting large employers is telling.[11] Recognition of states' interests as a stopgap to federal emergency mandates may upend long-standing, routine school, day-care, and other vaccination laws.[12] The Court's potential recognition of First Amendment rights to religious exemptions to all vaccination mandates could decrease inoculation rates nationally.[13]

Judicial retrenchment in antiquated constitutional concepts is especially treacherous in crises impacting national security. The COVID-19 pandemic warranted the most expansive use of public health emergency (PHE) powers in U.S. history.[14] Just when governmental stability was needed most, the pandemic became a catalyst for judicial "corrections." As states diverged over how, or even whether, to use their public health powers,[15] the Court reversed itself mid-pandemic to affirm First Amendment free exercise rights over social distancing measures.[16] It then curtailed federal agencies' authority to forestall residential evictions[17] and assure worker safety. Collectively these themes, discussed below, raise significant public health consequences.

Judicial retrenchment in antiquated constitutional concepts is especially treacherous in crises impacting national security. The COVID-19 pandemic warranted the most expansive use of public health emergency powers in U.S. history. Just when governmental stability was needed most, the pandemic became a catalyst for judicial "corrections." As states diverged over how, or even whether, to use their public health powers, the Court reversed itself mid-pandemic to affirm First Amendment free exercise rights over social distancing measures. It then curtailed federal agencies' authority to forestall residential evictions and assure worker safety. Collectively these themes raise significant public health consequences.

Reproductive Rights Reversals

Since the Court's decisions in *Roe v. Wade* (1973)[18] and *Planned Parenthood v. Casey* (1992),[19] states cannot ban or unduly burden pre-viability abortions (e.g., prior to 24 weeks gestation). The Court now appears poised to overturn *Roe* and de-constitutionalize individual rights to abortion following the October 2020 confirmation of Justice Amy Coney Barrett. In September 2021, the Court majority refused to block a Texas law which effectively banned abortions in the state.[20] Texas Senate Bill 8 enables individuals to enforce a 6-week abortion ban through private lawsuits, a novel legal maneuver which attempted to prevent federal courts from blocking it.[21] The Court eventually reasoned that Texas' law could be challenged without outright rejecting the notion that carefully-crafted legislation may avoid judicial scrutiny.[22]

In December 2021, the Court further signaled *Roe*'s impending demise at oral argument in *Dobbs v. Jackson Women's Health Organization*.[23] All six conservative Justices appeared open to upholding a Mississippi law banning abortions at 15 weeks,[24] well before viability. Justice Kavanaugh argued that since the Constitution is "neutral" on abortion, such matters should be left to Congress or state legislatures to decide.[25] Arguments grounded in "scrupulous[] neutral[ity]"[26] have the potential to eviscerate other rights not expressly spelled-out in constitutional text, as Justice Sotomayor acknowledged during *Dobbs'* oral argument.[27] These include rights to make parenting decisions, retain intimacy and privacy, obtain and use contraception, and marry.[28] An amicus brief filed by right to life proponents in *Dobbs* characterizes LGBTQ+ rights to privacy and marry as "court-invented rights"[29] from prior Supreme Court jurisprudence.[30]

Absent constitutional protections, recognition of reproductive interests falls to legislators' discretion —with dire consequences. Abortion rights bills introduced and passed in the House of Representatives in 2021[31] were blocked by the Senate. That same year 19 states enacted a total of 108 abortion restrictions: "the highest total …in any year"

since *Roe*.[32] These included 6–8 week abortion bans, prohibitions in cases of certain genetic anomalies, and limits on abortion medications.

Overturning *Roe* carries immediate negative public health effects. Twenty-one states' laws restrict (or intend to restrict) abortion in the absence of *Roe*, while only 15 states and D.C. expressly protect abortion rights.[33] Not all women in restrictive states will lose access, but those denied abortions are more likely to experience economic hardship, serious pregnancy-related complications, poorer overall health, and reduced self-esteem and anxiety.[34] A decade-long study published in 2020 found that "6.3% of women who gave birth reported potentially life-threatening conditions, compared to …0.5% of women receiving a first trimester abortion."[35] Women denied abortions received welfare benefits 6 months later at almost twice the rate of women who obtained abortions (15% vs. 8%).[36]

Reassessment of Vaccine Laws and Policies

On January 13, 2022, against the backdrop of the largest surge in COVID-19 cases seen during the pandemic due to the Omicron variant, the Supreme Court declined to allow the Occupational Safety and Health Administration (OSHA) to enforce its Emergency Temporary Standard (ETS).[37] The standard, issued on November 5, 2021, required covered employers with more than 100 employees to ensure workers were vaccinated against COVID-19 or submit to weekly testing and mask wearing on the job, subject to certain exemptions or accommodations.[38] Saving thousands of American lives was the goal. In *National Federation of Independent Businesses (NFIB) v. OSHA*, however, the Court questioned OSHA's statutory authority[39] despite an extensive regulatory history of protecting workers from multivariate risks.[40] While "Congress has indisputably given OSHA the power to regulate occupational dangers," reasoned the Court, "it has not given that agency the power to regulate public health more broadly."[41] On January 25, 2022, OSHA withdrew the ETS as an enforceable rule.[42]

The Court's decision not only erodes existing *Chevron* deference typically granted to federal agencies[43] but also has rippling effects in other cases. On January 21, 2022, a federal district court in Texas preliminarily stopped enforcement of President Biden's Executive Order requiring federal employees to be vaccinated for COVID-19.[44] Relying on *NFIB v. OSHA*, Judge Vincent Brown reasoned the President lacked authority to require the vaccine as a condition of employment because COVID-19 was a "universal risk" and not a "workplace risk." On February 9, the Fifth Circuit Court of Appeals declined to allow enforcement of the federal employee mandate while on appeal,[45] resulting in its temporary abeyance.[46]

For over a century, the Supreme Court has affirmed states' authority to require vaccinations under their police powers.[47] However, current legislation in multiple states reveals an alarming penchant for COVID-19 and other vaccine prohibitions akin to federal limits set by the Court. Initial legislation introduced in Georgia, for example, prescribed that "[n]o agency shall require proof of any vaccination of any person as a condition of providing any service."[48] Opponents feared that the bill would derail existing school vaccination requirements, although its sponsor later proposed narrowing its coverage solely to COVID-19 vaccines.[49] Passage of state-based anti-vaccination legislation may lead to vaccine-preventable disease outbreaks not seen in decades.

Regressive Federalism and National Security

Aggressive judicial limits on the scope and breadth of executive powers to quell the pandemic in the interests of national security surfaced in other contexts. After initially ruling inappositely in California[50] and Nevada[51] in the summer of 2020, the Supreme Court limited governments' social distancing powers later that same year in New York,[52] and then California[53] in early 2021. States were prohibited from broadly enforcing emergency executive orders limiting occupancy to prevent the spread of COVID-19 in religious institutions and gatherings. Placating separation of powers concerns, the Court prioritized First Amendment free exercise rights over PHE measures. On August 26, 2021, it blocked a residential eviction moratorium[54] set by the Centers for Disease Control and Prevention (CDC)[55] to reduce the spread of COVID-19 by encouraging social distancing and preventing homelessness. That same month the Court lifted part of a New York State moratorium on residential evictions.[56] CDC's moratorium was initially authorized by Congress in March 2020 pursuant to the Coronavirus Aid, Relief, and Economic Security (CARES) Act.[57] When Congressional authorization expired in July 2020, CDC reinstituted the moratorium under the federal Public Health Service Act (PHSA).[58] The Act authorizes the Department of Health and

Human Services (HHS) (and its subsidiary, CDC) to “make and enforce such regulations …necessary to prevent the introduction, transmission, or spread of communicable diseases.”[59] Corresponding federal regulations permit CDC to prevent the spread of infectious diseases when state or local responses are insufficient.[60] Initial judicial challenges to CDC’s eviction moratorium were rebuffed by the Supreme Court in June 2021.[61] Yet, when the moratorium lapsed and CDC attempted to renew it, the Court pounced. In *Alabama Association of Realtors v. HHS*, it determined that CDC lacked the “sweeping authority” under the PHSA to issue the moratorium,[62] questioning the scope of agency delegations, a theme it used later to reject OSHA’s power. It is “up to Congress, not the CDC,” concluded the Court, “to decide whether public interest merits further action here.”[63]

Together the Court’s COVID-19 cases limit federal agency powers, prioritize free exercise principles, narrow legislative authority, and elevate traditional states’ interests. Curtailing national emergency responses based on settled constitutional doctrine is one thing; limiting them based on re-constituted constitutional interpretations is another. The former is predictable and grounded; the latter is erratic and reckless. As noted by Justice Sotomayor, legal instability related to constitutional norms during pandemics can be deadly.[64]

Retrenchments of rights coupled with pronounced shifts in federalism and limits on agency authority via a conservatively-centered Supreme Court are concerning. Columnist Charles Blow queries whether we are “at an inflection point for an age of regression.”[65] There is unquestioned potential for generational-shifting of constitutional norms even after the Court’s membership changes with the impending retirement of Justice Breyer. Yet, this approach may also collapse. The role of the Constitution in protecting Americans from governmental abuses and malfeasance does not stop at the steps of Congress or the door of the White House. Sometimes, as seen throughout U.S. history,[66] the abuses that the Constitution are designed to prevent emanate from the Court itself.

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About This Column

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Public Health Protection vs. Freedom of Commercial Expression in the Commonwealth Caribbean: The

Case of Barbados and Jamaica

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ABSTRACT (ENGLISH)

This chapter explores the tension between public health protection and the freedom of commercial expression from a Commonwealth Caribbean perspective, using Barbados and Jamaica as case studies. First, it assesses the scope of the right to freedom of expression. Second, it discusses the extent to which public health protection may be invoked to restrict the right. The authors conclude that Commonwealth Caribbean states can justifiably restrict commercial speech about tobacco products and unhealthy food and beverages.

FULL TEXT

1. Introduction

In response to the growing noncommunicable disease (NCD) epidemic,[1] Commonwealth Caribbean Heads of Government have endorsed the adoption and implementation of a suite of cost-effective, evidenced-based legal interventions.[2] These interventions, which include restrictions on advertising, promotion and sponsorship of tobacco products and the marketing of unhealthy food and beverage products, are upstream interventions for healthier people and environments.[3] However, transforming largely unregulated environments, currently manipulated by Big Tobacco, Food, and Soda,[4] might require the implementation of measures that infringe commercial operators' constitutional right to freedom of expression.[5] Notwithstanding this, Commonwealth Caribbean states, having ratified various international human rights treaties,[6] nevertheless have internationally binding obligations to respect, protect and fulfil human rights, including to prevent commercial operators from interfering with the right to health.[7]

This Chapter explores the tension between regulating the NCD risk factors of tobacco and unhealthy diets and commercial operators' right to freedom of expression. First, it assesses the scope of that right, using the Constitutions of Barbados and Jamaica as case studies. Second, it discusses the extent to which public health may be invoked as a justification forrestricting the right to freedom of commercial expression. It concludes that Barbados and Jamaica, and by extension other Commonwealth Caribbean states, can justifiably restrict commercial expression by imposing restrictions on the sale and marketing of tobacco and unhealthy food and beverage products, provided the measures are reasonable and proportionate public health responses to the NCD epidemic.

2. The Scope of Freedom of Expression

Freedom of expression is a broad and inclusive constitutional right in the Commonwealth Caribbean. In Barbados, this right, contained in section 20(1) of the Bill of Rights,[8] includes freedom to hold opinions, as well as to receive and communicate ideas and information without interference. In addition, the right includes freedom from interference with one's correspondence and other forms of communication.[9] The right to freedom of expression in Jamaica, as outlined in sections 13(3)(c) and (d) of the Jamaican Charter of Fundamental Rights and Freedoms, includes "the right to freedom of expression" and the "right to seek, receive, distribute or disseminate information, opinions and ideas through any media," respectively.[10] Notably, section 13(3)(c) of the Jamaican Charter is a stand-alone right, while section 13(3)(d) is intended to be "complementing and supplementing [to] the right to freedom of expression where certain form of media is concerned…", such as broadcast media.[11]

This Chapter explores the tension between regulating the NCD risk factors of tobacco and unhealthy diets and commercial operators' right to freedom of expression. First, it assesses the scope of that right, using the Constitutions of Barbados and Jamaica as case studies. Second, it discusses the extent to which public health may

be invoked as a justification for restricting the right to freedom of commercial expression. It concludes that Barbados and Jamaica, and by extension other Commonwealth Caribbean states, can justifiably restrict commercial expression by imposing restrictions on the sale and marketing of tobacco and unhealthy food and beverage products, provided the measures are reasonable and proportionate public health responses to the NCD epidemic.

Neither the Barbadian Bill of Rights nor the Jamaican Charter explicitly mentions a right to freedom of commercial expression. Nor do those instruments state that commercial expression is protected. However, Barbadian and Jamaican courts have acknowledged that commercial expression is protected under the broad right to freedom of expression.[12] For instance, the Barbadian Court of Appeal in *Weel v. Attorney General of Barbados and Another*[13] acknowledged that there was "highly persuasive authority for the view that the right [to freedom of expression] in section 20(1) [of the Barbados Constitution] undoubtedly includes commercial speech or, in other words, the right to communicate commercial ideas and information to others."[14] Similarly, the Jamaican court, in its most recent Charter inquiry concerning freedom of expression —*Bignall v. The General Legal Council and the Attorney General of Jamaica*,[15] stated that there was not "any dispute that commercial speech, advertising, in particular, falls for protection under section 13(3)(c) [of the Jamaican Charter]."[16] Commercial operators in the Commonwealth Caribbean enjoy much freedom to advertise their goods and services, including unhealthy food and beverage products.[17]

Despite the broad scope of the right to freedom of commercial expression, the right is not absolute and may be restricted, subject to certain criteria being met. Section 11 of the Barbados Constitution, which is the preamble to the Bill of Rights, indicates that the rights or freedoms which follow are "subject to such limitations of that protection as are contained in those provisions, being limitations designed to ensure that the enjoyment of the said rights and freedoms by any individual does not prejudice the rights and freedoms of others or the public interest."[18] Importantly, section 20(2) of the Barbados Constitution deals specifically with the permissible limitations on the right to freedom of expression, and provides, in part, that "[n]othing contained in or done under the authority of any law shall be held to be inconsistent with or in contravention of this section to the extent that the law in question makes provision [….] that is *reasonably required in the interests of* defence, public safety, public order, public morality or *public health* …(emphasis added)."[19] Conversely, section 13(2) of the Jamaican Charter includes a single limitation clause making the enjoyment of rights and freedoms, including freedom of expression, subject to measures that are "demonstrably justified in a free and democratic society."[20]

3. Public Health As A Justified Restriction On The Right To Freedom Of Commercial Expression

In Barbados and Jamaica, for any restriction to be deemed constitutional, that is, to be a justified infringement on constitutional rights, it must *generally* (1) pursue a legitimate aim or have a sufficiently important objective, and (2) be proportionate to that legitimate aim or sufficiently important objective. That general approach reflects the judicial interpretation of the detailed and general limitation provisions in Barbados' Bill of Rights and Jamaica's Charter, noted above.

The Tests for Constitutionality

The only inquiry into restrictions on freedom of expression for public health interests within the Barbadian context is found in *Weel*.[21] In *Weel*, the Barbados Court of Appeal was tasked with determining the constitutionality of a regulation that restricted dentists, like the appellant, from advertising in certain respects. Rule 14(2)(b) of the 1973 Dental Registration Rules provided that "any form of advertising, canvassing or promotion either directly or indirectly for the purpose of obtaining patients or promoting his own professional advantage" was actionable professional misconduct.[22] In deciding whether rule 14(2)(b) was constitutional, that is, reasonably required in the interests of public health, the court relied heavily on the approach adopted in the Canadian case of *Rocket v. Royal College of Dental Surgeons of Ontario*[23] and the Trinidadian case of *Suratt v. Attorney General of Trinidad and Tobago,*[24] to articulate the aforementioned two-part test. First, whether the rule pursued a legitimate aim, and second, whether it was proportionate to that aim.

Correspondingly, the Jamaican Full Court in *Bignall*[25] reaffirmed its adoption of the two-part test for constitutionality laid down by C.J. Dickson in *R v. Oakes*[26] as the correct test for determining the constitutionality of derogations from

Charter rights and freedoms.[27] First, the objective of the measure restricting the freedom must be "sufficiently important,"[28] addressing societal concerns that are "pressing and substantial."[29] Second, the measure must be "reasonable and demonstrably justified in a free and democratic society."[30] This second step, which can be considered a proportionality test, involves three components. First, the measure "must be fair and not arbitrary, carefully designed to achieve the objective in question and rationally connected to that objective."[31] Second, the measure should "impair the right in question as little as possible."[32] Third, "there must be proportionality between the effects of the limiting measure and the objective —the more severe the deleterious effects of a measure, the more important the objective must be."[33] Dickson CJ, however, later modified the second criterion of the proportionality test, requiring that the measure impair the right "as least as is reasonably possible."[34]

"Legitimate Aim" or "Sufficiently Important" Objective

In *Weel*, the Barbados Court of Appeal, in determining whether rule 14(2)(b) pursued a legitimate aim, relied on the plain language of the rule as its starting point. The court concluded that there was a legitimate purpose, namely "to maintain a high standard of professionalism among dentists and to protect the public from irresponsible and misleading advertising," and that such was connected to the interest it sought to protect, namely public health.[35] It is noteworthy that the Barbadian court considered the rule's connection to the interest being protected to determine the legitimacy of the aim. Therefore, in determining whether a restriction pursues a legitimate aim, consideration should be given to both the plain language of the rule and its connection to that aim. In other words, clear objectives capable of passing the muster of this first limb, and the second one, as will be shown, are critical.

The Barbadian court, citing the *Rocket* case from Canada,[36] considered the difficulty of the "average consumer" to verify claims of competence across professionals. While this consideration relates to the legitimacy of the aim, it also refers to the importance of the measure —to protect consumers. Thus, the importance of the aim should be considered as a feature in determining its legitimacy.

Similarly, in analyzing the limits that may be imposed on freedom of expression in *Bignall*, J. Barnaby, also referenced a Canadian case —*Irwin Toy v. AG*,[37] which found a law prohibiting commercial advertising directed at persons under thirteen years old to be constitutional. In *Irwin*, the court reasoned that protecting children from advertising was pressing, substantial and important since commercial advertising can have persuasive effects on children. The *Irwin* court opined that protecting children from manipulation was a substantially important goal. More recent analysis of the extent and impact of children's vulnerability and exposure to marketing generally further justify marketing restrictions in the interests of public health.[38]

Within the diet-related NCD context, marketing restrictions aimed at reducing "both the exposure of children to, and power of, marketing of"[39] unhealthy foods and beverage products would also satisfy the first limb of the test for constitutionality. As C.J. Dickson correctly noted in *Irwin*, children are especially vulnerable to advertising. This vulnerability subjects them to the powerful and pervasive content directed at influencing their diets, often negatively. It is difficult for children to sort and sift through commercial expression around legal but harmful products, such as unhealthy food and beverage products. Indeed, courts would benefit from recognizing conflict-free evidence about the rates of obesity and overweight among Caribbean children, the effectiveness of marketing to children, and how regulating products through advertising restrictions can mitigate the risk of children developing NCDs.[40]

Further, the aim of such marketing restrictions would support the legally binding obligation of states, such as Barbados and Jamaica, to protect children's rights against interference by third parties.[41] Importantly, the fact that such a public health measure is most effective as part of a comprehensive package of other measures also reinforces the legitimacy of appropriately crafted objectives and each measure's rational connection to overarching public health interests. Hence, the sufficiently important aim of NCD prevention among children, the legitimacy of that aim and its rational connection to public health interests, should arguably be difficult to deny.

With respect to tobacco control, it is perhaps undisputable that tobacco control regulations that restrict tobacco advertising would satisfy the first limb of the test for constitutionality. In fact, several Caribbean states have already started to implement comprehensive bans on tobacco advertising, promotion and sponsorship.[42] Certainly, preventing individuals, including children, from death, disability, impoverishment, and the ill-health associated with

the use of and exposure to tobacco is a legitimate aim and a sufficiently important objective. Public health measures to regulate the NCD risk factors of tobacco and unhealthy diets are capable of passing this first limb.

Proportionality

The second limb of the tests in Barbados and Jamaica can be referred to as the proportionality test. At this stage of the inquiry, courts often assess whether a measure goes beyond what is necessary to achieve its objective.

In *Weel*, in applying the proportionality test, the Barbados Court of Appeal considered whether rule 14(2)(b) was reasonably required in the interest of public health. It again considered the language of rule 14(2)(b) and stated "[o]n its plain words, appropriate advertising is permissible under this rule. Its ambit of the prohibition on advertising extends only to advertising 'for the purpose of obtaining patients or promoting his own professional advantage.'"[43] The specific restriction identified within rule 14(2)(b) was perceived as being "limited and narrowly drawn" and striking a fair balance between an individual's right and society's interest in obtaining information about dentists.[44] Rule 14(2)(b) was therefore proportionate to the objectives. The Jamaican Full Court took a similar approach in *Bignall*,[45] albeit centering its analysis of the proportionality test on the latitude that the legislature has to select the most appropriate measure to meet its policy objective.

The significance of clear objectives is also pertinent to this limb of the test. It is upon the objective that the public health measure will be assessed to determine its necessity and proportionality. It is perhaps trite that blanket bans are generally considered to be disproportionate to achieve legislative aims. However, within the NCD context in the Caribbean, the other extreme —zero restrictions, should also be recognized as having a disproportionate burden on public health as well as economic wealth and social wellbeing, notably of these low-and middle-income countries, and subpopulations within them, such as children and persons living in poverty.[46] Further, the absence of any restrictions on commercial operators and arguably, the adoption of ineffective measures, may also conflict with the aforementioned human rights obligations of these Caribbean states.

What then is the balance to be struck between the right to freedom of commercial expression and public health interests in Barbados and Jamaica? A fair balance between these competing interests will not necessarily be some midway point, if that can even be identified. Instead, given the specific objective of the public health measure, such as the earlier marketing restrictions aimed at reducing the exposure to and power of marketing of unhealthy beverages and food products to children, a fair balance may arguably be struck at different points depending on the exposure and power of marketing within specific environments,[47] as well as any applicable considerations for decision-making, such as the best interests of the child.[48] For instance, with respect to school environments, the balancing of competing interests, such as commercial operators' free speech versus children's health and other rights, must take the best interests of the child as a primary consideration.[49] The least restrictive means, and the fair balance to be struck, may see more protective measures against the corporate "vectors of disease" preying on children in school settings compared to strictly adult environments.[50]

The reality is that the mostly unregulated exercise of freedom of commercial expression in Barbados and Jamaica means that unhealthy food and beverage product marketing is pervasive. Consequently, the means used to limit said unregulated freedoms in the interest of public health, may, even in their least restrictive manner, nonetheless appear broad. Here, due consideration must also be given to whether the *Irwin*[51] framework would equally apply to comprehensive advertising bans, that is, bans on all advertisements relating to unhealthy food and beverage products. While adults may not be as vulnerable as children from a biological or psychological perspective, unregulated environments increase everyone's vulnerability. Parents' responsibility for children and children's pester power over parents strongly suggest that their vulnerabilities are not mutually exclusive and both need to be protected. Whilst such an argument may appear paternalistic, the reality is that in both Barbados and Jamaica, Consumer Protection legislation[52] already aims to protect all consumers from deceptive and misleading advertising. Going beyond, to protect consumers from commercial speech which may not be captured within the "deceptive and misleading" parameters, but which is nonetheless harmful to health, is not only permissible but necessary and proportionate to the objectives in focus. The objective of addressing the exposure and power of pervasive marketing can only be effectively achieved with comprehensive marketing restrictions.

Undoubtedly, freedom of commercial expression, captured in the freedom of expression provisions of the Constitutions of Barbados and Jamaica, is not absolute. It may be subject to certain limitations, including limitations in the interest of public health. The growing body of evidence of the efficacy of marketing bans and further, of an integrated package of measures, provides a solid foundation on which to craft public health policies that incorporate these measures.

With respect to tobacco control measures, the aim of reducing exposure to advertising associated with tobacco products would also be afforded constitutional safe harbour by satisfying the second limb of the test of constitutionality. For instance, it is almost trite that tobacco advertising, promotion, and sponsorship bans are rationally connected to the objective of reducing tobacco consumption, and not so severe as to outweigh the objective of reducing tobacco consumption.

There is also value in appreciating that the prohibition in *Irwin*[53] was not the least restrictive, a distinguishing feature from *Weel*, in which the court was detained with this exercise. The *Irwin* court considered that it would not "in the name of minimal impairment, take a restrictive approach to social science evidence and require legislatures to choose the least ambitious means to protect vulnerable groups."[54] This is a powerful statement, underscoring the latitude the Jamaican legislature has, to implement the most effective public health measure, and the Jamaican courts to uphold such as constitutional.

Ultimately in *Weel,* the Barbados Court of Appeal highlighted the "public interest in obtaining relevant and appropriate information about dentists"[55] and found the advertisement to be "one of naked commercialism aimed at attracting patients ostensibly by providing less expensive services than that provided by other dentists."[56] In finding Weel's advertisement to be "misleading and disparaging of the services provided by other dentists," the court rejected any contemplation of constitutional protection as commercial or professional speech.[57] Adopting this approach, it is submitted that commercial speech that fails to disclose known harms should also be considered misleading and deceptive.[58]

4. Conclusion

Undoubtedly, freedom of commercial expression, captured in the freedom of expression provisions of the Constitutions of Barbados and Jamaica, is not absolute. It may be subject to certain limitations, including limitations in the interest of public health. The growing body of evidence of the efficacy of marketing bans and further, of an integrated package of measures, provides a solid foundation on which to craft public health policies that incorporate these measures. Based on the similar approach of the Barbadian and Jamaican courts to the interpretation of limitations on freedom of expression, albeit dealing with textually different provisions, it seems likely that appropriately designed public health policies would be able to withstand judicial scrutiny, should the issue arise. Indeed, evidence will play a critical role in making these determinations. However, so too should the binding obligations on these Caribbean states to respect, protect and fulfil human rights and related features, such as the best interest of the child. In this regard, close-knit Caribbean jurisdictions should design robust conflict of interest policies to safeguard the entire regulatory process and manage risks of corporate capture by those whose freedoms must inevitably be limited for public health.

DETAILS

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Restricting Unhealthy Food and Beverage Advertising in Brazil: Challenges and Opportunities

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ABSTRACT (ENGLISH)

In Brazil, the normative landscape around advertising is complex, not the least because of limitations inherent to dispute resolution mechanisms. Focusing on unhealthy food and beverages, this case study identifies some challenges and opportunities around advertising restrictions, including in relation to freedom of speech.

FULL TEXT

Over the years, the advertising of unhealthy food and beverages has become the object of legal debate in Brazil. On the one hand, civil society has developed tools to identify ads deemed to be misleading or abusive, including the Observatory of Food Advertisement, a platform that allows for such ads to be reported by the public and analyzed by legal teams, eventually leading to proceedings filed before administrative or judicial bodies.[1] Their premise is that the food and beverage industry frequently engages in advertising that infringes on existing laws and regulations, and —most importantly —that it must be held accountable by third parties. On the other hand, the food and beverage industry has participated in campaigns of responsible advertising, such as *Take responsible advertising seriously*,[2] a series of posts in social media aimed at corporations launched in partnership with, among others, advertisers and trademark associations.[3] They rely on the premise that companies are capable of holding themselves to high standards.

These opposing narratives are best exemplified by the issue of advertising to children, including but not limited to food and beverages. Civil society has repeatedly stated that advertising to children is necessarily abusive and therefore illegal, pointing to decisions issued by judges of the Superior Tribunal of Justice (hereinafter STJ) —the highest court for federal law interpretation in Brazil.[4] By contrast, the Advertisers Association has openly questioned this position, recently issuing guidelines on *Responsible Marketing: Safeguards and Limits of Advertising to Children* , where they argue that advertising to children is not necessarily abusive and that the specific situations in which children get taken advantage of should be assessed on a case-by-case basis.[5] Setting aside this normative discussion, advertisement to children, including of unhealthy food and beverages, is still common in Brazil.[6]

From the legal standpoint, the dynamics of unhealthy food and beverage advertising in Brazil is both a product of, and results in, structural challenges worth noting. First, identifying, reporting and eventually litigating unlawful ads is a lengthy and cumbersome process that demands considerable resources. By the time this process concludes, even if corporations are ordered to take down the ad in question and/or to pay a fine, airing it may still have been profitable. Second, the cases that make it to court can lead to relevant —even landmark —decisions, but these do not always carry the same weight as precedents would in common law countries.[7] In this sense, every ad identified, reported and challenged before a court of law does not necessarily prevent other potentially unlawful ads, which might then need to undergo the same process, leading to a whack-a-mole situation that can prove extremely costly for society.

This case study seeks to identify and analyze some challenges and opportunities relevant to the debate around advertising restrictions in Brazil, focusing specifically on the advertising of unhealthy food and beverages. We start with a brief overview of the legal framework on free speech and advertisement, with an emphasis on legislation, as opposed to all normative acts, exploring only select provisions of the Brazilian Constitution and the Consumer Protection Code. We then analyze existing dispute resolution mechanisms, exploring specifically the shortcomings of self-regulation by the National Council of Advertisement Self-Regulation (hereinafter CONAR) and landmark court decisions. Finally, we discuss one recent state law, with potential to increase the protection of public health in primary schools, which was recently questioned in court on the grounds of free commercial speech.
This case study seeks to identify and analyze some challenges and opportunities relevant to the debate around advertising restrictions in Brazil, focusing specifically on the advertising of unhealthy food and beverages. We start with a brief overview of the legal framework on free speech and advertisement, with an emphasis on legislation, as opposed to all normative acts, exploring only select provisions of the Brazilian Constitution and the Consumer Protection Code. We then analyze existing dispute resolution mechanisms, exploring specifically the shortcomings of self-regulation by the National Council of Advertisement Self-Regulation (hereinafter CONAR) and landmark court decisions. Finally, we discuss one recent state law, with potential to increase the protection of public health in primary schools, which was recently questioned in court on the grounds of free commercial speech.

Brief Overview of the Normative Landscape

The adoption of the Constitution of 1988, which re-established democracy following the military dictatorship in Brazil, and the enactment of the Consumer Protection Code in 1990, set important limits to advertising.

The Constitution establishes freedom of expression as a fundamental right, protecting the free expression of thoughts (article 5, IV) and of intellectual, artistic, scientific and communications activities regardless of censorship or licensing (article 5, IX). Regarding advertisement, the Constitution lays the foundation for its restriction by establishing that “it is within the competence of federal law to: (…) establish legal means which afford persons and families the possibility of defending themselves against (…) the advertising of products, practices, and services which may be harmful to health or to the environment” (article 220, §3, II). More specifically, it states that “the advertising of tobacco, alcoholic beverages, pesticides, medicines and therapies shall be subject to legal restrictions (…) and shall contain, whenever necessary, a warning concerning the damages which may be caused by their use” (article 220, §4).[8]

Law No. 9.294 in 1996 fleshed out the constitutional provision on advertising. In particular, it defined the time period when the advertisement of alcoholic beverages and tobacco could be aired in radio and television, as well as set rules on the creation of an advertising piece, including, for example, restrictions on associating cigarettes and alcoholic beverages with sports and suggesting that tobacco products have calming or stimulating properties.[9] In 2011, this law underwent an important reform that prohibited “the commercial advertising of cigarettes, cigarillos, cigars, pipes or any other smoking product, derived from tobacco or not.”[10] To date, however, no specific federal law has yet implemented article 220, §3, II of the Constitution, and thereby given “persons and families the possibility of defending themselves against (…) the advertising of products, practices and services which may be harmful to health or to the environment.”

The Consumer Protection Code also contains important provisions related to advertising, especially the prohibition of “all misleading or abusive advertisement” (article 37).[11] In order for advertisement to be considered misleading, the information conveyed needs to be fully or partially false or withhold essential information, inducing consumers to make a mistake.[12] In turn, abusive advertising is essentially anti-ethical advertising that preys upon consumers’ vulnerability and goes against basic social values, harming society as a whole.[13] The general ban on misleading and abusive advertising has been particularly relevant in the context of unhealthy food and beverages due to the fact that, unlike tobacco and alcohol, there is no specific federal law restricting their advertising.[14] However, as institutional communications by the STJ itself show, the limits of advertising in relation to consumer protection are not always clear, leading to constant disputes that need to be resolved.[15]

Confronting Limitations in Dispute Resolution

The prevailing model of dispute resolution has long centered on CONAR,[16] charged with applying the Brazilian Self-Regulation Advertising Code.[17] This model was adopted in the mid-1970s in a context of mistrust of government agencies —particularly in relation to limitations to free speech —during the military dictatorship (1964-1985).[18]

To this day, the self-regulatory model is in force and provides that complaints against misleading or abusive advertising must be assessed by CONAR's Council of Ethics. The Council of Ethics conducts this assessment when prompted, necessarily after the circulation of the advertising piece in question. If the advertising piece is considered not to have violated the rules of the Brazilian Self-Regulation Advertising Code, the Council of Ethics can dismiss the complaint. If the advertising piece is instead considered to have violated those rules, the Council of Ethics can recommend the suspension or modification of the advertising piece, or issue a mere warning to the advertisers behind it. Notably, it cannot issue fines to the advertisers, although in any case fines could fall short of disincentivizing companies from airing ads that are expected to be highly profitable.[19]

Self-regulation by CONAR presents considerable problems of both procedural and substantive nature. On the procedural side, CONAR's governance rules clearly favor advertisers over consumers, consumer associations and consumer protection entities.[20] For instance, despite governance rules setting aside space in the Council of Ethics for civil society representatives, the selection of such representatives is done by CONAR's Superior Council, which is in turn made up by representatives of CONAR's founding members, who are all connected to the advertising industry.[21] Finally, the volume of cases considered by CONAR is arguably small in a country of continental proportions with massive investment in advertising:[22] according to data found on CONAR's website, the average is 236 cases per year.[23]

On the substantive side, CONAR openly frames its mission in defense of free commercial speech; including the "promot[ion of] free speech in advertising and [the] defen[se of] the constitutional prerogatives of… advertising."[24] This sets the tone of their reasoning in decision-making. For example, in 2011 CONAR dismissed a complaint by Alana, a non-governmental organization, about a McDonald's ad exhibited during the trailer of animated film "Rio."[25] In the decision, the rapporteur of the case portrayed Alana as a witch who hates children, stating that "[w]hen the witch Alana comes into scene, children live on bread and water… [N]o more cheeseburgers, fries, milkshake or soda." They went on to frame the complaint as part of a broader strategy of demonizing advertising to ideologically control children.[26] In response, Alana said it no longer recognized CONAR as a serious entity to safeguard ethics in advertising due to the open mockery displayed in this decision.[27]

The judiciary can also exert control over advertising to the extent that it potentially violates relevant laws and regulations, including the Consumer Protection Code. For example, at the state level, the court of appeals of São Paulo ruled that McDonald's engaged in abusive and therefore unlawful advertising to children by holding Ronald McDonald concerts —which they framed as educational —in nurseries and primary schools, both public and private. The lawsuit had been filed by the Public Defender's Office in São Paulo, following reports to government entities.[28]

At the national level, two decisions issued by judges in the STJ are especially relevant. In March 2016, the 2nd Chamber upheld the conviction of a food company for the "Time for Shrek" marketing campaign, which targeted children by using the well-known animated character. Upon the purchase of five cookies of the brand, plus a payment of R$ 5.00, the consumer could receive a Shrek watch. The judges in the STJ found that the marketing campaign was abusive because it aimed, directly or indirectly, at children, in addition to other arguments.[29] In April 2017, the 2nd Chamber of the STJ considered a similar advertising campaign, known as "Sadia Mascots." Upon the purchase of five products of the same brand, plus a payment of R$ 3.00, the consumer could receive a collectible stuffed animal, the company mascot. Though the product here —frozen food —was meant for an adult audience, the judges concluded that the kind of prize indicated that the marketing campaign targeted children and was therefore abusive and unlawful.[30]

These are landmark decisions for consumer protection, but ultimately their legal effects are limited to the concrete cases considered, meaning that despite their persuasive power they may or may not be followed by the other judges adjudicating over similar cases across the country.[31] The food and beverage industry has already taken advantage of this characteristic of the legal system in Brazil. For example, when the National Agency of Health Surveillance

issued Resolution 24 in 2010 —a binding normative act of lower rank than legislation —restricting the advertisement of unhealthy food and beverages, multiple associations from the private sector questioned it in court, filing diffuse actions across different jurisdictions that led to conflicting decisions. The issue is yet to be definitively resolved by high courts.[32]

Taking advertising to children as an example again, the fact that the industry continues to push the legal narrative that it is not necessarily abusive[33] —irrespective of these recent rulings by judges in the STJ —signals that they are likely to continue such practices. The situation is ever more complex in the context of unhealthy food and beverages, in the absence of specific federal laws limiting advertising. In the end, the broader the legislation, such as general bans on misleading and abusive advertising, the greater the leeway for decision-makers across the judiciary to ascertain their sometimes-conflicting views.

Considering Emerging Opportunities for the Limitation of Commercial Speech

Attempts to adopt specific federal laws regulating the advertisement of unhealthy food and beverages have not yet been successful in Brazil, despite the introduction of several bills in Congress that moved past the general prohibition of misleading and abusive advertising.[34] In general, these initiatives tend to face strong resistance from both the advertising industry and the food and beverage industry, who have argued in the past that such limitation violates freedom of commercial speech among other arguments.[35]

In March 2021, the Supreme Federal Tribunal (hereinafter STF) —the highest constitutional court in Brazil —upheld State Law No. 13.582 of 2016, as amended by State Law No. 14.045 of 2018, which prohibits commercial communication to children in primary schools in the state of Bahia.[36] State Law No. 14.045 significantly altered the content of State Law No. 13.582. Before the reform, Law No. 13.582 prohibited the advertisement of unhealthy food and beverages aimed at children on radio and television at certain times, as well as in schools at all times. Since the reform, Law No. 13.582 prohibits not only the advertisement of unhealthy food and beverages, but all commercial communication to children, though this prohibition is now limited to primary schools.[37]

The constitutionality of this law was questioned in the STF by the Association of Radio and Television Networks, based in part on the alleged violation of the freedom of commercial speech. In the ruling, the judges indicated that advertising “instrumentalizes free enterprise under commercial speech,”[38] and unanimously held that (i) commercial speech is included in freedom of speech; (ii) freedom of speech is not absolute and can therefore be subject to restrictions; and (iii) restrictions must be proportionate. Though the decision did not lay out a detailed roadmap for the assessment of proportionality, it did list some factors that had shaped their analysis, namely the scope of the ban (commercial communication to children, primary schools). However, the judges did not analyze the nature of commercial speech in detail; for example, whether the protection granted to commercial speech rises to the same level of non-commercial speech.[39]

The STF also touched upon other relevant points. Importantly, it clarified that the advertising restrictions listed in the Constitution under article 220, §4º are not exhaustive, but rather constitute a list of examples. In other words, by enumerating tobacco, alcoholic beverages, pesticides, medicines and therapies, the Constitution merely illustrated one possible pathway to the restriction of the freedom of commercial speech, in order to promote or protect other fundamental rights, including health —framed not only as an individual’s right, but also as the State’s duty, and one of utmost priority. In particular, the STF stressed the role of government in leading the control of unhealthy food and beverage advertising, relying on recommendations issued by the World Health Organization.[40] This indicates that health considerations can be paramount in the analysis of advertising restrictions.

Overall, this decision paves the way for other states to pass legislation restricting commercial communication in primary schools, given that it weakens probable legal arguments grounded on the freedom of commercial speech, provided that the measures restricting advertising —including that of unhealthy food and beverages —are proportionate. Most importantly, even if at the state level, laws like the one in Bahia are relevant because they move the needle from more general to more specific regulation of advertising, leaving less (though far from non-existent) room for interpretation in a context of potentially widespread litigation, as described above.

Conclusion

In Brazil, the normative landscape around advertising is complex, not so much due to the lack of applicable norms, but rather to the limitations inherent to dispute resolution mechanisms. The Constitution and existing legislation, not least the Consumer Protection Code, already impose restrictions on advertising. In particular, misleading and abusive unhealthy food and beverage advertising is prohibited. However, in the judiciary, there are structural difficulties related to the limited effects of some high-court decisions that interpret these general provisions. In this sense, more specific laws like the one in the state of Bahia can be strategic in moving forward with protecting public health —not least because it confronts the argument of free commercial speech in relation to other fundamental rights in the context of advertising restrictions, possibly setting an example for other states in the country.

DETAILS

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Commercial Speech and the Prohibition of Tobacco Advertising: The Colombian Constitutional Court Approach

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ABSTRACT (ENGLISH)

This article argues that the decision by the Columbian high court to totally ban the advertising and promotion of tobacco products is sound and could indeed be applied to other types of harmful products.

FULL TEXT

In 2010, the Constitutional Court of Colombia ("the Constitutional Court") issued the decision C–830/2010 declaring that the total ban of advertising and promotion of tobacco products enacted by Law 1335 of 2009 (Law 1335) was constitutional.[1] In line with the World Health Organization Framework Convention for Tobacco Control (FCTC), Law 1335 establishes provisions aimed at discouraging the use of tobacco, such as the ban on its advertising and promotion or the prohibition of its consumption in closed spaces, as well as measures aimed at protecting children and the non-smoker population from tobacco's harmful effects.

The decision was issued after a Colombian citizen, Pablo Cáceres Corrales (the plaintiff) filed a petition to the Constitutional Court asking to declare articles 14, 15, 16, and 17 of Law 1335 as unconstitutional. The Colombian

legal system allows any citizen to file actions before the Constitutional Court in order to obtain an abstract judicial review on the constitutionality of any statute or provision of any statute enacted by Congress.[2] Both, procedural and substantive arguments can be presented to support the petition. To challenge statutes under procedural grounds, the petition must be presented within a year after their official publication. If it is declared unconstitutional on procedural grounds, the content of the statute can be enacted again. On the contrary, substantive challenges to statutes can be raised at anytime, subject to the limitation of *res judicata*.[3] Decisions declaring a statute or some provisions of a statute as unconstitutional have general effects and prohibit Congress from enacting the same statute or provision in the future.

As the plaintiff's arguments were related to substantive matters, decision C-830/2010 declaring the constitutionality of the total ban of promotion and advertising on tobacco products is of major importance. Because it confirms that such prohibition is compatible with the constitutional framework, this declaration has general effects and limits the nature and scope of potential future challenges related to these issues.

Importantly, in this piece we argue the relevance of this decision is not limited to the specific context of tobacco. Several reasons call for an expanded analysis of decision C - 830/2010. One is that the Constitutional Court framed the case in the broader context of the role of the State in the regulation of the economy and the margin for interventions when public, general and social interests are at stake. Furthermore, although the Constitutional Court takes into consideration the international obligations imposed by the FCTC to strengthen its analysis, the main contents of the reasoning are not necessarily tied to the existence of such instrument. In fact, the Constitutional Court based its analysis on previous cases dealing with a wide variety of State interventions in the field of economics where the type of reasoning and the specific test used by the Constitutional Court is applicable, in general, to interventions beyond the context of tobacco as well as to other types of marketing bans and restrictions. Based on this premise, in Section 1 we summarize the reasoning of the Constitutional Court and in Section 2 we propose an analytical framework to explore the applicability of such reasoning to other bans or restrictions on advertising of other unhealthy commodities.

1. The Double Function of Advertising and the Constitutionality of its Total Ban Regarding Tobacco Products

The plaintiff's main argument claimed that the prohibition of promotion and advertising of tobacco products was unconstitutional because it violated the free private initiative and freedom of enterprise, both protected under the Colombian Constitution. According to the plaintiff, if producing and selling tobacco products is legal, the promotion of such products should also be legal.

In this piece we argue the relevance of this decision is not limited to the specific context of tobacco. Several reasons call for an expanded analysis of decision C - 830/2010. One is that the Constitutional Court framed the case in the broader context of the role of the State in the regulation of the economy and the margin for interventions when public, general and social interests are at stake. Furthermore, although the Constitutional Court takes into consideration the international obligations imposed by the FCTC to strengthen its analysis, the main contents of the reasoning are not necessarily tied to the existence of such instrument.

However, the Constitutional Court seized the opportunity to develop a more comprehensive analysis of the potential tensions between the impugned prohibition and the Constitution, examining them from the lens of free private initiative and freedom of enterprise and from the consumers rights perspective and freedom of expression. The double function of commercial advertising was crucial in the Constitutional Court's determination of the nature and scope of the three levels of tensions with constitutional rights and values. This approach was fundamental to the Court's findings on the intensity of the judicial scrutiny of the prohibition on advertising of these products.

With regards to the double function of advertising, the Constitutional Court noted: one function is to incentivize the consumption of the advertised products, and the other function is to provide information to consumers. In other words, commercial advertising can aim both to persuade and inform. Based on this distinction, the Constitutional Court established that the persuasive component could only be in tension with economic freedoms. At the same time, the informative component also related to consumers' rights could be in tension with the right to freedom of expression and information. However, the Constitutional Court was explicit in framing the latter tension as

“exceptional and restrictive” compared with the protection of other types of speech.

The Analysis of the Advertisement Prohibition under Economic Freedoms

Regarding the persuasive function of advertising, the Constitutional Court established that restrictions on economic liberties are constitutional if they are established by law, do not affect the essential core of freedom of enterprise, are grounded in adequate and sufficient reasons, are compatible with the principle of solidarity and are proportionate and reasonable. The level of proportionality and reasonableness scrutiny in this context is “weak,” a standard similar to a rational basis test. Therefore, for a restriction to pass such scrutiny it is required that the purpose of the measure is not prohibited under the Constitution, and the measure is both potentially adequate for achieving its intended objective and is not patently unnecessary or disproportionate.

In its analysis, the Constitutional Court first stated that the essential core of freedom of enterprise is to produce goods and services and the possibility to commercialize them in the market. The Constitutional Court considered that the prohibition on advertising has no impact nor creates barriers on either core component.

The Constitutional Court noted that it had identified the objective of discouraging the consumption of tobacco products as legitimate and stemming from the right to the enjoyment of the highest attainable level of health in previous decisions. Furthermore, the Constitutional Court considered the global consensus that tobacco use and exposure to tobacco smoke cause mortality, morbidity, and disabilities, as well as the evidence showing that tobacco products were carefully designed to create dependence.

Regarding the proportionality and reasonableness of the measure, and considering the documented link between advertising, promotion, and sponsorship of tobacco products and its increased consumption, the Constitutional Court found the measure suitable to achieve its purpose. The Constitutional Court also recalled that under the weak level of scrutiny applicable to this matter, the aim–means causal relation only needs to be reasonable and no demonstration of the actual achievement of the aim is required.

Moreover, the Constitutional Court expressed that the total ban on advertising of tobacco products was directly proportional to its negative impact on constitutional values. Bearing in mind the devastating effects of tobacco consumption, an intense intervention such as a complete prohibition of advertising and promotion was determined to be admissible. The Constitutional Court reinforced this determination by referring to international law, particularly focusing on the FCTC and its interpretive guidance. Specifically, it emphasized that a full ban on advertising has been recognized by these instruments as the most effective way to discourage tobacco consumption.

Furthermore, the Constitutional Court concluded that the measure was compatible with the principle of solidarity, as the protection of public health and the environment are objectives of great importance. The Colombian constitutional framework allows for the production and commercialization of tobacco products, that are intrinsically hazardous to physical integrity and to the environment, but strongly restricts the direct and indirect promotion of their consumption, aiming at discouraging it rather than prohibiting it. It is possible, under the constitutional framework, that a licit commercial activity be disincentivized by the State based on general interests such as public health and others.[4] This approach was framed by the Constitutional Court as the creation of a passive market scheme in which these activities were tolerated but not encouraged by the State. Moreover, they can be discouraged with restrictions and even more intense interventions such as total prohibitions.

The Analysis of the Advertisement Prohibition Under Consumer Rights and Freedom of Expression and Information

The previous analysis dealt with the persuasive component of advertising. Regarding the informative component, the Constitutional Court established that the total ban on advertising did not affect such component of commercial speech. To reach this conclusion, the Constitutional Court distinguished tobacco from other goods and services, emphasizing that it is “intrinsic[ally] harmful” to health and the environment. Specifically, the Constitutional Court ruled that the informative component of commercial speech that is constitutionally protected under “consumer rights” is the provision of information to the consumer related to the harms or risks of harm of the product. This aspect was not affected by the prohibition. Moreover, the Constitutional Court stated that the legislator had already established mechanisms to guarantee consumers’ right to access information about tobacco products and the harmful consequences of use, supporting the conclusion that a total ban on advertising did not affect such right.

The other potential tension the Constitutional Court identified concerning the informative function of commercial advertising relates to freedom of expression and information. The Constitutional Court considered that commercial advertising was granted restrictive and exceptional protection under such a fundamental right. Two main arguments support this differentiated —and certainly weaker —protection of commercial advertising.

On the one hand, that an equal degree of protection should be granted is not consistent or does not adequately acknowledge the integrality of the relevant constitutional contents that have a bearing on the degree of protection of commercial advertising. Therefore, the standards of analysis applicable to economic freedoms and consumer rights are also determinant and affect the degree of protection. In other words, the constitutionality of the State intervention in commercial advertising must be determined based on the rules applicable to the different constitutional contents affected.

On the other hand, the Constitutional Court highlighted that the informative component of commercial advertising was not related to political participation or democratic deliberation. Consequently, such speech was not protected at the same level of other manifestations of information and ideas. In this sense, the State has the power to impose restrictions that will be valid from a constitutional point of view if the objective pursued is legitimate in relation to the State function as director of the economy and/or its duty to protect consumer rights, and if the measure is proportionate and reasonable.

In the next section, we will examine whether the Court's reasoning concerning the dual dimensions of advertising could apply to other unhealthy products, as well as the challenges that such extrapolation could raise from a constitutional perspective.

2. Bans on Advertising of Unhealthy Products Beyond Tobacco

Like tobacco products, several studies have widely documented the link between the consumption of other unhealthy products, such as alcohol or unhealthy foods and beverages, with the development of adverse health, economic, societal, and environmental outcomes.[5] Furthermore, public health authorities and human rights bodies have called for the adoption of measures to discourage the consumption of unhealthy products, including restrictions to advertising.[6] In this context, it is relevant to examine whether the Constitutional Court's reasoning in the C-830/10 decision, could be applicable —and, if so, to what extent —to similar bans in relation to other unhealthy products.

According to decision C-830/10, advertising plays an essential role in incentivizing the consumption of a given product, which is exclusively protected under the freedom of enterprise. Therefore, in general, the constitutional framework considers admissible strong restrictions and even bans on advertising if the measure does not pursue a prohibited objective and the measure chosen to achieve such end is reasonable and not patently disproportionate.

Following the reasoning of the Constitutional Court, a ban on advertising unhealthy products, is not considered to affect the essential core of freedom of enterprise. A ban on advertising unhealthy products does not amount to a prohibition of manufacturing or selling them on the market. These are the two main components of the essential core of the freedom of enterprise. Consequently, States enjoy a wide permissible margin to intervene in economic freedoms provided such essential core is not affected, including adopting bans and restrictions to advertising. Based on this logic, legal challenges to those interventions based on the impact to the core of freedom of enterprise would have to demonstrate exactly how the intervention prevents production or commercialization.

As to the potential legitimacy of the aim pursued, the reasoning of decision C–830/10 can be easily expanded to other unhealthy products. As previously mentioned, it has been widely documented that consumption of unhealthy foods and drinks, and the harmful use of alcohol, have negative impacts on health and in society. It may be argued that States have a legitimate interest in discouraging consumption of unhealthy foods or use of alcohol to protect constitutional rights and public health and must adopt measures to achieve that purpose. Therefore, a restriction or ban on advertising unhealthy products could be considered as pursuing a constitutionally valid objective.

The next step would be to assess the suitability of the measure, that is, the reasonableness between the means selected and the purpose. Considering advertising operates as an economic instrument to increase the consumption of unhealthy products and expand the markets for these products, a ban on advertising could potentially be suitable and an effective way to discourage the consumption of such products.

However, it could be argued that a total ban is the most radical measure and that the State could have chosen a less restrictive measure to achieve its goals. In the context of Colombia, where economic freedoms are combined with a relevant power and duty of the State to regulate the economy, the proportionality analysis of the interventions is weak or similar to a mere rational basis analysis that does not include a necessity or less restrictive alternative test. Therefore, the evidence on the relation between consumption of unhealthy products and advertising would suffice for this level of scrutiny. However, the proportionality analysis could differ among diverse types of unhealthy products and consider different types of interventions on advertising, ranging from total bans to other types of restrictions.

The final step of the Constitutional Court's analysis requires assessing the compatibility of a ban on advertising other unhealthy products with the principle of solidarity. As the objectives to be achieved through the ban are of analogous importance to the ones pursued in the context of tobacco, it could be argued that a ban or other restrictions could be compatible with this principle.

Although, at this point it could be concluded that the considerations of the decision C–830/10 can be extended to bans or restrictions to advertising of other types of unhealthy products, it is necessary to study the compatibility of such an intervention from the point of view of the informative role of advertising. As mentioned before, this other function of advertising can be analyzed for other constitutional contents, specifically, freedoms of expression and information and consumer rights.

The Court's reasoning regarding the informative dimension of advertising is based on the understanding that tobacco is an intrinsically harmful product. A significant challenge to this approach when extended to other unhealthy products is that not every unhealthy product, particularly when it comes to food, can be considered intrinsically harmful to health. Even if tobacco and other unhealthy commodities create adverse individual, social and environmental outcomes, the available information regarding the potential of such products to be harmful is less consistent across products.

Additionally, the intrinsically harmful nature of tobacco allowed the Constitutional Court to conclude that the only information that could be furnished through advertising of this product was on the damages its use produced. Considering that regulations on labelling and packaging already include such information, the Constitutional Court concluded that a total ban on advertising of tobacco products did not impact consumers rights.

In contrast, to make informed decisions, consumers purchasing unhealthy products —that are not necessarily intrinsically harmful —have a legitimate interest in accessing information other than on the harms the product could cause. For example, the geographical origin of a product, the type of production (industrial, artisanal, organic, agroecological), the content (allergens, raw material), among other factors, can be considered as relevant information to consumers.

To assess if a restriction or prohibition on advertising of other unhealthy products is constitutional from the point of view of providing information, other variables, beyond economic liberties, should be considered. An analysis on whether the restrictions or prohibitions impact consumer rights may include a study of the legislative and regulatory framework related to the provision of information beyond the risks associated with consumption. Such an analysis would determine to what extent the ban or restriction impacts the consumers' interest in making informed decisions. Thus, in assessing the proportionality of the measure, the State's behavior in complying with its duty to adopt measures to protect and guarantee the right to information of consumers could have a crucial role.[7] Whether the regulatory framework promotes consumers' full access to relevant information will vary according to the unhealthy product in question. However, if advertising is the only or a key channel to access information regarding specific types or products, and there is no substitute for access to such information, the elimination of this source of information could have a disproportionate impact on consumers' rights. Still, other restrictions different from total bans can be considered in these cases.

3. Conclusion

Decision C-830/10 opens the door to consider bans or other restrictions on advertising unhealthy products, beyond tobacco, as constitutionally valid. It also reflects the relevant role that the State plays in regulating the economy.

A ban on advertising of these products could be considered constitutionally valid from the persuasive dimension of advertising standpoint. However, when it comes to the informative dimension of advertising, other factual and normative variables need to be considered. This includes an analysis of the scope and level of protection for consumer rights and freedom of speech and information in a specific legal system.
Moreover, extending the Constitutional Court's reasoning to other constitutional frameworks that are less open to State interventions in the economy could benefit from a stronger and more robust emphasis on these measures not only as admissible interventions in the economy, but as means to comply with human rights obligations in the face of private activities that interfere with the realization and enjoyment of such rights.

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The Right to Free Commercial Speech in South Africa and its Tension with Public Health Interventions

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ABSTRACT (ENGLISH)

Marketing restrictions to promote public health invoke competing rights, including the right to free commercial speech which for-profit entities use to protect their freedom to market products without undue regulation. The right to free commercial speech in South Africa has been developed through case law since the adoption of the first democratic constitution in South Africa in 1996. This article examines the impact of this recent judgment and the lessons for policy makers to ensure effective regulation of marketing practices in South Africa.

FULL TEXT

1. Introduction

In 1994, South Africa became a democratic country which moved from a racist apartheid government to a constitutional democracy based on principles of, *inter alia*, equality. This had two major impacts on local markets: a large section of the South African population started to be reintegrated in the formal economy both as consumers and as earning members of the labour force, and trade sanctions were lifted allowing global companies to enter the South African market.[1] Over the past two decades, industries producing unhealthy commodities, including food and

beverages, experienced significant changes in commercial practice, including increases in foreign direct investments.[2] Marketing practices adopted by industries producing unhealthy commodities have been linked to changes in consumer behavior and often, poorer health outcomes.[3]

In 2020, the government of South Africa proposed that increased restrictions to the marketing of unhealthy products including alcohol and unhealthy foods and beverages, to children should form part of its communications policy.[4] Previously restrictions on marketing of tobacco products were challenged by the industry as violating the right to freedom of expression. These restrictions are in tension with the right to freedom of expression and more specifically the right to free commercial speech.[5] This case study will explore the protection given to commercial speech in South Africa through a chronological exposition of case law in the South African superior courts. It will discuss three cases which note a progression in the understanding of how commercial speech can be limited to protect other rights. Finally, it will discuss a 2021 judgment which is discordant with other case law and risks promoting commercial speech over the protection of the rights of members of the South African public.

2. Relevant Legal Context

The South African Constitution includes a right to free speech in the form of a right to freedom of expression which provides that:

Everyone has the right to freedom of expression, which includes —

- (a) freedom of the press and other media;
- (b) freedom to receive or impart information or ideas;
- (c) freedom of artistic creativity; and
- (d) academic freedom and freedom of scientific research.[6]

In addition to the public health purpose the restrictions serve, the Constitution also protects a number of rights implicated in public health such as the rights to human dignity, life, a safe environment, access to health care services and nutrition, and certain protections extended to children such as the guarantee to access basic nutrition and health care services, and are generally invoked in analyzing the proportionality of a limitation where a public health intervention is at tension with other rights.

This right has been expanded to include the protection of commercial speech, including advertising.[7] The right to freedom of expression is subject to two types of limitations: an internal limitation contained in section 16 and the general limitations clause in section 36 of the Constitution. Section 16(2) contains an internal limitation which excludes propaganda of war, incitement of imminent violence or hate speech from constitutional protection.[8] This internal limitation does not include or apply to general commercial speech. Speech that is protected under section 16(1) may still be limited through the general limitation clause under section 36 which allows for any rights in the Constitution to be limited if certain criteria are met.[9] These criteria are assessed through the use of a flexible proportionality test, succinctly summarized as follows:

“[L]imitations on constitutional rights can pass constitutional muster only if the Court concludes that, considering the nature and importance of the right and the extent to which it is limited, such limitation is justified in relation to the purpose, importance and effect of the provision which results in this limitation, taking into account the availability of less restrictive means to achieve this purpose.”[10]

The purpose behind the limitation of a given right has some bearing on whether the limitation can be justified. In this regard, the impact the limitation may have on the protection or fulfillment of other rights may assist in justifying the limitation. This is where the interaction between commercial speech and these efforts aimed at promoting public health can clash is with the advertisements of unhealthy commodities, such as tobacco, alcohol and unhealthy food

and beverages.

In addition to the public health purpose the restrictions serve, the Constitution also protects a number of rights implicated in public health such as the rights to human dignity,[11] life,[12] a safe environment,[13] access to health care services and nutrition,[14] and certain protections extended to children such as the guarantee to access basic nutrition and health care services, [15] and are generally invoked in analyzing the proportionality of a limitation where a public health intervention is at tension with other rights.[16]

3. Progression of Limitation to Commercial Speech

South Africa contains a range of commodity specific interventions related to marketing restrictions. This measures include limits to the marketing of specific categories of products adopted through legislation such as the Liquor Act,[17] Tobacco Products Control Act,[18] and Foodstuffs, Cosmetics and Disinfectant Act.[19] However, the primary content regulator of marketing practices in South Africa is the Advertising Regulatory Board (ARB) which is a voluntary body that administers the Advertising Code of Practice.[20] There has also been litigation concerning the tension between measures restricting commercial speech and the right to freedom of speech.

One of the first post-democracy cases on commercial speech in South Africa was *City of Cape Town v Ad Outpost* where the validity of by-laws which contained a very broad restriction on outdoor advertising to protect the environmental aesthetic of the City of Cape Town was challenged in the Cape High Court.[21] The applicants successfully relied on the protection of commercial speech enshrined under the constitutional right to freedom of speech. The Judge was very critical of submissions by the City of Cape Town that commercial speech requires less protection than other forms of speech, stating that:

The tendency to conclude uncritically that commercial expression bears less constitutional recognition than political or artistic speech needs to be evaluated carefully. So much speech is by its very nature directed towards persuading the listener to act in a particular manner that artificially created divisions between the value of different forms of speech requires critical scrutiny. Whatever the role of such speech within a deliberative democracy envisaged by our Constitution, it is clear that advertising falls within the nature of expression and hence stands to be protected in terms of s 16(1) of the Constitution. To the extent that its value may count for less than other forms of expressions, account of this exercise in valuation can only be taken at the limitation enquiry as envisaged in s 36 of the Constitution.[22]

This decision is one of the few to deal expressly with whether there ought to be a distinction between the protections afforded to commercial speech versus general speech.

The next case of significance was *British American Tobacco* case (hereafter “BATSA”) when the ban on advertising of tobacco products was introduced in 2008.[23] The tension between public health objectives and limitations on commercial speech was the central issue in both the High Court and the Supreme Court of Appeal (SCA) though we discuss the SCA decision. In BATSA, the SCA was asked to declare sections of local legislation which prohibited the advertisement of tobacco products as a violation of section 16 of the Constitution.[24] The industry contended that that the ban was an unjustifiable limitation of the right to freedom of expression because it was a blanket ban and was overly restrictive in limiting advertising to existing smokers.[25] Though the SCA did not disagree with the statements made on commercial speech in the *Ad Outpost* case, instead the Court tempered the protections afforded to commercial speech where the products caused harm, stating:

When commercial expression is used …for the purpose of inducing people to engage in harmful and addictive behaviour, its value becomes tenuous.[26]

The SCA engaged in a proportionality assessment considering whether the public health interests could serve to justify the limitation on commercial speech. The Court concluded that though commercial speech was worthy of

protection, this could not be at the cost of public health, stating:

The right to commercial speech in the context of this case is indeed important. But it is not absolute. When it is weighed up against the public health considerations that must necessarily have been considered when imposing the ban on advertising and promotion of tobacco products it must, I think, give way.[27]

This decision resulted in a strong statement that public health considerations could outweigh the protections afforded to commercial speech, particularly where the products being marketed were harmful.

Thirdly, in *Herbex* —which was ultimately settled out of court —a producer of weight loss products (termed complimentary medicines) was subject to an adverse finding by the Advertising Standards Authority, the precursor to the ARB (ASA) due to breaches of the South African Code of Advertising Practice. The company was not a member of the ARB and therefore challenged the finding in court based on the ASA's lack of jurisdiction over the company as a non-member. There was no reasoned judgment in this matter and instead the settlement between the ASA and the company was made an order of court. The agreement conceded that the ASA may not have direct jurisdiction over non-members but recognized that the ASA may communicate any finding on an advertisement to parties that are members (publishers) regardless of the origin of the advertisement.[28] Consequently, findings against non-members may still result in the restriction of certain advertisements. While this case does not inform the content of how commercial speech is to be interpreted, it provided the basis for more far-reaching interference —by a non-state actor —in commercial speech where marketing practices violates norms aimed at protecting certain social values.

4. Regression: The Bliss Case

The *Bliss* case followed *Herbex* and concerned a similar issue following the dissolution of the ASA and the creation of the ARB in its place. A company that was not a member of the ARB, challenged the use of the ARB's ad-alert —a mechanism where it communicates to its members that an advertisement by a non-member violates the Code of Advertising Practice, and therefore should decline to publish the advertisement.

The Court considered the oversight function over non-members of the ARB as an "indirect boycott."[29] The Court therefore relied on the applicants' right to trade rather than on freedom of speech.

It stated that the Advertising Code of Practice "being a self-imposed authority to regulate the standards of advertising in the public interest, does not justify the infringement of this foundational right [to trade]."[30] The Court then continues to provide that statutory mechanisms exist to oversee advertising in the absence of the ARB and that its lack of oversight does not lead to a regulatory gap.[31] It cites laws on intellectual property, as well as laws that regulate certain commodities (medicines, foodstuffs, tobacco). It also cited the South African Consumer Protection Act which prohibits misleading statements in marketing practices. The authors submit that the Court is mistaken in its understanding of the scope, content, and efficacy of these statutory measures. Amongst others, the ARB Code is the only mechanism to protect consumers from malpractices on social media such as undisclosed influencer marketing. There also exists no other mechanism to restrict unscrupulous marketing of products, especially unhealthy food and beverages, to children outside of the Food and Beverage Code operated by the ARB.

The Court, however, highlighted some legitimate concerns in relation to the structure of the ARB, the foremost being a concern over its perceived lack of independence. The judge cites a concern with the funding model of the ARB, stating that it is problematic due to members funding the organization where non-members, and therefore non-funders, might be impacted by decisions.[32] This understanding of the ARB's funding model is incorrect or perhaps insufficiently explained in the judgment —there are no membership fees and funding occurs on an ad hoc basis, but the authors submit that the *ad hoc* nature of the funding model is still sufficiently problematic to validate the Court's concern.

Overall, the Court declared operation of the Advertising Code of Practice to be unconstitutional in instances where a

non-member company's rights are implicated.[33] The case is pending appeal.

5. Analysis: The Treatment of Commercial Speech and Public Health in South Africa

The *Bliss* case resulted in a regression from the developments that had eroded and lessened freedom given to companies to engage in marketing practices without regulation. For example, in *BATSA*, the court, in reference to McDonald Corp case, went as far as rejecting the idea that a consumer opting into harmful behavior does not require a regulatory intervention to both protect the individual, as well as the society at large.[34] The Court's approach thus rejects an individual responsibility narrative as a work-around for policy intervention, as well as incorporating a more group-level assessment of the harm posed by the marketing activity. The Court's holistic reading of health-related rights and cognizance of the danger possible by commercial speech is very progressive. In contrast to this rights-responsive approach, the Court in *Bliss* narrowly formulated the type of content that requires regulatory oversight and formulates "public interest" as a competition issue (trade) only. The possible implications of limiting the ARBs powers on other rights were not considered at all.

The effect of the *Bliss* judgment is that South Africa has effectively removed the only independently-administered mechanism that can be employed to protect children from harmful marketing in general, and specifically with relation to unhealthy foods and beverages. The Court ignores the editorial freedom of publishing platforms to set standards to protect consumers —It allows for companies that face censure over marketing practices to simply withdraw its membership from the ARB. It raises the question whether or not publishers or broadcasters will be able to employ any form of discretion in choosing to decline commercial content it deems harmful, or if such exercise of discretion will also be deemed an "indirect boycott."

However, the Bliss judgment must also serve as a warning to policy makers to take steps to provide clear legal recognition to the ARB and to intervene to ensure its independence is guaranteed. Voluntary self-regulation does not have sufficient coercive power to be effective and a system of state or co-regulation is desirable to protect South Africans from the harms posed by certain forms of commercial speech.

6. Conclusion

The South African jurisprudence on the protection of commercial speech and its tension with public health objections has undergone considerable development over the past two decades. Initial decisions underscored the importance of freedom of speech, irrespective of its commercial status. This was followed by cases which underscored the importance of public health and the need to restrict commercial speech, particularly where health was implicated. Unfortunately, some of this progress has been undone in the more recent decision in the *Bliss* judgment and, as South Africa moves towards restricting marketing of unhealthy products, it is likely that this issue will once again come to the fore in the judicial system.

DETAILS

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Balancing the Scales: The Role of the Canadian Supreme Court in Weighing Commercial Speech and Public Health

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ABSTRACT (ENGLISH)

The Supreme Court of Canada has established that commercial speech is protected under the Canadian Charter of Rights and Freedoms and that commercial speech exists along a continuum of utility and value, which is balanced against objectives such as public health. This article examines jurisprudence to determine when infringements on commercial speech are acceptable, analyzing considerations of evidence, rational connections between policies and outcomes, proportionality, and minimal impairment.

FULL TEXT

Noncommunicable diseases (NCDs) impose significant human and economic costs on Canadians, with thousands of deaths per year and a large burden of disability attributable to NCDs, costing approximately $190 billion yearly.[1] These numbers are largely due to modifiable risk factors including tobacco consumption, alcohol use, and unhealthy diets, which has led the Canadian government to implement a range of regulatory measures such as health warning labels to reduce tobacco consumption and, most recently, to seek to implement front-of-package labeling (FOPL) and restrictions on advertising of unhealthy foods and beverages to children. However, as the Canadian government has moved towards addressing these modifiable risk factors, industries in the business of selling these unhealthy commodities have deployed their usual playbook to delay or challenge any potential regulation that could impact their profits.[2] One tactic has been to use legal avenues to prevent or delay regulations meant to protect the health of Canadians. In particular, corporate actors have increasingly argued that regulatory measures violate their constitutionally protected freedom of expression, as was seen when the Canadian Parliament sought to regulate tobacco advertising, first in the 90s and again in the early 2000s.[3] These challenges will likely continue as the Canadian government pursues measures to reduce the burden of NCDs.

This paper will examine the case law of the Supreme Court of Canada (hereinafter "the Court") on the relationship between freedom of expression —in particular commercial speech —and other societal objectives such as public health. After exploring the evolution of the constitutional protection of commercial speech under the *Canadian Charter of Rights and Freedoms* (hereinafter "*Charter*"), this paper's analysis focuses on the informational component of commercial speech as both the basis for its constitutional protection and how the Court has circumscribed protection of such speech. In particular, this paper seeks to highlight the roadmap the Court has laid for legislators, and to encourage the thoughtful design of public health regulations that both protect and improve the health of Canadians, as well as survive possible constitutional challenges.

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circumscribed protection of such speech. In particular, this paper seeks to highlight the roadmap the Court has laid for legislators, and to encourage the thoughtful design of public health regulations that both protect and improve the health of Canadians, as well as survive possible constitutional challenges.

Introduction to Freedom of Expression and Commercial Speech in Canada

In Canada, commercial speech is regulated by a variety of normative instruments issued by regulatory bodies, statutory provisions, and the *Charter* entrenched in the Canadian Constitution. The Canadian regulatory landscape is a complex patchwork, involving a range of public, private and judicial actors at both the provincial and federal levels, regulating not only the channels of commercial speech, but also the content of such speech and the audiences to which it can be directed.[4]

Where commercial speech in Canada is regulated by different actors and at different levels of government, the judiciary has played a critical role in determining if and to what extent commercial speech is protected under freedom of expression in the *Charter*.[5] In determining where commercial speech fits within the constitutional framework, Canadian courts have had to grapple with two fundamental questions. First, whether commercial speech, although not enumerated in the *Charter*, falls within the sphere of "freedom of thought, belief, opinion and expression" protected by s.2(b); and second, whether specific limitations on commercial speech imposed by Parliament are "reasonable limits prescribed by law as can be demonstrably justified in a free and democratic society" under s.1 of the *Charter*.[6]

Commercial Speech in the *Charter*: Protecting Information for Consumers

Where freedom of expression was traditionally conceived as protecting political speech, courts have expanded their vision of expression that is valuable in a democratic society. Following this trend, Canadian courts evolved from offering no recognition, and therefore no constitutional protection, to commercial speech, to a comprehensive approach that recognizes, protects and regulates commercial speech as a constitutionally protected freedom in Canada.

Commercial speech disputes first came before provincial courts in the years immediately following the introduction of the *Charter* in the early 1980s, however there was no consistent or unanimously accepted approach across jurisdictions. First, in a challenge brought against the Law Society of Upper Canada as a result of an advertising prohibition imposed on members of the legal profession, the Ontario Superior Court (ONSC) found that purely economically motivated speech did not fall within the scope of protected expression.[7] In coming to this conclusion, Justice Callaghan wrote:

Simply because commercial speech involves expression does not mean that it is protected under s. 2(b) of the *Charter*. Form should not be confused with substance. Pure commercial speech mimics political speech in form (both involve expression) but not in substance or function. Commercial speech flows from the realm of economic activity; political speech from that of politics and government. In a democratic society the economic realm must be subordinate to the political realm.[8]

While the ONSC concluded that commercial speech was not constitutionally protected, other courts disagreed. In *Re Grier*, the Alberta Court of Appeal tied the value of commercial speech to consumer protection, stating that "[t]he valued activity engaged […] is the dissemination of service and product information for consumer protection."[9] This decision marked a shift from thinking about commercial speech's value to the business or service provider to its value to the consumer.

The Supreme Court settled this question in *Ford v. Quebec (Attorney General)*, concluding that commercial speech is protected under s.2(b) of the *Charter* because it is critical for providing consumers with information necessary to make "informed economic choices, an important aspect of individual self-fulfillment and personal autonomy."[10] By shifting the focus from the "speakers" of commercial speech (i.e. businesses and service providers), to the "listeners" (i.e. consumers), the Court concluded that the informational aspect of commercial speech was necessary to protect in a free and democratic society.[11]

In a series of cases decided after *Ford* involving challenges to banning advertising to children (*Irwin Toy*), the prohibition of advertising dental practices (*Rocket*), and the regulation of tobacco advertising (*RJR* and *JTI*), the

Supreme Court solidified the constitutional protection of commercial speech, further establishing that information for consumer decision-making is the core of why such speech deserves constitutional protection.

In *Irwin Toy,* the first step of the Court's analysis required it to determine whether advertising aimed at children fell within the scope of s.2(b). It wrote that "[a]ctivity is expressive if it attempts to convey meaning," and that the advertising at issue "[s]urely [aimed] to convey a meaning, and [could not] be excluded as having no expressive content."[12] In *Rocket,* the Supreme Court took this analysis of commercial speech under s.2(b) further. It found that the advertising ban placed on dentists contained important information including, for example, "dentists' office hours, the language they speak, and other objective facts relevant to their practice," all information that serves "an important public interest by enhancing the ability of patients to make informed choices."[13]

The goal of protecting consumers was also at the core of both cases involving Parliament's attempts to regulate tobacco advertising in Canada, where the tobacco industry used constitutional arguments to challenge the legislation. In *RJR*, the Court struck down the provisions of the *Tobacco Products Control Act* that broadly prohibited, with few exceptions, advertising and promotion of tobacco products and required unattributed health warnings on tobacco products.[14] The Majority noted that the total ban extended "to advertising which arguably produces benefits to the consumer while having little or no conceivable impact on consumption" of tobacco products.[15] At the root of its analysis, the Court could not uphold the infringement because the ban prevented "[p]urely informational advertising, simple reminders of package appearance, advertising for new brands and advertising showing relative tar content of different brands," all of which would deprive consumers "of an important means of learning about product availability to suit their preferences and to compare brand content with an aim to reducing the risk to their health."[16] This view was reiterated in *JTI*. For the Court, consumers of legal, albeit noxious, products, deserve access to information upon which they can form the basis of their purchase decisions.[17]

Limitations on Commercial Speech in a Free and Democratic Society

However, while the Court stated that protecting consumers is at the core of protecting commercial speech, it also acknowledged the existence of a continuum that extends beyond pure information. While also protected under s.2(b), commercial speech along this continuum would be more easily subject to restrictions justifiable under s.1 of the *Charter*.

The Court established that "[f]reedom of expression claims must be weighed in light of their relative connection to a set of even more fundamental or core values," identifying some of these "core values" as ""the search for political, artistic and scientific truth, the protection of individual autonomy and self-development, and the promotion of public participation in the democratic process."[18] As the Court's jurisprudence on commercial speech exemplifies, this core is relevant in analyzing the value of the speech being challenged and the corresponding degrees of infringement to *Charter* in light of the objectives being sought by Parliament. When considering the spectrum of protected speech, the Court has found that "[w]here the expression in question is farther from the core of freedom of expression values, a lower standard of justification may be applied" in determining whether an infringement is justified in a free and democratic society.[19] The Court's jurisprudence points to two areas in particular that fall far from this core in the continuum: (1) commercial speech not meant to inform the consumer but rather to induce them to use the product; and (2) commercial speech targeted at vulnerable groups.

(1) Commercial Speech Not Meant to Inform but Rather to Induce Consumers to Use the Product

Where the Majority in *RJR* noted that the total ban disproportionately impacted freedom of expression and unjustifiably impacted the core of commercial speech, the judgment in *JTI* added nuances to this decision, particularly as it relates to how the informative value of commercial speech fits into the determination of whether infringements imposed by Parliament are justified.

Specifically, the factual scenario of *JTI* and the Court's corresponding analysis recognized instances of commercial speech where that information crosses a line and no longer helps consumers. Unlike the total ban in *RJR*, at issue in *JTI* was Parliament's new scheme in the *Tobacco Act* that permitted information and brand-preference advertising but banned specific categories of advertising. These categories included: (1) false or misleading advertising or promotion, (2) a total ban on lifestyle advertising and promotion, as well as sponsorship, and (3) all advertising

appealing to young persons.[20] Parliament provided specificity as to the context, purpose, need and audience of such bans and explained the careful tailoring of these categories. In its proportionality analysis, the *JTI* decision relied on the fact that, in each category of banned advertising, the speech in question did not provide information that would help consumers.

The first category —*false or misleading advertising or promotion* —was "set in the factual context of a long history of misleading and deceptive advertising by the tobacco industry,"[21] and was created with the intention of protecting consumers by combatting "misleading false inferences about product safety and to promote informed, enlightened consumer choice."[22] While some information is critical for reasoned decisions, "the right to invite consumers to draw an erroneous inference as to the healthfulness of a product" is "of low value," particularly in the face of Parliament's public health objectives.[23] Expression based on false or misleading information is situated far from the core of protected speech and therefore restricting such speech would likely be upheld at the proportionality stage of the infringement analysis.

In the same case, the Court's logic for upholding the ban on the second category of *lifestyle advertising and promotion and sponsorship* was based on a similar analysis of the speech at issue and the means chosen by Parliament to achieve its public health objectives. Banning lifestyle advertising was proportionate because "[s]uch advertising crosses the line when it associates a product with a way of life or uses a lifestyle to evoke an emotion or image that may, by design or effect, lead more people to become addicted or lead people who are already addicted to increase their tobacco use."[24] It also noted that the expression in question —"the inducement of increased tobacco consumption" —was of low value because it did not provide useful information for consumers and was outweighed by the "significant benefits of lower rates of [tobacco] consumption and addiction."[25]

(2) Commercial Speech Targeted at Vulnerable Groups

The Court in *JTI* also found that the third category - a complete ban on *advertising and promotion to young persons* —was a justifiable infringement, reiterating its position from previous cases as to the importance of protecting vulnerable groups. Most notably, the Court's analysis in *JTI* mirrored its conclusion in *Irwin Toy,*[26] which found that protecting children from commercial manipulation is not only a pressing and substantial objective, but is also supported by the evidence about children's limited "cognitive ability" and evidence of the tactics used by corporations to take advantage of this limitation.[27] This position has led to the Court being more willing to grant greater deference to Parliament when the health or welfare of vulnerable groups is in question.

JTI examined the relationship between a manufacturer's rights to commercial speech in light of the public health goals of the full advertising prohibition directed at young persons, reframing the value of information in relation to this particular group. Where the Court found that certain kinds of information may be valuable to consumers that already use tobacco products, it found that such information was less worthy of protection under s.2(b) when it came to groups such as young persons, that have not yet taken up this habit. In considering the value of the commercial speech in relation to the protection of vulnerable people in the last prong of the s.1 analysis, the Court wrote:

The prohibited speech is of low value. Information about tobacco products and the characteristics of brands may have some value to the consumer who is already addicted to tobacco. But it is not great. On the other hand, the beneficial effects of the ban for young persons and for society at large may be significant. […] Moreover, the vulnerability of the young may justify measures that privilege them over adults in matters of free expression.[28]

Interestingly, the Court went so far as to comment on the value of purely informational advertising going beyond an analysis in relation to vulnerable groups. While this obiter seemingly contradicts the Court's previous determination that informational and brand-preference advertising would likely be outside the scope of the public health objectives being sought, this comment may have resulted from the increased evidence available to the Court and to the public at large as to both the harms of tobacco use and the nefarious practices undertaken by the tobacco industry.

Evidentiary Standards for Upholding Limitations on Commercial Speech

Irrespective of the value of the speech impacted by a regulation, the burden of proof still rests on Parliament to justify an infringement on protected speech. The scope, type and amount of evidence that may be needed to justify restrictions have been distilled through the case law of the Court.

The Court's jurisprudence sets out the criteria for the standard of proof relevant to a s.1 analysis as well as the parameters of the deference owed to Parliament in relation to complex social issues and those that involve vulnerable groups. First, the s.1 analysis –the multi-pronged test to determine whether infringing legislation is justified in a free and democratic society - uses a civil standard of proof. This standard "does not require scientific demonstration" but can be "established by the application of common sense to what is known, even though what is known may be deficient from a scientific point of view."[29] Secondly, Parliament deserves a certain amount of deference depending on the complexity of the social issue at hand. In *RJR*, Justice McLachlin wrote that "[t]he difficulty of devising legislative solutions to social problems which may be only incompletely understood may also affect the degree of deference that the courts accord to Parliament or the Legislature."[30] When it comes to legislation that attempts to address complex social issues such as the control and prevention of NCDs, deference will be given to the government so long as they provide evidence as to the reasoning of their decision. The Court is also prepared to allow a wider margin of appreciation to the government when it comes to the goal of protecting vulnerable groups, confirming that it "would not take a restrictive approach to social science evidence and require legislatures to choose the least ambitious means to protect vulnerable groups."[31]

Central to the Court's decision not to uphold the complete ban in *RJR* was the fact that the government failed to provide evidence to support either a rational connection between the law and objective or to find that the law minimally impaired the manufacturers' rights. In particular, the Court found that Parliament's scheme was not supported by a sufficient evidentiary record at trial to justify sweeping infringements of a *Charter* right or freedom.[32] The Majority found that Parliament did not provide direct or indirect proof to establish a rational connection between the total ban and the goal of reducing tobacco consumption. With regards to "indirect evidence," the Court noted that it could have found a connection based on "reason" or "logic," however, to do so, it would require a certain degree of evidence supporting the claim that "purely informational advertising" was meant to increase the total market for their products.[33]

In determining whether the ban minimally impaired commercial speech, another step of the s.1 analysis, the Court again found it could not give deference to Parliament's decision because it "had presented no evidence showing that a less comprehensive ban on advertising would not have been equally effective."[34] The Court noted that, while "in the calm of the courtroom" it may "be possible to imagine a solution that impairs the right at stake less than the solution Parliament has adopted,"[35] the Court's job is only to assess whether the measure in question "falls within a range of reasonable alternatives" and could therefore be considered a reasonable infringement.[36] Despite this flexibility, the lack of evidence supporting the full ban was fatal in this case. Justice McLachlin noted that "while one may conclude as a matter of reason and logic that lifestyle advertising is designed to increase consumption, there is no indication that purely informational or brand preference advertising would have this effect."[37] She then suggested a range of alternative measures that would be considered reasonable, including a ban that would allow information and brand preference advertising, a ban on lifestyle advertising only, and prohibitions of advertising aimed at children and adolescents.[38]

In *JTI*, Parliament maintained the broad objective of reducing consumption of tobacco —the same as the objectives of the legislation at issue in *RJR* —however, it enacted more specific legislation by creating categories of advertising, as described above.[39] This approach allowed the government to provide context-specific evidence in support of banning each category, particularly by highlighting advertising tactics undertaken by industry. Because of the specificity of the new legislation and the corresponding evidentiary record provided at trial in *JTI*, the Court unanimously found that the specific bans were proportional to the objectives being sought within each category.[40]

The requirement of warning labels on tobacco products, at issue in both *RJR* and *JTI*, also provides key insights into the kinds of evidence the Court will consider when making a determination as to the legality of an infringement. In *RJR*, the legislation required tobacco manufacturers to include unattributed health warnings, which meant that the labels seemed to be communicated by the tobacco companies, rather than Health Canada.[41] While the objective of the warning labels —"to discourage people who see the package from tobacco use"[42] —was important, the government's scheme failed the proportionality test because the government did not provide any evidence that

unattributed warning labels would be more effective than attributed ones.

Despite having developed a landscape where, under the right social and evidentiary circumstances, future legislation and regulation for public health could withstand constitutional challenges,46 industry has devised tactics that have prevented legislation from being able to even reach the Court. Industry has worked to ensure that constitutional challenges are unnecessary by influencing the legislative process both directly and indirectly. Industry interference in public health policymaking is perfectly exemplified by the recent attempt of the Canadian government to pass the Child Health Protection Act (Bill S-228), which sought to restrict marketing of food and beverage products high in salt, saturated fat and sugar to children 12 and under.47 Despite overwhelming support from Senators, Parliamentarians, and the general Canadian public, the Bill failed in the Senate the second time around

In its revised scheme in *JTI*, Parliament required larger health warnings on tobacco products —increased from 33% to 50% of the principal display surface —that were attributed to Health Canada.[43] Although the Court concluded that the health warning was an infringement on freedom of expression, it found that it was justified based on the evidence of the increased effectiveness of the larger label. Specifically, the Court relied on legislative schemes from other jurisdictions —Australia, Belgium, Switzerland, Finland, Singapore and Brazil —that required warning labels at least as large as the ones proposed by Canada.[44] The Court also accepted evidence from Canada's international commitments to support the reasonableness of the increased size of the health warnings, including the ratified Framework Convention on Tobacco Control, which "stipulates that warning labels "should" cover at least 50 percent and "shall" cover at least 30 percent of the package."[45] The willingness to accept international legal commitments and examples from other jurisdictions as convincing evidence on par with more traditional kinds of evidence demonstrates the Court's willingness to defer to Parliament's public health agenda when it is thoughtfully supported by evidence. As global consensus on the role of public health regulations in preventing NCDs grows, legislators should remember that this evidence is compelling to the Court, and use it to support their policy decisions.

Conclusion

The Court has firmly entrenched commercial speech as a component of the constitutionally protected freedom of expression, largely due to the informational value that such expression can provide consumers. However, the jurisprudence examined in this article shows not only that commercial speech exists along a continuum where some elements —such as objective informational elements —may be worth more protection than others, but that societal objectives may be sufficient to curtail even valuable expression when supported by proper evidence.

Despite having developed a landscape where, under the right social and evidentiary circumstances, future legislation and regulation for public health could withstand constitutional challenges,[46] industry has devised tactics that have prevented legislation from being able to even reach the Court. Industry has worked to ensure that constitutional challenges are unnecessary by influencing the legislative process both directly and indirectly. Industry interference in public health policymaking is perfectly exemplified by the recent attempt of the Canadian government to pass the *Child Health Protection Act* (Bill S-228), which sought to restrict marketing of food and beverage products high in salt, saturated fat and sugar to children 12 and under.[47] Despite overwhelming support from Senators, Parliamentarians and the general Canadian public, the Bill failed in the Senate the second time around.[48] Research examining the Canada Lobbyist Register revealed that food and advertising industries heavily lobbied the bill, representing 80 percent of interactions with the government.[49] The involvement of industry at other stages of the legislative process, exemplified by Bill S-228 and by industry's role in setting key advertising codes in Canada[50], indicates that future legislation and regulation aimed at protecting Canadians against health harms may face challenges long before they are able to reach the Court.

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The Regulation of Alcohol Marketing in France: The Loi Evin at Thirty

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ABSTRACT (ENGLISH)

When adopted in 1991, the French Loi Evin was pioneering as one of the first in the world to regulate alcohol marketing as extensively. This short contribution assesses whether it remains fit for purpose over 30 years later. To this effect, it assesses its main provisions, considers the legislative amendments that have ensued as well as the extensive interpretation French courts have given of its scope, before concluding that the prospects for its revisions are limited in the near future.

FULL TEXT

The growing evidence that alcohol marketing contributes to earlier initiation and increased consumption of alcoholic beverages has led to the recommendation that such marketing should be regulated at international, regional and national levels.[1] When it was adopted, the 1991 French Loi Evin, named after the then Health Secretary of State who proposed it to Parliament, could rightly be seen as pioneering, as one of the first in the world to regulate alcohol marketing as strictly, and notwithstanding the existence of a powerful wine lobby in the country. To date, it is often cited as a model of successful public health intervention. However, the question arises whether this emblematic example remains fit for purpose over 30 years after its adoption. The debate has been extremely polarized. On the one hand, various civil society organizations have tried to protect the law from erosion, not least the Addictions Association,[2] which has initiated public interest litigation for infringements of the Loi Evin. On the other hand, alcohol manufacturers have called for more freedom of expression and have vividly criticized the Loi Evin for lacking precision, for being applied too strictly and for its ineffectiveness.

After assessing the main components of the Loi Evin and its legislative amendments (1), this short contribution considers the extensive interpretation of its provisions by French courts (2) and the future prospects for a revision of the existing regulatory framework in France (3). Due to space constraints, this contribution does not discuss the complex relationship between European Union and national alcohol marketing rules.[3]

1. The Loi Evin and its Legislative Amendments: The Tension Between Free Commercial Expression and Public Health Protection

The French Parliament adopted the Loi Evin to protect public health from tobacco and alcohol use in 1991, amending the Public Health Code.[4] The general position is that alcohol marketing is allowed in France, whilst tobacco marketing is prohibited. However, alcohol marketing is strictly regulated both in terms of permitted media and in terms of the content of the commercial message. All advertising or other forms of promotion of alcohol must also be accompanied by a health warning.[5]

After assessing the main components of the Loi Evin and its legislative amendments (1), this short contribution considers the extensive interpretation of its provisions by French courts (2) and the future prospects for a revision of the existing regulatory framework in France (3).

Compulsory Health Messaging

All promotional messages for alcoholic beverages must be accompanied by a health message that is intended to warn consumers that "excessive alcohol consumption is harmful" and to encourage them to restrict their consumption and "consume in moderation."[6] In 2010, the French Professional Advertising Regulation Authority[7] adopted a recommendation specifying how the message had to appear in printed media to ensure that it was clear and legible and would not be confused with the commercial communication itself.[8]

In February 2005, the Loi Evin was amended by the Disabled Persons Act, requiring the use of either a textual health warning on foetal alcohol syndrome ("the consumption of alcoholic beverages during pregnancy, even in small quantity, can have serious consequences for the health of your child") or a graphic health warning representing a prohibition sign on which appears a pregnant woman on a red background.[9] This additional requirement has led alcohol manufacturers to promote alcohol free beverages to ensure that they do not lose female consumers during pregnancy.

Mandating health messages to limit the impact of the advertising of unhealthy commodities is a popular regulatory approach in France. Beyond health warnings on tobacco, France was the first country in the world to impose a disclosure requirement on unhealthy food advertisements.[10] Some studies have attempted to determine the effectiveness of alcohol health warnings and have concluded that their impact is more important when these warnings are specific (e.g. for pregnant women), as general messages/warnings tend to be too vague, not sufficiently visible and not renewed often enough to avoid a habituation phenomenon.[11]

Limiting the Freedom to Promote Alcoholic Beverages on Public Health Protection Grounds

The Loi Evin provides an exhaustive list of the media where alcohol can be promoted: printed press for adults, radio with hourly limits, billboards, posters and displays at points of sale, digital media, including the internet and apps, except if young people are specifically targeted or the advert is surreptitious or hidden (for example, through undisclosed influencer marketing). All other media and settings, which are not listed, cannot promote alcoholic beverages. They include television, cinema, sponsorship of cultural or sports or other events, and placement for alcoholic beverages and brands.

Originally, the list of media prohibiting alcohol marketing was more limited. However, the provisions of the law have been eroded, as a result of legislative reforms which have expanded the list of media where alcohol marketing may be allowed. Alcohol advertising was allowed in public spaces in 1994.[12] The list was further modified to explicitly include digital media in 2009.[13]

Nevertheless, whenever alcohol advertising is allowed, the Loi Evin requires that it should be limited to the provision of objective information on the product.[14] It is therefore possible to indicate the alcohol content per volume (this is actually mandated by European Union law), the origin, the name, the composition, the name and address of the manufacturer or its agents, as well as the methods of production, the sale conditions and the use of the product. Following the adoption of another legislative reform in 2005, advertising can also include references concerning production areas and related distinctions, designations of origin and geographical indications, as well as objective references concerning the color, taste or smell of a given product.[15]

The Loi Evin did not originally exclude editorials from the definition of advertising and did not require that the brand had to pay for its placement. Therefore, when the actress Scarlett Johansson lent her image to a brand selling alcohol beverages for their global marketing campaign, the Loi Evin prohibited the gossip magazine *Paris Match* to

refer to the event. Several criticisms were then mounted against the Act on the basis that it limited freedom of expression and freedom of the press. In particular, the wine industry, and the Champagne industry more specifically, highlighted the importance of maintaining the French traditional wine culture and providing oenological information without such information being categorized as advertising. This ultimately led to an amendment of the Loi Evin in 2016. This amendment was proposed by Senator Gérard César[16] who emphasized the importance of preserving freedom of expression and freedom of the press. The government and the President of the Republic himself lent their support to this proposal, notwithstanding the objections that the Health Secretary had voiced against it.[17] The amendment included in the Act on the modernization of the public health system has allowed the communication on alcoholic beverages in journalistic, institutional, cultural or tourism editorial pieces. In other words, such communication is allowed on the basis that it relates to protected designations of origin and protected geographical indications and has an objective content (on the region of production, know how, history…) which is distinct from commercial advertising.[18]

The rationale for this distinction is precisely to strike a balance between the promotion of a given product or brand and public health imperatives: consumers can be informed on the product and its attributes, but they cannot be incited to consume the product. Needless to say that this distinction is thin and has proven extremely difficult to draw in practice, giving rise to an extensive body of case law.

2. The Judicial Interpretation of the Loi Evin in a Rapidly Changing Media Landscape

Over 30 years after its adoption, the Loi Evin continues to give rise to a rich case law, demonstrating its ability to adapt to a rapidly changing media landscape. We briefly review three main issues that French courts have considered to argue that French courts have, overall, ensured that the Loi Evin could still serve its original purpose of protecting public health from harmful alcohol marketing.

A Strict Interpretation of the Media Where Alcohol Marketing is Permitted

French courts have interpreted strictly the freedom granted to alcohol manufacturers to promote their products. This is particularly true regarding digital media, as the notion of subliminal advertising has been interpreted broadly to restrict the extent to which alcohol companies can promote their products and brands. In particular, courts have ruled that advertising covers both the messages directly promoted by brands themselves, as well as messages forwarded by consumers. In other words, viral marketing falls within the scope of the restrictions on alcohol marketing which the Loi Evin imposes. In particular, the Cour de cassation (the highest court competent to settle points of law arising in private law cases) held in 2013 that the free smartphone app “Un Ricard: Des Rencontres” (“A Ricard: Some Encounters”) inviting viewers to share their cocktail recipes on its Facebook account (via the sharing button “share on my wall”) constituted a form of viral marketing that was prohibited by the Loi Evin.[19]

Ultimately, therefore, the interpretation of the media permitted to carry alcohol marketing has been rather strict so that alcohol companies have been left with no option but to rely primarily on billboards, where they have tended to promote beer, and on printed media, where they have tended to promote wine and champagne more specifically. Even then, however, the Paris Court of Appeal ruled that a large cover of the famous historical building of the Hôtel de la Monnaie was not a billboard and could not therefore depict a Heineken “Open your World” advert without infringing the Loi Evin.[20] It similarly held that the letters spread over eight meters on the grass at a rock festival constituting the word Kronenbourg were prohibited by the Loi Evin, rejecting the argument that the purpose of these letters was purely decorative.[21]

A Strict Interpretation of the Freedom to Provide Objective Information

French courts have also tended to interpret strictly the requirement of objectivity, further restricting the freedom granted to alcohol manufacturers to promote their products, though the case law has evolved in this respect.

In a few cases, French courts have recognised the need to make allowances to promote advertising creativity. In particular, the Cour de cassation ruled that an attractive background could be used to promote alcohol,[22] and therefore allowed the impression of pleasure the advert facilitated, on the basis that that did not exceed what was necessary to promote the products.[23]

More recently, however, we note a stricter interpretation of the dividing line between what is and what is not allowed.

In 2020, the Cour de cassation interpreted extensively the requirement of the Public Health Code that only objective information may be included in alcohol advertising. In particular, it ruled that advertising was allowed only if all the information provided in a given advert was objective, beyond those specifically enumerated in the Public Health Code.[24] Similarly, the Paris Court of Appeal ruled that an advert online presenting strong similarities with the cult series Games of Thrones with reference to "territory games" and the slogan "legendary intensity" had none of the informational and objective characteristics required by law.[25] The Cour de cassation has also ruled that any reference to a human behaviour cannot be relied upon in advertising campaigns, whilst the taste properties of the product can. In particular, in its Cabernet d'Anjou decision, it ruled that the slogan "Cabernet d'Anjou: Who dares tell young people that 'jeunesse' ('youth') does not rime with 'délicatesse' ('delicacy')?"[26] Ultimately, therefore, French courts have established that every component of the advertisement —both the imagery and the written text used —must guarantee the objectivity that the law mandates.

An Extensive Interpretation of the Notion of Advertising to Cover Both Direct and Indirect Advertising

French courts have also ruled that it was prohibited to promote alcoholic beverages to consumers *indirectly* through the use of the brand or other distinctive marks (for example any graphic implying an alcoholic beverage or an alcohol brand).

This question has given rise to extensive case law in relation specifically to the sponsorship of sports or musical events. For example, the "pression live" promotional campaign drew on elements characterising the Kronenbourg brand. In particular, it used red and white colours, in a geometric configuration representing the checkerboard one finds on the top of the beer bottles sold by the company. The Court of Appeal of Paris considered this constituted an indirect form of marketing the Loi Evin prohibited.[27]

Similarly, the use of an inciting slogan using the name of a brand cannot be used to avoid the prohibition. Therefore, the Paris Court of Appeal ruled against the use of the slogan "Heineken Open your World" on the ground that it was promotional.[28]

3. Looking Ahead

Despite the extensive interpretation that French courts have adopted of the restrictions it imposes on alcohol advertising, the Loi Evin contains various loopholes. The problems are further compounded by its lack of effective application, as the number of infringement cases mounted by the Addictions Association demonstrates.[29]

Some authors have argued that the legislative reforms have led to the "erosion" of the Loi Evin to the point that it has been denatured and is no longer fit for purpose.[30] Such erosion has proven particularly problematic in digital media. The explicit allowance for alcohol advertising on digital media, following the 2009 amendment of the Loi Evin, has given rise to increased exposure to such advertising. More specifically, the provision prohibiting the specific targeting of minors with alcohol advertising is insufficient to limit the exposure of children and young people to such advertising. This is because minors are exposed to digital media that are not considered to be specifically targeting them, even though they are designed for a mixed audience including them.[31] The problems are all the more acute as age controls do not work, as French courts have explicitly acknowledged.[32]

Moreover, it has become more complex over time to determine what falls within the scope of the Loi Evin, whose amendments have increased the opportunities for the alcohol industry to test the boundaries of what is and what is not allowed. In particular, the alcohol industry has resorted to alibi marketing to increase the appeal of their brands at sports events without referring to any specific products, which would have been unlawful as alcohol sponsorship is prohibited.

These loopholes have prompted calls for a revision of the Loi Evin, particularly in relation to digital media. The Court of Auditors specifically recommended that online marketing, particularly on social media, should be prohibited.[33] However, the prospects of amending the Loi Evin to better protect public health is most unlikely at present, bearing in mind the close ties that the President of the Republic has established with the alcohol industry. During the campaign that led to his re-election on 24 April, Emmanuel Macron promised not to amend the Loi Evin to further limit the scope of lawful alcohol marketing in France.[34]

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Letter From The Editor

Hutchinson, Ted

FULL TEXT

This issue marks a significant milestone in the history of the *Journal of Law, Medicine &Ethics*: it is the first of our 50th volume. A half-century of publishing is cause enough to pause, if only for a moment, and look back at a few of the many highlights in our history. I hope you will indulge me as I reflect on a few of the more pivotal decisions in our *Journal's* history.

Our publication began in 1972, under the title *Medicolegal News*. George J. Annas served as the inaugural editor-in-chief, and Frances Miller was our first associate editor. Both George and Fran continue to teach at Boston University (our home institution) today, and Fran's office is located in the ASLME suite; thus we have a great deal of institutional memory to draw on. During the 1970s ASLME also began to publish other journals, including the *American Journal of Law &Medicine* and *Nursing, Law &Ethics*. In 1981 *Nursing Law* was combined with *Medicolegal News* to form a new journal: *The Journal of Law, Medicine &Healthcare*. In 1993 the word "ethics" was added to the title, completing the name of the journal you now hold in your hands, the *Journal of Law, Medicine &Ethics*.

During the last fifty years innumerable people have contributed to the *Journal*, either as an executive director of ASLME, an editor-in-chief, an editor, a column editor, or a designer, a list that is both a who's-who of the health law world and a roll call of some of our closest friends. That list would include George Annas, Elliot Sagall, Edward Doudera, Larry Gostin, Benjamin Moulton, Kelly McDonald, Kathleen Boozang, Mark Rothstein, James Hodge, Judi Haviland McCormick, Heather Barrett Marshall, Sandra Johnson, Ana Iltis, Kevin Outerson, Cathy Richmond Robinson, and Courtney McClellan. I am fortunate enough to be the longest-tenured editor in the history of *JLME*, serving for nearly half of the publication's entire existence. It remains a pleasure to come in every day because I work with my brilliant colleague and dear friend Margo Smith. Together we report in on a near-daily basis to our wonderful editor-in-chief, Aaron Kesselheim.

Carrying on the legacy of these scholars and friends is reason enough to be proud of the work we do. But we also consider ourselves caretakers and trustees of this wonderful journal, both for the people who came before and the people who will follow. We do it, more than anything, for our loyal members and readers, who have sustained us and supported us in good times and bad. For our 50th anniversary issue we tried to bring you something exciting and new (see my Foreword to this issue's symposium on Anti-Racism and Heath Law) but the greatest part of our job is

that we try to bring you something exciting and new with every issue. Thank you for being the reason we have been here for fifty years.

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INTRODUCTION Health Law and Anti-Racism: Reckoning and Response

Goodwin, Michele; Holly Fernandez Lynch

ABSTRACT (ENGLISH)

Law and racism are intertwined, with legal tools bearing the potential to serve as instruments of oppression or equity. This Special Issue explores this dual nature of health law, with attention to policing in the context of mental health, schools, and substance use disorders; industry and the environment in the context of food advertising, tobacco regulation, worker safety, and environmental racism; health care and research in the context of infant mortality, bias in medical applications of AI, and diverse inclusion in research; and anti-racist teaching and practice in the context of building an interprofessional curriculum and medical-legal partnerships.

FULL TEXT

2020 was a remarkable year

The world was hit with a pandemic that we proved ill prepared for, despite extensive warnings —a pandemic that laid bare excruciating inequalities along the lines of race, ethnicity, and social class, revealing a great deal about the law and politics of public health. The pandemic exposed underlying institutional and infrastructural inequalities across a broad spectrum of life, both in the U.S. and globally.

At the same time, long-standing efforts to address systemic and interpersonal racism swelled into a national reckoning following the murder of George Floyd by Minneapolis police officers, among many other examples of racial violence by both law enforcement and civilians. This violence is heaped on top of extensive evidence documenting the myriad ways that racism inhibits the flourishing of Black and other minoritized populations.

There is much to be criticized about what it has taken for the nation's current racial reckoning to scratch the surface of the social consciousness of many Americans and our institutions. Much remains to be done to address the barriers to full inclusion that remain at every level of society. But important work is beginning to get the attention and support it deserves.

Against this backdrop, the American Society of Law, Medicine &Ethics (ASLME), of which we have both served as members of the board, sought to use the tools at its disposal to advance the work of anti-racism in the realm of health law and policy. As one step, ASLME committed to produce this special issue of the *Journal of Law, Medicine &Ethics*, culminating in a public conference in March 2022 to further the discussion and related action. We are grateful to ASLME, the Department of Medical Ethics and Health Policy and the Carey Law School at the University of Pennsylvania, and the University of California Irvine for co-sponsoring this special issue and symposium.

As the articles included here demonstrate, law and racism are deeply intertwined, with legal tools bearing the potential to be wielded as both instruments of racial oppression and means to promote racial equity. This potential is exemplified in the specific context of health law. For example, laws imposing work requirements as a condition of

accessing health benefits disproportionately harm minoritized racial and ethnic groups,[1] while tobacco control laws and restrictions on environmental pollution can promote health equity. Government policies around vaccine allocation demonstrate how facial neutrality can mask inequitable access: allocating vaccines first to people 75 and older ignored the fact that a smaller proportion of Black Americans reach that age compared to white people.[2] The pandemic has also demonstrated how the lack of an equitable national paid family and medical leave program for all workers makes Black, Indigenous, and people of color (BIPOC) individuals and families most susceptible to economic and health-related harm.[3] The law is, of course, not the only means to advancing health equity, and it has its limits, but it is nonetheless a critical tool.

Accordingly, we invited authors from all disciplines to explore the dual nature of health law and its connection to racial justice, from both a systemic and interpersonal perspective, welcoming contributions at the intersection of race and law, medicine, health, science, technology, and bioethics. We ultimately selected 12 articles for inclusion, as well as the winner of ASLME's inaugural graduate student writing competition. Contributions were selected on the basis of their relevance, clarity, and potential impact, also with an eye towards how they would complement one another in a cohesive set.

Although we did not formally collect demographic information about contributors, we did strive for diverse inclusion across race, ethnicity, gender, career stage, and perspective. In light of legitimate and growing concern about "health equity tourism," a term coined by Dr. Elle Lett to refer to circumstances in which those with "little or no background or training in health equity research, often white and already well-funded" rush in to scoop up new opportunities in this space over those who have been enmeshed in the work long before its value was widely recognized,[4] we note that many of the articles in this special issue reflect the contributors' core work and career-long focus.

The issue begins with a foundational contribution from Courtnee Melton-Fant, "New Preemption as a Tool of Structural Racism: Implications for Racial Health Inequities." Melton-Fant argues that preemption is now being used to intentionally subvert and undermine local action or punish localities. She makes the case that the current iteration of preemption, "new preemption," is deployed and weaponized as a policy tool or mechanism of structural racism. The danger that Melton-Fant calls attention to is that efforts by local municipalities to promote health and social justice may be undermined by state legislatures or governors, thereby upending efforts to promote and advance equality at the local level.

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The issue then proceeds in small groups of topically-related articles, the first of which focuses on how contemporary challenges intersecting law, public health, and social welfare extend to matters of health law and policing, with racially disparate impacts in various settings including mental health, schools, and substance use.

In their article, "Involuntary Commitment as a 'Carceral-Health Service': From Healthcare-to-Prison Pipeline to a Public Health Abolition Praxis," Rafik Wahbi and Leo Beletsky show how civil commitment functions as a "pipeline" into the carceral system, which disproportionately incarcerates poor and BIPOC individuals compared to white people, by "forcibly institutionalizing individuals with mental health disorders who appear to 'threaten the safety of society.'" The result, they argue, is a "social system of racial and class control" that disproportionately harms the most vulnerable people of color.

Similarly, Thalia González, Alexis Etow, and Cesar De La Vega argue in their article, "An Antiracist Health Equity Agenda for Education," that a glaring failure of the twin projects of education and criminal justice reform have yet to calibrate effectively to address the harms to children of color receiving an education in the United States. They refer to this as a "critical missing piece" in the inquiry about racism serving as a "significant driver of health inequities within our preschool to 12 education system." Particularly worrisome, as they note, are the increasing ways in which children become ensnared in the criminal justice system even while in elementary, middle, and high school. Most compellingly, the authors are able to convey the health crisis materializing in the wake of the rise of policing inside of

schools.

A theme carried throughout the articles in this issue are the many ways in which a two-tiered system of social value and justice dominate not only law, but also healthcare access. Kelly Dineen and Elizabeth Pendo address substance use disorder (SUD) in their contribution, “Engaging Disability Rights Law to Address the Distinct Harms at the Intersection of Race and Disability for People with Substance Use Disorder.” As the authors note, the treatment of SUD reflects social biases —for good or bad —which can compound racism, sexism, and homophobia. They argue that meaningful solutions must include federal protections and to do better, treatments for people with SUD must be grounded in anti-racism and disability justice.

The next group of articles can broadly be described as addressing health law and race in the context of industry and the environment. The first contribution in this set, from Marice Ashe, Anne Barnhill, Amanda Berhaupt-Glickstein, Nicholas Freudenberg, Sonya Grier, Shiriki Kumanyika, Susana Ramírez, and Karen Watson, grew out of the 2021 Levi Symposium held at the Johns Hopkins Berman Institute of Bioethics. In “The Racialized Marketing of Unhealthy Foods and Beverages: Perspectives and Potential Remedies,” these authors draw attention to the phenomenon of racialized food marketing, a structural racism challenge stemming from marketers’ strategic decisions about how and where unhealthy foods are promoted and sold, as well as racially-driven product development and pricing factors. Although the authors note that food and beverage companies are not necessarily motivated by discriminatory intent, their approaches contribute to and exacerbate health disparities and therefore call for race-conscious structural solutions. In particular, the authors recommend that companies “consider the differential effects of their products on communities of color when formulating their business models, creating products, and designing marketing practices.” They also suggest legal and regulatory strategies for addressing the problem, in addition to proposing “dietary outcome sales targets,” similar to performance-based approaches to climate change. Overall, the authors argue that addressing racialized food marketing and its disparate impacts would be an advance for racial equity.

Moving from unhealthy foods to tobacco, Amirala Pasha and Richard Silbert offer a controversial perspective in their article, “Fresh Take: Pitfalls of the FDA’s Proposed Menthol Ban.” The authors describe the disproportionate use of menthol cigarettes by Black Americans and the tobacco industry’s history of targeting the Black community, as well as state and federal efforts to regulate flavored tobacco products and menthol in particular. While recognizing the health concerns around smoking and the importance of efforts to avoid initiation and continued tobacco use, Pasha and Silbert take issue with FDA’s proposed menthol ban, arguing that it is inappropriately paternalistic, that it disproportionately impacts Black Americans, and that it may exacerbate problematic patterns in policing Black communities should an illicit market for mentholated cigarettes emerge. They further worry that the ban may not achieve its public health goals if it leads to use of non-flavored cigarettes rather than cessation or is not adequately supported by the community it is intended to benefit. In publishing this article, we recognize that it contrasts with arguments in favor of a menthol ban from both the public health community[5] and leading Black community organizations.[6] On this controversial and important topic, then, our goal is to build dialogue to help address potential unintended consequences and facilitate responses to critiques of FDA’s proposed action.

From consumer products to the workers who produce them, the next paper in this section addresses “Structural Discrimination in Pandemic Policy: Essential Protections for Essential Workers.” Authors Abigail Lowe, Kelly Dineen, and Seema Mohapatra draw attention to “the inequities in commitments to and funding for pandemic preparedness outside the context of traditional health care settings, using meat-processing workers as an example.” Meat-processing workers, many of whom are minoritized and multiply-marginalized, have long been “disenfranchised and disempowered” through structural racism in worker protection policies, health care access and quality, and social programs. During the pandemic, the authors explain that meat-processors were designated “essential,” but health and safety recommendations for their unique work environments did not keep up, with greater attention to infection and protection control measures in health care settings. As a result, meat-processing workers were left without critical protections, which the authors attribute to structural and individual racism. To prevent similar problems in future epidemics and pandemics, the authors propose that research and planning should “account for the

converging interests of the oppressors and the oppressed" in workplace safety. In other words, keeping meat-processing workers and other marginalized essential workers safe is good for them and good for business. The authors call for more funding and attention to address research gaps in infectious disease safety in essential industries beyond health care with high numbers of minoritized workers.

The final article in this section, Gabrielle Kolencik's "Harmony between Man and His Environment: Reviewing the Trump Administration's Changes to the National Environmental Policy Act in the Context of Environmental Racism," was selected by a panel of judges as the winner of the 1st Annual ASLME Graduate Student Writing Competition in Health Law and Anti-Racism. In it, Kolencik draws attention to key changes to the National Environmental Policy Act adopted by the Trump administration —changes that are facially neutral but risk exacerbatimg environmental injustice to the detriment of minoritized communities by reducing both requirements and opportunity for careful analysis of the environmental impact of agency actions and making it more difficult for affected communities to engage. Given that Black, Native American, Hispanic and Latinx, and Asian communities are disproportionately exposed to environmental pollution in the U.S., Kolencik argues that structural efforts to weaken environmental protections amount to environmental racism and must be quickly addressed.

The third group of articles in this issue addresses topics focused on race in the context of health care and research. To this end, Wangui Muigai's contribution, "Framing Black Infant and Maternal Mortality," brings urgent attention to this prevailing tragedy and fills an important void in the academic literature by taking a historical perspective, examining efforts focused on regulating birth attendants and access to birthing spaces. Black infants and their mothers die at two to three times the rate of their white counterparts, excessive death rates that have persisted since the government first began reporting on such matters in the 1800s. Muigai concludes that the complex factors leading to these disparities cannot be adequately addressed by any single intervention and that we must "look[] to the past in order to explore new ways of thinking about the role of law and policy in combatting racial inequities in birth today."

The next article, by Kristin Kostick-Quenet, Glenn Cohen, Sara Gerke, Bernard Lo, James Antaki, Faezah Movahedi, Hasna Njah, Lauren Schoen, Jerry Estep, and Jennifer Blumenthal-Barby, focuses on "Mitigating Racial Bias in Machine Learning." Here, the authors argue that emerging responses to the problem of bias in artificial intelligence/machine learning (AI/ML) in the health care sector "overemphasize developers' responsibility for mitigating bias, even though many sources of bias found in algorithms may be systemic." The authors use a case study of a prognostic ML algorithm intended to provide decision-support for patients with severe heart failure considering treatment with a left ventricular assist device (LVAD). They identified significant bias in the available training dataset, which was based only on individuals who had received an LVAD, excluding those who had not. However, since there are important disparities in the patients to whom LVAD is offered, the authors determined that "the apparent absence of racial differences may falsely convey equity in *outcomes* while masking socioeconomic inequities in *access or distribution"* of LVADs. Despite recognition of the problem, the authors note that it remains unclear what developers ought to do. Unfortunately, there is little existing hard law available to address this important concern, proposed initiatives to avoid discrimination in ML focus on improving data quality in ways that are insufficient to address systemic sources of bias, and suggestions to rely on transparency about the limitations of ML algorithms will not fix justice-based concerns. The authors end on a somewhat pessimistic note, emphasizing the difficulty but necessity of finding ways to generate data on systemic influences on health outcomes to incorporate into ML training datasets.

In the last article of this section, "Applying Civil Rights Law to Clinical Research: Title VI's Equal Access Mandate," Joseph Liss, David Peloquin, Mark Barnes, and Barbara Bierer offer an underappreciated tool in the push to diversify clinical research: federal civil rights law prohibitions on disparate impact discrimination. As the authors explain, Title VI of the Civil Rights Act of 1964 prohibits federally-funded educational institutions and health care centers —including the hospitals and universities that serve as sites of much clinical research in the U.S. —not only from overtly discriminating on the basis of race, color, or national origin, but also from behaving in ways that result in unequal opportunities for these groups, including the opportunity to participate in clinical research. However,

because only the government may enforce disparate impact discrimination claims, the current lack of enforcement action on these grounds in research contexts has stood in the way of meaningful change. In fact, as the authors point out, many in the research and enforcement communities may not fully appreciate Title VI's reach in this area, which could be used to demand that "clinical researchers at universities, academic medical centers, hospitals, and community centers take affirmative steps to ensure that all individuals have an equal opportunity to participate in clinical research." The authors call on the federal government to clarify these obligations and enforce them going forward.

In the fourth and final section of the special issue, authors address anti-racism in interprofessional practice. In their article, "An Interprofessional Antiracist Curriculum Is Paramount to Addressing Racial Health Inequities," Kate Mitchell, Maya Watson, Abigail Silva, and Jessica Simpson present their experience offering the "Health Justice Lab" at Loyola University Chicago, an interprofessional course for law, medicine, and public health students covering topics such as medical experimentation, environmental justice, maternal mortality, epigenetics, and health impacts of inequities in policing and education —many of the topics covered here. The authors also describe additional experiential curricular and volunteer opportunities to facilitate work toward antiracist goals in improving health outcomes. Acknowledging that law, medicine, and public health professions have and continue to be complicit in contributing to structural racism and health inequities, the authors make a restorative call for training future professionals to dismantle these systems and their effects together. Although there are some challenges to providing this training, it is increasingly expected and supported by professional schools and their overarching organizational bodies.

Finally, in "Towards Racial Justice: The Role of Medical-Legal Partnerships," Medha Makhlouf urges medical-legal partnerships (MLPs) to move beyond their original framing as anti-poverty mechanisms intended to address "health-harming social conditions," including income and insurance, housing and utilities, education and employment, legal status, and personal and family stability. Instead, she calls on the MLP movement to explicitly adopt an anti-racist frame, naming and addressing individual, institutional, and structural racism. Makhlouf argues that an intersectional racial justice lens rather than a singular poverty lens will help MLPs reach their full potential in addressing the underlying causes of racially disparate health outcomes, for example, by centering the effects of racialization on the population served and avoiding the ideology of personal responsibility for "problems that originate in racist policies, institutions, and systems."

We thank all the contributors and the journal for making this special issue possible. There is much more to say on each of these topics that lie at the intersection of health law and anti-racism —and many other topics that we lacked the space to address here. Just as health law has been described as the "law of the horse" because it touches on such a diversity of legal topics, race and racism affect every aspect of life in the U.S., with a particular impact on health. We look forward to the evolution of the field in ways that apply legal tools to promote health equity for all and that teach generations of lawyers and health professionals to come to do the same.

Note

The authors have no conflicts of interest to disclose.

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Engaging Disability Rights Law to Address the Distinct Harms at the Intersection of Race and Disability for People with Substance Use Disorder

Dineen, Kelly K; Pendo, Elizabeth

ABSTRACT (ENGLISH)

This article examines the unique disadvantages experienced by Black people and other people of color with substance use disorder in health care, and argues that an intersectional approach to enforcing disability rights laws offer an opportunity to ameliorate some of the harms of oppression to this population.

FULL TEXT

I. Introduction

The unethical, separate, and unequal system of health care for people with substance use disorder (SUD), a condition effecting approximately 20 million people each year,[1] is the product of long standing and mutually reinforcing systems of racism and ableism in the U.S.[2] Addiction exceptionalism in health care access, coverage,[3] and treatment[4] devastate the health and wellbeing of people with SUD and disproportionately harm people of color.[5] Beyond traditional health care settings, the experiences of daily life for people with SUD —especially people of color

with SUD —are informed by profound epistemic, racial, and disability injustice that compound these harms. Legal norms that further this injustice include prohibitionist drug policies that selectively criminalize drug use and possession;[6] racist policing, enforcement, and sentencing in the criminal legal system;[7] refusals by drug courts and in carceral setting to allow appropriate medical care for people with SUD;[8] child welfare law enforcement targeting Black pregnant women who use drugs;[9] and continued efforts to block harm reduction services that effectively reduce morbidity and mortality from drug use made risky by prohibition.[10] Across these settings, tools of structural oppression combine to subjugate people, especially Black, Latinx, and Indigenous people who use drugs, including those with SUD.[11]

Over 30 years ago, Kimberlé Crenshaw coined the term "intersectionality" to capture forms of oppression that overlap and compound across multiple identities.[12] Disability studies scholars have combined critical theories of race, gender, and disability in interesting ways, often with a focus on education and school discipline.[13] A growing number of legal scholars have explored race and disability discrimination using different approaches.[14] An intersectional scholarly approach focuses on the unique and compounded harms of oppression experienced by people who are members of two or more marginalized groups (e.g., a Black woman with a disability). Rather than addressing each marginalized identity separately,[15] this approach employs critical theories to explore "how race and disability were co-constituted, informed and motivated by the intent to not only to uphold racial hierarchy/white supremacy, but also uphold the related racial project of ableism."[16] For example, scholars and advocates have engaged disability critical race theory (DisCrit) to explore unique disadvantages at the intersection of race and disability in education[17] police encounters,[18] prison litigation,[19] immigration law,[20] and employment discrimination.[21]

Less academic attention has been paid to the unique disadvantages at the intersection of race and disability in health care. This may be due in part to a lack of information and data. A 2019 report published by the National Academies, *Compounded Disparities: Health Equity at the Intersection of Disability, Race, and Ethnicity*, summarized the available evidence while noting that "research on health and health disparities at the intersection of disability and race/ethnicity is very limited."[22]

A small but growing body of research highlights specific compounded disadvantages experienced by people of color with disabilities, people who are "multiply marginalized." We know that intersections with race, ethnicity, gender, LGBTQIA+ status, and other characteristics intensify certain health inequities experienced by people with disabilities …These intersectional health inequities are reflected in the disproportionate harms during the COVID-19 pandemic, including among multiply marginalized people with SUD. There is a need for additional research focusing on the health care experiences and outcomes of people with disabilities in disadvantaged racial and ethnic groups, as well as further interrogation of the relationship between white supremacy, ableism, and the treatment of people with SUD.

Here, we examine the unique disadvantages experienced by Black people and other people of color with SUD in health care,[23] and argue that the intersectional approach we describe above to enforcement of disability rights laws offers an opportunity to ameliorate some of the harms of oppression to this population.[24] Although disability rights law does not explicitly address intersectional discrimination, specific features of the laws are well-suited to address the particular forms of discrimination and disadvantage experienced by people of color with SUD. These laws extend to individuals who are excluded or denied health care services based on SUD, as well as individuals who are victims of widespread but incorrect and often racialized assumptions about SUD or stigma based on a past SUD. These laws consistently require individualized assessment based on objective medical or scientific evidence which has the potential to interrupt racial and ableist bias and assumptions related to SUD. Finally, disability laws can be used to challenge multiple modes of discrimination, including intentional discrimination, segregation, and failure to accommodate people, as well as policies and practices that have a disparate impact on people of color with SUD.

II. Structural Racism, Ableism, and Health Inequities for People with SUD

Racism and ableism have long worked together as symbiotic oppressive forces, centering and empowering white non-disabled persons and resulting in significant health inequities for people who are members of underserved racial and ethnic groups[25] and for people with disabilities.[26] Structural forces also work to *create* disability, and scholars

have examined social disablement for many who are Black, Latinx, Indigenous, or other people of color.[27] A small but growing body of research highlights specific compounded disadvantages experienced by people of color with disabilities,[28] people who are "multiply marginalized."[29] We know that intersections with race, ethnicity, gender, LGBTQIA+ status, and other characteristics intensify certain health inequities experienced by people with disabilities; for example, although more research is needed, several studies indicate that people of color with disabilities experience greater inequities in health status and access to health care.[30] These intersectional health inequities are reflected in the disproportionate harms during the COVID-19 pandemic,[31] including among multiply marginalized people with SUD.[32] There is a need for additional research focusing on the health care experiences and outcomes of people with disabilities in disadvantaged racial and ethnic groups,[33] as well as further interrogation of the relationship between white supremacy, ableism, and the treatment of people with SUD.[34]

The racism that fuels the ongoing "war on drugs" enables serious inequities for people of color with SUD in accessing treatment at all, much less standard of care treatment.[35] The mutually reinforcing systems of white supremacy and ableism created and support constructions of people who use drugs, especially people of color who use drugs, as deviant and damaged to justify their segregation, criminalization, surveillance, and denials of legal protections.[36] If they manage to access care, racialized minorities who use drugs report high levels of interpersonal discrimination in health care settings.[37] They are more likely to become entangled with law enforcement than offered tools for safe drug use, medical care, or community supports. Exclusion from civil rights protections of laws like the Fair Housing Act and the Americans with Disabilities Act (ADA) is also common, negatively impacting social determinants of health.[38]

In fact, U.S. drug policy is a centuries long white supremacy project,[39] and the Controlled Substances Act and its progeny has disproportionately harmed Black communities and other communities of color.[40] This is by design.[41] Despite equivalent rates of drug use and SUD among racialized groups, non-white individuals are disproportionately arrested, sentenced, and incarcerated, [42] and incarceration itself keeps multiply marginalized individuals from completing community-based SUD treatment at disproportionate rates.[43]

Entanglement in the criminal legal system may in fact cause more substance use, harm, and even death. According to Taleed El-Sabawi and Jennifer Carroll,

Among individuals with a history of substance use, for example, law enforcement interaction is known to be positively associated with the initiation of substance injection. Incarceration is known to be positively associated with both fatal and non-fatal overdose, and the growing evidence base is congruent with the hypothesis that this relationship is *causal* (meaning that incarceration most likely causes new overdose events directly, not simply that people more likely to overdose are also more likely to become incarcerated at some point).[44]

Racism in SUD treatment access and quality persists in the criminal legal system, and non-evidence-based approaches dominate.[45] Among the people with opioid use disorder (OUD) in diversionary programs who get "referred" for treatment, less than five percent receive the standard of care treatment, i.e., medication for opioid use disorder (MOUD).[46] Even then, one study found that white defendants were more than twice as likely as Black defendants to have their treatment paid for by the court.[47]

Incarceration and post-incarceration periods are also dangerous for multiply marginalized people with SUD. In addition to a lack of access to treatment, harm reduction, and the increased infectious disease risks while incarcerated,[48] the period after incarceration can be deadly.[49] Those with OUD who do not receive MOUD or are released with no treatment continuation die at rates as high as 129-fold that of the general population in the two weeks following release.[50] As Jamelia Morgan has explained, however, that while carceral settings are "particularly dangerous and damaging for people with disabilities, it is precisely because of the their disability that the [ADA], where enforced, has the potential to protect them."[51] A handful of recent legal victories have opened the door to more appropriate treatment of some people with SUD in carceral settings;[52] however, involvement in the criminal legal system almost universally continues to harm people with SUD.

The criminal legal system also intrudes into the regulation of medicine and combines with institutional and individual discrimination in health care to produce serious and deadly consequences for multiply marginalized people with

SUD as well as those perceived to have a SUD, such as those with persistent pain who may benefit from prescription opioids. The care of people with SUD is legally segregated from and more extensively regulated than the rest of medicine, including enhanced criminal surveillance of health care providers and patients alike.[53] MOUD treatment is governed by distinct regulatory regimes —where methadone is dispensed only through separate Opioid Treatment Programs (also known as methadone clinics)[54] and the prescription of buprenorphine for addiction is less regulated but still requires additional prescribing permissions (known as a DATA waiver), patient limits, and data collection.[55] Interestingly, the *exact same medications,* at the same or even higher doses, can be prescribed in the same way as any other drugs as long as they are being prescribed for a condition *other than addiction*, such as persistent pain. Even then, white patients are far more likely to receive appropriate treatment with prescription medications for their pain. For example, in a recent meta-analysis, Black patients and Hispanic patients were 36% and 30% less likely to receive treatment for acute pain in the emergency department than similarly situated white patients.[56] For those on long-term opioids for persistent pain, Black patients are more likely than white patients to be surveilled with regular urine drug testing and more likely to have their medications unilaterally discontinued following a concerning drug test.[57] Practically, the expansion of prescribing surveillance and law enforcement scrutiny make these providers and patients targets as well.

Providers willing to treat people with SUD or persistent pain are operating at the boundary of health care and criminal law. They do so with tangible personal risk, as prescribers in several federal circuits may face imprisonment for nothing more than mistaken or negligent prescribing for pain or SUD.[58] The “lucky” few patients who manage to access medical care for these conditions are subjected to trickle-down surveillance as a condition of receiving care because of myriad legal requirements combined with providers’ overzealous compliance and risk management practices.[59]

The deterrent effect of prescribing surveillance and the salience of the recent “opioid crisis” combine powerfully with other mutually reinforcing systems of discrimination to leave people with SUD[60] and persistent pain discounted, mistreated, and untreated across a range of settings,[61] a reality even more common for multiply marginalized people of color with these conditions.[62] People die as a result. For example, the extensive non-evidence-based laws and policies to curtail only *prescription* opioid use resulted in provider abandonment and avoidance of people with persistent pain and SUD, shifting many to the much riskier illicit supply, with an overall *increase* in overdose deaths, albeit from illicit rather than prescription substances.[63] Despite constructions of opioid-related overdoses as harming mostly white people, overdose rates among Black people have increased by approximately 40 percent while rates among other populations have remained stable,[64] a trend that continued during the COVID-19 pandemic.[65] Others died by suicide —a problem significant enough to prompt new warnings for prescribers from the Food and Drug Administration against too rapid and involuntary discontinuations of prescribed opioids.[66]

At the same time, health care providers routinely ignore SUD and related treatment needs. While SUD is highly treatable and affects upwards of 20 percent of patients in many health care setting,[67] most patients are never screened, assessed, or treated for SUD.[68] In acute care settings, even those hospitalized *because of drug use* are simply treated for the complications of drug use while their underlying SUD is ignored. For example, people with SUD who are hospitalized with injection drug-related infections (e.g., endocarditis) are typically left to suffer through painful withdrawal,[69] while providers treat only the infection. There is some limited evidence of racial bias in these treatment decisions as well.[70]

Health care providers often surveil and stigmatize hospitalized patients with SUD,[71] center the patient as the cause of their own suffering, and characterize them as irrational and defective —leading to disproportionate numbers of people with SUD leaving the hospital against medical advice.[72] Even the majority of people hospitalized for a life-threatening overdose are discharged without treatment or referral for SUD treatment, and the rates are even worse for women and Black and Hispanic patients.[73] Instead, only the immediate physical instability is addressed, usually by treating the life-threatening respiratory depression with an opioid antagonist (e.g., Naloxone),[74] and the patient is observed and discharged without any SUD receipt or referrals for standard of care treatment (e.g., MOUD).[75] This is not only a missed opportunity to provide appropriate care. It is also a deadly practice. The reversal agent corrects

the respiratory depression by displacing the opioids from the patient's opioid receptors, placing the recipient in painful withdrawal,[76] setting them up to use again to relieve the symptoms. People who survive an overdose have a rate of death in the following year 24 times higher than the general population,[77] and about a quarter of people discharged from the emergency department die within a month —with the highest risk of death within 48 hours of discharge.[78] Initiation of methadone or buprenorphine can cut the mortality risk in half,[79] which nearly every prescriber can administer for up to 72 hours,[80] even without a DATA waiver or special certificate of registration to dispense methadone.[81]

Thanks to structural, institutional, and individual discrimination, most health care providers do not see those with SUD as whole people worthy of respect and patient-centered care. They certainly do not regard treating a SUD as their problem thanks to the legal isolation of addiction medicine from the rest of health care, which impacts the multiply marginalized people with SUD profoundly. The de-medicalization of addiction and the segregation of addiction care began in earnest after the passage of the Harrison Narcotic Act in 1914 and subsequent Supreme Court cases declared addiction treatment was not the "legitimate practice of medicine."[82] This quickly left people with SUD without professional treatment options outside of a few government run "narcotic farms" that targeted marginalized groups.[83] The void was filled by individuals and organizations offering "treatments" ranging from self-help groups with limited evidence of effectiveness,[84] to much more malicious and unregulated practices with a trail of traumatized and even dead former "clients."[85] For example, people with SUD who receive rapid detoxification or pay tens of thousands of dollars for abstinence only treatments for opioid and polysubstance use disorders are at higher risk of death after these "treatments" than if they had received no "treatment" at all.[86]

In the case of people with OUD, the lucky 20 percent of people who manage to access appropriate care are presented with extraordinary barriers to initiation and continuation that are designed to cause "failures," especially for the multiply marginalized.[87] People of color are less likely to receive MOUD, and those that do are less likely than white people with OUD to receive buprenorphine,[88] which has fewer barriers to access and retention in treatment than methadone. Multiply marginalized groups are also more likely to live in areas without adequate access to buprenorphine prescribers.[89] These are not benign differences. Both methadone and buprenorphine are extremely effective treatments —more effective than the best available therapies for many other health conditions.[90] However, receiving methadone requires people with OUD to meet far more stringent criteria for access and retention in therapy, an active SUD for a full year prior to enrollment with few exceptions,[91] random drug screenings,[92] required counseling and detoxification,[93] and daily visits to the clinic for supervised medication ingestion —regardless of their access to transportation or conflicting work or caregiving responsibilities.[94] Methadone also carries more drug risks and produces more severe withdrawal symptoms than buprenorphine for patients who miss doses. Of the available MOUDs, methadone is the most stigmatized, and has a troubling history as a purported means of control of multiply marginalized people with SUD.[95] For these populations, the intersection of the disability of SUD and race, among other marginalized identities, creates significant harms for which structural changes are required.

III. Distinctive Features of Disability Law and the Compound Disadvantages of People of Color with SUD

Federal civil rights laws have been used to address racial discrimination in health care over the last 60 years. Title VI of the Civil Rights Act of 1964 prohibits discrimination based on race, color, and national origin in programs and activities receiving federal financial assistance.[96] Title VI has been used to challenge forms of intentional discrimination in health care, such as the explicit exclusion of minorities from hospitals and racial segregation in hospital wards.[97] However, it has been less effective at challenging practices or policies with a discriminatory effect or instances of implicit racial bias in the absence of intentional discrimination. This is due, in part, to the Supreme Court's decision in *Sandoval* which requires private plaintiffs to show discriminatory intent, as well as a lack of consistent and robust enforcement by the Office for Civil Rights (OCR).[98]

Years later, the ADA was enacted to address widespread discrimination against people with disabilities and to ensure integration and equal opportunity in all areas of American life.[99] Title II of the ADA applies to state and local government services, including state Medicaid programs and health care services provided by public hospitals and clinics.[100] Title III covers places of public accommodations, which include private physician's offices, private

hospitals, private nursing homes, and private SUD treatment programs open to the public, regardless of federal funding.[101] The ADA expands the protections of the Rehabilitation Act of 1973, which similar to Title VI prohibits disability discrimination in federal employment and in programs and activities that receive federal financial assistance such as SUD treatment programs, hospitals and health clinics, pharmacies, contracted service providers, medical and dental providers, and nursing homes.[102]

Section 1557 of the Affordable Care Act amends the Rehabilitation Act to provide additional protections in certain health care programs, activities, and settings[103] although the scope of its protections is uncertain.[104] Because Section 1557 extends the reach of multiple existing nondiscrimination laws, it has the potential to recognize intersectional discrimination. For example, the 2016 final rule issued by HHS under the Obama Administration noted that Section 1557's prohibition of discrimination reaches multiple bases of discrimination, for example, "discrimination against an African-American woman could be discrimination on the basis of both race and sex."[105] The acknowledgement of a distinct and intersectional form of discrimination based on multiple characteristics —a whole that is greater and different than the sum of its parts —echoes judicial decisions under Title VII of the Civil Rights Act of 1964 which prohibits discrimination in employment on the basis of race, color, religion, sex, and national origin.[106] For example, in *Jefferies v. Harris County Community Action Ass'n,* the 5th Circuit recognized that discrimination could exist against the plaintiff based on her distinct experiences in the workplace as a Black woman, regardless of whether those experiences were shared by Black men or white women.[107] However, as observed by civil rights attorney Alice Abrokwa, now Senior Counsel of OCR, courts "have offered little guidance on how to articulate and prove the [Title VII] claims."[108] Similarly, the mechanism for addressing intersectional claims —as opposed to addressing multiple claims each based on a single characteristic —under Section 1557 or the laws it amends has not been developed.

Recent guidance from the HHS OCR affirmed that people with SUD are protected under the ADA, Rehabilitation Act, and Section 1557 when the condition substantially limits a major life activity (which includes major bodily functions such as neurological and brain functions). Recognition of SUD as an actual disability under the first part of the definition sends an important message that SUD is both a medical condition and a socially constructed disability, and that people with SUD are worthy of the same protections and care we are obligated to provide to people with other disabilities.

As we continue to develop approaches consistent with the view of intersectional discrimination we describe here, strong and consistent enforcement of disability nondiscrimination laws can be used to remove barriers to treatment in health care services and programs and other areas of persistent discrimination against people with SUD, especially those that are multiply marginalized. This section examines specific features of the laws that are particularly well-suited to addressing the distinct forms of discrimination and disadvantage experienced by people of color with SUD.

A. SUD as an Actual and Socially Constructed Disability

The ADA protects individuals with a physical or mental impairment that substantially limits a major life activity, those with a history of an impairment, and those who are regarded as having an impairment.[109] Amendments to the ADA in 2008 clarified the definition of disability should be construed in favor of broad coverage of individuals.[110] Recent guidance from the HHS OCR affirmed that people with SUD are protected under the ADA, Rehabilitation Act, and Section 1557 when the condition substantially limits a major life activity (which includes major bodily functions such as neurological and brain functions).[111] Recognition of SUD as an actual disability under the first part of the definition sends an important message that SUD is both a medical condition and a socially constructed disability,[112] and that people with SUD are worthy of the same protections and care we are obligated to provide to people with other disabilities.

The ADA extends protections to individuals who are victims of widespread but incorrect assumptions about SUD or stigma based on a past SUD, reflecting the social model of disability which recognizes disability as a social construct rather than simply a biological trait of the individual. It is a rejection of what Morgan describes as the centering of the harms experienced by people with SUD "in the bodies and minds of the [individual]… rather than in the systems and structures that contribute to their disablement."[113] The "regarded as" prong protects people who are incorrectly

assumed to be using unlawful drugs (but who are not in fact using drugs),[114] as well as people taking lawfully prescribed opioids for treatment of persistant pain or another medical condition who are incorrectly assumed to have a SUD —both common errors supported by racialized and ableist framing of drug use and drug users.[115] The ADA's protections for people with a history of SUD are reinforced by a new nondiscrimination provision in the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) [116] that prohibits discriminatory use by recipients of disclosed SUD treatment information in areas including health care; employment and receipt of worker's compensation; rental or sale of housing; access to courts; and social services and benefits funded by federal, state, or local governments.[117]

Of course, this expansive view of protections for people with SUD is undercut by the ADA's explicit exclusion of individuals who are currently engaged in the illegal use of drugs,[118] itself a form of structural discrimination that further compounds existing racism in drug policy. Some scholars (including the authors) have argued that the harmful and unnecessary exclusion for current illegal use of drugs should be removed from the ADA and other nondiscrimination laws.[119] Fortunately, under the Rehabilitation Act, current illegal use of drugs is not a basis to deny health services in hospitals and outpatient facilities or services provided in connection with drug rehabilitation, vocational rehabilitation programs and services, and other covered programs and services funded if the individual is otherwise entitled to such services.[120] In addition, as we have written elsewhere, there is no statutory exclusion of current illegal substance users in the new CARES Act protections for individuals whose patient records reveal or appear to reveal current or past SUD.[121]

B. Requirement of Individualized, Evidence-Based Assessments

The ADA's consistent focus on individualized assessment has the potential to interrupt explicit and implicit biases at the intersection of race, disability, and SUD. For example, the ADA allows employers to ask about an employee's disability if that employee poses a "direct threat" to workplace health and safety, which is defined as a "significant risk of substantial harm to the health or safety of others" that cannot be eliminated or reduced by a reasonable accommodation.[122] Recent enforcement actions by the Equal Employment Opportunity Commission (EEOC) against employers for discrimination against applicants or employees being treated with MOUD or prescription opioids underscore the requirement that employers engage in an individualized assessment of what, if any, impact the medication has on the individual's ability to perform the job safely, rather than relying on stereotypes or assumptions.[123] The Supreme Court in *Bragdon v. Abbott* established that assessment of a direct threat must rely on analysis of objective medical scientific evidence, rather than stereotypes or misconceptions, even if held in good faith.[124] EEOC guidance for employers[125] and for health care providers[126] on existing legal protections in the workplace for individuals who are using opioids or individuals with a current or former SUD place similar emphasis on these requirements.

We think of people with SUD as patients, but they are also providers. In health care settings, health care providers with a SUD are often viewed with suspicion and as incapable of performing their professional roles. In many instances, physicians and other professionals are forced to choose between their profession and effective treatment for their own SUD. Participation in physician health programs or similar programs is often a condition of maintaining state licensure and employment for professionals with SUD.[127] However, many of those organizations maintain blanket prohibition of medication as part of treatment (including MOUD) under the unexamined presumption that those medications render these providers less safe, an assumption based on the enduring legacy of stigma and addiction exceptionalism rather than available evidence.[128] MOUD is also associated with lower employee health care and productivity costs for employers in other settings.[129] Not only are these bans expensive for all involved, the alternative "treatments" require near constant surveillance of the provider —in the form of frequent random drug screenings and even full time "monitors" in the workplace. Several scholars have noted that the programs' blanket MOUD prohibitions and other practices violate the ADA,[130] but this has yet to be tested in practice.

Decisions about accommodation of disability in health care settings also calls for individualized assessment. The ADA and the Rehabilitation Act require health care providers, systems, and institutions to make reasonable "accommodations" to ensure that people with disabilities have equal opportunities to benefit from health care

programs, services, and facilities.[131] A reasonable accommodation for an individual with a SUD in long-term care might include, for example, making arrangements with the patient's Opioid Treatment Program or the patient's DATA waived buprenorphine prescriber to avoid an interruption in their MOUD therapy.[132] In acute care settings, hospitals should have, at a minimum, DATA waivered clinicians available to offer and continue MOUD and ideally, an addiction medicine consult service to provide appropriate, individualized care. Accommodation decisions should be collaborative, focused on the patient's specific needs, and should always include consideration of patient preferences and perspectives.[133] Focus on the patient's specific needs, preferences and perspectives provides space to consider the role of race, gender, and other characteristics in formulating an appropriate response.[134] However, the first national study of physician knowledge of the ADA suggests that less than one-third of practicing physicians know who is responsible for making decisions about disability accommodations.[135]

C. Multiple Modes of Discrimination

The ADA provides tools to address different forms of discrimination that obstruct access to health care services and programs and cause needless suffering for people with SUD. The ADA addresses disparate treatment, or intentional discrimination because of disability, as health care providers and institutions cannot exclude or deny services to people based on disability.[136] Studies of practicing physicians suggest that most physicians understand this obligation,[137] although we know that exclusions and refusals to treat based on SUD and other disabilities persist. Recent DOJ settlements with primary care providers,[138] specialists,[139] skilled nursing facilities,[140] and organ transplant programs[141] illustrate the persistence of refusals to provide health care services to patients who are receiving MOUDs.

The ADA also requires that people with SUD be treated in integrated settings. The Supreme Court's decision in *Olmstead v. L.C.*[142] established that unnecessary segregation of people with disabilities constitutes discrimination in violation of Title II of the ADA. This means that people with SUD cannot be shunted into separate health care settings or programs unless a separate setting is the most integrated setting appropriate to the needs of the patient. As noted above, people with SUD can also use disability nondiscrimination laws to challenge failure to accommodate their disability-related needs as a justification for segregation.

Disability nondiscrimination laws can also be used in the absence of evidence of intentional discrimination to challenge policies and practices with a disparate impact on people with SUD. The Supreme Court in *Alexander v. Choate* assumed the availability of disparate impact claims under the Rehabilitation Act.[143] However, it further held that the requirements of the law are met when individuals with disabilities are provided "meaningful access" to programs, services, and activities.[144] There is also uncertainty as to whether a claim of disparate impact based on disability requires a showing of intent (e.g., "deliberate indifference"). Some courts have borrowed the analysis of intent from Title VI, while others have not.[145]

D. Enforcement Efforts and Education

Disability nondiscrimination laws are powerful tools to address stigma and discrimination against people with SUD, but enforcement of these laws, including public enforcement of the nondiscrimination requirements of the ADA, Rehabilitation Act, Section 1557, and the CARES Act must be robust and equitable. Many experts claim that the ADA and Section 504 are underenforced, and the promises of these laws have yet to be realized, especially in health care settings.[146] Others have described how the ADA's enforcement has not led to "equal access, social inclusion, and freedom from discrimination …particularly[for] multiply marginalized disabled People of Color."[147] We note that outside of the employment context, enforcement of the ADA for discrimination against people with SUD was non-existent until a few years ago, despite the long-standing protections in the law. Anything but robust and equitable enforcement of disability nondiscrimination laws furthers able-bodied and white supremacist ideologies.[148] The recent trend toward enforcement of protections for people with SUD must continue.

Enforcement efforts must include education. The DOJ has worked to provide education about the protection of people with SUD under existing law in health care settings.[149] In 2018, OCR launched a public education campaign [150] aimed at increasing access to evidence-based treatments, including MOUD, by clarifying the federal civil rights protections[151] for people with SUD and providing specific guidance in the context of OUD.[152] Continued educational

initiatives about the pervasive discrimination faced by people with SUD and new and existing nondiscrimination requirements are needed. In particular, health care providers, institutions, and systems need education about SUD as a disability, barriers to care for people with SUD, and compounded inequities for multiply marginalized people with SUD, along with the existing civil rights protections that protect and promote accessible health care for individuals with disabilities.[153]

Finally, collecting better data at the federal, state, local, and health systems level that can be disaggregated by disability, race, and other characteristics is critical to understand and address inequities experienced by people with SUD at the intersection of these identities.[154]

IV. Conclusion

The compound disadvantages conferred upon people of color with disabilities by the function of structural, institutional, and individual discrimination is an area deserving of more scholarly attention. For people of color with SUD in health care settings, the structural forces of existing criminal, health care, and even disability nondiscrimination laws create profound disadvantages and barriers to humane and appropriate treatment. Nothing short of foundation changes in the criminal legal system, drug policy, and myriad other laws —including removing the exclusion from protection disability nondiscrimination laws of those "currently using illegal drugs" —will afford justice to multiply marginalized people with SUD. In the interim, we have suggested that intersectionality-conscious and robust enforcement of existing protections in the ADA, Rehabilitation Act, Section 1557, and the CARES Act offer the best opportunity for just outcomes for people of color with SUD in health care.

Note

The authors have no conflicts to disclose.

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2. There is very little work on the intersection of gender, race, and disability status specific to people with substance use disorders outside of people who are pregnant and women who have children. See, e.g., A.J. Gunn et al., "'That's Not Me Anymore': Resistance Strategies for Managing Intersectional Stigmas for Women with Substance Use and Incarceration Histories," Qualitative Social Work 17, no. 4 (2018): 490–508. Although worthy of more attention, the scope of this article is limited to intersections of race and disability.

3. See S.A. Tovino, "State Benchmark Plan Coverage of Opioid Use Disorder Treatments and Services: Trends and Limitations," South Carolina Law Review 70 (2019) 764–949.

4. See, e.g., K.K. Dineen and E. Pendo, "Ending the War on People with Substance Use Disorder in the Health Care System," American Journal of Bioethics 21, no. 4 (2021): 20–22; W. C. Goedel et al., "Association of Racial/Ethnic Segregation with Treatment Capacity for Opioid Use Disorder in Counties in the United States," JAMA 3 (2020): 1-10.

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7. See, e.g., A.Y. Davis, "Race and Criminalization: Black Americans and the Punishment Industry," in The House that Race Built (New York: Vintage Books, 1994): at 284; A.A. Akbar, "Toward a Radical Imagination of Law," New York University Law Review 93 (2018): 405-479; T. El-Sabawi and J.J. Carroll, "A Model for Defunding: An Evidence-Based Statute for Behavioral Health Crisis Response," Temple Law Review 94 (forthcoming 2022).

8. See, e.g., B. Andraka-Christou, "What Is 'Treatment' for Opioid Addiction in Problem-Solving Courts? A Study of 20 Indiana Drug and Veterans Courts," Stanford Journal of Civil Rights and Civil Liberties 13 (2017): 189–254; Issue

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9. See, e.g., D.E. Roberts, “Unshackling Black Motherhood,” Michigan Law Review 95 (1997): 938–964.

10. See, e.g., L. Beletsky and J. Goulka, Letter to Scott County Commissioner Re: Litigation Risk of Terminating the Syringe Service Program in Scott County, Indiana, available at <https://www.dropbox.com/s/vajr98qop3qyy8a/Litigation%20risk%20of%20terminating%20Scott%20County%20SSP%20copy.pdf?dl=0 >(last visited December 30, 2021).

11. People of color who use drugs for enjoyment and those who use drugs as part of a SUD are structurally harmed by the white and able-bodied supremacy of drug policy. Contrary to the hysteria that attends the “just say no” and other approaches to drug use, many people use drugs without developing a substance use disorder. See C.L. Hart, Drug Use for Grown-Ups: Chasing Liberty in the Land of Fear (New York: Penguin Random House, 2021). Prohibition, for example, creates demand for an illicit supply of drugs with inconsistent and unknown contents and quality, drives people to use alone or in unsafe conditions, deters people from seeking help for fear of imprisonment, and contributes to infectious disease by denying access to sterile injection supplies. See generally, L. Beletsky and C.S. Davis, “Today’s Fentanyl Crisis: Prohibition’s Iron Law, Revisited,” International Journal of Drug Policy 46 (2017): 156 - 159.

12. K. Crenshaw, “Mapping the Margins: Intersectionality, Identity Politics, and Violence against Women of Color,” Stanford Law Review 43 (1991): 1241–1299; K. Crenshaw, N. Gotanda, G. Peller, and K. Thomas, Critical Race Theory: The Key Writings That Formed the Movement (New York: The New Press, 1996).

13. See, e.g., A. Asch, “Critical Race Theory, Feminism, and Disability: Reflections on Social Justice and Personal Identity,” Ohio State Law Journal 62 (2001): 391–423; F.A. Kumari Campbell, “Exploring Internalized Ableism Using Critical Race Theory,” Disability and Society 23 (2008): 151-162.

14. J.E. Harris, “Reckoning with Race and Disability,” Yale Law Journal Forum 130 (2021): 916–958 (review of recent scholarship on race and disability).

15. A. Frederick and D. Shifrer, “Race and Disability: From Analogy to Intersectionality,” Sociology of Race and Ethnicity 5 (2019): 200–214 (arguing that “centering the positionality of disabled People of Color demands not analogy but intersectional analyses that illuminate how racism and ableism intertwine and interact to generate unique forms of inequality and resistance”).

16. J.N. Morgan, “Toward a DisCrit Approach to American Law,” DisCrit Expanded: Inquiries, Reverberations &Ruptures (Forthcoming 2022): 1-29.

17. S. Ancy Annamma, B.A. Ferri, and D.J. Connor, “Disability Critical Race Theory: Exploring the Intersectional Lineage, Emergence, and Potential Futures of DisCrit in Education,” Review of Research in Education 42 (2018): 46–71 (summarizing research).

18. C.A. Nelson, “Racializing Disability, Disabling Race: Policing Race and Mental Status,” Berkeley Journal of Criminal Law 15 (2010): 1–64.

19. J.N. Morgan, “Reflections on Representing Incarcerated People with Disabilities: Ableism in Prison Reform Litigation,” Denver Law Review 96 (2019): 973–991.

20. M.B. Kashyap, “Toward a Race-Conscious Critique of Mental Health-Related Exclusionary Immigration Laws,” Michigan Journal of Race and Law 26 (2021): 87–111.

21. A. Abrokwa, “‘When They Enter, We All Enter’: Opening the Door to Intersectional Discrimination Claims Based on Race and Disability,” Michigan Journal of Race and Law 24 (2018): 15–74 at 48.

22. S. Yee, et al., “Compounded Disparities: Health Equity at the Intersection of Disability, Race, and Ethnicity, ”The National Academies of Sciences, Engineering, and Medicine (2019): 1–177, at 69. There are some empirical studies that tangentially address the intersection of race and SUD as disability without explicitly describing it as such. See, e.g., W.C. Goedel, et al., “Association of Racial/Ethnic Segregation With Treatment Capacity for Opioid Use Disorder in Counties in the United States,” JAMA Network Open 3, no. 4 (2020): e203711 (correlating geographic

areas with more non-white residents with methadone treatment availability only and the lower burden buprenorphine access with areas with high numbers of white residents); G. Pro and N. Zaller, “Interaction Effects in the Association Between Methadone Maintenance Therapy and Experiences of Racial Discrimination in U.S. Healthcare Settings,” PLOS ONE 15, no. 2 (2020): e0228755 (finding that patients who were Black, Hispanic/Latino, or American Indian and who had a history of receiving methadone to treat their substance use disorder were more likely to experience racism in the health care setting than those who had never received methadone).

23. Although intersectionality is not directly engaged in their public policy statement, the American Society of Addiction Medicine has explicitly detailed the ways in which racism has and continues to disproportionately harm people of color with SUD. See American Society of Addiction Medicine, “Public Policy Statement on Advancing Racial Justice in Addiction Medicine,” 2021, available at <https://www.asam.org/docs/default-source/public-policy-statements/asam-policy-statement-on-racial-justiced7a33a9472bc604ca5b7ff000030b21a.pdf?sfvrsn=5a1f5ac2_2 >(last visited December 30, 2021).

24. J.N. Morgan has argued along similar lines. See Morgan, supra note 16, at 11 (“[a]n intersectional approach to disability [demonstrates] how disability and historically marginalized identities and statuses interact to render some disabled persons even more vulnerable to disability discrimination, and how recognizing that cuts in favor of strengthening legal protections under the ADA.”)

25. See, e.g., 2019 National Healthcare Quality and Disparities Report, December 2020, available at <http://www.ahrq.gov/research/findings/nhqrdr/nhqdr19/index.html >(last visited December 30, 2021); Institute of Medicine, Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care (2003), available at <https://www.nap.edu/catalog/12875/unequal-treatment-confronting-racial-and-ethnic-disparities-in-health-care >(last visited December 30, 2021).

26. E. Pendo and L.I. Iezzoni, The Role of Law and Policy in Achieving Healthy People’s Disability and Health Goals around Access to Health Care, Activities Promoting Health and Wellness, Independent Living and Participation, and Collecting Data in the United States, Department of Health and Human Services, Office of Disease Prevention and Health Promotion, 2020, available at <https://www.healthypeople.gov/sites/default/files/LHP_Disability-Health-Policy_2020.03.12_508_0.pdf >(last visited December 30, 2021); Yee, et al., supra note 18.

27. See e.g., K. Paul-Emile, “Blackness as Disability? ”Georgetown Law Journal 293 (2018): 293 - 364; Frederick and Shifrer, supra note 15; Morgan, supra note 19.

28. See National Disability Institute, Race, Ethnicity and Disability: The Financial Impact of Systemic Inequality, National Disability Institute (August 2020), available at <https://www.nationaldisabilityinstitute.org/reports/research-brief-race-ethnicity-and-disability/ >(last visited December 30, 2021). See also, E.H. Mereish, “The Intersectional Invisibility of Race and Disability Status: An Exploratory Study of Health And Discrimination Facing Asian Americans with Disabilities,” Ethnicity and Inequalities in Health and Social Care 5, no. 2 (2012): 52–60 (AAPI individuals with a disability reported more experiences of everyday discrimination than AAPI individuals without a disability in the study).

29. This terminology emerged from the DisCrit literature and reflects the compound disadvantage experienced by people who are members of multiple groups that are historically and currently subjugated. See, e.g., S. Mac Dougall, “Over-the-Counter Access to Oral Contraception: Reproductive Autonomy on Pharmacy Shelves or A Political Trojan Horse? ”Columbia Journal of Gender &Law 30 (2015): 204–253, at n. 6 (explaining the meaning of multiply marginalized).

30. Yee et al., supra note 22.

31. See generally R. Yearby and S. Mohapatra, “Law, Structural Racism, and the COVID-19 Pandemic,” Journal of Law and the Biosciences 7, no. 1 (2020): 1 - 20; P. Chandan et al., “Demonstrating the Vital Role of Physiatry Throughout the Health Care Continuum: Lessons Learned from Impacts of the COVID-19 Pandemic on the Disability Community,” American Academy of Physical Medicine and Rehabilitation 13 (2021): 589-598.

32. See, e.g., U.G. Khatri et al., “Racial/Ethnic Disparities in Unintentional Fatal and Nonfatal Emergency Medical Services–Attended Opioid Overdoses During the COVID-19 Pandemic in Philadelphia,” JAMA 4, no. 1 (2021): 1–4

(detailing significant and disproportionate increases in drug overdoses among Black people during the pandemic in Philadelphia).
33. Yee et al., supra note 22, at 47.
34. Morgan, supra note 16.
35. See, e.g., American Society of Addiction Medicine, supra note 23. See also, P.A. Lagisetty et al., "Buprenorphine Treatment Divide by Race/Ethnicity and Payment," JAMA Psychiatry 76 no. 9 (2019): 979–980 (finding white and higher-income individuals receive standard of care treatment at disproportionate rates).
36. See S. Mendoza et al., "Re-racialization of Addiction and the Redistribution of Blame in the White Opioid Epidemic," Medical Anthropology Quarterly 33 (2018): 242–262.
37. C. McKnight et al., "Perceived Discrimination among Racial and Ethnic Minority Drug Users and the Association with Health Care Utilization," Journal of Ethnicity in Substance Abuse 16, no. 4 (2017): 404–419.
38. See discussion infra in Part III.
39. Racism has consistently served as the foundation for U.S. drug policy, including the de-medicalization and criminalization of addiction. For a historical account of the anti-Chinese, anti-Mexican, and anti-Black racism that has fueled drug laws in this country, see, e.g., D.M. Provine, Unequal Under Law: Race in the War on Drugs (Chicago: University of Chicago Press, 2008).
40. See, e.g., Davis, supra note 7, at 284; A. Akbar, "Toward a Radical Imagination of Law," New York University Law Review 93 (2018): 405–479.
41. See, e.g., D. Baum, "Legalize It All: How to Win the War on Drugs," Harper's Magazine, April 2016 (interviewing Nixon's former domestic policy advisor who said "The Nixon White House had two enemies: the antiwar left and Black people …We knew we couldn't make it illegal to be either against the war or black, but by getting the public to associate the hippies with marijuana and blacks with heroin, and then criminalizing both heavily, we could disrupt those communities. We could arrest their leaders, raid their homes, break up their meetings, and vilify them night after night on the evening news. Did we know we were lying about the drugs? Of course we did"); B. Andraka-Christou, "Addressing Racial and Ethnic Disparities in the Use of Medications for Opioid Use Disorder," Health Affairs 40, no. 6 (2021): 920–927.
42. See, e.g., R. Camplain et al., "Racial/Ethnic Differences in Drug- and Alcohol-Related Arrest Outcomes in a Southwest County From 2009 to 2018," American Journal of Public Health 110 (2020): S85–S92.
43. G. Pro et al., "Incarceration as a Reason for US Alcohol and Drug Treatment Non-completion: a Multilevel Analysis of Racial/Ethnic and Sex Disparities," Journal of Behavioral Health Services &Research 47 (2020): 464–475.
44. El-Sabawi and Carroll, supra note 5, at 19 (emphasis added, internal citations omitted).
45. See e.g., E.M. Kerrison, "Exploring How Prison-Based Drug Rehabilitation Programming Shapes Racial Disparities in Substance Use Disorder Recovery," Social Science &Medicine 199 (2018): 140–147.
46. N. Krawczyk et al., "Only One in Twenty Justice-Referred Adults in Specialty Treatment for Opioid Use Receive Methadone or Buprenorphine," Health Affairs 36, no. 12 (2017): 2046–2053.
47. M.X. Sanmartin et al., "Racial Disparities in Payment Source of Opioid Use Disorder Treatment among Non-Incarcerated Justice-Involved Adults in the United States," Journal of Mental Health Policy and Economics 23, no. 1 (2020): 19–25.
48. See, e.g., G.E. Macalino, "Prevalence and Incidence of HIV, Hepatitis B Virus, and Hepatitis C Virus Infections among Males in Rhode Island Prisons," American Journal of Public Health 94, no. 7 (2004): 1218–1223.
49. See, e.g., T.L. Rowell-Curisolo et al., "Access to Harm Reduction Treatment Among Formerly Incarcerated Individuals During the COVID-19 Era," Health Security 19, no. S1 (2021): S95–S101.
50. I.A. Binswanger et al., "Release from Prison—A High Risk of Death for Former Inmates," New England Journal of Medicine 356 (2007): 157–165.
51. J. Morgan, "Reflections on Representing Incarcerated People with Disabilities: Ableism in Prison Reform Litigation," Denver Law Review 96, no. 4 (2019): 973–991, at 977–978.

52. See, e.g., Pesce v. Coppinger, 355 F. Supp. 3d 35, 39 (D. Mass. 2018); Smith v. Aroostook County, 376 F. Supp. 3d 146, 149 (D. Me. 2019), aff'd, 922 F.3d 41 (1st Cir. 2019).
53. See J.D. Oliva, "Dosing Discrimination: Regulating PDMP Risk Scores," California Law Review 110 (forthcoming 2022): 101–234; J.D. Oliva, "Prescription Drug Policing: The Right to Health Information Privacy Pre and Post Carpenter," Duke Law Journal 69 (2020): 775-853; K.K. Dineen, "Definitions Matter: A Taxonomy of Inappropriate Prescribing to Shape Effective Opioid Policy and Reduce Patient Harm," Kansas Law Review 67 (2019): 961-1011.
54. 42 C.F.R. §8.
55. 21 C.F.R. §1301.28. See also J. Berk, "To Help Providers Fight the Opioid Epidemic, 'X The X Waiver,'" Health Affairs Blog, March 5, 2019, available at <https://www.healthaffairs.org/do/10.1377/hblog20190301.79453/full/ >(last visited January 1, 2022).
56. P. Lee et al., "Racial and Ethnic Disparities in the Management of Acute Pain in US Emergency Departments: Meta-Analysis and Systematic Review," American Journal of Emergency Medicine 37, no. 9 (2019): 1770–1771.
57. J.R. Gaither et al., "Racial Disparities in Discontinuation of Long-Term Opioid Therapy Following Illicit Drug Use among Black and White Patients," Drug and Alcohol Dependence 192 (2018): 371–376.
58. See, e.g., J.D. Oliva and K.K. Dineen (writing on behalf of Professors of Health Law and Policy), Brief of Amici Curiae in Support of Petitioner, Ruan v. United States, United States Supreme Court, filed May 7, 2021,cert. granted November 5, 2021, available at <https://www.supremecourt.gov/DocketPDF/20/20-1410/178631/20210507164642254_Ruan%20Amici%20Brief%20-%20Final%20for%20Filing%20-%205-7-21.pdf >(last visited January 1, 2022).
59. See, e.g., K.K. Dineen, "Definitions Matter," supra note 53; K.K. Dineen and J.M. DuBois, "Between a Rock and a Hard Place: Can Physicians Prescribe Opioids to Treat Pain Adequately While Avoiding Legal Sanction? "American Journal of Law &Medicine 42, no. 1 (2016): 7–52.
60. See e.g., L.C. van Boekel et al., "Stigma Among Health Professionals towards Patients with Substance Use Disorders and Its Consequences for Healthcare Delivery: Systematic Review," Drug and Alcohol Dependence 131 (2013): 23–35 ("Most evidence indicated that health professionals generally have lower regard, less motivation and feelings of dissatisfaction when working with this patient group").
61. See Dineen, supra note 53.
62. See, e.g., J.D. Oliva, "Dosing Discrimination, "supra note 53; K.K. Dineen, 'Opioid Prescribing in Stigmatized and Special Populations,' in J. Peppin, J. Coleman, K.K. Dineen, &A. Ruggles, eds., Prescription Drug Diversion and Pain: History, Policy, and Treatment, (Oxford University Press, 2018): 190-204 (reviewing the undertreatment of people of color in acute pain from sickle cell crisis).
63. Dineen, supra note 53.
64. M.R. Larochelle et al., "Disparities in Opioid Overdose Death Trends by Race/Ethnicity, 2018–2019, From the HEALing Communities Study," American Journal of Public Health 111 (2021): 1851–1854.
65. U.G. Khatri et al., "Racial/Ethnic Disparities in Unintentional Fatal and Nonfatal Emergency Medical Services–Attended Opioid Overdoses During the COVID-19 Pandemic in Philadelphia," JAMA Network Open 4, no. 1 (2021): e2034878.
66. Id.; U.S. Food &Drug Administration, "FDA Safety Communication: FDA Identifies Harm Reported from Sudden Discontinuation of Opioid Pain Medications and Requires Label Changes to Guide Prescribers on Gradual, Individualized Tapering," April 9, 2019, available at <https://www.fda.gov/drugs/drug-safety-and-availability/fda-identifies-harm-reported-sudden-discontinuation-opioid-pain-medicines-and-requires-label-changes >(last visited January 1, 2022).
67. See T.A. McLellan, "Substance Misuse and Substance Use Disorders: Why Do They Matter in Healthcare? "Transactions of the American Clinical and Climatological Association 128 (2017): 112–130 (explaining substance use disorders is present in 20 to 70% of the patients in the health care system, with variation based on the specific setting).
68. See, e.g., J. McNeely et al., "Barriers and Facilitators Affecting the Implementation of Substance Use Screening

in Primary Care Clinics: A Qualitative Study of Patients, Providers, and Staff," Addiction Science and Clinical Practice 13, no. 8 (2018): 1–15.
69. S.D. Kimmel et al., "Association of Treatment with Medications for Opioid Use Disorder with Mortality after Hospitalization for Injection Drug Use–Associated Infective Endocarditis," JAMA 3, no. 10 (2020): 1–12.
70. D.P. Serota et al., "Disparity in Quality of Infectious Disease vs Addiction Care Among Patients with Injection Drug Use–Associated Staphylococcus aureus Bacteremia," Open Forum Infectious Diseases 6, no. 7 (2019).
71. See, e.g., J.B. Jalay et al., "A 30-Year-Old Patient Who Refuses to be Drug Tested," Clinical Chemistry 62, no. 6 (2016): 807–810.
72. See, e.g., R. Simon et al., "Understanding Why Patients with Substance Use Disorders Leave the Hospital against Medical Advice: A Qualitative Study," Substance Abuse 41, no. 4 (2020): 519–525; M.A. Incze, "At the Cusp—Reimagining Infective Endocarditis Care Amid the Opioid Epidemic," New England Journal of Medicine 384 (2021): 297-299; K.K. Dineen, "It's Not the Patient, It's the System," Journal of Addiction Medicine 15, no. 6 (2021): 443-445.
73. See A.S. Kilaru et al., "Incidence of Treatment for Opioid Use Disorder Following Nonfatal Overdose in Commercially Insured Patients," JAMA Network Open, 3, no. 5 (2020): e205852 (finding overall less than 17% of patients are referred for treatment after overdose and that Black, Hispanic, and female patients were the least likely to be referred to treatment).
74. See, e.g., S.E. Johns et al., "Utilizing Buprenorphine in the Emergency Department after Overdose," Trends in Pharmacological Sciences 39, no. 12 (2018): 998–1000.
75. See, e.g., A.M. Reichheld et al., "A National Survey of Approaches to Manage the ICU patient with Opioid Use Disorder," Journal of Critical Care 54 (2019): 42–47 (finding only 37% of ICUs offered patients hospitalized for opioid overdoses any resources on OUD treatment, including referrals at discharge); S.M. Bagley et al., "Characteristics and Receipt of Medication Treatment among Young Adults Who Experience a Nonfatal Opioid-Related Overdose," Annals of Emergency Medicine 751 (2020): 29-38 (finding that only 30% of adolescents received MOUD after overdose in the ED or within the 4 months after overdose).
76. See, e.g., S.E. Johns et al., "Utilizing Buprenorphine in the Emergency Department after Overdose," Trends in Pharmacological Sciences 39, no. 12 (2018): 998–1000.
77. M. Olfson et al., "Causes of Death After Nonfatal Opioid Overdose," JAMA Psychiatry 75 (2018): 820–827, at 823.
78. S.G. Weiner et al., "One-Year Mortality of Patients After Emergency Department Treatment for Nonfatal Opioid Overdose," Annals of Emergency Medicine 75 (2020): 13–17.
79. T. Santo, Jr. et al., "Association of Opioid Agonist Treatment with All-Cause Mortality and Specific Causes of Death among People with Opioid Dependence: A Systematic Review and Meta-Analysis," JAMA Psychiatry 78, no. 9 (2021): 979–993. See also M.R. Larochelle et al., "Medication for Opioid Use Disorder after Nonfatal Opioid Overdose and Association with Mortality: A Cohort Study," Annals of Internal Medicine 169, no. 3 (2018): 137-145.
80. 21 C.F.R. §1306.07 (b).
81. 21 U.S.C. §823 (g).
82. See United States v. Doremus, 249 U.S. 86 (1919); Webb v. United States, 249 U.S. 96 (1919). See generally, D.F. Musto, The American Disease: Origins of Narcotic Control, 3rd ed. (New York: Oxford University Press, 1999).
83. Id. (Musto).
84. See, e.g., K. Humphreys et al., "Self-Help Organizations for Alcohol and Drug Problems: Toward Evidence-Based Practice and Policy," Journal of Substance Abuse Treatment 26, no. 3 (2004): 159–165.
85. See e.g., M. Szalavitz, "Forced Rehab Isn't the Solution," Vice, January 9, 2018, available at <https://www.vice.com/en/article/qvwwkv/massachusetts-forced-rehab-law >(last visited January 1, 2022). See also, P. Haden, "'Body Brokers' Get Kickbacks to Lure People with Addictions to Bad Rehab," NPR, Health Shots, August 15, 2017, available at <https://www.npr.org/sections/health-shots/2017/08/15/542630442/body-brokers-get-kickbacks-to-lure-people-with-addictions-to-bad-rehab >(last visited January 1, 2022).

86. See, e.g., P.D. Friedmann and J. Suzuki, “More Beds Are Not the Answer: Transforming Detoxification Units into Medication Induction Centers to Address the Opioid Epidemic,” Addiction Science &Clinical Practice 12 (2017): 1–3.
87. See generally, National Academies of Sciences, Engineering, and Medicine, Medications for Opioid Use Disorder Save Lives (Washington, DC: The National Academies Press, 2019).
88. Id.; see also P.A. Lagisetty et al., “Buprenorphine Treatment Divide by Race/Ethnicity and Payment,” JAMA Psychiatry 76, no. 9 (2019): 979–981; S.E. Hadland et al., “Receipt of Timely Addiction Treatment and Association of Early Medication Treatment with Retention in Care among Youths with Opioid Use Disorder,” JAMA Pediatrics 172, no. 11 (2018): 1029-1037.
89. See e.g., W.C. Goedel et al., “Association of Racial/Ethnic Segregation with Treatment Capacity for Opioid Use Disorder in Counties in the United States,” JAMA 3, no. 4 (2020): e203711.
90. See National Academies, supra note 87.
91. 42 C.F.R. §8.12 (e).
92. 42 C.F.R. §8.12 (f)(6).
93. 42 C.F.R. §8.12 (f)(5) (counseling); 42 C.F.R. §8.12(e)(4) (detoxification).
94. 42 C.F.R. §8.12 (h).
95. See B. Andraka-Christou, “Addressing Racial and Ethnic Disparities in the Use of Medications for Opioid Use Disorder,” Health Affairs 40, no. 6 (2021): 920–927.
96. 42 U.S.C. §2000d.
97. B.R. Clark, “Hospital Flight from Minority Communities: How Our Existing Civil Rights Framework Fosters Racial Inequality in Healthcare,” DePaul Journal of Health Care Law 9 (2005): 1023–1100.
98. S. Rosenbaum and J. Teitelbaum, “Civil Rights Enforcement in the Modern Healthcare System: Reinvigorating the Role of the Federal Government in the Aftermath of Alexander v. Sandoval,” Yale Journal of Health Policy, Law, &Ethics 3 (2003): 215–252.
99. Americans with Disabilities Act, 42 U.S.C. §12101 et seq. (2008).
100. See e.g., Nondiscrimination on the Basis of Disability in State and Local Government Services, 28 C.F.R. §35.101–.999 (2020) (including numerous examples in health care programs and settings).
101. U.S. Department of Justice., “ADA Title III Technical Assistance Manual 31–32 (2020),” available at <https://www.ada.gov/taman3.html >[https://perma.cc/CC9Y-E4Y3] (last visited January 1, 2022); see also 42 U.S.C. §12181(7)(F).
102. 29 U.S.C. §701; U.S. Department of Health and Human Services, Nondiscrimination and Opioid Use Disorder, 2018, available at <https://www.hhs.gov/sites/default/files/fact-sheet-nondiscrimination-and-opioid-use.pdf >(last visited January 1, 2022).
103. 42 U.S.C. §18116.
104. The Biden Administration has signaled that it will propose a new final rule reversing many of the limitations imposed by the Trump Administration’s 2020 revised final rule. See M. Musumeci et al., “Recent and Anticipated Actions to Reverse Trump Administration Section 1557 Non-Discrimination Rules,” Kaiser Family Foundation, June 9, 2021, available at <https://www.kff.org/racial-equity-and-health-policy/issue-brief/recent-and-anticipated-actions-to-reverse-trump-administration-section-1557-non-discrimination-rules/ >(last visited January 1, 2022).
105. U.S. Department of Health &Human Services, “Nondiscrimination on the Basis of Race, Color, National Origin, Sex, Age, or Disability in Health Programs or Activities Receiving Federal Financial Assistance and Health Programs or Activities Administered by the Department of Health and Human Services or Entities Established under Title I of the Patient Protection and Affordable Care Act,” 45 C.F.R. Part 92, 81 Fed. Reg. 31376, 31405 (May 18, 2016).
106. 42 U.S.C. §2000e.
107. Jefferies v. Harris County Community Action Ass’n, 615 F.2d 1025, 1032 (5th Cir. 1980).
108. Abrokwa, supra note 21, at 15.
109. 42 U.S.C. §12102(1).
110. Id. at §12102(4)(A).

111. See Office for Civil Rights, U.S. Department of Health &Human Services, Fact Sheet: Drug Addiction and Federal Disability Rights Laws (October 25, 2018), available at <https://www.hhs.gov/sites/default/files/drug-addiction-aand-federal-disability-rights-laws-fact-sheet.pdf >[https://perma.cc/7WT2-TUCY] (last visited January 1, 2022); U.S. Department of Health &Human Services, Nondiscrimination and Opioid Use Disorders Fact Sheet (October 25, 2018), available at <https://www.hhs.gov/sites/default/files/fact-sheet-nondiscrimination-and-opioid-use.pdf >[https://perma.cc/Z2Z4-MU5Y] (last visited January 1, 2022).
112. See Frederick and Shifrer, supra note 15, at 204 ("People of Color and those from lower socioeconomic backgrounds have disproportionately experienced the harm that comes from medical coercion and surveillance of disabled people, the very forms of medical injustice that have driven the rejection of the medical model. But these groups also commonly experience lack of access, or denial of access, to quality medical care that middle-class white Americans are less likely to endure. In other words, there is a privilege in being able to call for a distancing from the biomedical regime, a privilege not enjoyed by those whose oppression has included denial of medical care").
113. Morgan, supra note 16, at 13.
114. 42 U.S.C. §12114(b)(3); see also Nielsen v. Moroni Feed Co., 162 F.3d 604, 610 (10th Cir. 1998) ("[T]he ADA protects employees who are erroneously regarded as being current illegal drug users.").
115. See Hart, supra note 11.
116. CARES Act, Pub. L. No. 116-136, §3221, 134 Stat. 281, 375–79 (2020) (codified at 42 U.S.C. §290dd-2).
117. K.K. Dineen and E. Pendo, "Substance Use Disorder Discrimination and the CARES Act: Using Disability Law to Inform Part 2 Rulemaking," Arizona State Law Journal 52 (2021): 1143–1165.
118. 42 U.S.C. §12114(a); see also 29 U.S.C. §705(20)(C)(i) (Rehabilitation Act); 42 U.S.C. §3602(h) (FHA).
119. L. Francis, "Illegal Substance Abuse and Protection from Discrimination in Housing and Employment: Reversing the Exclusion of Illegal Substance Abuse as a Disability," Utah Law Review 2019, no. 4 (2019): 891–913; E.G. Aoun and P.S. Appelbaum, "Ten Years After the ADA Amendment Act (2008): The Relationship between ADA Employment Discrimination and Substance Use Disorders," Psychiatric Services 70 (2019): 596-603. See also M.J. Egan, Comment, "When Does 'Currently' Using No Longer Apply? The Americans with Disabilities Act, the Opioid Crisis, and a Search for the Solution," George Mason Law Review 27 (2019): 307-344.
120. See Office for Civil Rights, supra note 79.
121. Dineen and Pendo, supra note 117.
122. 42 U.S.C. §12113(a)-(b), 42 U.S.C. §12111(3); 29 C.F.R. §1630.2(r).
123. Id., at 3; Breaux v. Bollinger Shipyards, LLC, No. 16-2331, 2018 WL 3329059, at *12 (E.D. La. July 5, 2018); Pollard v. Drummond Co., No. 12-CV-03948, 2015 WL 5306084, at *7 (N.D. Ala. Sept. 10, 2015); Equal Emp. Opportunity Comm'n v. Hussey Copper Ltd., 696 F. Supp. 2d 505, 517–18 (W.D. Pa. 2010). See also, "Cases Involving Discrimination Based on Treatment with Medication for Opioid Use Disorder (MOUD)," 2020, available at <https://perma.cc/RFJ6-3UZQ >(last visited January 1, 2022).
124. Bragdon v. Abbott, 524 U.S. 624 (1998).
125. U.S. Equal Employment, Opportunity Commission EEOC–NTVA–2020–2, "Use of Codeine, Oxycodone, and Other Opioids: Information for Employees," 2020, available at <https://www.eeoc.gov/laws/guidance/use-codeine-oxycodone-and-other-opioids-information-employees >[https://perma.cc/S2NJ-EMUM] (last visited January 1, 2022).
126. U.S. Equal Employment Opportunity Commission, EEOC–NTVA–2020–1, "How Health Care Providers Can Help Current and Former Patients Who Have Used Opioids Stay Employed," 2020, available at <https://www.eeoc.gov/laws/guidance/how-health-care-providers-can-help-current-and-former-patients-who-have-used-opioids >[https://perma.cc/AB5J-MYAU] (last visited January 1, 2022).
127. L. Beletsky et al., "Practicing What We Preach—Ending Physician Health Program Bans on Opioid-Agonist Therapy," New England Journal of Medicine 381 (2019): 796–798.
128. Id.
129. See R. Mosher Henke et al., "Opioid Use Disorder and Employee Work Presenteeism, Absences, and Health

Care Costs," Journal of Occupational and Environmental Medicine 62, no. 5 (2020): 344–349.
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Structural Discrimination in Pandemic Policy: Essential Protections for Essential Workers

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ABSTRACT (ENGLISH)

An inordinate number of low wage workers in essential industries are Black, Hispanic, or Latino, immigrants or refugees — groups beset by centuries of discrimination and burdened with disproportionate but preventable harms during the COVID-19 pandemic.

FULL TEXT

I. Introduction

Minoritized and socially disenfranchised populations have suffered disproportionate morbidity and mortality during

every U.S. public health emergency.[1] The COVID-19 pandemic is no different. Structural discrimination and resulting inequities were aptly demonstrated by both the treatment of and health outcomes for low-wage workers, such as long-term care workers, home health aides, and food supply workers during the first year of the pandemic.[2] These essential workers were harmed not only by the virus but by the compounded disadvantages of structural racism in worker protection policies, health care access and quality, and social programs.[3] Moreover, those working in meat processing plants would not have prepared to be part of an essential workforce in the way that health care and emergency services workers do.

Among the food supply workers, meat-processing workers are a case study in the ways disease outbreaks thrive in the presence of long-standing structural discrimination and policy makers steeped in white supremacy —meaning the political, legal, and social structures that consistently advantage and privilege the interests of white-identified people and groups such that subrogation is normalized.[4] The responses of the federal government, many states, and the meat industry to COVID-19 outbreaks and heightened SARS-CoV-2 transmission risks worked in concert to induce, rather than prevent, harm. Key federal and state policy makers and regulatory bodies, including the Centers for Disease Prevention and Control (CDC) and Occupational Safety and Health Administration (OSHA), upheld white supremacist principles in their construction of the value of “essential work” by the many low wage minoritized workers in this category. The criteria for qualifying as an essential business have been criticized for being vague, which, as a result, allows more industries to qualify as essential thereby putting more workers at risk. Many essential workers that suffered significant harms are non-white. For example, the CDC reported in July 2020 that 87% of COVID-19 cases in meat processing plants involved minoritized workers, specifically in Hispanic (56%), Black (19%), and Asian (12%) workers.[5] White workers only represented 13% of the cases while representing approximately 30% of meat-processing workers nationwide.[6] These agencies failed to account for existing structural racism, the inherent value of the workers and their communities, the nature of the threat of an aerosolized virus, and the prioritization of industry goals over worker safety. Across the board, policy makers failed to reckon with structural forces and meet their ethical and legal obligations to protect the health of already disenfranchised and disempowered workers. The policies and practices that combined with existing structural inequities to harm these workers have been described elsewhere, along with strong recommendations for anti-racist policies to enhance workplace protections and ameliorate financial, food, housing, and health insecurity.[7] We echo the critical need for sweeping changes to worker protections.

The focus of this article is to draw attention to a narrow, but mostly overlooked, issue of the inequities in commitments to and funding for pandemic preparedness outside the context of traditional health care settings, using meat-processing workers as an example. These inequities meant that when the COVID-19 pandemic began, the evidence base was essentially non-existent for the effectiveness of respiratory protective equipment (RPE) and personal protective equipment (PPE) to reduce infection transmission and other infection prevention and control (IPC) measures under conditions of use inside meat-processing plants. This essay begins with a review of the history of pandemic inequities, and then turns to the structural and institutional factors that contributed to the disproportionate impact of COVID-19 on meat-processing workers. We review the failures to include non-acute care health workers in pandemic planning and research and examine the application of both solidarity and the concept of interest convergence to ground the inclusion of multiply marginalized essential workers in ongoing pandemic research and planning. We conclude by offering additional recommendations for (1) special attention to structural discrimination in the IPC preparedness and response efforts in critical infrastructure industries and (2) enhanced funding for applied and translational research on IPC measures, including PPE effectiveness for reducing respiratory pathogen transmissions under the conditions of use by workers in essential industries.

II. Pandemics, Structural Discrimination, and Structural Violence

Over the past several centuries, there has been a major influenza pandemic every 10 to 30 years.[8] In epidemics and pandemics, minoritized low-wage workers were left worse off than white workers.[9] Historical evidence demonstrates the enduring harms of white supremacy for the health and welfare of minoritized populations. In the 1918 influenza pandemic in the U.S., Black populations had a higher case fatality rates than did their white counterparts,[10] the

impact on Indigenous communities was severe,[11] and low wage workers experienced higher case rates and disease related morbidity and mortality.[12] Nearly a century later, those impacts were mirrored in the 2009 H1N1 outbreak, during which Latino migrant farm workers faced numerous structural barriers to H1N1 prevention and treatment, and were widely stigmatized as disease vectors.[13] Hispanic, Indigenous, and Black populations also had consistently higher rates of H1N1 disease, with hospitalization rates more than double that of white people in the U.S.[14]

Despite the history of health injustice in previous pandemics and calls from scholars for attention to structural discrimination in pandemic planning,[15] the COVID-19 pandemic progressed along the same patterns with minoritized and multiply-marginalized populations suffering disproportionate harm,[16] including in the workplace.[17] For example, as of July 30, 2021, 300 meat processing workers have died from COVID-19 among the close to 60,000 who contracted the virus,[18] with an unknown number experiencing "long COVID."[19] That is roughly 12,000 cases per 100,000 workers, a number unmatched in any other field.[20]

A. The Example of Meat-Processing Workers

Meat processing work has long been among the most hazardous occupations.[21] Workers describe high levels of dehumanization and disregard by the industry.[22] Workplace protections and worker empowerment have also eroded over time.[23] As the industry has consolidated into the hands of fewer, more powerful companies, they have also aggressively sought to reduce regulatory constraints, increase production speeds,[24] under-report workplace injuries,[25] and uphold arbitrary and punitive disciplinary point systems,[26] which are made possible, in part, because the industry also eliminated unionized workers while recruiting workers who are not positioned to assert their rights.[27] Today, meat-processing workers are disproportionately marginalized by virtue of multiple intersecting identities, [28] including their country of origin, limited English proficiency, immigration and refugee status, socioeconomic status, rural locale, and race and ethnicity.[29]

Combined with federal action that kept meat processing plants open despite outbreaks, decisions to recommend less protective RPE and PPE, and the failure of OSHA to require evidence-based workplace protections were an indicator of decision makers' judgments about the relative worth of these workers. The federal government and private industry upheld white supremacist power structures and committed further acts of structural violence against meat processing workers, who were left with a choice between working with the significant risks of infection and the loss of their already fragile food and housing security. In addition to structural changes to remedy existing health and economic injustices, commitments by industry and governments to structurally competent pre-pandemic preparedness are necessary.

During the onset of COVID-19, meat processing facilities became among the largest epicenters of COVID-19 outbreaks in the United States.[30] Workers in meat processing facilities were particularly vulnerable to COVID-19 due to the high density of workers and prolonged close contact of personnel and indoor work environments.[31] After spring 2020 outbreaks at several large meat processing facilities, the multi-billion-dollar meat industry acted swiftly to apply political pressure on federal actors to protect their bottom line.[32] As a result, meat-processors were effectively deemed "essential" workers by an executive order issued by then President Trump (April 28 EO).[33] Facilities remained open or re-opened despite outbreaks with inadequate and inconsistent levels of IPC across the industry.[34]

Federal agencies also failed to protect workers. The Occupational Safety and Health Administration (OSHA) declined to issue an emergency temporary standard (ETS) to protect these workers,[35] and instead issued a voluntary joint interim guidance with the Centers for Disease Control and Prevention (CDC).[36] The Department of Labor also took separate affirmative steps to telegraph to industry that strict adherence to joint OSHA/CDC guidance for Meat Processing was not required and in fact, the federal government would *assist the meat industry rather than workers* in certain circumstances if a meat corporation was sued by workers.[37] The CDC's actions also upheld existing power structures. For example, the CDC issued IPC guidance to protect acute care health care workers—a group with higher incomes, education, social power, and fewer workers from minoritized groups —beginning on January 17, 2020,[38] and continued updating it as evidence emerged to ensure safety of heath care workers.[39] Of course, health care workers faced dire challenges in supply and staffing shortages, but their workplaces are

accustomed to protecting them from infectious diseases. On the other hand, workers in the meat-processing industry lacked basic IPC guidance for safety in their workplace more than a month after the outbreaks began.[40] The CDC/OSHA interim guidance was finally released only April 26, 2020 —only 48 hours before the April 28 EO was signed in the midst of ongoing outbreaks.[41]

As further evidence emerged that masking is one of the most effective non-pharmaceutical interventions for reducing COVID-19 transmission,[42] protections for meat processing workers, such as industry wide mask mandates, did not increase in response.[43] Increased scientific understanding of airborne SARS-CoV-2 transmission warranted stepped up safety measures (e.g., more protective face coverings such as fit tested N-95 respirators, air filtrations systems, dedensifying measures etc.) to mitigate the risk to workers.[44] Yet, neither the CDC guidance nor the position of OSHA changed, and there was a clear deficit in research and resources to adequately protect workers. Instead, the CDC issued a scientific brief that acknowledged airborne transmission in discrete environments (e.g., congregate settings, poor ventilation, etc.) but did not address IPC guidelines to protect essential workers accordingly.[45] They continued working despite the lack of reasonable protections (N95 filtering facepiece respirators, air filtration systems) and appropriate commitments from the government and industry to protect them from COVID-19 infection.[46]

Combined with federal action that kept meat processing plants open despite outbreaks, decisions to recommend less protective RPE and PPE, and the failure of OSHA to require evidence-based workplace protections were an indicator of decision makers' judgments about the relative worth of these workers. The federal government and private industry upheld white supremacist power structures and committed further acts of structural violence against meat processing workers,[47] who were left with a choice between working with the significant risks of infection and the loss of their already fragile food and housing security.[48] In addition to structural changes to remedy existing health and economic injustices, commitments by industry and governments to structurally competent pre-pandemic preparedness are necessary.[49]

B. Structural Discrimination in Planning and Research

Structurally competent emergency and pandemic preparedness efforts should include explicit attention to the multiply marginalized.[50] While considerable financial resources have been devoted to pandemic influenza preparedness planning at the federal and state levels, national planning efforts do not address protecting low-wage, multiply marginalized workers in essential industries.[51] One group of researchers previously called for the inclusion of meat processing workers in pandemic planning;[52] however, those calls were based on the risks of occupational zoonotic influenza infection and the potential for the emergence of novel pathogens in these settings rather than occupational risk of person to person inhalation transmission of a pandemic pathogen.[53] The existing research on workplace infectious disease transmissions are not targeted to the conditions of use in meat processing plants.[54]

Prior research on the application and effectiveness of IPC measures in meat processing facilities is sparse to non-existent:[55] we found no research in the context of PPE or engineering controls effectiveness for reducing occupational exposure to respiratory viral pathogens with pandemic potential in meat processing workers before the COVID-19 outbreaks. In fact, there is little evidence of research for effectiveness of IPC measures in non-health care workplaces at all; a 2018 systematic review of social distancing effectiveness in workplaces was the first (and possibly only) systematic review of such measures in the workplace.[56] The implication being IPC strategies to reduce transmission depend on a contextual evaluation of the workplace and workers involved. Given that much of IPC is based on practices in healthcare that are focused on patient safety,[57] emerging scientific evidence on SARS-CoV-2 with relevance to IPC measures for meat processing facilities, long-term care facilities, and non-healthcare essential industries were challenging to interpret and adapt into protective guidance in real time.[58]

Instead, appropriate planning should include widespread study and modeling of the effectiveness of PPE and other workplace administrative and engineering controls *before* a pandemic. In its absence, scientists were forced to start without directly applicable research,[59] and infectious disease scientists were left translating evidence-based IPC guidelines developed in healthcare settings for use in meat processing.[60] Yet, the differences between the conditions of use in health care and those in meat-processing plants are quite stark —they are also dissimilarly resourced and

regulated, with varied prioritization of safety, compliance, and worker education on the effective use of RPE and PPE and adherence to other IPC measures.[61] Any forward looking public health guidance to protect workers from future pandemics must ensure equity in research and preparedness when it comes not only to vaccine and therapeutic allocation, but IPC measures for essential workers.

III. Ethical Considerations for Worker Protections

Early in a pandemic, disproportionate burdens create obligations for regulators and employers to keep workers as safe as possible, which, in turn minimize possible harms to others, including to their families and other community members.[62] An antiracist approach calls for affirmative commitments to effectively reposition these workers in ways that account for structural voids in pandemic protections.

A. Shared Vulnerability

During the first few months of the COVID-19 pandemic, messaging responding to shared vulnerability to a spreading virus was emphasized, especially as more white people fell ill. The media and public health agencies responded by encouraging masking as a form of “we’re all in this together” type of solidarity.[63] Solidarity acknowledges interdependence within a community,[64] and solidarity underpins how we take account for our shared vulnerability through the delivery and maintenance of important social infrastructures —a relational concept based on common interests and mutual advantage.[65] Solidarity also recognizes the equal moral worth of people across a population. Dawson and Jennings conception of solidarity in public health ethics requires a public action, motivated by correcting past or present injustices, as well as advocating for and protecting others.[66] It necessitates that we improve health and well-being and reduce suffering through action.[67] To demonstrate solidarity in the context we have described, government officials would need to act to help those working in essential industries by enacting measures for the delivery and management of infection prevention and control to protect their health and well-being. Though there is shared vulnerability to an emerging infectious disease, our experiences in the pandemic demonstrate disparate vulnerabilities due to structural inequality.[68] Marginalized workers continued to work without protections that science deemed necessary —as structural and individual racism allowed their continued invisibility and the normalization of their subrogation.

Effective safety practices and regulation necessitate research to develop appropriate and effective IPC measures, RPE, and PPE products. Research and innovation can serve to demonstrate how the health and safety of essential workers furthers both government and employer interests. Of course, this is not actual solidarity, which depends on treating others as having inherent value regardless of their social power or the benefits they confer on others. Solidarity also falls short, in part, because it does not account for the disparate vulnerabilities due to structural inequalities, and the way that privileges in protections are conferred on some by the state through regulations and institutions.[69]

B. Shared Benefits

Although solidarity in its purest form does not involve benefit to oneself, the concept of interest convergence may be helpful to influence protective laws and policies in future emergencies. Critical race scholar Derrick Bell theorized that laws and policies that benefitted Black Americans were only likely to be passed if they also served an interest to the white majority.[70] The concept of interest convergence has been applied in numerous legal and policy concepts,[71] and it is apt in public health law as well.[72] Take the meat processing example. The spread of the virus presented hardships for the meat processing industry and state economies. If employers had information showing how use of IPC measures could help avoid reduction in production and financial losses without also incurring the sequela of continued outbreaks, lawsuits, and negative press, perhaps they may have implemented measures consistently. Similarly, if government actors had contextual data showing efficacy of IPC measures in the workplace, even governments “captured” by the industry may have acted expeditiously to protect workers and the economic interests of the industry. Research demonstrating IPC measures that satisfy the health and safety interests of workers along with the long-term business interests of the industry are needed.

IV. The Need for Commitments in Planning and Research

Pandemic planning and research must explicitly include non-health care essential workers. The industries,

governments, and consumers that benefit from their labor have a moral obligation to advocate for their protection. Moral claims, however, have rarely superseded interests in entrenched power structures and selective economic gain; therefore, the planning should account for the converging interests of the oppressors and the oppressed in appropriate workplace IPC measures. During the initial wave of a pandemic, the level of and adherence to IPC interventions will largely determine the extent of transmission, morbidity, and mortality until medical counter measures (vaccines and therapeutics) are widely available.[73] However, IPC measures, which are largely based on practices in healthcare need to be expanded to worker safety in non-healthcare essential industries and workplace settings. Creating research-driven public health guidance and protections for vulnerable workers is an important step toward detailing how to mitigate structural discrimination, as well as establishing essential workers' rights and obligations prior to future epidemics or pandemics.

To begin to scope out appropriate preparedness plans, translational and applied research on IPC in a variety of workplace settings is needed. A central recommendation necessary to achieve any level of equity in protections is to fund research on IPC measures (protective equipment, engineering controls, administrative controls) to inform preparedness efforts for essential industries, as well as cost-effectiveness and outcomes research to quantify how IPC measures save both financial and human capital. Currently, the National Occupational Research Agenda (NORA), which is a partnership program to stimulate innovative research and promote widespread adoption of improved workplace health and safety practices thus in many ways guiding National Institute of Occupational Safety and Health (NIOSH), must update its agenda to include further research on IPC for epidemics and pandemics to account for inequity in disease burden resultant from inequity in protections.[74] Specifically, additional funding should be allocated for NIOSH and other federal health agencies to address research gaps specifically for worker safety in essential industries with high numbers of minoritized and low wage workers. Federal funding should be provided to support state, local, and professional efforts to develop workplace hazard-assessment and control programs that include recognition and identification of aerosol exposures and prioritize workplace controls at the top of the hierarchy of controls.[75] Moreover, federal funding should support a robust research agenda targeted to workplace settings with high numbers of minoritized workers that includes: modeling research to support predictive transmission dynamics and disease spread to support rapid IPC guidance development based on emerging evidence, research on the role and design of ventilation; development and deployment of evidence based and inexpensive ventilation assessment tools and methods; training, fit-testing, and related respiratory-protection program support for all essential industries that lack the necessary resources and expertise to establish effective respiratory-protection programs.[76] Furthermore, to adequately address structural racism for meat processing and similarly situated essential workers, policy solutions and research agendas must be informed by sustained engagement with worker communities. Those in power, including professionals in occupational health and safety, emergency and pandemic preparedness and health security, and worker advocacy groups should demand that any future planning and research proceed with a focus on structural inequities, informed by the lessons of COVID-19 and other pandemics.

V. Conclusion

Public health agencies work to protect people from health threats. The COVID-19 pandemic demonstrated how the lack of evidence-based IPC guidance harmed multiply marginalized workers. To protect these populations, funders must prioritize scientific, preparedness, and bioethics projects aimed at protecting vulnerable workers. To avoid repeating the structural violence inflicted on low-wage essential workers during the pandemic, research and preparedness efforts should center on multiply marginalized workers' needs *before* the next epidemic or pandemic.

Note

The authors do not have any conflicts of interest to disclose.

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DETAILS

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Anti-Selection is Only the Beginning

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ABSTRACT (ENGLISH)

This commentary proposes the need for greater normative debate about when, if ever, it is appropriate for insurers to access genetic information of insureds to combat anti-selection.

FULL TEXT

Much of insurance regulation is framed as a balance of two competing interests. Insurers want as much information as possible about prospective clients, so they can avoid pay outs, earn profits, and compete for business with low premiums. They argue that they require this knowledge to combat “anti-selection,” or the outsized enrollment of high-risk individuals who know their risk when insurers do not.[1] Insureds, especially high-risk ones, fear that risk-rating will oust them from the comforts of community pooling, leaving them to bear their risks alone. The fear of losing insurance could lead people to forgo potentially valuable health-related information. In the context of genetics, people may avoid taking genetic tests or participating in genetic research as a result. Some countries have enacted legislation that bars insurers from considering genetic information under certain circumstances to ease anxieties about genetic discrimination.[2] However, denying insurers access to actuarially sound information—even for the greater good —could potentially lead to anti-selection, adversely impacting insurance markets.

How are regulators to respond to these conflicting concerns? The authors of “Anti-Selection &Genetic Testing in Insurance: An Interdisciplinary Perspective” make an important contribution to the literature by suggesting oft-cited concerns by insurers about anti-selection may be overblown.

To start, people may have internal barriers to opportunistic insurance purchasing.[3] The authors rightly point out that when a person receives a positive genetic test, her first impulse may not be to run out and purchase the optimal amount of insurance coverage. Genetic risk is difficult to understand and people with low health literacy may also have low financial literacy, which could lead them to forgo additional insurance even when it would benefit them. Even sophisticated parties might not know just how much insurance to buy following a genetic test because of incomplete risk information.[4] Genetic predispositions interact with other factors like the environment and adopting preventative or mitigating measures will alter a person’s risk profile.

External barriers could also lead even a perfectly rational person with complete knowledge of her genetic risks to forgo needed insurance.[5] First and foremost, purchasing additional insurance costs money, money that people who are at heightened genetic risk may not have. Second, insurance systems are notoriously complex, and people may not know where to begin. Third, purchasing insurance does not occur in a vacuum; it may take significant time to collect the necessary documents and to undergo required medical evaluations.

Last, when a person takes a genetic test, versus when she purchases insurance, can also have an effect on whether anti-selection occurs.[6] People may already have insurance or may opt to purchase it before taking a genetic test. In such cases, no information asymmetry exists, again minimizing the effects of anti-selection.

Ultimately, “Anti-Selection &Genetic Testing in Insurance: An Interdisciplinary Perspective” is a well-argued call for greater study of the magnitude of anti-selection in the real world to inform policymaking, domestically and abroad. We must understand better whether fears of anti-selection are overblown by insurers, to better inform our policies. If the evidence bears out that some anti-selection does exist, the answer is not to simply provide access to that information. Instead, we should ask ourselves whether the costs of anti-selection are justifiable to further the public good. Whether anti-selection affects the market should be the beginning —not the end —of the conversation for insurance regulators. If we must allow risk-selection in insurance, how do we create the social supports to assist not only those with costly genetic conditions, but all citizens regardless of disability, age, or socio-economic status?

We agree greater empirical study of anti-selection is necessary, especially in the context of genetics, and argue that normative considerations are equally important to inform insurance policymaking.

Is it proper to consider genetics at all in risk-selection? Yes, those with genetic conditions like Huntington's Disease may deplete the insurance pool more than others, but are they owed any communal support? As the authors point out, risk-selection in genetics can compound generationally, as first one, then the next, then the next generation is denied the benefits of disability, life, or health insurance.[7] The consequence can be extreme economic disadvantage for families over time, especially in countries like the US that rely on private insurance as a poor substitute for adequate social safety nets. Widespread use of genetic testing for risk-selection turns what should have been a tool of public health into an instrument of disadvantage for some of the most vulnerable people in our society.

Furthermore, if risk-selection must be had, why use genetic information as opposed to some other information? It is the mere availability of the information that draws insurers to genetic risk. Other factors may equally impact the insurance pool, but in less predictable manners, through accidents or injuries. Moreover, highly predictive genetic tests tend to be for relatively rare conditions. Thus, underpricing the policies of the handful of people at heightened risk will probably not adversely impact the market.[8] People who test positive for less penetrant conditions may not be inclined to purchase additional insurance in the first place.9

We must understand better whether fears of anti-selection are overblown by insurers, to better inform our policies. If the evidence bears out that some anti-selection does exist, the answer is not to simply provide access to that information. Instead, we should ask ourselves whether the costs of anti-selection are justifiable to further the public good. Whether anti-selection affects the market should be the beginning —not the end —of the conversation for insurance regulators. If we must allow risk-selection in insurance, how do we create the social supports to assist not only those with costly genetic conditions, but all citizens regardless of disability, age, or socio-economic status?

Note

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DETAILS

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Physician Liability for Suicide after Negligent Tapering of Opioids

Rothstein, Mark A; Irzyk, Julia

ABSTRACT (ENGLISH)

The precipitous and medically contraindicated reduction or “tapering” of opioids for patients with chronic pain due to serious medical conditions has caused needless suffering and, increasingly, suicide. Physicians could be liable for wrongful death based on negligent tapering of opioids.

FULL TEXT

Drug overdose deaths in the United States caused a total of 500,000 deaths from 1999-2019,[1] and the tragedy is getting worse. Between April 2020 and April 2021, there were approximately 100,000 deaths from accidental and intentional drug overdoses.[2] Numerous causes of the opioid crisis have been noted,[3] including aggressive and misleading marketing by pharmaceutical companies,[4] overprescribing by physicians,[5] lack of diligence in filling prescriptions and bulk orders by retail pharmacies and drug distributors,[6] unsuccessful interdiction of illicit opioids,[7] inadequate levels of drug treatment,[8] and socio-economic struggles in many parts of the country.[9]

The magnitude of the opioid crisis has led to drastic policy changes that directly and indirectly affect prescribing practices. These measures include state prescription drug monitoring laws, opioid contracts between providers and patients, and clinical guidelines and institutional policies limiting opioid prescribing. Some of these measures, however, have had grievous, unintended consequences for chronic pain patients, including unremitting pain, anxiety, depression, decreased quality of life, accidental overdoses, and even suicide. This article focuses on the possibility of legal liability for physicians whose negligence in reducing or “tapering” the opioids of a patient results in suicide.[10]

The Pendulum Swings Back Too Far

Pain control became an important part of American healthcare policy in the mid-1990s, as pain as the “fifth vital sign” and hospitals including pain control questions on patient satisfaction surveys drove the prescribing of opioid analgesics.[11] OxyContin, an extended-release opioid originally developed to relieve chronic cancer pain,[12] received unrestricted approval from the Food and Drug Administration in 1995. The package insert for OxyContin contained the following baseless statement: “Delayed absorption, as provided by OxyContin tablets, is believed to reduce the abuse liability of the drug.”[13] With such flagrant misstatements of the drug’s capacity to cause addiction and aggressive marketing to physicians,[14] sales of OxyContin skyrocketed from $45 million in 1996 to $1.1 billion in 2001.[15]

Opioid prescriptions and opioid use disorder (OUD) continued to increase in the next decade and peaked in 2012, when American physicians wrote 255 million prescriptions for opioid pain relievers, enough for every adult in the United States to have a bottle of opioid pills.[16] By 2016, “only” 215 million opioid prescriptions were dispensed by retail pharmacies.[17] The National Institute on Drug Abuse estimated that in 2015, 91.5 million Americans were taking opioids, such as OxyContin and Vicodin.[18] In 2015, at least 2 million Americans had OUD involving prescription opioids.[19]

In response to the widespread harms caused by overprescribing of opioids, in 2016, the Centers for Disease Control and Prevention (CDC) issued its Guideline for Prescribing Opioids for Chronic Pain.[20] Because most of the opioid prescriptions were written by primary care providers (including physicians’ assistants and nurse practitioners), the Guideline “provides recommendations for the prescribing of opioid pain medication by primary care clinicians for

chronic pain (i.e., pain conditions that typically last >3 months or past the time of normal tissue healing) in outpatient settings outside of active cancer treatment, palliative care, and end-of-life care."[21] Despite the best of intentions by the CDC, the Guideline has been an unmitigated disaster for individuals with chronic pain by making access to essential pain relief difficult or impossible to obtain.[22] According to the American Medical Association: "It is clear that the CDC guideline has harmed many patients."[23]

Concerns about possible legal or professional jeopardy have been a significant factor in drastically reducing opioid prescribing by physicians. Liability for failing to prescribe opioids when medically indicated, especially if it results in a patient's suicide, may now be emerging as a countervailing force against the heedless tapering of patients with chronic pain.

There are at least five major problems with the Guideline:

First, the Guideline recommends that "[n]onpharmacologic therapy and nonopioid therapy are preferred for chronic pain."[24] This unequivocal statement, though supported by some pain management experts,[25] has been contested by other experts, including a recent comprehensive review of the literature. "Because of the absence of comparative effectiveness studies, there are no scientific grounds for considering alternative non-pharmacologic treatments as an adequate substitute for opioid therapy but these therapies might serve to augment opioid therapy, thereby reducing dosage."[26]

Second, the Guideline recommends a 90 morphine milligram equivalents (MME) daily dosage cap. It further states that use of opioids for "more than seven days will rarely be needed,"[27] positions that do not account for the needs of individuals with long-term, extreme pain who have tolerated higher MME levels. "Many patients currently receiving long-term opioids were started when opioids were still considered a viable treatment option and if satisfied with their pain control and using their medications appropriately should not be unilaterally compelled to wean off opioids."[28]

Third, although expressly limiting its applicability to outpatient settings and primary care clinicians, the Guideline has been applied in numerous inpatient settings and by pain management physicians. "[T]he guideline has achieved its greatest impact by convincing health care provider organizations that violations of the guideline by their member physicians may increase organizational liability exposure."[29] The Guideline also served to encourage the enactment of prescribing restrictions by legislatures in 30 states.[30]

Fourth, the Guideline explicitly states that it is not applicable to cancer care or end-of-life care. Nevertheless, its use for both situations has resulted in inexcusable misery for the most vulnerable patients. A recent study of older patients dying of cancer found a substantial reduction in the number and strength of opioid prescriptions, especially those for long-acting opioids.[31]

Fifth, the Guideline recommends the tapering of opioid patients. Aggressive, especially nonconsensual, tapering is unethical[32] and dangerous. The Guideline specifically calls for gradual reductions with the consent of patients,[33] but it has been applied without the consent of patients, abruptly, and with tragic results. A recent study of more than 100,000 patients receiving opioids long-term for pain found a 68 percent increase in overdoses and a doubling of mental health crises in tapered versus untapered individuals.[34] Another study found that up to 30 percent of all overdose deaths are suicides.[35]

Slone v. Commonwealth Pain and Spine

Concerns about possible legal or professional jeopardy have been a significant factor in drastically reducing opioid prescribing by physicians. Liability for failing to prescribe opioids when medically indicated, especially if it results in a patient's suicide, may now be emerging as a countervailing force against the heedless tapering of patients with chronic pain. The first successful wrongful death case involving drastic reduction in opioid dosage was decided in Louisville, Kentucky in 2021.[36]

In 2011, Brent Slone was severely injured in a car accident, sustaining a broken pelvis, compressed spinal cord, and paralysis from the waist down. In 2014, he became a patient at Commonwealth Pain and Spine (Commonwealth), which has several clinics in Kentucky and Indiana. Mr. Slone was prescribed an opioid dose of 240 MME for his pain, although the subsequent 2016 CDC guideline recommended a limit of 90 MME.[37] In 2016, Mr. Slone started traveling to California for advanced wound care after pressure sores from his wheelchair caused bone infections. In

the summer of 2017, Mr. Slone went to California for surgeries, including skin grafts, and he had his recovery at a nursing facility in La Jolla. His pain level increased, and his daily opioid dosage rose to 400 MME, on occasion reaching 540 MME.

On August 11, 2017, Mr. Slone was discharged from the nursing facility to travel to Kentucky. His medical team in California contacted Commonwealth and said he had enough medication to last through August 16. Dr. Stephen Young, who along with Dr. James Jackson, was his pain management physician at Commonwealth, wrote him a bridge prescription at 540 MME to last until his August 22 appointment. At that appointment, Mr. Slone's dose was summarily dropped to 240 MME. This dosage was inadequate for Mr. Slone, and he began taking 300 to 400 MME per day. By September 11, he was running out of medicine, though his next appointment was scheduled for September 18. On September 12, Dr. Young denied a refill or bridge prescription to last until his appointment, saying that Mr. Slone had violated his narcotic contract by taking more than the prescribed dosage. On the afternoon of September 12, Mr. Slone texted his wife: "they denied script im done love you." Shortly thereafter, he took his own life. He was 40 years old.

His widow brought a wrongful death action against Commonwealth and Drs. Young and Jackson, alleging negligence in summarily reducing his dosage from 540 MME to 240 MME and in failing to provide him a bridge prescription when the 240 MME dose proved to be inadequate to relieve his pain. A jury in Jefferson County, Kentucky Circuit Court awarded the plaintiff $6.925 million, with $3 million designated for Mr. Slone's daughter.[38] According to the lead lawyer for the plaintiff, based on post-trial interviews the jurors had a negative impression of the pain clinic, but they did not have a negative view of Mr. Slone, a long-time user of opioids for chronic pain.[39]

Elements of a Legal Action for Negligent Tapering

A legal action to recover for the death of a patient allegedly caused by a physician's improper tapering of the patient from opioids would be based on negligence. The well-known elements of an action for negligence are duty, breach, causation, and damages.[40] In a wrongful death action[41] the defendant is alleged to have breached a duty to the decedent by failing to exercise reasonable care under all the circumstances, [42] which led to the death of the decedent. The issues of duty and causation are especially important in cases based on negligent tapering of opioids.

Duty

A duty is "an obligation, recognized by the law, requiring the person to conform to a certain standard of conduct, for the protection of others against unreasonable risks."[43] Professionals, including physicians, have a higher standard, "to have and use the knowledge, skill, and care ordinarily possessed by members of the profession in good standing."[44] Physicians also have ethical obligations to their patients, as noted by the American Medical Association. Relationships between patients and physicians are inherently unequal: the fact of illness renders patients vulnerable, in greater or lesser degree, and dependent on physicians' expertise and fidelity. Yet patients bring to interactions with physicians their values, goals, and preferences as well as their needs. Patients must therefore be able to trust not only that their physicians have the knowledge and skills to provide competent care, but equally that their physicians will do so with respect for the patient as a moral agent and compassion for the patient as a human being.[45]

Patients treated for chronic pain with opioids are highly vulnerable. They have medical conditions with severe pain that cannot be controlled by other treatment modalities or less potent analgesics. Their underlying medical condition, their pain level, and the opioids they take all may interfere with their cognitive or reasoning abilities. They are dependent on their physician's renewal of their prescriptions; there are no safe and effective alternatives. Significantly, they bear the stigma of requiring drugs often associated with personal immorality or criminal activity.[46] As a price for access to a substance that allows them to lead the semblance of a normal life, patients with chronic pain are often required to sign contracts pledging compliance with terms imposed on them,[47] to submit to periodic or random urine testing,[48] and to bear humiliation by a society that is frequently fearful, suspicious, and intolerant. Few other patients are subject to such indignities.[49]

The substantial vulnerability of patients treated for chronic pain means that the duties of their treating physicians are heightened, especially when a patient is taking higher doses of opioids, is being treated for depression, or

demonstrates possible self-damaging behavior.[50] The duty includes monitoring the patient, especially when the individual's opioid dosing is being changed via tapering or otherwise, conducting in-person assessment of the patient's condition, and referring the patient for consultation with a specialist (e.g., psychiatrist, pain management specialist) when medically indicated. Vulnerable patients should not be abandoned or have their treatment unreasonably delayed when they are at risk of accidental or intentional overdosing.

Breach

A plaintiff must prove that the defendant-physician failed to meet the appropriate standard of care, which almost always requires expert testimony. An important issue is whether the standard may be established by the introduction of nonbinding professional guidelines or recommendations. In *In re Jankowski*,[51] a state licensing agency brought disciplinary proceedings against a physician for, among other things, prescribing excessive levels of opioids without medical justification. The appellate court, in affirming sanctions against the physician, held that the 2016 CDC Guideline was the standard of care for a pain management physician, notwithstanding the statement in the Guideline that it applied only to primary care clinicians.[52]

Causation

In a negligence case, "a plaintiff must prove that it is more likely than not that, if the defendant had not acted tortiously, the plaintiff's harm would not have occurred."[53] This causation-in-fact is relatively easy to prove, especially in a case such as *Slone* because of the final text message he sent to his wife. It is much more difficult for a plaintiff to prove that the action of the defendant was the proximate or legal cause of suicide.[54] This latter issue involves complex and contested matters of public policy.

In wrongful death cases, the traditional rule is that suicide is considered a superseding cause that precludes liability of the alleged wrongdoer.[55] The decedent's act is considered unforeseeable as a matter of law. Three limited exceptions to the general rule have been recognized: (1) if the decedent's action was caused by delirium, insanity, or irresistible impulse;[56] (2) if the defendant had a duty to protect the decedent, especially in a custodial setting such as a jail, hospital, or mental institution;[57] and (3) if there was a special relationship between the defendant and the decedent, such as a psychoanalyst-patient relationship in which the decedent displayed suicidal ideation.[58]

There is a trend in recent cases to reject the old, inflexible rule and hold that the question of whether a suicide was foreseeable should be decided by juries applying a modern "scope of liability" analysis. Several of the cases holding that the jury could conclude that suicide was foreseeable involved the suicide of young people, thereby underscoring the role of public policy. For example, courts upheld verdicts for plaintiffs where a middle school student's suicide was foreseeable to the school board because of two recent on-campus suicide attempts,[59] where a college knew that a student had previously threatened suicide,[60] and where a 13-year-old student who stuttered was the subject of intense bullying.[61]

In a series of medical malpractice cases the courts also have upheld jury verdicts finding that suicide was foreseeable.[62] These include a case where negligent surgery left the decedent partially paralyzed and in intense, continuous pain[63] and where the decedent took his life after unknowingly ingesting a prescription that his wife, on the physician's advice, gave to him secretly.[64] Of most relevance to this article, *Edwards v. Tardif*[65] involved a patient who had been treated for depression for several years. When she had a recurrence of depression she called her regular physician's office. An internist who had never treated the decedent and who was covering for her regular physician, without reviewing the decedent's chart or examining her, prescribed 100 anti-depressant pills with two refills of a drug that was contraindicated for a patient who also had a history of alcoholism. Eight days later she took her own life. According to the Supreme Court of Connecticut, "a physician may be liable for a patient's suicide when the physician knew or reasonably should have known of the risk of suicide and the physician's failure to render adequate care and treatment proximately causes the patient's suicide."[66]

These cases strongly suggest that at a time when the opioid crisis is causing at least 30,000 suicides a year by drug overdose, it is foreseeable that the negligent tapering of a chronic pain patient taking opioids could result in suicide.

Damages

Successful plaintiffs in wrongful death actions are able to recover a range of compensatory damages, including pain

and suffering, lost income, and loss of consortium. Punitive damages also are recoverable if the defendant's conduct was willful, wanton, or evidenced a reckless disregard for the health of their deceased patient.

Defenses

Few traditional defenses to medical malpractice are applicable in a typical wrongful death case for negligent tapering resulting in suicide. Comparative negligence, however, might be relevant in some jurisdictions. For example, in the *Slone* case discussed above, the jury determined that Mr. Slone was two percent at fault.[67] In a jurisdiction that only permits a plaintiff to recover if the decedent's suicide was caused by delirium, insanity, or irresistible impulse, if the decedent was in such a compromised mental state, then the defense of comparative negligence would appear to be precluded because the decedent lacked the capacity to act negligently. However, in jurisdictions that apply general foreseeability principles, the decedent need not be so profoundly impaired, and comparative negligence could be applicable.

Conclusion

America's opioid crisis is well into its third decade. There are many causes of this problem and resolving them will take a variety of measures over an extended time. Unfortunately, some past efforts to reduce the morbidity and mortality associated with improper use of prescription opioids have been ineffective and led to disastrous unintended consequences. One such attempt to limit the supply of prescription opioids involved the issuance of prescribing guidelines. Between 2012 and 2020, the number of opioid prescriptions declined dramatically from 255 million to 142 million,[68] but the number of overdose deaths soared from 41,000 to 100,000.[69] One of the most tragic consequences of curtailing the use of opioids for managing severe, chronic pain has been an increase in suicides, which now account for an estimated 30 percent of drug overdose fatalities.[70] It is not known how many suicides result from a physician's negligent, aggressive tapering of opioids.

Many physicians are concerned that prescribing opioids could lead to criminal prosecution, license revocation, loss of employment or hospital privileges, or malpractice litigation.[71] On the other hand, legal jeopardy for failing to continue prescribing opioids to existing patients, even when the standard of care requires it, does not seem to be a widespread concern. Wrongful death actions for negligent tapering of opioids resulting in a patient's suicide is a legal theory that more courts are likely to accept and thus could become a counterbalancing concern for physicians. Although sound health policy should not be based on dueling litigation risks, if fear of liability for discontinuing medically necessary opioids leads to appropriate treatment of vulnerable patients with chronic pain, then it will serve an important purpose.

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DETAILS

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Consciousness, Conflations, and Disability Rights: Denials of Care for Children in the “Minimally Conscious State”

Fins, Joseph J

ABSTRACT (ENGLISH)

This essay critiques the fiercely utilitarian allocation scheme of Cameron et al. Children have no hope of recovery if their lives are cut short based on administrative protocols that misrepresent the nature of their conditions. Unilateral futility judgements - especially those based on a false predicate - are discriminatory. When considering the best interests of children, we should see possibility in disability and not advance ill-informed utilitarianism.

FULL TEXT

In their essay, “Raqeeb, Haastrup and Evans: Seeking Consistency Through a Distributive-Justice Based, Approach to Limitation of Treatment in the Context of Dispute,”[1] Cameron et al. advance a fiercely utilitarian framework to deny care to children described as being in the minimally conscious state (MCS). Their argument is made within Britain’s National Health Service, a universal coverage system which Norman Daniels describes as a closed system of justice where saved resources accrue back to beneficiaries.[2] Beyond the questionable generalizability of their argument beyond Britain’s NHS, their appeal to distributive justice is flawed by its mischaracterization of MCS in children. This error undermines the factual basis for their appeal to distributive justice as they seek to deny care to children with

serious brain injury.

MCS is state of liminal consciousness in which patients demonstrate an awareness of self, others, or the environment.[3] In contrast to patients in the vegetative state,[4] those in MCS may respond to their name, look up when someone enters the room, reach for a cup, and even speak. At a physiologic level, they are also distinct from patients who are vegetative[5] because they have intact distributed neural networks.[6] On neuroimaging they can perceive language[7] and experience pain.[8] Fundamentally, unlike those in the vegetative state MCS patients are conscious.

Despite the protestations of the authors about the high costs of ventilator support, MCS patients do *not*, by definition, need to be on a ventilator. While they may need respiratory hygiene to prevent aspiration, they have intact brain stems and so breathe on their own. This is a salient factual error given that the authors' rationing scheme is predicated upon the cost of mechanical ventilation, asserting that its benefit should be subject to the same scrutiny as other treatments.

Speaking of definitions, it is curious that despite the predicate of the expense of MCS and the alleged need for ventilator support, the authors never once proffer a definition of MCS. This is even more troubling because the authors make the claim that their appeals constitute "…'Precision Justice,' mirroring the advance of precision medicine." It is difficult to weigh utilities when one gets the particulars wrong at an evidentiary level. Indeed, as I have asserted in a forthcoming anthology on precision medicine,[9] there is an emerging science related to disorders of consciousness where precision of diagnosis is tied to emerging treatments such as the use of amantadine [10] and neuromodulation.[11]

The lack of an evidence base advanced by Cameron et al. is even more scientifically and normatively problematic given that the American Academy of Neurology, the American College of Rehabilitation Medicine and the National Institute on Disability, Independent Living and Rehabilitation Research have issued a practice guideline setting standards for the diagnosis and treatment of patients with disorders of consciousness based on a ten-year evidence-based review.[12]

Instead of therapeutic nihilism, why not view our collective obligations to children with severe brain injury through the prism of disability law? Why not invoke new insights from translational neuroscience to frame our collective obligations? When consciousness is present, it should be identified, celebrated, and given voice. When considering the best interests of children, we should see possibility in disability.

Despite this progress, diagnosis, and prognostication in MCS patients remains challenging. The behaviors that distinguish MCS from VS are episodic and intermittent so when MCS patients do not exhibit signs of awareness they can appear vegetative, leading to a failure to identify consciousness in 41% of cases.[13] Prognosis is equally perplexing as the temporal dynamics of MCS are *not* time dependent. As Lammi has shown, the length of time one is in MCS is *not* predictive of emergence from MCS.[14] Finally, there is the challenge of covert consciousness, or cognitive motor dissociation, where patients evidence volitional responsiveness on neuroimaging but not do so behaviorally.[15]

Pediatric diagnostic and prognostic challenges are even more challenging as children start off with a primitive nervous system that is developing. Early on, it may be difficult to classify children as minimally conscious as the requisite visual, motor, and language-based skills necessary for assessment have yet to develop.[16] Moreover, assessment tools used to evaluate MCS in adults[17] are only now being modified and calibrated for a pediatric population.[18] Given this evolving nosology, it is remarkable that the authors use MCS as a stalking horse for their rather draconian approach to limit the care of these children. For many of them, MCS is a conceptual conflation that may not even exist as a legitimate diagnostic category.

The authors' epistemic certainty of what constitutes the "best interest" of the child becomes ever more disquieting because a child's nervous system is in flux. Early in life there is the potential for developmental workarounds.[19] This hopeful biological process, however, can be derailed absent human engagement, focused rehabilitation, and access to assistive technologies. If children are neglected and relegated to what is euphemistically described as "custodial care,"[20] they will miss critical developmental milestones compounding the impact of their initial injury.

Of course, children have no hope of recovery if their lives are cut short based on administrative protocols that mischaracterize the nature of their conditions. These unilateral futility judgements marginalize parents, the child's natural surrogates, and operate in willful violation of disability law, including the UN Convention on the Rights of Persons with Disabilities and the Americans with Disabilities Act, each of which call for the integration of people with disabilities into civil society.[21] It is self-evident that children who are prematurely withdrawn from life-sustaining therapy before they can manifest their potential will be irreversibly marginalized. While decisions to withhold or withdraw care can be ethically proportionate,[22] the factual predicate asserted by Cameron et al. makes any judgement of proportionality impossible. In this context, it is discriminatory to assert that continued treatment is harmful because of cost.

Instead of therapeutic nihilism, why not view our collective obligations to children with severe brain injury through the prism of disability law?[23] Why not invoke new insights from translational neuroscience to frame our collective obligations?[24] When consciousness is present, it should be identified, celebrated, and given voice.[25] When considering the best interests of children, we should see possibility in disability.[26]

Note

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Fresh Take: Pitfalls of the FDA's Proposed Menthol Ban

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ABSTRACT (ENGLISH)

In April 2021, the U.S. Food and Drug Administration announced its intention to ban menthol flavoring in cigarettes and cigars. The Agency's decision was based in part on the disproportionate impact of menthol flavoring in Black communities.

FULL TEXT

Introduction

In Spring 2021, the U.S. Food and Drug Administration (FDA) announced plans to ban menthol as a characterizing flavor in cigarettes and cigars. The agency based its decision in part on menthol's disproportionate impact on communities of color and association with increased youth smoking rates. We agree that these are among many worthwhile reasons to limit menthol use. However, there are potential pitfalls of using a ban to achieve these goals. We argue that a ban is a top-down, paternalistic approach that may lead to an illicit market for menthol products, exacerbate racial disparities in policing, and stifle the broad community buy-in essential for the effort's success. We recognize that the tobacco industry has also advanced many of these arguments, albeit with different motives and significant conflicts of interest. This article does not seek to defend the tobacco industry or menthol cigarettes. Instead, we hope to offer a different point of view on the FDA's current proposal, namely that using race as a principal justification for a ban, even if well-intentioned, may lead to unintended negative consequences.

Since Doll and Hill in 1954 purported a link between smoking and lung cancer, there have been many federal and local efforts to regulate tobacco products.[1] Principle among these is the 2009 Family Smoking and Tobacco Control

Act (TCA) which made the FDA responsible for comprehensive tobacco regulation. Considering their disproportionate use among youth smokers, the regulation of flavored tobacco products was a chief concern of the TCA.[3] The 2009 bill banned all characterizing flavors other than menthol in cigarettes. National survey and modeling data estimated that the 2009 flavored cigarette ban reduced the predicted rates of cigarette smoking in both youth (ages 12-17) and young adults (ages 18-25) by 27% and 43%, respectively.[4] Although difficult to establish a direct causal relationship, it has been observed that while cigarette smoking rates declined, usage of Electronic Nicotine Delivery Systems (ENDS) products skyrocketed, particularly among youth. In January 2020, the FDA announced that all ENDS cartridge-based flavor products (excluding tobacco and menthol flavors) would be subject to prioritized enforcement of a previously unenforced requirement that all ENDS products must obtain premarket authorization.[5] As no ENDS products have this authorization, the announcement amounted to a de-facto ban of all current non-menthol flavored ENDS products.

Menthol Use and Marketing

Menthol is an ingredient naturally found in peppermint plants that creates a cooling sensation when smoked, allowing it to decrease the harshness of cigarette smoke. Menthol flavor was introduced in cigarettes in 1925, and ever since, it has been an integral part of the flavored tobacco landscape.[6] Youths and adults who reported that their first tobacco product was any flavored tobacco product had higher tobacco smoking rates a year later.[7] Of particular concern is the use of menthol among the youth; the Population Assessment of Tobacco and Health (PATH) study from 2013-2014 found that 59.5% of youth smokers used menthol products compared to 37.1% of adults.[8]

The disproportionate use of menthol cigarettes by Black Americans is no accident. This racially disproportionate consumption of mentholated cigarettes developed over time due to affirmative actions taken by the tobacco industry. By the 1950s, Black Americans' rapidly expanding purchasing power, the prevalence of segregated communities, migration to urban areas, and this population's distinct cultural wants and needs created an ideal advertising market. The tobacco industry was one of the first manufacturers to exploit this opportunity.

While overall smoking rates have declined over the past several decades, between 2004 and 2014, the rate of menthol cigarette use has declined more slowly. Over a quarter of all cigarettes sold in the United States since the 1970s have been mentholated. Other studies have estimated that there are nearly 18.6 million current smokers of menthol cigarettes amongst adult and youth smokers in the U.S. However, the use is not uniform; while only 30% of white smokers are menthol smokers, various studies have estimated that 70-85% of Black smokers smoke menthol cigarettes. Additionally, from 2011 to 2018, declines in menthol cigarette use were seen among non-Hispanic white youth but not among Black or Hispanic youth.[9]

The disproportionate use of menthol cigarettes by Black Americans is no accident. This racially disproportionate consumption of mentholated cigarettes developed over time due to affirmative actions taken by the tobacco industry. By the 1950s, Black Americans' rapidly expanding purchasing power, the prevalence of segregated communities, migration to urban areas, and this population's distinct cultural wants and needs created an ideal advertising market. The tobacco industry was one of the first manufacturers to exploit this opportunity. For instance, by 1962, Ebony carried twice as many cigarette ads as did Life. The millions of pages of tobacco industry documents made publicly available after the Master Settlement Agreement between state attorneys general and the major tobacco producers, paint a picture of a deliberate effort by the tobacco industry to target Black Americans through advertising to increase the market share of menthol cigarettes in this community. The tobacco industry advertising campaign targeting Black communities was often coupled with generous financial support of Black community organizations, including civil rights groups. According to scholarship by Yerger and Malone, this was done for three specific business reasons: "to increase African American tobacco use, to use African Americans as a frontline force to defend industry policy positions, and to defuse tobacco control efforts." This is not to claim that Black community organizations were directly involved in promoting menthol cigarettes, but by supporting these organizations, some tobacco industry executives felt they might prevent Black community organizations and leaders from attacking cigarette manufacturers.[10]

In addition to targeting the Black community as a whole, there is evidence that the tobacco industry was involved in

deliberately targeting Black children. For instance, evidence presented during a successful lawsuit against the maker of Newport cigarettes showed that in the late 1950s and early 1960s, the company provided Black children as young as nine years old with free cigarettes. Furthermore, one study found that in comparison to other neighborhoods, the cost of Newport cigarettes was significantly lower in convenience stores located near minority-serving high schools.[11]

While manufacturers often billed menthol cigarettes as healthier, scientific evidence has been mixed, and studies have shown that menthol cigarettes may even pose an increased health risk.[12] Furthermore, a systematic review of eighty-two studies on menthol cigarettes revealed an association between menthol flavor and youth smoking, increased nicotine dependence among menthol smokers compared to non-menthol smokers, and a relationship between menthol flavor and reduced smoking cessation success.[13] However, to date, when considering the totality and weight of the available evidence, there is little to support that menthol cigarettes inherently carry any more or less health risk compared to non-menthol cigarettes.[14]

History of Menthol Regulation

In the absence of federal action and in part because of fierce advocacy by tobacco control groups, state legislatures and regulators have taken steps to limit the sale of menthol tobacco products, especially menthol cigarettes. Massachusetts became the first state to ban the sale of all flavored tobacco products starting with e-cigarettes and later to expand to all products; currently, it remains the only state with such a broad ban. Connecticut, New Jersey, New York, and Rhode Island have followed suit, but their bans are limited to flavored e-cigarettes. There are efforts in New York to expand the flavor ban to include all tobacco products; however, such a move is facing opposition in the General Assembly, in part due to concerns for potential losses in tobacco excise tax revenue as a consequence of expanding the ban. While California has also passed such a law, its implementation is pending a referendum vote.[15] Other states, including Minnesota, have proposed similar bans, but their bills have not become law as of August 2021. Additionally, numerous localities have passed restrictions banning the sale of menthol cigarettes, although these restrictions vary widely in their application.[16] One commonality among all these efforts is that the bans primarily target the sale and distribution of flavored tobacco products, without penalizing their use.

Both the 2009 cigarette flavor ban and the 2020 ENDS cartridge flavor ban excluded menthol, though it had been considered each time. In 2009, the TCA created the Tobacco Products Scientific Advisory Committee (TPSAC), whose first task was to guide decisionmaking on menthol cigarette regulation. Their 2011 report, known as the "Menthol Report," concluded that banning menthol would be in the interest of the nation's public health. Shortly after the report, Lorillard, one of the nation's largest tobacco companies, sued the FDA, claiming multiple violations of the Administrative Procedure Act (APA) and, in particular, the appointment of committee members with alleged financial conflicts of interest. The trial court ruled that the members of the Committee were in fact conflicted, thereby tainting the work product of the Committee. Consequently, the court ordered the FDA to reconstitute the TPSAC membership and enjoined the agency from using the Menthol Report. Even though this was subsequently reversed by the appellate court on standing grounds, progress on further regulation of menthol flavor stalled within the agency.[17] Since then, congressional action on banning menthol flavor through legislative action has also been unsuccessful.[18]

In 2013 the Tobacco Control Legal Consortium filed a Citizen Petition with the FDA urging the agency to use its regulatory authority under the TCA to remove menthol cigarettes from the market.[19] In 2020, a coalition of public health, civil rights and educational organizations, including the American Medical Association, led by the African American Tobacco Control Leadership Council and Action on Smoking and Health, filed a lawsuit against the FDA. The suit alleged that the FDA had failed to act on menthol cigarettes contrary to the duties imposed by the TCA in violation of the APA. In particular, the lawsuit alleged that the FDA's failure to act to prohibit menthol flavor in cigarettes despite ample evidence and two Advanced Notices of Proposed Rulemaking in light of the TCA's requirement for periodic reevaluation of existing tobacco product standards amounted to "unreasonable delay" of agency action. The lawsuit also alleged that the FDA had failed to provide substantive response to the 2013 Citizen Petition by various public health groups. Among other petitioned reliefs, the plaintiffs requested an order to direct the

FDA to begin the rulemaking process for adding menthol to the list of characterizing flavors banned by the TCA, as well as an order directing the agency to provide a substantive response to the 2013 Citizen Petition. Although the case is still active as of August 2021, the FDA had agreed to respond to the amended 2013 Citizen Petition by April 29, 2021, on which date the FDA announced its intention to propose product standards to ban menthol as a characterizing flavor in cigarettes and all characterizing flavors in cigars.[20]

The Pitfalls of a Menthol Ban: Paternalism

In the FDA's announcement, Acting FDA Commissioner Janet Woodcock said the proposed ban would "reduce youth initiation, increase the chances of smoking cessation among current smokers, and address health disparities experienced by communities of color, low-income populations, and LGBTQ+ individuals, all of whom are far more likely to use these tobacco products." This was followed by a statement from the director of the FDA's Center for Tobacco Products, Mitch Zeller, acknowledging that progress associated with smoking cessation has not been experienced by everyone equally, referring to the disproportionate effect of tobacco use on Black Americans. He further explained that "[t]hese flavor standards would reduce cigarette and cigar initiation and use, reduce health disparities, and promote health equity by addressing a significant and disparate source of harm."[21] Although it appears well-intentioned, such paternalistic statements and justifications for government action on their face are problematic.

Paternalism is commonly defined as the "interference with a person's liberty of action justified by reasons referring exclusively to the welfare, good, happiness, needs, interests or values of the person being coerced."[22] There is a spectrum of paternalistic approaches, but bans are generally viewed as the hardest manifestation of paternalism. Admittedly, in some instances, even extreme curtailing of liberty in the name of public health measures are justified, but they must be closely scrutinized to ensure that the secured benefits outweigh the restrictions on liberty.[23] Furthermore, when the burden of coercion is unevenly carried by a single racial group, namely Black smokers in this case, as evident from the demographics of menthol smokers, it becomes even more suspect. In contrast to menthol flavor, other previously banned flavors were not used disproportionally by any single racial group; consequently, the coercion associated with the ban applied evenly to all racial groups. Although the merits of those other bans can also be debated, they are less problematic from a paternalistic standpoint. Therefore, the ultimate question is, what justifies government intervention limiting choice among Black smokers while leaving white smokers largely unaffected?

The Pitfalls of a Menthol Ban: Criminalization

Beyond concerns regarding the ill effects of paternalism, civil rights organizations have voiced fears of worsening racial disparities in policing and the criminal justice system due to the unintended consequences of this ban. Following the FDA's April 2021 announcement, a coalition of criminal justice organizations and the American Civil Liberties Union (ACLU) raised "deep concerns" in a letter to the FDA over the agency's move to ban menthol cigarettes. While recognizing the FDA's good intentions, the ACLU letter highlights the potential for negative implications on racial justice and potentially increasing tensions between local law enforcement and minority groups. Although the FDA has acknowledged that it lacks jurisdiction (and the intention) to enforce a ban on individual possession and use of tobacco products, the sale and distribution of banned cigarettes is a federal crime punishable as a felony.[24] Consequently, the proposed FDA ban will in effect criminalize the sale and distribution of menthol cigarettes under federal law. Similarly, many previously discussed state laws banning menthol flavor also criminalize the sale and distribution of banned products. There already exists a substantial illicit cigarette market in the U.S., estimated to be at least 8.5% of the market, with other estimates being as high as 21%. Even using the low end of the estimate, there has been an almost three-fold expansion in the illicit market, from 3.2% in 1992-1993 to 8.5% in 2010-2011, primarily due to increased cigarettes taxes.[25] Undoubtedly, a federal menthol ban will also lead to the expansion of illicit markets for cigarettes with a higher concentration of such markets specifically for menthol cigarettes in Black communities, risking repeating the recent tragic history of tobacco-related police interactions leading to the death of unarmed black men, including Eric Garner. Therefore, there is a high risk of exacerbating existing racial disparities in the criminal justice system due to unintended consequences of criminalization of menthol

flavor by transforming a public health issue into a policing matter.[26] Multiple national Black law enforcement organizations and members of Congress, including congresswoman Clarke of New York, a member of the Congressional Black Caucus, have also echoed these concerns.[27]

The Pitfalls of a Menthol Ban: Limitations to Prohibition

The realistic public health gains from a menthol ban are also debatable. Studies have attempted to quantify the potential benefits of a menthol ban. A 2011 modeling study estimated that as a result of a menthol ban, by 2050 there would be an overall reduction in smoking prevalence of 9.7% and a 24.8% reduction of smoking prevalence among Black Americans. This reduction was estimated to translate into 633,252 overall fewer deaths and 237,317 fewer deaths in Black Americans. The study used a validated smoking simulation model and data, assuming a 30% quit rate among current menthol smokers and that 30% of those who would have otherwise initiated as menthol smokers would not initiate tobacco use.[28]

However, real-world analyses, though limited, have been less promising. A recent study, which was part of a larger multi-national survey, analyzed the effects of the menthol ban in seven Canadian provinces. The study found that only 21.5% of menthol smokers quit smoking while others either switched to non-menthol cigarettes or continued to smoke menthol cigarettes.[29] Meanwhile, after Massachusetts instituted its ban on menthol cigarettes, there was a sharp decline in cigarette sales in the Commonwealth. Unfortunately, this decline was coupled with a significant increase in cigarette sales in neighboring states, indicating little to no decrease in tobacco consumption.[30] While a national ban would be harder to circumvent, these two real-world examples indicate that the ban on its own is unlikely to have as large of an effect as modeling studies have indicated.

Failures of another recent top-down effort, COVID-19 vaccination in minority communities may be the best predictor of potential pitfalls of a top-down effort to ban menthol flavor. Like menthol cigarette use, COVID-19 pandemic case rates and mortality have disproportionately affected the Black community. As vaccines neared approval, national committees such as the National Academies of Sciences, Engineering, and Medicine urged vaccine prioritization that focused on remedying racial health disparities.[31] The difficulty of an equitable rollout was underscored by polling indicating higher levels of vaccine hesitancy among Black respondents.[32]

To tackle the challenge, state and national agencies designed programs to boost minority vaccination rates, including vaccine mega-sites, allocating doses specifically for underserved communities, and holding special vaccination events in those communities.[33] Despite being well intentioned, these efforts did not anticipate community needs such as lack of transportation, poor internet access, and inability to miss work to get vaccinated. In some cases, these efforts led to a paradoxical widening of a racial gap in vaccinations.[34] In others, better-resourced white recipients were able to co-opt vaccines allocated to minority communities.[35] In contrast to often flawed state and national initiatives, community-led vaccination efforts have seen higher vaccination rates of underserved populations by offering vaccination without appointments, deploying mobile vaccination sites, and taking an individualized approach to combating vaccine hesitancy.[36]

The vaccination example emphasizes the potential limited success of a menthol ban if it does not have broad national and local buy-in from the communities it seeks to serve. Similar cautionary tales of the risks of paternalistic policymaking can be seen in historical efforts to regulate payday lending, limit unhealthy food choices for SNAP recipients, and mandatory sentencing guidelines initially designed to help crime-impacted communities.

As of summer 2021, the Black community's response to a menthol ban has been mixed. The National Association for the Advancement of Colored People, The Center of Black Health and Equity, and the majority of the Congressional Black Caucus, to name a few, have supported a menthol ban.[37] On the other hand, the ACLU letter to the FDA mentioned above had 26 cosigners expressing reservations, many of them small or regional civil rights groups.[38] Previously, a nonprofit founded by prominent civil rights leader Al Sharpton helped defeat a proposed 2019 menthol ban in New York City.[39] It is important to note that the Black community is not a monolith, and local variations in support for the ban may lead to a nationwide mosaic of both its success and failure in addressing health disparities.

Conclusion

There is ample evidence to support the claim that the tobacco industry has intentionally targeted the Black community through the years to promote and sell menthol flavored tobacco products. Furthermore, research has shown that menthol cigarettes are implicated in increasing youth smoking, increasing dependence rates, and reducing cessation success rates. Therefore, the FDA's move to ban menthol flavor is certainly justifiable from a purely scientific standpoint. However, such a national ban on its own may not be the most effective means of addressing disparities associated with tobacco abuse or even achieving the desired goal of reducing tobacco abuse and thereby reducing its associated morbidity and mortality. If history is any guide, it may exacerbate other areas of racial inequality or further alienate a vulnerable population. A better approach to address the disproportionate prevalence of menthol use among racial minority groups would be to engage stakeholders from those communities and facilitate solutions generated from within.

Note

The authors have no conflicts to disclose.

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Law Journals, Biomedical Journals, and Restraint of Trade

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ABSTRACT (ENGLISH)

Law journals permit submission of scholarly manuscripts to multiple journals concurrently, but biomedical journals strictly forbid submission of manuscripts to more than one journal at a time. Law journals may then compete for the publication of manuscripts. This article examines whether the single-submission requirement of biomedical journals may constitute restraint of trade in violation of Section 1 of the Sherman Antitrust Act.

FULL TEXT

As readers of the *Journal of Law, Medicine &Ethics* well know, when a legal scholar submits a manuscript to a law journal for consideration for publication, the author often submits the manuscript to multiple journals concurrently, commonly a dozen or more.[1] When the author receives an offer of acceptance of the manuscript from a journal, the author may either accept this offer or contact other journals to which the manuscript was submitted and request an "expedited" decision. Requests for expedited decisions may be made to journals that the author considers preferable (i.e., more highly ranked) to the journal that made the initial offer, based, for example, on the rankings of law journals maintained by Washington &Lee School of Law.[2] In this circumstance, the author may now be at a competitive advantage. Those journals — should they so choose — may issue counteroffers and thereby enter a "competition" to acquire the author's manuscript for publication, and the author may have the opportunity to select among several or more acceptances for publication.

The practice among law journals of multiple simultaneous manuscript submissions generally works to the author's advantage, allowing authors to negotiate with several or more law journals once they have an initial acceptance in hand. Multiple simultaneous submissions may also expedite manuscript acceptance and publication, as will be discussed subsequently. A potential disadvantage of this system is that lower ranked law journals may lose out when they make an offer (after investing the time and effort to conduct a careful review of the manuscript) but the author decides to accept an offer from a higher ranked journal. Still, on balance, the multiple submission policy has the advantage of allowing free and fair competition among journals, which determines the ultimate outcome of the manuscript selection process, and authors clearly may derive benefit from the opportunity to select among offers.

Friedman has provided a thoughtful critique of the editorial procedures and practices at law journals and has

suggested revisions.[3] Among them is, "… limiting the number of simultaneous submissions, and — ultimately — requiring authors to accept the first offer that is extended." He concludes, "This would be a huge change in the culture, to be sure, but it is an appropriate one."[4] Friedman also points out that potential advantages, from authors' points of view, of the current law journal system are that most every article eventually finds an acceptable venue for publication and the process is reasonably expeditious.

As compared with scholarly law journals, the procedures for manuscript submission for scholarly biomedical journals are quite different. Biomedical journals generally require that manuscripts be submitted to only one journal at a time, and authors must attest upon submission that they have submitted the manuscript only to that journal. If the author fails to adhere to the policy of single submission and pursues duplicate submissions, the manuscript may be rejected by both journals.

Unlike authors of law journal manuscripts, authors submitting to biomedical journals do not derive the benefit of receiving competing offers of acceptance from multiple journals. Instead, they must wait for a decision from the journal of first submission, and if rejected, then move on to another journal. This procedure of sequential submissions (biomedical journals), as compared with simultaneous submissions (law journals), requires that the clock be reset at the time of each new submission to a biomedical journal. The process is therefore potentially quite time-consuming, and it may take months or even years to have a manuscript finally accepted and published in a scholarly biomedical journal. This is detrimental to the biomedical research community that may want to have timely access to the new research, as well as to the author's professional advancement. The sequential submission process is the principal reason that preprint servers, such as medRxiv (for biomedical science) and bioRxiv (for biological science), have been developed, are now being used more frequently, and are more widely accepted by the editors of traditional biomedical journals. Preprint posting, which is acceptable to law journal editors, has been a common practice for legal scholars for some time (the preprint server SSRN.com is often used). Posting a manuscript on a preprint server provides the manuscript for public access but does not constitute official publication.

Why have these two disparate manuscript submission procedures been adopted by law and biomedical journals? A possible explanation lies with the Sherman Antitrust Act of 1890 (15 U.S.C. § 1),[5] with which law journal editors — but not necessarily biomedical journal editors — are closely familiar. A persuasive argument may be made that the single manuscript submission procedure required by biomedical journal editors constitutes a form of restraint of trade, possibly in violation of Section 1 of the Sherman Act. Section 1 is applicable specifically to restraint of trade within US interstate commerce, and the fact that biomedical journals typically publish research manuscripts submitted from every state throughout the US (and indeed throughout the world) — and are distributed to and read by individuals in every state — unquestionably places biomedical journals squarely within interstate commerce. The single submission rule interferes with competition and restrains authors' rights to negotiate freely with multiple biomedical journals. The fact that authors have the right to submit manuscripts to the journals of their first choice does not mitigate the disadvantage resulting from elimination of competition in the process of manuscript selection. The single submission rule may violate Section 1 of the Sherman Act, but (to my knowledge) causes of action have not been filed on this matter. This could soon change.

Single Submission Policies and the Ingelfinger Rule

In 1978, a small group of self-selected editors of international general medical journals met together to form the Vancouver Group (the location of the Group's first meeting), an organization now known as the International Committee of Medical Journal Editors (ICMJE).[6] This group of editors currently represent 13 international biomedical journals and 2 additional scholarly organizations: *Annals of Internal Medicine*, *BMJ* (*British Medical Journal*), *Bulletin of the World Health Organization*, *Deutsches Ärzteblatt* (*German Medical Journal*), *Ethiopian Journal of Health Sciences*, *JAMA* (*Journal of the American Medical Association*), *Journal of Korean Medical Science*, *Nature Medicine*, *New England Journal of Medicine*, *New Zealand Medical Journal*, *The Lancet*, *Revista Médica de Chile* (*Medical Journal of Chile*), *Ugeskrift for Laeger* (*Danish Medical Journal*), the US National Library of Medicine, and the World Association of Medical Editors. Of the 13 member journals, the 3 US journals (*Annals of Internal Medicine*, *JAMA*, and the *New England Journal of Medicine*) are founding members. The Committee maintains the ICMJE

Recommendations, also called “The Uniform Requirements for Manuscripts Submitted to Biomedical Journals.”[7] This document is a comprehensive listing of requirements for all aspects of manuscript preparation, review, editing, and publication for biomedical journals. Although the core membership of the ICMJE numbers only 15 journals and organizations (with some periodic rotation of member journals/organizations), numerous other biomedical journals are listed as following the ICMJE Recommendations/Uniform Requirements.[8] A biomedical journal that does not follow the ICMJE Recommendations runs the risk of being marginalized among the endorsing cohort of international journals, and therefore there is “peer pressure” for journals to follow the Recommendations, many of which are valuable in setting consistent editorial standards for editorial manuscript review and publication.

Among the specific ICMJE Recommendations is the statement in Section IIID1 about submission timing practices:

Authors should not submit the same manuscript, in the same or different languages, simultaneously to more than one journal. The rationale for this standard is the potential for disagreement when two (or more) journals claim the right to publish a manuscript that has been submitted simultaneously to more than one journal, and the possibility that two or more journals will unknowingly and unnecessarily undertake the work of peer review, edit the same manuscript, and publish the same article.[9]

(emphasis added)

The fact that this section of the ICMJE Recommendations notes, “the potential of disagreement when two (or more) journals claim the right to publish a manuscript” on its face may reflect the editors’ misunderstanding of US antitrust doctrine (which would apply only to US journals and their editors). When two (or more) journals offer acceptances to an author and compete for a manuscript, as happens regularly with law journals, the author may benefit from having the opportunity to make a choice of where to publish. The key text of the ICMJE Requirements that “Authors should not submit the same manuscript…to more than one journal” may not withstand scrutiny based on an analysis of anti-competitive conduct according to Section 1 of the Sherman Act.[10] Also, on the basis of longstanding precedent at law journals, it is evident that offers of acceptance by more than one journal are a matter that many law journals have incorporated into their routine editorial procedures and is in the best interest of authors. Most scholarly law journals allow the practice of multiple simultaneous submissions of manuscripts and conduct their editorial work successfully within this framework.

The single submission policy for biomedical manuscripts mandated by the ICMJE had its origins in the Ingelfinger Rule, which was established in 1969 by then editor of the *New England Journal of Medicine*, Franz J. Ingelfinger. Because of his insistence that the *New England Journal of Medicine* retain priority in the publication of research articles submitted to the *Journal*, Ingelfinger formulated the following rule:

Papers are submitted to the *Journal* with the understanding that they, or their essential substance, have been neither published nor submitted elsewhere.[11]

(emphasis added)

Though the Ingelfinger Rule, which currently remains an established policy of the *New England Journal of Medicine*, applies broadly to most forms of pre-publication/dissemination of manuscripts prior to official publication in the *Journal* (exempting meeting abstract presentations), the specific focus in this article is on Ingelfinger’s proscription of multiple concurrent submissions. Ingelfinger regularly rejected papers when authors were not in compliance with the rule, as did his successor, Arnold S. Relman.[12] Both were long-term leaders of the *New England Journal of Medicine* , and they consistently enforced the rule during their respective tenures. It continues to be enforced today. As the *New England Journal of Medicine* was among the founding biomedical publications of the ICMJE, the substance of the original Ingelfinger Rule was also incorporated into the original Uniform Requirements of the ICMJE (and has been retained in later versions the ICMJE Recommendations).

Neither the multiple submission policy followed by law journals, nor the single submission policy followed by biomedical journals is a perfect solution — as a matter of editorial policy — to the management of the selection process for scholarly articles. Nevertheless, in establishing any publication policy, it is mandatory to abide by the law.

For many years, the *New England Journal of Medicine* and other prestigious biomedical journals have benefited

from the single submission requirement. Since authors are more likely to submit their manuscripts to the most prestigious journals (generally reflected by a journal's impact factor)[13] on the initial round of submission, journals such as the *New England Journal of Medicine*, *JAMA*, and *Annals of Internal Medicine* receive priority in the selection of manuscripts for publication. Unlike the multiple submission policy at law journals, upon submission to the first biomedical journal, there is no competition with that journal in the selection process for publication. Only if the journal of first submission decides to pass on the manuscript does the next journal in the author's preference list get an opportunity to consider the manuscript. Thus, due in part to the lack of competition in the process, the most prestigious journals, which may select first, have the upper hand in choosing those manuscripts that are most likely to sustain their high impact factors and preserve their top positions in the hierarchy of scholarly biomedical journals. Given that the journal receiving the first manuscript submission has no competition for that manuscript from other journals — unless and until the editors of the first journal decide to reject the manuscript — there is also little incentive for editors to pursue an expeditious review process, and this may introduce further delays. As mentioned previously, the *ad seriatim* manuscript review process inherent in the single submission policy (i.e., moving from one journal to the next) may result in a slow pathway to publication. The lack of incentive for medical journal editors to execute an efficient manuscript review procedure may add further delay to an already unhurried process. While it is important to the editorial decision that manuscript reviews be performed deliberately, it is in the interest of neither the author nor the wider research community for review procedures to be excessively protracted.

Antitrust Analysis

In establishing the single submission requirement in Section IIID1 of the ICMJE Recommendations, the ICMJE member editors collaborated in the development of a presumptively anti-competitive policy. Section 1 of the Sherman Act reads[14]:

Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal.

In the single submission policy, the ICMJE editors have not only created an anti-competitive arrangement, but they have also collaborated in the creation of the practice, another potential violation of Section 1 of the Sherman Act. Of course, US antitrust doctrine, as set out in the Sherman Act, would be applicable only to US journals, though other countries have their own antitrust laws that could also be applicable to the single submission policy.

In July 2021, President Biden signed an ambitious Executive Order that encouraged several federal agencies, including the Federal Trade Commission and the Department of Justice, to promote competition in the US economy and established a White House Competition Council within the Executive Office of the President.[15] The purpose of this initiative was to ensure fair competition throughout the US economy. The Competition Order directed executive agencies to implement policies promoting that objective through rulemaking and litigation, the latter being the traditional approach to addressing antitrust violations. In this context, rulemaking, proposed by Chopra and Khan, is a novel intervention.[16] The release of the Competition Order should have alerted US biomedical journals to re-examine their single submission policies for manuscripts, which may be at variance with US antitrust law.

If the single submission policy of biomedical journals were to be subjected to antitrust scrutiny, how might this analysis proceed? To state a claim for a horizontal restraint on trade under Section 1 of the Sherman Act, there must be [1] an agreement, and [2] an anti-competitive restraint on trade. With the single manuscript submission requirement, there is clearly an agreement based on the codified rule. Under the second element, restraints may be analyzed as either [A] per se violations (i.e., categorically unlawful), or [B] under the rule of reason," which requires balancing the pro- and anti-competitive effects of the restraint. In the case of single manuscript submissions, the restraint would likely fall under the rule of reason. A relevant precedent occurred in *Polk Bros. v. Forest City Enterprises*, 776 F.2d 185 (7th Cir. 1985).[17] In the opinion written by Seventh Circuit Judge Frank Easterbrook, if the restraint is "ancillary" insofar as it contributes to the success of a cooperative venture, promising greater productivity/output, the restraint falls under the rule of reason.[18] It may be argued that the single submission restraint contributes to productivity by avoiding the duplication of peer review costs while incentivizing journals to compete to attract first submissions.[19] However, productivity may be enhanced in other ways, such as the sharing of peer

reviews among journals (another form of cooperation that is already currently practiced). It may also be argued that the anti-competitive effects nonetheless outweigh this potential benefit given that the rule incentivizes authors to submit their manuscripts first to the highest-ranked journals, which further entrenches the journal rankings. The single submission mandate also eliminates direct competition among journals for manuscripts, which arguably would benefit authors.

If a restraint-of-trade complaint were brought regarding the single submission procedure, the outcome would be determined by a court, and attempting to forecast the outcome is not the intent of this article. The principal argument being made here is that the matter of a single submission policy for biomedical journals, versus a multiple submission policy for law journals, raises an incontrovertible question about a potential antitrust violation that should be addressed and answered in an appropriate legal venue and/or by scholarly debate. The issue is not whether multiple submissions should become the standard for biomedical journals, but whether such a policy should be an option for biomedical authors. Were this option to be offered to authors, additional adjustments to the editorial process would be needed, but it is beyond the scope of this article to explore these details.

Conclusion

Neither the multiple submission policy followed by law journals, nor the single submission policy followed by biomedical journals is a perfect solution — as a matter of editorial policy — to the management of the selection process for scholarly articles. Nevertheless, in establishing any publication policy, it is mandatory to abide by the law. For many years, biomedical journals have collaborated to implement a potentially anti-competitive single submission requirement for manuscripts that may be in violation of the Sherman Act, and it is overdue that this matter be addressed. The Ingelfinger Rule may have been in violation of federal law when it was first adopted in 1969, and its recodification in Section IIID1 of the ICMJE Recommendations may be in violation today. In view of the Biden Administration's initiative on competition in the US economy,[20] the US biomedical journals that were involved in establishing and are today involved in maintaining an anti-competitive submission policy may be well advised to carefully reappraise this matter and, if necessary, consider appropriate revisions to their manuscript submission policies.

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About This Column

Aaron Kesselheim serves as the editor for Health Policy Portal. Dr. Kesselheim is the JLME editor-in-chief and director of the Program On Regulation, Therapeutics, And Law at Brigham and Women’s Hospital/Harvard Medical School. This column features timely analyses and perspectives on issues at the intersection of medicine, law, and health policy that are directly relevant to patient care. If you would like to submit to this section of JLME, please contact Dr. Kesselheim at akesselheim@bwh.harvard.edu.

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Framing Black Infant and Maternal Mortality

Muigai, Wangui

ABSTRACT (ENGLISH)

This article looks to the past to consider how government officials, health professionals, and legal authorities have historically framed racial disparities in birth and the lasting impact these explanations have had on Black birthing experiences and outcomes.

FULL TEXT

In the U.S., black mothers and infants die at two to three times the rate of their white counterparts.[1] Since government reports from the late 19th century first took note of the excess deaths, these racial inequities have persisted.[2] This article explores two historical eras that have had a lasting impact on how government officials, medical experts, and legal actors have explained the disparate outcomes and the ways their explanations have shaped black birthing experiences. Part I explores narratives of individualized blame: that is, the blaming of black midwives for maternal and infant deaths and the campaign waged by health and government officials in the early twentieth century to regulate, and criminalize, Black midwives. At a time when midwives provided critical maternity and neonatal care in Black communities, legal measures to push midwives out of practice left expectant mothers with fewer options for care and meant Black mothers and babies disproportionately suffered. Part II examines how these inequities endured despite progressive social welfare and legal developments in the 1960s, including federal mandates to desegregate hospitals and expand health care access. Though more Black mothers gave birth in hospitals, increased access to health care institutions did not eliminate racial disparities in birth outcomes or experiences of discrimination. In analyzing these historical efforts to regulate attendants and access, this article argues that policy responses to the death of Black mothers and infants depend on the way medical and legal authorities frame the issue —whether as a legal problem, racial injustice, or more persistently, as individual failure. Drawing on government reports, historical accounts, and, notably, Black women's first-hand perspectives, it demonstrates the importance of looking to the past in order to explore new ways of thinking about the role of law and policy in combatting racial inequities in birth today.

Part I

Recent studies show that midwives are associated with improved birth outcomes, lower rates of infant death, and that Black pregnant women in the U.S. report greater satisfaction with the care they receive from midwives than from physicians.[3] One hundred years ago, however, attitudes towards midwives were very different. Doctors and health officials blamed midwives for maternal and infant deaths, and considered mothers who relied on Black midwives to be uninformed and negligent.[4] This early 20th century framing of midwife attendants as the cause of maternal and infant mortality was a key argument that health professionals wielded to bring midwives under state supervision and regulation. Yet, listening to Black women's first-hand accounts of this era challenges these assertions and instead highlights how Black mothers navigated limited options for having a safe birth, and how Black midwives struggled to provide desperately needed care in their communities. Centering Black women's experiences of the early 20th century campaign to eliminate midwives reveals the ways government and physicians' efforts to restrict midwifery critically limited Black families' ability to have safe and healthy births.

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During the era of Jim Crow racial segregation when Black Americans had unequal access to health care, Black midwives were the main providers of maternal and infant care in their communities. Into the 1940s midwives attended to more than half of all Black births, and in the rural South Black families called on midwives eight times out of ten.[5] Even as roughly six million Black Americans moved north and west as part of the Great Migration of the early

to mid 20th century, most Black births and infant deaths took place in the South and at home. The reliance on midwives looked very different for white women, who were more likely to have a physician attend to them whether they gave birth at home or in a hospital.[6]

Black women preferred to have a midwife by their side through pregnancy, birth, and the postpartum period for several reasons. Midwives were valued for their expertise and skills providing physical and emotional support to women. A 1924 survey of white, Black, and Latina mothers found that many believed midwives "took more pains" than doctors to assist during labor and the initial days after birth. One of the Black mothers interviewed had such a traumatic delivery experience when attended by a doctor that she swore to never "have him again." For any future pregnancies, she would only call on a midwife as she explained: "Granny helps in your misery."[7]

Compared to the holistic care women received from midwives, Black women were more likely to endure humiliating, painful, and even deadly experiences when attended by physicians. Doctors were less willing to serve poor Black families. Dr. Halle Tanner Dillon Johnson, one of the first Black women physicians to practice in Alabama, noted that in the area where she practiced, white doctors charged for each mile they had to travel to reach patients, and that he "must be assured of his money before coming, often demanding cash" before agreeing to visit.[8] For Black sharecropping families with little access to cash, hiring a physician was out of the question. In contrast, midwives were more willing to accept alternate forms of payment, including crops, livestock, and other goods and services.

For Black women who had the financial resources to hire a physician, the ability to pay did not ensure that they would have a favorable experience, or even survive. A 1937 study found that physicians' errors were 50 percent more frequent in Black obstetrical cases.[9] Renowned physicians such as John Whitridge Williams at Johns Hopkins Hospital justified their use of risky, "last resort" procedures like Caesarean sections on Black women, arguing that because of biological differences (deformed pelvises and nutritional deficiencies were chief among the reasons cited), "blacks require radical interference much more frequently than whites."[10] White physicians' beliefs in racial biological difference undergirded their use of high-risk obstetric interventions that, ultimately, contributed to higher morbidity and mortality rates among Black mothers and babies.

Yet when health officials in the early 20th century tried to explain why Black maternal and infant death rates in the U.S. were higher than found among other racial and ethnic groups, they barely acknowledged the role that physicians played. Instead they directed their attention to the South, the region with the highest death tolls and largest concentration of midwives.[11] Behind tuberculosis and heart disease, the diseases and complications of birth were the third leading cause of death for Black residents of the South.[12] Rather than recognizing midwives as indispensable health care providers in this region, doctors and nurses regarded midwives as incompetent practitioners who posed "a serious menace to infant life and the lives of mothers."[13] From the 1910s through to the 1950s, many health professionals argued that eliminating Black midwives was the key to reducing Black maternal and infant death rates. As one nurse commented, "if the problem of infant mortality is to be solved …it would certainly simplify matters if we could remove from our midst the midwife."[14]

At the turn of the 20th century, doctors worked to reframe birth as a dangerous event that could only be properly managed by those with an accredited medical education. Physicians argued that midwives, who lacked formal training in obstetrics and bacteriology, needed to be closely supervised if they were to attend any deliveries, and they lobbied state legislatures and boards of health to establish licensing requirements for midwives.[15] Up until this point, most midwives worked without legal oversight.[16] The few southern states that had pre-existing laws, like Louisiana, actually allowed Black midwives to practice unsupervised since health authorities viewed "the so-called midwife of rural districts and plantation practice" as a lay healer who was not "practicing midwifery as a profession."[17] This exemption from regulation was based on the state's narrow definition that practitioners who accepted non-monetary compensation were not true "professionals," a framing that disavowed Black women's skilled labor.

Swayed by arguments that midwives were untrained and posed a grave threat to mothers and newborns, local legislatures enacted laws requiring midwives to be trained, tested, and licensed in order to practice.[18] Midwifery regulation intensified with the passing of the 1921 Sheppard Towner Act, which provided federal aid for maternal and infant health programs, particularly in rural areas. Many states, especially in the South, allocated a portion of the

funding to create midwife classes run by local health officials and state-employed nurses.[19] Through the classes, midwives learned of the new laws governing what they could and could not do when attending a birth. To ensure compliance, nurses closely surveilled midwives through administering tests, inspecting the equipment midwives carried, and conducting investigations and surprise home visits.

Midwives who resisted these measures and state requirements to register for a license faced criminal prosecution, including monetary fines of up to $500, license revocation, and imprisonment.[20] Mary Willingham, a Black nurse practicing in Georgia in the 1930s, recalled the fear that these penalties provoked, “It used to be anybody could wait on a ‘oman havin’ a baby …Now, that’s all changed. If you don’t have that ‘stificate they’ll put you in the penitentiary for life.”[21] She was not alone in being alarmed by the increasing government surveillance surrounding childbirth. Margaret Charles Smith, a midwife practicing in Alabama, understood perfectly that Black midwives had become the government’s primary targets of blame, remarking, “if anything happens bad to the mother, they’re calling you in.”[22]

In this medical-legal climate of intensifying regulation, midwives faced an ethical dilemma, caught between demands to comply with new laws and a responsibility to provide the care their clients requested and needed.[23] Many midwives resisted regulation, well aware that the limited care they could legally provide would be of little comfort to women. One midwife, exasperated by the restrictions she faced, informed her supervising nurse that she would resign. She stood firm in insisting, “You don’t know how it goes. Rubbing helps and teas help. If I can’t give them some hot teas which I know will help, I just well ought to give up.”[24] While midwives traditionally relied on herbal remedies to relieve labor pains and control bleeding, health authorities viewed such therapies as unscientific, with some alleging that midwives used herbal remedies not to promote healthy births, but to induce abortions.[25] Public health nurses issued stern warnings to midwives that “they better not catch nobody giving nobody no tea of no kind. If they do, she was going to jail and from there to the pen.”[26] In struggling to work in such a threatening and punitive environment, midwives found that state laws erected in the name of reducing maternal and infant deaths actually left them little room to utilize their community-valued skills to protect the wellbeing of mothers and babies.

As a result of state efforts to restrict midwifery practice through licensing, surveillance, and intimidation, the number of midwives drastically declined. This was as many doctors had hoped, writing in their professional journals that midwives “must be eliminated…and placed under state control.”[27] In 1925, over 9,000 midwives practiced in Georgia, and by 1950 that number had decreased to 1,322.[28] Similar declines occurred across the South.[29] Yet federal reports showed that even with national infant mortality rates falling, Black mothers and babies continued to die at twice the rate of whites, raising the question of whether midwives were actually to blame.[30] In this sense, physicians’ claims that midwives were responsible for the country’s maternal and infant deaths served more as a tactic to remove unwanted competition than to address the root causes of deaths surrounding birth. With midwives largely eliminated and overall infant death tolls declining, health officials paid less attention to the disparity between Black and white infant survival. Still, as one Mississippi health official raised, “who is to care for these women…some one must serve. The midwife can not be taken away even though she is not capable, until a better service is available to these mothers.”[31] The official’s comment exposed one racialized consequence of the government campaign to eliminate Black midwives —it left Black mothers and babies in a health care void, vulnerable to complications and premature death that could be prevented with accessible and equitable care.

Part II

Whereas health officials in the first half of the 20th century framed Black infant and maternal deaths as the fault of midwives, by the early 1960s a growing number of activists, lawmakers, and health professionals argued that the unequal access Blacks had to medical services explained their poorer health outcomes. Through lawsuits, civil complaints, and legislation, a range of reformers fought to transform the nation’s “separate but equal” medical system into one that ensured health care access for more Americans, regardless of race, age, or ability to pay.[32] Such efforts had a sweeping impact on the nation’s health care landscape, and some were optimistic that the progressive social policy reforms to expand access would reduce the nation’s stark health disparities.[33]

The stakes were particularly high for Black women as the government’s elimination of midwives left Black women with fewer options for having a safe birth at home. Compared to the 27 percent of Black babies delivered in hospitals

in 1940, by 1960 85 percent of Black births took place in a hospital.[34] Yet even as more Black mothers gave birth in hospitals, their restricted access to these segregated spaces meant they experienced multiple forms of discrimination and inferior medical care. In a 1963 report by the United States Commission on Civil Rights, 85 percent of Southern hospitals surveyed admitted to practicing some form of racial segregation or exclusion.[35] Hospitals such as St. Dominic-Jackson Memorial Hospital in Mississippi placed laboring Black women with all other Black patients instead of in the obstetrical ward, and confined Black newborns to a segregated section of the nursery. Black fathers were not allowed to be with their partners during delivery and could not visit their newborns.[36] In cities like Chicago that witnessed a significant rise in its Black population during the Great Migration, Black women could only deliver in two of the city's hospitals —Cook County and Provident Hospital —regardless of their ability to pay or proximity to other hospitals.[37] Both hospitals handled such a high volume of obstetrical cases that mothers were sent home with their babies "the evening of the first day after delivery if they were able to get out of bed."[38] Black women reported that they dreaded giving birth at Cook County, where "long labor lines …often stretch across the entire fifth floor."[39]

By the mid 1960s, lawsuits filed by Black patients and physicians, as well as new federal legislation, worked to expand health care access for Black Americans. Following the landmark 1963 decision in *Simkins v. Moses H. Cone Memorial Hospital* as well as the passage of the 1964 Civil Rights Act, hospitals that received federal funds and sought to participate in Medicare could no longer discriminate on the basis of race.[40] To comply with the new laws, more hospitals began to admit Black patients and remove structural markers of segregation such as separate entrances, waiting rooms, and wards.[41] More federal dollars went to fund maternal-child health programs, especially in urban, low-income areas. And through Medicaid, poor Americans who fell into certain categories —children, pregnant women, seniors, and people with disabilities —were now eligible for public health insurance.

Such legislative efforts to reduce racial, geographic, and economic barriers to health care offered good reason to be hopeful that racial disparities in health would disappear. Increased hospital access meant that when complications during childbirth arose, Black mothers and newborns could benefit from lifesaving therapies and medical technologies. One Black mother valued her decision to give birth at Philadelphia's Temple University Hospital when she had a difficult delivery in the 1960s. As she explained, "I knew they could revive the baby so long as they was getting a heartbeat." She recounted how the hospital staff worked to save her newborn, "First they cleared its mouth and nose of mucous, then they slapped it and tied the cord. When it wasn't crying by that time they sent for a respirator and did mouth-to-mouth respiration on it, and then it began to cry."[42] Health professionals shared in the mother's optimism that infants who a generation before would have likely died, now stood a good chance of surviving if delivered at a hospital.

Yet the expansions in health care access did not guarantee equal treatment or high-quality care for Black mothers and babies. Medicaid's eligibility restrictions left many without coverage, particularly in the rural South where poverty was most concentrated.[43] In addition, several hospitals were reluctant to do away with their practices of segregation, and attempted to circumvent federal mandates. One county hospital in Mississippi had long used a curtain to separate Black and white babies in its nursery. Even after the hospital was mandated to desegregate, the curtain remained, albeit it now separated "difficult" babies from other newborns. In response to complaints filed by patients and practitioners, investigators from the Office of Equal Health Opportunity responsible for ensuring compliance with federal law visited the hospital and found the "difficult" babies were almost always Black.[44] The health care landscape was not much better in the North, where municipal hospitals that served Black communities were often overcrowded, under-staffed, and under-funded. In the 1960s, thousands of poor Black women in Chicago were redirected from the city's overloaded public hospitals to private ones, where the care they received was primarily to "provide added teaching experience for interns and residents."[45] Such an arrangement perpetuated a longer history of Black women's access to health care being predicated on physicians having access to their bodies for educational and experimental purposes.[46]

Throughout the 1960s era of progressive social policy reforms, racial disparities in maternal and infant health narrowed slightly in some areas but still endured.[47] The persistence of these disparities, despite sweeping measures

to restructure health care, highlighted the limits to interventions focused solely on access. Indeed, Black mothers have continued to receive poorer and discriminatory health care. State investigations of New York hospitals in the 1990s found that white maternity patients were placed in wards separate from Black and Hispanic mothers, many of whom were on Medicaid. Hospital administrators asserted that segregating maternity patients based on insurance type allowed for "more efficient care," yet Black mothers placed in the 'Medicaid wards' testified that they received no information on breastfeeding and infant care, and were treated only by doctors in training, not senior physicians.[48] One Black mother shared that "the whole experience was devastating …I was very depressed."[49]

Since the 1990s, studies have shown that Black women have the highest rates of C-sections, which places them and their babies at greater risk for severe postnatal complications and death.[50] C-sections are routinely justified on grounds that Black women's pregnancies are high-risk due to pre-existing conditions like obesity or the circumstances of labor such as "failure to progress."[51] Such risk assessments are rooted in older, clinical views about Black women's behavior and biology, and can lead to charges that Black women are to blame for their pregnancy outcomes. Yet these clinical practices make it more likely for health care providers to fatally intervene in Black births.

As Black women and their babies have navigated health care institutions, they have been disproportionately subjected to mistreatment and discrimination in ways that threaten their livelihoods. In this sense, Black women's access to health care was, and continues to be, double-edged. While increased health care regulation and access has been framed as improving options and outcomes, such access has been tenuous, making Black women more vulnerable to medical and legal interventions —including disproportionate rates of C-sections, sterilization, and criminalization —that jeopardize their health and the health of their babies.[52]

Conclusion

Today's profound racial inequities in maternal and infant health have historical roots. Examining past efforts to address these inequities —through campaigns to regulate midwifery and health care access —reveals the power of frameworks to shape health care interventions. Indeed, the questions underlying these past campaigns —who is best equipped to manage birth and where can Black mothers safely give birth —continue to be debated in ways that highlight the importance of understanding the historic roots of these concerns and the need for new frames in efforts to improve the Black birthing experiences.

Note

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Towards Racial Justice: The Role of Medical-Legal Partnerships

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ABSTRACT (ENGLISH)

Medical-legal partnerships (MLPs) integrate knowledge and practices from law and health care in pursuit of health equity. However, the MLP movement has not reached its full potential to address racial health inequities, in part because its original framing was not explicitly race conscious.

FULL TEXT

Introduction

Law is one possible tool for addressing the social conditions that create and sustain racial health inequities. This article describes the potential of the medical-legal partnership (MLP) model for disrupting the systems responsible for creating and maintaining longstanding racial health inequities. It begins by briefly summarizing the relationships between racism, health, and access to justice. It then describes the development of the MLP model as a poverty-focused health equity intervention. It explains how MLPs employ legal interventions to address the *effects* of racism as a social determinant of health (SDOH), but do not generally acknowledge the anti-racist nature of this work or adopt explicitly anti-racist missions to address institutional and structural racism as root causes of poor health. This "colorblind" conception of MLPs may limit their potential to reduce racial health inequities and, in fact, may inadvertently reinforce some of the structures underlying racial health inequities. The final portion of the article discusses the need for a racial justice strategy for MLPs to work effectively toward their goal of health equity.

This article is styled as a self-critique, interrogating the norms of the MLP movement —namely, the assumption that anti-poverty advocacy is racial justice advocacy —in order to understand how they may be holding the movement

back from its health equity mission.[1] It also seeks to inform future scholarship on MLPs by urging scholars to adopt the standards for publishing on racial health inequities proposed by Boyd and coauthors —in brief, to describe racism as "a fundamental cause of disease and the …root of racial health inequities."[2] Embracing MLPs' potential to disrupt racist systems —in the conception of the model, in the scholarship evaluating MLPs' impact, and in our practice —will ensure that the movement's activities align with its mission and highlight its importance for advancing health equity.

I. Racism, Health, and Access to Justice

Racism at every level —interpersonal, institutional, and structural —negatively impacts health.[3] For example, individual-level racism, stereotyping, and bias in the health care system can reduce the quality of care that racial minorities receive.[4] Institutional racism perpetuates unequal access to material resources, including health care, through facially neutral organizational practices and policies.[5] Academics have defined structural racism in different ways; this article adopts a straightforward definition, offered by Yearby, that links structural racism and racial health disparities: "Structural racism is the way our systems (health care, education, employment, housing, and public health) are structured to advantage the majority and disadvantage racial and ethnic minorities. More specifically, it produces differential conditions between white populations and racial and ethnic minorities …leading to racial health disparities."[6] Systematic health differences by race and ethnicity in the United States are the fruits of structural racism, including "the way laws are written or enforced, which advances the majority, and disadvantages racial and ethnic minorities in access to opportunity and resources."[7] Structural racism is the root cause of racial inequities in health outcomes.

The relationship between health and access to justice runs in both directions: lack of access to justice contributes to poor health, and poor health can create obstacles to accessing justice. Nearly any type of unmet civil legal need can constitute a barrier to good health.[8] The "I-HELP" acronym is often cited to describe the legal domains in which MLPs frequently operate: Income and insurance, housing and utilities, education and employment, legal status, and personal and family stability.[9] MLPs have developed screening tools to identify unmet civil legal needs within these domains, such as stopping evictions, negotiating educational accommodations, and obtaining guardianships. MLP services improve patients' material and environmental conditions, which, it is theorized, will improve their health outcomes. For example, the Penn State Dickinson Law MLP Clinic, an experiential course in which law students provide legal services to clients under the supervision of a licensed attorney and law school faculty member, primarily represents noncitizens whose immigration status constitutes a barrier to health.[10] Its practice focuses on appealing wrongful denials of applications for public benefits like Medicaid, the Supplemental Nutrition Assistance Program, Temporary Assistance for Needy Families, and the Low-Income Home Energy Assistance Program. These programs promote health and well-being in qualifying low-income households by providing income and income supports.

Finally, law is a tool that can be used to address racism at each of the three levels described earlier. For example, lawyers can challenge the erroneous termination of health-promoting public benefits to Black, Indigenous, Latinx, and people of color who face intersectional discrimination because they have Limited English Proficiency (LEP) or limited literacy skills. The MLP Clinic at Penn State Dickinson Law has successfully advocated for restoration of public benefits for clients who were not provided with information in a format they can understand, as required by law. On an institutional level, lawyers can help health care providers address racial health care inequity within their institutions by adapting policies and practices to ensure that LEP patients, who are primarily noncitizens of color, receive health information through a certified medical interpreter. Continuing with this example, at the structural level, they can file lawsuits challenging executive agency actions to eliminate protections for LEP individuals in health care[11] or administrative complaints alleging underenforcement of health-promoting laws.[12]

II. Medical-Legal Partnership as a Poverty-Focused Health Equity Intervention

The MLP model is designed to foster collaboration between legal and health care professionals for the benefit of patients who have health-harming legal needs and do not have the resources to resolve them. The MLP model originated in 1993, when pediatricians at Boston Medical Center realized that they needed lawyers on their team to

help their patients be healthier.[13] Lawyers were helpful for "pressuring recalcitrant landlords [to fix poor housing conditions], helping families apply for food stamps and persuading insurance companies to pay for baby formula."[14] MLPs have been established in at least 450 sites in 49 states and the District of Columbia,[15] as well as in Canada and Australia.[16] The MLP movement has entered national consciousness, as indicated by President Biden's recognition of MLPs as "innovative and evidence-based solutions for access to justice,"[17] and is poised to grow.

MLPs are typically described as operating on three levels to improve patients' health: resolving legal issues for individual patients, influencing institutional practices to better serve those patients, and advocating to eliminate systemic barriers to good health for patients with few resources.[18] Health care providers are trained to identify patients' unmet, health-harming, civil legal needs and to refer those patients to the MLP.[19] MLP services, like other legal aid services, are provided to patients at no cost. MLPs rely on a patchwork of funding, including financial, staffing, and resource commitments by participating health care and legal services organizations and law schools; non-profit hospital community benefit funds; Health Resources &Services Administration enabling services funds; Legal Services Corporation funds; Interest on Lawyers Trust Account funds; legal aid fellowship programs; and philanthropy.[20]

MLP is a uniquely upstream/downstream, collaborative, and community-based model of legal services that is aimed at achieving health equity. In the context of MLPs, "health equity" has been defined as "an environment in which every individual has an equal opportunity to achieve and maintain good health."[21] By bringing lawyers on to health care teams to address unmet legal needs at the individual patient level but also supporting the identification and remediation of institutional and systemic issues that create health-harming legal needs, MLPs can be both a downstream intervention at the point of health care delivery and an upstream, population health intervention.[22] For example, MLPs can both ensure that housing codes on the books are properly enforced and advocate for better protections from health hazards for residents of subsidized housing.[23] MLPs are collaborative in that they seek to capture the synergy that results from interactions of legal and health care professionals who are committed to reducing health disparities.[24] When these relationships are not intentionally cultivated, efforts to address SDOH are more likely to be siloed and less effective. Co-locating legal services at the health care provider site, a feature of MLPs, brings legal services into the community in a way that providing services from a stand-alone office does not: It has the potential to reach clients who would not have otherwise sought out legal services.[25]

The mechanisms by which MLP has been theorized to reduce racial health inequities are identifying discriminatory practices through individual-level work;[26] intervening to remediate health-harming legal issues that disproportionately affect Black, Indigenous, Latinx, and people of color; and changing laws or the unjust application of laws that maintain racial health inequities.[27] Disparate access to the building blocks of health and wellness —such as health care, adequate nutrition, safe and secure housing, appropriate education, and protection from interpersonal violence —is linked to racial health inequities.[28] MLPs employ legal interventions to address these "health-harming legal and social challenges,"[29] such as by expanding access to financial resources, thus creating the opportunity to reduce poverty-related barriers to health for clients who are Black, Indigenous, Latinx, people of color, and other historically marginalized populations. At scale, MLPs could have an impact on racial health inequities at the community or population level.[30] However, the evidence base to support these claims is not yet established.[31]

Even though Black, Indigenous, and Latinx people are disproportionately affected by the poverty-related issues that MLPs address, it is not yet commonplace for MLPs to describe their approach as a racial justice intervention.[32] Rather, since its inception, MLP has been characterized as a legal intervention to improve the health of people affected by poverty-related issues.[33] When the term "health disparities" is used in the MLP literature, it is not always clear whether authors are referring to disparities by income, race, or the intersection of the two.[34] Similarly, while there certainly are MLPs that would characterize their work as anti-racist, it is not always apparent from their program descriptions or missions, which use phrases such as "health-harming social conditions" or "social determinants of health" without explicitly naming racism.[35] More recently, some participants in academic MLPs have sought to align the MLP model with the health justice framework, which emphasizes the importance of confronting racial injustice.[36] However, this conception is still emerging and may not be widely known or accepted among

researchers[37] or MLP practitioners on the ground.[38]

One barrier to recasting MLP as a racial justice intervention is its original framing through a singular poverty lens. This perspective was shaped by the institutions from which the MLP movement arose: legal services and health care.[39] The attorneys involved with the development of MLP were from the legal services sector, which exists to provide access to justice to low-income people.[40] Like many public interest attorneys,[41] the early MLP attorneys likely assumed that their anti-poverty efforts constituted anti-racist efforts, particularly when the majority of those served were people of color.[42] In addition, legal services attorneys typically ground their anti-poverty work in social justice, and therefore may not have felt the need to explicate their approach as civil rights or even anti-racism by proxy.[43] At times, MLP attorneys may have chosen strategically to use poverty-related proxies for structural racism in describing their missions in order to solidify partnerships with certain health care partners that may not have felt comfortable adopting the language of racial justice.[44] When the National Center for Medical-Legal Partnership (NCMLP) was established in 2006, its mission aligned with these perspectives, focusing on linking the legal and health care professions to address poverty-related legal issues.[45] Just as there is a racial reckoning happening in many of the institutions already participating in MLPs,[46] the time is right for MLPs to join these efforts if they have not already. Many MLPs have begun to recognize the limitations of the singular poverty lens for addressing racial health inequities, as described in Part III, and are thinking through ways to expand their mission and their capability to address structural racism.[47] The perspective of MLPs, which sit at the nexus of health care and legal services, is unique, and it is up to MLP practitioners to ensure that this value is recognized.

Just as there is a racial reckoning happening in many of the institutions already participating in MLPs, the time is right for MLPs to join these efforts if they have not already. Many MLPs have begun to recognize the limitations of the singular poverty lens for addressing racial health inequities, and are thinking through ways to expand their mission and their capability to address structural racism.

III. The Need for a Racial Justice Strategy for MLPs

Although the explicit racial barriers in laws and institutional policies that created racial stratification in U.S. society are mostly no longer in effect, present-day laws and policies continue to uphold forms of subordination that limit opportunities to be healthy. Often, these laws and policies are related to poverty, such as exclusionary zoning policies that prohibit affordable housing development in neighborhoods that would facilitate access to economic and recreational opportunities, high-quality education and health care, and healthy food options. Poverty-related laws implicate race because “racism across policies, institutions, and systems has resulted in the fact that people of color are more likely to be poor than their white counterparts.”[48] Recent data on poverty displays a predictable racial hierarchy: In 2019, the poverty rate for American Indians/Alaska Natives was estimated at 24.2%, compared with 21.2% for Black people, 17.2% for Hispanic people of any race, 9.7% for Asians/Native Hawaiians and Pacific Islanders, and 9.0% for non-Hispanic White people.[49] In other words, laws and policies that appear to reinforce stratification by income alone are also maintaining racial stratification because of the ways in which poverty and racial discrimination intersect to compound disadvantage. These forms of subordination operate independently and jointly to create and perpetuate health inequities.

Viewing the mission and practice of MLPs through an intersectional racial justice lens rather than a singular poverty lens may improve their ability to work effectively for health equity. A racial justice approach incentivizes organizations to identify racial injustice, analyze how racism is operating within their organization and in their policy spaces, and take corrective action. If, on the other hand, MLPs view their clientele and available interventions through a singular poverty lens, they risk reinforcing racial stratification.[50] For example, an MLP may provide excellent advocacy for students to receive appropriate Individual Education Plans, but consistently obtain fewer services for Black students as compared with white students because Black students are more likely to attend underfunded schools as a result of residential segregation. The MLP is thereby compounding existing racial stratification in access to high-quality education. Shek described this problem in an article describing why and how MLP Hawai’i centers racial justice and community lawyering in its mission and practice: “[U]nequal access [to good education, employment, housing, and food] is a crucial aspect of racial justice. But ending a health justice approach

at the promise of 'access' without also prioritizing racial justice and civic engagement risks maintaining structural inequalities and community powerlessness."[51] Along these lines, legal scholars developing the health justice framework have described how racial disparities in access to the material and environmental conditions that support health derive from laws and policies that enact racial subordination.[52] They urge those working for health equity to directly address laws and policies maintaining structural racism.[53] In the example described here, that could mean advocating for equitable funding and access to high-quality educational services in the public school system.

If MLPs are committed to addressing the root causes of health inequities, the first step, if they have not already done so, is to explicitly acknowledge structural racism as a driver of poor health.[54] If, upon reflection, MLP practitioners find that they have "presumed intersectionality" rather than adopting an explicitly race-conscious perspective, they might begin the process of moving toward a racial justice approach through self-education on the academic literature on structural racism as an important determinant of racial health inequities. The literature cited in Part I of this article may be a good place to start. To understand what MLP participants know and believe about the relationships among racism, health, and poverty on a wide scale, it would be advisable for the entire field to engage in self-examination through a survey on these topics. The results would provide information on how these views influence our work and help to chart a path forward for the MLP movement.

Not naming structural racism as a determinant of health risks creating an environment in which the effects of racialization on the population served is overlooked. It unnecessarily "restrict[s] the vocabulary for describing problems, limiting the availability of data for studying racial problems and discarding the tools with which to remedy them."[55] It provides an incomplete picture of the significance of racism as a driver of health inequities.[56] It can even make such discussions taboo. While some may raise concerns about focusing on racial health disparities because of potential stigmatization of racial and ethnic minorities, such concerns are short-sighted: the COVID-19 pandemic put a spotlight on racial health disparities, and it is better to preempt potential stigmatization by providing context for the appallingly disproportionate rates of morbidity and mortality in certain minority communities.[57] Similarly, failing to explain the reasons why many organizations, including MLPs, that aim to serve poor people primarily serve people of color creates a risk that people (MLP practitioners, clients, researchers, the general public) will provide their own explanations based on discredited theories about biological race[58] —theories that may have arose in part from overt exploitation or racialized stereotypes.[59] In the United States, illness, injury, and financial struggles are often attributed to personal failures rather than structural failures.[60] This ideology of personal responsibility underlies the tendency to blame patients' behaviors or biology for problems that originate in racist policies, institutions, and systems, making it harder to direct resources to addressing the underlying causes of racial health inequities.[61] Instead, resources are allocated to individual-level behaviorist interventions, some of which may actually enhance the disparities they seek to address.[62]

Once members of the organization are confident in their understanding of structural racism's role in creating health disparities, they might engage in an internal examination of the assumptions about race that have operated and currently operate within their organizations. It is critical for every member of the organization to understand why it has framed its work through a singular poverty lens, and the importance of using intersectional lenses that account for the compounded disadvantage that structural racism, among other forms of discrimination, imposes. The discussion in Part II of the history of the MLP movement, as well as the legal and medical professions from which it arose, is a place to start; however, it may be more impactful for individual MLPs to investigate their own forebearer institutions. This investigation may also serve as the basis for the MLP to develop strategies to hold their own institutions accountable for practices that create and maintain racial subordination.[63] For example, an MLP could find that the racial demographics of their clients do not represent the community in which they are located because Black, Indigenous, Latinx or people of color are being referred for services at lower rates than white patients. This is a matter of racial justice because exclusion of Black, Indigenous, Latinx, or people of color from services compounds historical inequities in access to civil justice for these communities. Corrective action may include changes to or automation of the referral process to eliminate implicit bias in the referral system, if this is determined to play a role in the problem. Intensive self-examination of this type —especially by organizations linked to institutions that

participated or participate in the subordination of minoritized groups —are more likely to achieve meaningful results from their racial justice efforts.[64]

Conclusion

This moment of racial reckoning is an ideal time to interrogate the central assumptions of the MLP field, examine their impact on its health equity mission, and take corrective action to ensure that our practice aligns with our values. This article summarizes information about the relationships among racism, health, and access to justice that is essential to understand before beginning this process. It also provides insights about the development of the MLP model that may inform the approaches of researchers and practitioners in the field. Finally, it makes the case for more widespread adoption of racial justice strategies in MLPs. To move closer to that goal, researchers and practitioners should assess potential frameworks for theorizing racial justice approaches in MLPs and publicize examples from the field of how to operationalize racial justice in the model, in our research, and in practice.

Note

The author has no conflicts to disclose.

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2. Id.

3. See, e.g., C.P. Jones, “Confronting Institutionalized Racism,” Phylon 7 (2003), at 7; American Public Health Association, “Research and Intervention on Racism as a Fundamental Cause of Ethnic Disparities in Health,” American Journal of Public Health 91, no. 3 (2001): 515-516; D.R. Williams et al., “The Concept of Race and Health Status in America,” Public Health Reports 109, no. 1 (1994): 26-41. Some empirical studies have begun to investigate and explain the relationship between structural racism and poor health, but there is a need for more research in this area to expand the evidence base. See Z. Bailey et al., “Structural Racism and Health Inequities in the USA: Evidence and Interventions,” Lancet 389 (2017): 1453-1463, at 1457.

4. See Jones, supra note 3, at 8.

5. See E. Benfer et al., “Health Justice Strategies to Combat the Pandemic: Eliminating Discrimination, Poverty, and Health Disparities During and After COVID-19,” Yale Journal of Health Policy, Law, and Ethics 3 (2020): 122–171, at 130.

6. R. Yearby, “Structural Racism and Health Disparities: Reconfiguring the Social Determinants of Health Framework to Include the Root Cause,” Journal of Law, Medicine &Ethics 48 (2020): 518 –26, at 518.

7. R. Yearby and S. Mohapatra, “Law, Structural Racism, and the COVID-19 Pandemic,” Journal of Law &the Biosciences 7, no. 1 (2020): 1–20, at 3-4.

8. B. Zuckerman et al., “Medical-Legal Partnerships: Transforming Health Care,” The Lancet 372 (2008): 1615–1617, at 1616.

9. M. Regenstein et al., “Addressing Social Determinants of Health through Medical-Legal Partnerships,” Health Affairs 37, no. 3 (2018): 378–385, at 380.

10. Penn State Dickinson Law, “Medical-Legal Partnership Clinic,” available at <https://dickinsonlaw.psu.edu/medical-legal-partnership-clinic >(last visited December 10, 2021).

11. See, e.g., Complaint for Declaratory and Injunctive Relief, Chinatown Service Center v. HHS (D.D.C. 2021), (No. 1:2021cv0031) (challenging a regulation that rolled back protections against discrimination in health care access, including language access provisions, during the COVID-19 pandemic).

12. See, e.g., National Health Law Program, Administrative Complaint, Discriminatory Provision of COVID-19 Services to Persons with Limited English Proficiency (April 30, 2021).

13. See C. Goldberg, “Boston Medical Center Turns to Lawyers for a Cure,” New York Times, May 16, 2001, at A20, available at <https://timesmachine.nytimes.com/timesmachine/2001/05/16/339733.html?pageNumber=18 >(last visited December 10, 2021). Medical-legal collaborations to improve patients’ health —including joint advocacy by attorneys on staff at the Delta Health Center in Mound Bayou, Mississippi, in the 1960s, and Whitman-Walker Health

in Washington, D.C., in the 1980s —existed long before this. See J. Teitelbaum and E. Lawton, “The Roots and Branches of the Medical-Legal Partnership Approach to Health: From Collegiality to Civil Rights to Health Equity,” Yale Journal of Health Policy, Law &Ethics 17, no. 2 (2017): 343–377, at 355. However, the MLP model developed in Boston was the one which inspired the current movement.
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15. National Center for Medical-Legal Partnership, “Medical-Legal Partnerships across the U.S.,” available at <https://medical-legalpartnership.org/partnerships/ >(last visited December 10, 2021).
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17. J.R. Biden Jr., “Memorandum on Restoring the Department of Justice’s Access-to-Justice Function and Reinvigorating the White House Legal Aid Interagency Roundtable,” The White House, May 18, 2021, available at <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/05/18/memorandum-on-restoring-the-department-of-justices-access-to-justice-function-and-reinvigorating-the-white-house-legal-aid-interagency-roundtable/ >(last visited December 10, 2021).
18. See, e.g., B. Zuckerman et al., “Why Pediatricians Need Lawyers to Keep Children Healthy,” Pediatrics 114, no. 1 (2004): 224–228, at 226.
19. Id.
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21. J.B. Teitelbaum et al., “Striving for Health Equity through Medical, Public Health, and Legal Collaboration,” Journal of Law, Medicine &Ethics 47, no. S2 (2019): 104–107, at 106.
22. E. Tobin-Tyler and J.B. Teitelbaum, “Medical-Legal Partnership: A Powerful Tool for Public Health and Health Justice,” Public Health Reports 134, no. 2 (2019): 201–205, at 201.
23. See, e.g., Teitelbaum and Lawton, supra note 13, at 369.
24. Zuckerman et al., supra note 8, at 1616.
25. Id. Less commonly, legal services providers in MLPs facilitate existing or new clients’ access to integrated medical care. One example is Terra Firma, an MLP that serves unaccompanied immigrant children. Terra Firma, available at <terrafirma.nyc> (last visited August 13, 2021).
26. See, e.g., Regenstein et al., supra note 9, at 380.
27. Teitelbaum et al., supra note 21, at 105.
28. See, e.g., P.A. Braveman et al., “Health Disparities and Health Equity: The Issue is Justice,” American Journal of Public Health 101, no. S1 (2011): S149–S155, at S151.
29. Teitelbaum and Lawton, supra note 13, at 366.
30. See, e.g., Teitelbaum et al., supra note 21, at 105.
31. O. Martinez et al., “Bridging Health Disparity Gaps through the Use of Medical Legal Partnerships in Patient Care: A Systematic Review,” Journal of Law, Medicine &Ethics, 45 (2017): 260–273, at 261, 269. The authors note the need for more “rigorous, replicable evaluations” of the MLP model generally. Id., at 266. There is evidence that MLPs positively impact patients’ health and wellbeing, housing and utility stability, and access to financial resources and concrete supports; health care systems and workforce; and policies, laws, and regulations. C. Murphy, Making the Case for Medical-Legal Partnerships: An Updated Review of the Evidence, 2013-2020, National Center for Medical-Legal Partnership, January 6, 2021, at 5.
32. See, e.g., D. Bowen Matthew, The Law as Healer: How Paying for Medical-Legal Partnerships Saves Lives and Money (January 2017): at 24 (“[C]urrently, no MLP in the nation focuses on reducing health disparities by directly addressing racial and ethnic discrimination in education or any other social determinant of health.”). In a review of 241 MLP websites, only eighteen explicitly stated in their program mission or description an intention to serve Black, Indigenous, Latinx, or people of color (or used terminology such as “marginalized populations” that one might infer to include the forgoing communities). M.D. Makhlouf, S. Carnahan, and P. Dhungana, MLP Mission Survey (June 24,

2021), n.p. This review provides some information about how MLPs are framing their work, but a more thorough study is warranted.
33. See, e.g., Regenstein et al., supra note 9, at 380; Zuckerman et al., supra note 8, at 224-227. A notable exception is D. Shek, "Centering Race at the Medical-Legal Partnership in Hawai'i," University of Miami Race &Social Justice Law Review 10 (2019): 109 –46, at 112-113, 119 (describing the racial justice vision and community lawyering approach of MLP Hawai'i).
34. See, e.g., Zuckerman et al., supra note 8, at 1615-16 (stating that MLP "is emerging as a key strategy to combat health disparities," but referring to the patients served as "on low incomes" and "vulnerable," without reference to racial health inequities); M.D. Makhlouf, interview with Ellen Lawton, Joel Teitelbaum, and Bethany Hamilton (June 7, 2021) (Ellen Lawton confirming that the foundational MLP articles and research often relied on proxies for race, racism, and even health disparities).
35. See Makhlouf et al., supra note 32 (finding that 72 of 241 MLP websites reviewed used such phrases without mentioning race, racism, people of color, or other terms connoting a race-conscious approach).
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37. Martinez et al., supra note 31, at 269 (noting that "[n]ot a single study in this review considered race, ethnicity or sexuality as mediating factors impacting health outcomes.").
38. See, e.g., Bowen Matthew, supra note 32, at 24; Makhlouf et al., supra note 32.
39. This brief description of the professional cultures influencing the development of the MLP movement does not mean to ignore the role of dissenting/activist and explicitly anti-racist traditions within those fields. It will be critical to draw upon those traditions when thinking about frameworks for operationalizing racial justice in MLPs.
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46. See, e.g., American Medical Association, "Organizational Strategic Plan to Embed Racial Justice and Advance Health Equity," 2021-2023; National Legal Aid &Defender Association, "Racial Justice Action Plan," October 2018, available at

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50. See, e.g., Ford and Airhihenbuwa, supra note 1, at 1395.
51. Shek, supra note 33, at 116. See also Ford &Airhihenbuwa, supra note 1, at 1391 (describing how, in public health research, “racial inequities generally are attributed to non-racial (e.g., socioeconomic) factors while potentially relevant racial factors (e.g., discrimination) remain largely unexamined.”).
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53. Id. at 138.
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60. See Boyd, et al., supra note 59.
61. Id.
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Mitigating Racial Bias in Machine Learning

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ABSTRACT (ENGLISH)

When applied in the health sector, AI-based applications raise not only ethical but legal and safety concerns, where algorithms trained on data from majority populations can generate less accurate or reliable results for minorities and other disadvantaged groups.

FULL TEXT

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New Preemption as a Tool of Structural Racism: Implications for Racial Health Inequities

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ABSTRACT (ENGLISH)

Preemption is a substantial threat to achieving racial equity. Since 2011, states have increasingly preempted local governments from enacting policies that can improve health and reduce racial inequities such as increasing minimum wage and requiring paid leave.

FULL TEXT

Introduction

Following the murder of George Floyd in the summer of 2020, a racial reckoning unfolded in the United States. There were calls for truly addressing structural racism —the policies, systems, and institutions that cause racial health inequities. In fact, over 170 cities, counties, and states declared racism as a public health crisis. However, preemption, the ability of a higher level of government to limit or eliminate the power of a lower level of government, threatens to derail that momentum and the accompanying policy changes. Historically, the federal government has preempted states and localities from enacting discriminatory policies, and state preemption was reserved to determine if a new local law conflicted with existing state law.[1] However, preemption is now being used to

intentionally thwart local action or punish localities. Briffault[2] coined this aggressive form of state preemption of local governments as “new preemption” to differentiate it from previous uses. In this paper, I will make the case that the current iteration of preemption, new preemption, is being used as policy tool (i.e., mechanism) of structural racism. Structural racism can be described as “the totality of ways in which societies foster discrimination, via mutually reinforcing systems of discrimination (e.g., in housing, education, employment, earnings, benefits, credit, media, health care, criminal justice, etc.) that in turn reinforce discriminatory beliefs, values, and distribution of resources).”[3] For example, racial residential segregation, a primary pathway connecting structural racism to health outcomes, was established through the federal government’s housing policies and the judicial system.[4] Policies like redlining and highway construction resulted in people of color being more likely to live in under-resourced neighborhoods that lack access to employment, health care, green space, clean air, fresh food, and other social supports that are important for health.[5] Additionally, the mass incarceration of Black people, and the adverse health consequences of incarceration, is a direct result of policy choices such as three-strike laws, the War on Drugs, and mandatory minimum sentences. These intersecting systems of racism are independently and collectively associated with adverse health outcomes including premature mortality,[6] adverse birth outcomes,[7] myocardial infarction,[8] and breast cancer[9] among Black people and less access to adequate health care among Latinx.[10] Yearby positions law as the tool of structural racism that codifies and enforces those inequities.[11] These policies create differential access to resources and different conditions for white people and people of color. Colorblind laws and policies, like new preemption, are a primary mechanism of structural racism.[12]

The mass incarceration of Black people, and the adverse health consequences of incarceration, is a direct result of policy choices such as three-strike laws, the War on Drugs, and mandatory minimum sentences. These intersecting systems of racism are independently and collectively associated with adverse health outcomes including premature mortality, adverse birth outcomes, myocardial infarction, and breast cancer among Black people and less access to adequate health care among Latinx. Yearby positions law as the tool of structural racism that codifies and enforces those inequities. These policies create differential access to resources and different conditions for white people and people of color. Colorblind laws and policies, like new preemption, are a primary mechanism of structural racism.

Preemption as a Tool of Structural Racism

Preemption is “the invalidation of one jurisdiction’s law by the law of a higher jurisdiction.”[13] Federal law can trump state law, and state law can trump local law. There are two types of preemption, floor preemption and ceiling preemption. In ceiling preemption, a higher level of government prohibits or limits the authority of a lower level of government to adopt stronger laws. In floor preemption, the higher level of government sets a minimum standard and lower jurisdiction are able to adopt stronger laws. A 2012 report by the Institute of Medicine recommended that “when the federal government regulates state authority, and the states regulate local authority in the area of public health, their actions, wherever appropriate, should set minimum standards (floor preemption) allowing states and localities to further protect the health and safety of their inhabitants.”[14] Because ceiling preemption is most commonly being used in the era of new preemption, I am referring to ceiling preemption when discussing the current iteration of state preemption of local governments in this paper.

Cities are creatures of states, and states have always had the power to confer and limit authority to cities. Preemption has been around since the nineteenth century and preemptive policies and mechanisms have evolved over time.[15] Additionally, preemption is a policy tool and is not inherently negative or positive. Therefore, an equity lens must be employed when evaluating the application of preemption. Using an equity-first lens, new preemption is different from past uses and is illustrative of colorblind racism described by Bonilla-Silva.[17] He characterizes colorblind racism as lacking explicit racial terminology, pursuing a racial agenda through political matters (e.g., states’ rights, personal responsibility, and state intervention) and working through invisible mechanisms. In the next sections, I will discuss how new preemption has been enacted through a political agenda of state intervention, uses covert tactics to pass and justify policies, and does not use explicitly racial terminology.

Preemption and Concentration of Power at the State-Level

Due to inaction at the federal and state level, cities have taken the lead on public health, environmental, and worker-

related policies with much of this innovation happening in more liberal cities. Many of these liberal cities are in states with Republican controlled state legislatures. This dynamic has resulted in states passing preemption laws after progressive policies have been passed at the local level.[18] Consequently, local governments are increasingly unable to enact policies that may reduce inequities and improve health such as increasing the minimum wage, requiring paid leave, regulating firearms, and adopting smoke free laws.[19] States are limiting the authority of localities without offering alternatives that tackle the issues localities are interested in.[20] This concentrates power at the state-level where localities must rely on state legislatures to enact policies that target the needs and desires of their communities. This becomes problematic when local governments are willing but unable to address local issues and state governments are not providing any solutions either. It appears the goal of preemption is not to address problems but to maintain the status quo.

Although this trend is seen across the country, preemption is more prevalent in the South. Furthermore, majority white state legislatures are often preempting policies that would disproportionately benefit Black people and other people of color. For example, the majority white Alabama legislature blocked a city minimum wage ordinance in Birmingham where 69% of the residents are Black. The Texas legislature blocked a paid sick leave ordinance in Dallas that would have overwhelming benefited Black and Latinx workers.[21]

Racialized language is also used when new preemption is being applied. New preemption is driven primarily by the American Legislative Exchange Council (ALEC), trade associations and corporations, and conservative animosity of urban lawmakers who are seen as too liberal and interfering with free market principles. ALEC is comprised of state legislators, conservative philanthropies, wealthy donors, right-leaning advocacy groups, and private-sector businesses. Their major strategy for advancing their agenda is the development and dissemination of model bills.[22] Although ALEC has been writing preemptive bills since the 1990s, the rise of new preemption has been fueled by polarization (e.g., urban vs. rural, liberal vs. conservative) and the Republican control of state governments that began in 2011. The majority of states are controlled by Republican governors, but most cities are led by Democrats.[23] ALEC has stated that “local governments have become victims of far left organizations manipulating the public and local officials to create policies that hurt economic development and individual freedom.”[24] To combat this perception, ALEC has used and popularized state preemption. Research by Hertel-Fernandez attributes some of ALEC’s success to their organization filling a void —providing political strategy, research assistance, prewritten bills, and talking points to state legislators with limited time and resources.[25] Efforts to address new preemption should consider the underlying factors that have led to ALEC’s success.

Conservative disdain of urban lawmakers is beyond a political ideology grounded in limited government and free markets and cannot be divorced from larger racial dynamics. The term *urban* is associated with Black people and other people of color and is often used in contrast to rural which reads as *white*.[26] This concept and coded language is often present when majority white (i.e., rural) legislatures dismiss issues as only urban problems or enact preemptive policy directed at the urban constituents in the state. I have witnessed this pattern in my home state of Tennessee when the city of Memphis removed a Confederate monument. The state legislature passed new legislation limiting local governments’ ability to remove statues and withheld state grants from the city of Memphis. Unfortunately, Tennessee is not unique. Seven other southern states preempt local control over monument removal. Unsurprisingly, many of these same states also preempt minimum wage and paid sick leave laws.[27]

Invisible Tactics Used to Pass Preemption Bills

Pomeranz and Silver conducted the only comprehensive analysis of tactics used by state legislatures to pass preemption bills. They found states employ practices like (1) quickly passing bills (2) adding preemption to pre-existing bills on unrelated topics (3) bundling preemption bills with multiple unrelated topics and (4) using titles that do not reflect the substance of the bill.[28] Kentucky introduced and passed a paid leave preemption bill in four days, Missouri in one day, and Ohio introduced and passed the bill on the same day. In addition to passing a bill quickly, Ohio’s paid leave preemption bill is an example of bundling unrelated topics. Ohio’s paid leave preemption was included in its “Petland Bill” that regulates dog sales and license pet stores.[29]

Arkansas’ “Intrastate Commerce Improvement Act” is an example of using a title that does not reflect the substance

of a bill. In 2015, Arkansas passed a bill that preempted localities from creating new protected classifications. This retaliatory bill was passed after the Fayetteville City Council passed a bill prohibiting discrimination based on sexual orientation or gender identity.[30] The title of the preemptive bill obscures both the content and purpose of the legislation. In addition to using a title that is unrelated to the topic of the bill, this is yet another example of how a broad, yet targeted preemption bill disproportionately effects structurally marginalized groups.

Another strategy is coupling preemption with other punitive strategies (i.e., preemption plus), such as threatening agencies or officials, withdrawing or denying local funds, or stripping agencies of regulatory authority.[31] A common preemption plus policy is prohibiting localities from enacting policies that limit their cooperation with federal immigration officials and imposing financial penalties for violating the preemptive policy.[32] These tactics limit the ability to debate these bills, obfuscates the purpose of the bill, and does not allow constituents to organize and mount opposition to the bills. Legislators also do not have time to discuss the effects of these bills with their constituents.

Preemption Policies as a Form of Colorblind Racism

Law is a tool to disrupt or legitimize social stratification of groups. From the inception of the United States to the 1960s, the dominant form of racism was explicit and characterized by overt acts of discrimination in education, housing, jobs, and health care in both the public and private sector. This form of racism was government sanctioned and commonly called Jim Crow racism, redneck racism, or old-fashioned racism.[33] Due to the Civil Rights Movement and other mass protests by Black people in the 1960s and 1970s, Jim Crow racism effectively ended and was replaced by a more covert form of racism still undergirded by negative beliefs about Black people and Black culture but expressed through formally race-neutral policies that maintain and reify the racial hierarchy of Jim Crow racism.[34] Bonilla-Silva refers to this racism as colorblind racism, but others have labeled it as modern racism, symbolic racism [35], or laissez-fair racism.[36]

Colorblind interpretation of the law treats race as a category that reflects only skin color and/or country of origin ignoring the historical and social implications of race in America.[37] Proponents of colorblind approaches to the law believe these approaches are superior to race-conscious approaches because they are based on merit alone and are not corrupted by considering race. They believe that considering race is unfair and makes a decision seem “political” or “special interest.”

Colorblind policy is a myth. In order to be colorblind, one has to acknowledge race and then actively choose to ignore it.[38] These policies acknowledge group identity but ignore the consequences of group identity. Ultimately, this approach has racially explicit consequences and reinforces white dominance in the racial hierarchy.[39] New preemption policies function in this same way. Preemptive policies are enacted without considering the historical and social aspects of race or how preemptive policies may have different effects on said groups because of the larger context of race.

Under federal law, colorblind policies that disproportionately impact minorities are deemed discriminatory and violate Title VI, regardless of the intent of the law.[40] There is growing evidence and interest in the racially disparate effects of preemption policies. In my previous work, state preemption of local inclusionary housing policies was associated with poor health outcomes, particularly among Black people.[41]

Clearly outlining how new preemption is being utilized as a legal tool of structural racism will inform interventions and mitigation efforts. This understanding is also important because colorblind policies are often politically acceptable because they focus on providing equal opportunity. The ideology of equal opportunity is paired with a political focus on personal responsibility and individual rights. If individuals are given equal opportunities, regardless of systemic and historical burdens, the inequalities in outcomes and consistent disparities are inevitable and acceptable.[42] If racial inequities are a product of colorblind policies, those inequities are not happening because of the policies. Inequities must be a product of other factors like genetic differences or cultural deficiencies.[43] This creates a misdiagnosis of the problem and an inability to offer the correct remedy. If new preemption is not understood as a tool of structural racism that causes racial health inequities, policy will not be deemed an appropriate tool for addressing those inequities.

Preemption and Racial Health Inequities

Preemption of mandatory paid sick leave laws and local police budgeting are important examples of how new preemption relates to racial health inequities. These policies were chosen because they highlight two different pathways connecting new preemption to racial health inequities (1) disparate effects due to colorblind application of laws and (2) direct targeting of policies intended to improve the health of people of color.

Paid Sick Leave and Racial COVID-19 Inequities

Access to paid sick leave during the coronavirus pandemic is a recent example of how colorblind preemption policies contributed to racial health inequities. Paid sick leave allows people to care for themselves and other family members when they are not well. Lack of paid leave forces people to choose between economic security and their health. When faced with the choice between economic security and health, many workers may choose to go to work. Going to work while sick increases the risk of getting sick for both the individual and the larger community. Lack of access to paid leave is even more consequential when trying to contain an infectious disease like COVID-19.

Before the pandemic, 23 states had preempted localities from enacting mandatory paid sick leave laws.[44] Localities in these states were at a disadvantage when trying to contain the pandemic in their communities. Some local governments were unable to pass emergency paid sick leave laws[45] that would have protected frontline workers who are disproportionately people of color, particularly women of color.[46] Advocates in many states recognized the importance of this policy and asked their governor's to suspends preemption of paid sick leave to address COVID-19.[47]

Yearby and Mohapatra name paid sick leave as one of the primary mechanisms connecting systemic racism and COVID-19 pandemic response policies.[48] Preemption of paid sick leave laws is a colorblind policy. These policies do not explicitly deny Black and Latinx people access to paid leave or force them to work jobs that do not offer them. Yet, these policies are disproportionately harmful to Black and Latinx communities.

Structural racism is compounding and interconnected. Preemption of paid leave policies amplifies longstanding racial discrimination in all aspects of employment including hiring,[49] pay,[50] and promotion.[51] Full-time workers and higher wage workers are more likely to have access to paid sick leave.[52] Low-wage workers, who are disproportionately Black and Latinx[53] have less access to benefits such as health insurance and paid leave.[54] In 2017, an estimated 68.8% of white workers had access to paid leave compared to 65.4% of Black workers and 56.6% of Latinx workers. The differences between low-wage and higher-wage earners is even more stark. Only 24.4% of lower-wage workers had access to paid sick leave compared to 74.4% of higher wage workers.[55]

Because the United States does not have a national paid leave policy and only 13 states and the District of Columbia have adopted paid family medical and leave policies, employers largely determine which workers have access to paid leave.[56] Depending on employers to provide access to paid leave is not a comprehensive policy solution. As of June 2020, only 25% of private industry employers had responded to the pandemic by creating a paid sick leave plan or adding additional days to an existing plan.[57] Leaving the health of workers, especially historically marginalized workers, to private industry is not an equitable policy solution. Instead of creating policy to counteract racial discrimination in the private market, state governments have used preemption to block access to paid leave without providing an alternative. State policy choices are critically important for health inequities. While the federal Families First Coronavirus Response Act (FFCRA) expanded access to emergency paid sick leave, only 20% of workers were eligible.[58] Employers with more than 500 workers were exempt from the policy, and employers with fewer than 50 employees could opt out of the policy.[59] Ultimately, state preemption of paid leave, in concert with other systems of oppression, resulted in increased COVID-19 related morbidity and mortality among Black and Latinx people.

Local Police Budgeting and the Health of Communities of Color

Following the police shooting deaths of George Floyd, Breonna Taylor and countless others, longstanding calls for police reform, defunding the police, and abolition of the police became part of the public conversation. Some localities tried to take steps in this direction by reallocating police budgets. Yet, preemption stands in the way.

In response to these actions and discussions at the local level, seven states proposed bills threatening localities for

cutting or reallocating their police budgets. A Missouri bill would make localities ineligible for state funding if they decrease the law enforcement budget by more than 12% relative to other items in the proposed budget. A bill in Louisiana would allow the state legislature to reduce sales tax appropriations to a locality if the locality reduces the annual police department budget and the legislature determines that the reduction will have a significant adverse effect on public safety. Similar bills were filed in Indiana, Arizona, New Jersey, and Texas.[60] The city of Austin decided to divert some of its police budget to pay for supportive housing programs and other services. However, the governor of Texas publicly criticized their approach and voiced support for legislation prohibiting cities from cutting their police budgets. Other states are considering similar legislation preventing localities from reducing and/or diverting funds from their police and public safety budgets.[61] Previous research has found that police budgets are associated with health outcomes. Ronzio et al.[62] found that higher city police expenditures were associated with higher all-cause mortality and premature mortality.

State preemption of local police budgeting is a colorblind policy that maintains the existing racial hierarchy. The bills are enacted under the guise of public safety and do not explicitly mention race. However, whose safety are states interested in protecting? States are opposing local government actions that are trying to address police violence against Black people. Preemption is a convenient and effective policy tool of structural racism.

Black, Latinx, and Indigenous communities are more likely to be victims of lethal and non-lethal police violence with Black men and boys being particularly vulnerable.[63] Research has found that both lethal and non-lethal police violence have negative heath consequences for Black people and other people of color.[64] Black people of all socioeconomic backgrounds are more likely to be killed by police than white people.[65] One analysis found that Black males are 21 more times likely to be killed by the police than white males.[66]

Police violence also has far-reaching effects on Black people who do not personally experience police violence. Bor et al.[67] found that police killings of unarmed Black people within a state were associated with worse mental health among all Black people within the state where the killing took place. Watching videos of police killings of unarmed people of color is associated with poor mental health outcomes among adolescents. The adverse health effects are not limited to poorer mental health. Both personal and vicarious experiences of police mistreatment have negative physiological effects as well.[68]

It is not possible to reduce racial health inequities without addressing the interactions between law enforcement and Black people.[69] Preemption threatens local government's ability to align their budgets with their goals and address the needs of their communities, particularly around racism as a public health crisis.

Conclusion

New preemption has created racial health inequities and threatens future efforts to ameliorate those inequities. One of the many dangers of new preemption is its ability to stifle the implementation of solutions at the appropriate level. Some states are emboldened by the actions of other state legislatures, and local governments are discouraged and less likely to even attempt to implement innovative policy solutions for fear of their laws being preempted or implementing laws that are in violation of existing policies. Preemptive policies are notoriously difficult to overturn. If they are overturned, it takes an average of 11 years to repeal them.[70] Localities are using three major tactics to fight preemption: grassroots movement, legally challenging the constitutionality of preemption efforts, and invoking home rule provisions in state constitutions or statutes.[71] However, the volume of and speed at which new preemptive policies are being enacted suggests that these tactics are not enough. Structural racism is comprehensive and sophisticated. A multifaceted strategy to address new preemption is needed that focuses on (1) preventing these policies from being passed in the first place (2) mitigating the negative effects of preemptive policies in communities of color (3) helping local governments address needs without triggering state intervention (4) developing creative, potentially new, legal approaches to repealing and challenging these laws.

As a researcher, I cannot speak to specific legal approaches for challenging preemption policies. However, researchers, particularly public and population health researchers, have an important role to play. First, understanding new preemption as a tool of structural racism places the use of this legal tool in the longer legacy of racist policies in the United States. Secondly, that contextual understanding can inform empirical research on the

racially disparate effects of new preemption. Lastly, evidence is helpful to amplify ongoing grassroots movements against new preemption and can potentially inform creative legal efforts to combat new preemption.

Note

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Reminiscences on Public Health Law and JLME

Hodge, James G

ABSTRACT (ENGLISH)

This contribution marks a dual milestone at the intersection of public health law and *JLME*: my 50th publication of a substantive manuscript in the 50th anniversary of the *Journal* in 2022. In recognition of these coinciding landmarks, this installment of the Public Health Law column for *JLME* features observations and reflections of the field based largely on prior publications.

FULL TEXT

DETAILS

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Anti-Selection &Genetic Testing in Insurance: An Interdisciplinary Perspective

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ABSTRACT (ENGLISH)

Anti-selection occurs when information asymmetry exists between insurers and applicants. When an applicant knows they are at high risk of loss, but the insurer does not, the applicant may try to use this knowledge differential to secure insurance at a lower premium that does not match risk.

FULL TEXT

Introduction

One of the fundamental principles of insurance is the law of large numbers, which makes a collective management of independent and similar risks more cost-effective and less risky than managing them individually. Private insurers collectively manage risk by creating homogeneous risk pools through underwriting and risk classification. Insurers therefore argue that they need information about major risk factors in order to appropriately allocate risk and set rates commensurate with an individual's likely losses. For some conditions, genetic testing can bring greater accuracy to the underwriting process, making it of particular interest to insurance companies. As artificial intelligence and big data gain importance in the business world, underwriting practices may become more granular. Against this background, we expect the question of how to handle genetic information to receive renewed attention in the forseeable future.

During risk classification, those categorized as high risk may be denied insurance or be charged a higher premium. Such negative consequences for individuals categorized unfavorably are endemic to any classification scheme, and genetic information is no exception in those jurisdictions where use of this information remains legal. Therefore, applicants may fear disclosing genetic information to insurers. This fear hinders some individuals from undergoing genetic testing or participating in genetic research —a choice that may have adverse consequences for public health.[1] However, if applicants are not required to disclose predictive genetic information, those at higher risks could apply for greater policy coverage without insurers being able to assess risk and set appropriately higher premiums, a concept known as anti-selection. Insurers argue that anti-selection may reduce available coverage levels and lead to increased prices for all consumers, even those without genetic predispositions.

These competing interests of consumers and insurers in individually underwritten insurance lines, such as life insurance, are often at the heart of regulatory activity in this area. Though different types of genetic tests may have distinct implications for both private and public insurance, regulations tend to focus on the privately issued, individual-underwritten policies and on predictive genetic tests. This paper does the same.

For any regulator contemplating whether to restrict insurers' use of predictive genetic information, an initial consideration may be: how much of an economic impact will restrictions have on insurance markets? If the economic impact is too dire, financial concerns may outweigh genetic privacy and non-discrimination concerns; if it is minimal, regulation may be justifiable to promote human rights and public health. The severity of the economic impact on insurers depends, in part, on whether individuals will change their insurance-purchasing behavior after receiving an adverse genetic test result.

Given that any potential effect of anti-selection depends on human behavior and practical realities, such as time, monetary, or knowledge constraints, we argue that there is a role for a broader, interdisciplinary community. Specifically, those researching the ethical, legal, and social implications (ELSI) of genetic testing can enrich the prevailing actuarial and economic perspectives about individuals' insurance purchasing behaviors following genetic testing.

This paper begins with a discussion of anti-selection theory and modeling, then explores regulatory approaches taken in four common law and one mixed (common and civil law) jurisdictions from around the world, and then turns to a discussion of how insurance purchasing behavior may be impacted by genetic testing. This section provides a robust bibliography of current literature across disciplines on the topic. Given that any potential effect of anti-selection depends on human behavior and practical realities, such as time, monetary, or knowledge constraints, we argue that there is a role for a broader, interdisciplinary community. Specifically, those researching the ethical, legal, and social implications (ELSI) of genetic testing can enrich the prevailing actuarial and economic perspectives about individuals' insurance purchasing behaviors following genetic testing. Additionally, in the ELSI community there has been extensive attention on genetic discrimination and its impact on individuals, but there has been far less research on the behavior of individuals regarding insurance uptake following a genetic test. We conclude by exploring why individuals who learn that they are at increased genetic risk may decide not to, or be unable to, purchase higher insurance coverage. These reasons fall into four domains: (1) internal barriers, (2) external barriers, (3) genetic dimensions, and (4) system dimensions.

I. Anti-Selection and Genetics

Broadly conceived, anti-selection results from asymmetric information between a prospective insured and the insurer, whereby the insured knows more about her risk than the insurer and this informational advantage leads to lower premiums.[2] With increasing rates of predictive genetic testing, there is now greater chance of such information asymmetry. The result may be that if insurers are unable to learn of this heightened genetic risk, they may not charge a sufficient premium to cover it.

One worry raised by insurers is if they set prices according to the average risk in the population, they could over-attract higher-risk customers, which may create a need to raise premiums.[3] If relatively better risks then drop out of the insurance market, premiums could rise anew, with the potential that in the end only very high-risk types will be insured. The worst-case perceived risk of anti-selection is that even high-risk individuals might find premiums prohibitively high, potentially leading to a complete 'unraveling' of the market.[4] In general, anti-selection is not a purely hypothetical scenario and there some existing evidence exists that shows it could be an issue in some insurance markets.[5] However, whether it is an issue for genetic information specifically is debated and some argue that this is unlikely.[6]

This is complicated by additional factors that can lead to information asymmetry outside of the anti-selection problem: the insurer's underwriting process could fail to identify, or an applicant could fail to disclose, risk that is known to the applicant; an insurer could incorrectly assess the weight of the information provided; or the insurer could be prohibited from considering certain risks if their country or jurisdiction restricts this by law or other policy. In this paper we focus on the scenario where information asymmetry is caused by regulation that prevents insurers from collecting or considering genetic test results.

It is important to note that not all genetic information is the same. Single gene disorders or diseases, which arise as a result of a single gene operating in isolation, are relatively rare. Examples of such diseases include Huntington's disease, a progressive neurological disorder, and Lynch Syndrome, a genetic predisposition to colon and endometrial cancer. Multifactorial diseases are more common and arise from a complex interaction of (often) multiple genes and environmental factors.[7] Examples of such diseases include some types of heart disease and some cancers, and the genetic basis of these diseases is somewhat less understood. At present, insurers are most likely to take into account predictive single-gene conditions. Even then, relatively few genetic tests are currently useful in insurance underwriting, in part given the relative rarity of genetic conditions and the ability for individuals to undertake preventive measures. Additionally, almost all currently known single-gene genetic variants have

incomplete penetrance, meaning that not everyone with the genetic variant will develop symptoms.
Anti-selection as it relates to genetic information is most relevant for lines of insurance that underwrite on the basis of morbidity and mortality, like life, long-term care, critical illness, or disability income insurance. Health insurance is often offered through public insurance programs and/or is community rated, so can be less impacted. However, to the extent that a jurisdiction, such as the United States, has a private, individually underwritten health insurance market, this line of insurance can also be implicated.

A. Anti-Selection and Regulation

Since anti-selection largely arises from information asymmetry, the best protection insurers have against it is to ensure that all applicants fully disclose all relevant risk information. However, in some cases, in order to protect the human rights of individuals or to encourage uptake of medically necessary genetic testing and research, regulators have restricted insurers' collection or use of genetic test results under a variety of approaches,[8] each with likely different potential effects on anti-selection.[9] Policies span the spectrum from those that allow insurers to use genetic information to those that place restrictions, such as a benefits cap, to those that prohibit insurers' use.[10] This section focuses on five home countries of the authors as case studies.

1.united kingdom (uk)

In the UK, the Code on Genetic Testing and Insurance (UK Code) binds insurers and prevents them from using predictive genetic test results to discriminate against applicants. The agreement sets a monetary benefit cap under which customers are not required to disclose the results of predictive genetic tests —£500,000 for life insurance and £300,000 for critical illness, income protection, and long-term care insurance.[11] Benefit caps are a relatively common policy approach, especially in Europe.[12] This prevents applicants from trying to take out large amounts of cover based on their knowledge about genetic risk, while still providing protections for amounts of cover regarded as reasonable.[13] The Code also bars insurers from asking applicants to take a genetic test.
However, the UK Code further limits insurers. Even if the amount of cover is above the prescribed cap, insurance companies are only allowed to require the disclosure of a genetic test whose relevance has been approved by an independent committee. The only test approved in the over 20 years that the policy has been in place is Huntington's Disease for life insurance policies.[14] Indeed, the committee has since been disbanded due to inactivity. Thus, for all practical purposes, the only benefit cap that exists in the UK applies to applicants for life insurance with a positive genetic test for Huntington's Disease.

2.australia

Health insurance in Australia is community-rated (via legislation) and thus not subject to genetic discrimination. The Disability Discrimination Act 1992 prohibits discrimination on the basis of genetic status, but makes an exception for risk-rated insurance underwriting. The Act requires life insurers to have actuarial justification for using medical information, including genetic test results in underwriting, but studies have shown this documentation is rarely produced or enforced.[15] However, after growing pressure from researchers and advocates, in 2019, the Australian life insurance industry adopted a Moratorium with a benefit cap, similar to the UK.[16] The Australian Moratorium is an industry policy as it does not change the legal or regulatory situation in the country. It only allows insurers to seek genetic test results for life insurance policies above $500,000 in lump sum death or total permanent disability coverage, $200,000 in trauma/and or critical illness coverage and $4,000 monthly in income protection, salary continuance or business expenses coverage. The Moratorium allows life insurers to take into account a favorable genetic test result an applicant chooses to disclose, irrespective of the amount of cover; for example, to show that they are not carrying a genetic variant associated with developing an illness that runs in their family. In general, an applicant must only disclose family history for first-degree relatives. Life insurance industry standards likewise prohibit insurers from asking an applicant to take a genetic test.[17]

3.canada

Canada's Genetic Non-Discrimination Act, passed in May 2017, prohibits "any person" from requiring another "to undergo a genetic test as a condition of (a) providing goods or services to that individual, (b) entering into or continuing a contract or agreement with that individual, or (c) offering or continuing specific terms or conditions in a

contract or agreement with that individual."[18] It is also illegal to discriminate based on an individual's refusal to undergo a genetic test or decision not to disclose the results.[19] Despite efforts from the Canadian Life and Health Insurance Association (CLHIA) and the Canadian Institute of Actuaries (CIA) to get an exception into the law for the life insurance industry,[20] the Canadian Genetic Non-Discrimination Act passed with broad language capturing all lines of individually underwritten privately issued insurance policies and a broad definition of "genetic test," which, unlike the UK Code, is not limited to predictive tests. The law recently underwent constitutional review. In 2019, the Quebec Court of Appeal found the law to be invalid, but in 2020 the Canadian Supreme Court reversed the decision, holding that the federal government had jurisdiction to pass the law.[21]

4.united states (us)

The United States' response to growth in genetic technology and increased access to genetic test results is the Genetic Information and Nondiscrimination Act of 2008 (GINA).[22] GINA prevents health insurers and employers from collecting and discriminating on the basis of genetic information, including test results, family medical history, and use of genetic services.[23]

In addition to GINA at the federal level, the states across the US provide varying levels of protection against genetic discrimination and genetic testing in insurance. While GINA protects applicants in the health insurance industry, several states extend protection against genetic discrimination in various ways to life, long-term care, and disability insurance.[24] This variation across states can create confusion, and in some cases even enforcers are unsure about the extent of the protections that they are tasked to implement.[25] In 2020, Florida became the first state to bar the use of genetic test results in all three lines of insurance.[26]

5.ireland

In Ireland, use of genetic test results by insurers is limited. The Disability Act 2005 (Part 4) regulates and controls genetic testing in various third party contexts, including insurance.[27] Specifically, the processing of genetic test results is prohibited in relation to a policy of assurance, a policy of health insurance or health-related product, an occupational pension, a retirement annuity contract or any other pension arrangement, unless the consent of the person has been obtained,[28] thereby implying the necessity for informed consent.[29] Therefore, in insurance settings, insurers are not permitted to request, take into account or process the results of genetic tests without a person's consent.[30] For example, application forms or health questionnaires that ask health related questions of an insurance applicant should not include any question about genetic tests. Despite these protections, there is a gap in the legislation regarding the use and access to family medical history information by insurers and other third parties. The definition of 'genetic data' in the legislation is narrow does not include family medical history.[31]

The protection of genetic information in Ireland is further strengthened by the General Data Protection Regulation (GDPR) at European Union level.[32] Article 9 of GDPR identifies genetic data as a special category of personal data subject to additional privacy protection; providing that processing of this data is prohibited except in limited circumstances as set out in article 9 (for example, if the data subject has given their explicit consent to the processing of this data).

Although these are reasonably decent privacy protections, there are no legislative protections in Ireland against the discriminatory use of such genetic information by insurance companies.[33]

6.impact of regulation on anti-selection

These examples of international regulation and industry guidance highlight how insurers or government policy can impact the potential extent of anti-selection. In the context of genetic anti-discrimination, policies that largely bar insurers from considering genetic test results, such as in Canada or the US health insurance market, could theoretically increase anti-selection because insurers are prohibited from gathering information. Thus, the policy creates an asymmetric situation between insurers and applicants where the insurer cannot know potentially relevant genetic information about the individual they are insuring. This is sometimes referred to as regulatory adverse selection because the imposition of information asymmetry is stemming from government policy.[34] The benefit cap approach, such as in Australia, is a policy that protects individual interests for low to moderate levels of coverage but preserves the insurers' right to seek information symmetry for policies with higher benefit caps. The question

remains, however, how much these industry guidances and regulations would lead to increased anti-selection and how this would affect insurance market outcomes.

II. Modeling Anti-Selection

Generally, we must rely on modeling to measure the potential impact of barring insurer collection and use of genetic test results because direct measurement of anti-selection in insurance markets is difficult. Take, for example, the UK Code on Genetic Testing and Insurance, and its precursor policy, the Concordat and Moratorium. Since this policy went into effect, there has not been evidence of greatly increased premiums or instability in the insurance market, despite insurers inability to consider predictive genetic test results in all but a very small handful of applications.[35] However, because UK insurers are unable to collect genetic test results, it is also impossible to measure the extent to which anti-selection is actually impacting markets. Given that the UK insurance markets are continuing to thrive, it is clear that an 'unraveling' has not occurred, but without data, it is unknown what potential anti-selection effects, if any, there were in the UK market following the moratorium. Thus, we can only model what the impact of a ban on collection of genetic test results would be, based on hypothetical scenarios.

Two primary disciplines model anti-selection in insurance broadly, and the impact of genetic testing specifically: actuarial science and economics. The two disciplines vary in methodology and focus, so the conclusions do not always align. Even within the disciplines, findings vary greatly as to the impacts of genetic testing, as is discussed further below. Ideally, in both disciplines, models attempt to approximate reality as best as possible—taking into account such evidence as may exist of insurance markets and human behavior. Sometimes, however, assumptions in the models may not capture true human behavior following a genetic test. As will be discussed further below, ELSI scholarship can help provide insight regarding human behavior to bolster assumptions about how individuals might react following a genetic test. Below we briefly summarize modeling of anti-selection across disciplines.

A. Actuarial Modeling of Anti-Selection and Genetic Testing

Actuarial modeling attempts to assess whether and to what extent anti-selection will impact premiums and whether this may change across lines of insurance. Such modeling poses two main challenges.

First, the risk of ill-health or premature death associated with a particular genetic variant must be estimated. All the major single-gene disorders now have a considerable epidemiological literature, so in principle these estimates can simply be taken from there. However, there are major traps for the unwary modeler: the rarity of genetic conditions, the testing setting, and the differences in manifestation and onset of genetic conditions.[36]

Relevant high-risk genetic disorders, such as hereditary breast and ovarian cancer or Huntington's Disease, are comparatively rare, which makes prospective studies of unselected populations (the gold standard of epidemiology) too costly. Therefore, study populations tend to be small and selected *because* they are known to be at risk, such as through manifested symptoms or family history.[37] Those with deleterious variants who do not meet the selection criteria are never studied. The result is that mortality associated with carrying certain variants can be overstated.

Genetic testing relevant for insurance has so far been largely confined to clinical settings. The tested population broadly coincides with the population selected for epidemiological studies, so such studies can, with caveats, be applied to persons who are tested. This is *not* true of any hypothetical extension of genetic testing to a larger population, for example by whole-genome sequencing at birth.

Some disorders manifest sooner than others with detectable clinical symptoms which are disclosable to an insurer. Compare breast cancer and cardiomyopathies (inherited heart disorders). Mutations in the *BRCA1* and *BRCA2* genes can indicate risk of breast cancer that may only develop decades in the future, while no cancerous tissue is present or detectable. Cardiomyopathies very often present major and detectable changes to the heart muscle at early ages.[38] In this case, barring insurers from using genetic test results does not deprive them from obtaining other health information about the early existence of a serious condition.

Second, anti-selection is a behavior, that can be represented in a model, but the empirical evidence varies by line of insurance and is not consistent across studies. A model must represent the (different) information available to the individual and the insurer. This is not confined to genetic test results, but includes family history, especially if this caused the genetic test to be taken (in a clinical setting, see above) and measures from non-genetic biomarkers.

Two studies can help shed light on the important role of informational and behavioral assumptions in actuarial modeling. Macdonald &Yu (2011) modelled a wide variety of scenarios, mostly resulting in anti-selection costs being a fraction of one percent of total premiums.[39] They acknowledged that these results could be scaled up if more disorders were covered, or if `adverse selectors' chose very large sums to insure. Howard (2014) modelled a single scenario, in which 75% of `adverse selectors' took out ten times the average sum insured.[40] This model projected life insurance premiums in Canada to increase by 12%, and male and female mortality (among insured lives) by 36% and 58% respectively. The great majority of these costs were accounted for by the inclusion of several cardiomyopathies and differences in assumptions about insurance purchasing behavior.

B. Economic Modeling of Anti-selection and Genetic Testing

Whereas actuaries use information about risk, the course of disease, and potential informational constraints to model the potential impact on insurance premiums, economists assess the potential consequences of anti-selection by looking at efficiency and measures of overall social well-being, or so-called 'social welfare' on insurance market outcomes.[41] When insurers face informational constraints, market outcomes are less efficient than if information was shared between insurers and policyholders. Models focusing on efficiency find that a ban on risk classification entails a loss in efficiency because full disclosure is always the most efficient system.[42]

Different conclusions may be reached when taking an ex-ante view that focuses on social welfare.[43] For example, if we consider two groups, people at high-risk and people at low-risk, there could be a policy change that benefits those at high-risk at the expense of those at low risk. A ban on risk classification can be beneficial if the advantage gained by those at higher risk outweighs the burden imposed on those at lower risk.[44] From an ex-ante view, a ban on risk classification can thus protect individuals from facing classification risk, which may otherwise deter them from genetic testing altogether. Therefore, there are arguments that policies that restrict certain types of risk classification may be preferable on distributional grounds. While there is a more efficient way to achieve these redistributive goals in principle, it is far from clear whether this could be achieved in practice. Recently, others have looked at anti-selection from a similar perspective called 'loss coverage' and found a comparable overall effect where even if there is some anti-selection, the benefit to those at high-risk can outweigh the extra cost to those at lower risks.[45]

The typical anti-selection models need to be modified in the context of predictive genetic testing because here the applicant has information based on a choice to take a genetic test and the outcome of that test. Early economic analyses concluded that a regulatory regime allowing insurers to use genetic test information is better than one which prohibits it.[46] Since then, this conclusion has held across other economic studies.[47] For example, other studies have incorporated psychological costs from testing, such as feelings of anxiety about the future[48] or tested the findings across genetic information that has decision-making value for the individual because preventive treatment options may be available.[49] A recent study, however, modeled that, when premiums are so large that access to insurance becomes an issue, policies that allow for use of genetic test information may not be as good in terms of social welfare as those that ban genetic information.[50] These models mostly apply to private health insurance and long-term care insurance where contracts are exclusive, meaning that individuals do not buy policies from multiple insurers. In the life insurance context, however, models predict varied outcomes for the impact of genetic testing on insurance,[51] in some instances finding that prohibiting insurers from using genetic information increases social welfare.[52]

Several additional studies that have analyzed anti-selection in life insurance specifically for genetic testing are of note. An early 1999 study predicted that, in the case of life insurance, failure of insurers to adequately obtain genetic test results related to breast or ovarian cancer could lead to "unbearable" costs related to anti-selection.[53] However, the study concluded that such costs could be manageable if family history is adequately taken into account.[54]

Another study found only modest anti-selection welfare costs from banning life insurers' access to *BRCA1/2* test results, but point out possibly large efficiency costs, for family background groups who are at high risk for carrying the genes, should the test become widely adopted.[55] Another study also focused on the *BRCA1/2* genes and concluded that anti-selection due to genetic testing is a manageable problem for insurance companies as long as testing rates are low and only a few highly predictive genetic tests are available.[56]

III. Anti-selection, Genetic Testing, and Insurance Purchasing Behavior

When modeling the potential for anti-selection, economists, actuaries, and other researchers must make several assumptions to incorporate into their analysis. One such assumption is whether individuals will alter their insurance purchasing behavior after receiving the results of a predictive genetic test. If insurers cannot price-discriminate based on genetic test results, individuals with a positive test may opportunistically buy more coverage than they otherwise would —but the full extent of such behavior is unknown. Therefore, models must anticipate whether individuals who learn that they have an increased risk for a genetic disease and have no duty to disclose will subsequently purchase insurance, increase their coverage, or maintain the status quo.

So which assumptions regarding the percentage of individuals who may purchase insurance best approximate reality? The evidence is limited and seems to depend on the specific line of insurance and the type of genetic test. The actuarial models discussed above approached this assumption in very different ways. The Howard model, for example, made a bold assumption: 75% of those who received a positive result for one of thirteen genetic conditions would opportunistically apply for as much life insurance coverage as they could get while everyone else would not apply for additional coverage.[57] A US Society of Actuaries (SOA) study ran the model several times, varying the estimated percentage of individuals purchasing insurance following a positive genetic test. These varied assumptions led to different predicted results for the life insurance industry.[58]

So which assumptions regarding the percentage of individuals who may purchase insurance best approximate reality? The evidence is limited and seems to depend on the specific line of insurance and the type of genetic test. For example, one retrospective study examining *BRCA1/2* in a cohort of women, found that 37 women (6% of those surveyed) changed their life insurance coverage after genetic testing, including 27 (4%) who increased their coverage.[59] Those women who chose to increase their life insurance policy were more likely to carry a *BRCA1/2* mutation, raising prospects of anti-selection.[60] While this small study highlights the possibility of some anti-selection, it is nowhere near the 75% assumption level incorporated into the Howard model described above. Additionally, another study found no influence from *BRCA1* research results on participants' purchasing of life insurance policies.[61]

Several studies have found potential evidence of anti-selection specific to long-term care insurance. For example, one found that those with a positive Huntington's Disease mutation are five times more likely to have long-term care insurance than the general public.[62] This study, however, did not assess when individuals took out insurance relative to their genetic test. So, it is possible that for some portion of these individuals, there was no information asymmetry regarding genetic testing between the insurer and the applicant at the time of their application for insurance. To address this, the study compared levels of long-term care insurance between those with a family history of Huntington's disease who were tested and did not carry the familial mutation versus those who did. Those with the familial mutation had rates of long-term care insurance ownership 20 to 30 percentage points higher than those without, although this observation comes from only 71 individuals who opted to get tested.[63]

Another study found those who tested positive for increased risk for Alzheimer's Disease reported making more changes and to have been thinking about making changes to their long-term care insurance policies (p-value of .0511), but found no significant changes in insurance purchasing behavior in health, life, and disability insurance.[64] Additional checks to ensure that these estimates were robust found that the results were 'only suggestive'.[65] Overall, the variance in the literature suggests no widespread agreement on the impact of genetic tests on insurance purchasing behavior and, therefore, anti-selection and that any evidence that there is an impact is based on studies with small sample sizes and focused on diseases with high penetrance and few preventive measures.

IV. Insurance Purchasing Behavior in the Real-World

Modeling and actuarial projections currently attempt to incorporate information about human behavior into predictions, but assumptions must be made in order to fill in evidentiary gaps. While some studies have explored how individuals react regarding insurance post-genetic testing, these studies have been relatively limited and focused on a small handful of severe genetic conditions. Greater ELSI research in this area can help support estimates of anti-selection by highlighting and empirically measuring the real-world complications that can affect

individuals' insurance purchasing behaviors following a predictive genetic test.

In this section we explore multiple factors that may contribute to insurance purchasing decisions and categorize them into four types: (A) internal barriers, which are those that are intrapersonal to the individual, (B) external barriers, which are the societal experiences that influence decision-making, (C) genetic dimensions, including different testing types and the information they produce, and (D) system dimensions, including alternative methods insurers may use to find information about the applicant.

A. Internal Barriers: Not Everyone Will Act 'Rationally' Following a Genetic Test

1.avoidance and coping mechanisms

Individuals react very differently to information about threats, including potential threats to their health. Self-regulation theory, for example, "refers to the processes through which individuals direct their thoughts, emotions, and actions to achieve desired outcomes and minimize harms."[66] The theory has been applied in the context of learning about future genetic risk to help understand individual reaction to risk information.[67] One aspect of self-regulation is that information that elicits fear or negative emotion can lead to coping behaviors such as avoidance.[68] Discussions of coping behaviors in the context of genetic testing highlight that individuals may avoid learning about genetic risk, may avoid discussion of risks with family members or medical care teams, or avoid recommended screenings.[69] Others could use coping mechanisms that minimize the importance or deny the accuracy of the risk information.[70] Generally, papers discussing avoidance and denial mechanisms following genetic test results do not specifically discuss insurance purchasing behavior. However, it is conceivable that individuals who are coping with negative or fearful information by ignoring, minimizing, or otherwise avoiding coming to terms with the information are unlikely to apply for greater insurance coverage as this would require direct acknowledgement of the risk information.

Studies also show evidence of information avoidance in the context of health information. Several papers model a patient's anxiety and fears arising from expectations about possible adverse health conditions.[71] In the context of genetic testing, individuals who are sensitive to "message uncertainty" associated with the taking of a genetic test may prefer to forego testing altogether and stick with their current belief despite the predictive value of genetic information.[72]

Some studies and modeling support this claim. First, in practice, take-up rates for existing genetic tests are low. When anonymous and costless genetic testing for Huntington's disease was offered, one study found that the percentage of individuals at risk who requested testing varied from 9 to 20%.[73] Similarly, another study finds take-up rates of 10%.[74] However, other studies related to hereditary breast and ovarian cancer have found high testing uptake rates of 78.2%.[75] These findings are notable given the differences between Huntington's Disease and hereditary breast and ovarian cancer. The former has no current clinical interventions, whereas knowledge of predispositions to breast cancer can lead to more intensive screening or preventive surgery. It is also important to note that public attitude towards genetic testing varies over time and may depend on the perception in the general population, experience by family members and peers, knowledge about prevention and treatment opportunities, and other factors. For example, after actress Angelina Jolie wrote an editorial in the *New York Times*, there was a measurable "Angelina-Jolie effect." One such measurement was conducted 15 days after the publication of the editorial and found a significant increase in daily *BRCA1/2* testing rates by almost 60%.[76]

2. understanding of risk

Individuals face another barrier when they do not know what to make of their genetic test results. Information about genetic risk is complex and difficult to fully understand, especially for those with lower health literacy. Even if individuals know the possible medical consequences of predictive genetic test results, many questions may linger about impact across other aspects of their lives, including financial ramifications.

It is well documented that many individuals have low health and financial literacy and that this makes it difficult for them to process risk and decision-making in healthcare generally[77] and genetics specifically.[78] An individual who misunderstands their level of risk may make insurance purchasing decisions based on their personal perception of risk, not their actual risk. For instance, some applicants may perceive their risk to be higher than it actually is

causing some to purchase more insurance than they need, which may then benefit insurers. For example, in the study of the rates of long-term care insurance and Huntington's disease, 27% of those who had a family history of the disease, but a negative genetic test result —and thus at no risk of developing Huntington's disease —had long-term care insurance compared to 10% in the general population.[79] Others may undervalue their risk and purchase too little insurance to cover their expected loss. In either case, misunderstanding of risk may make the insurance purchases of individuals appear irrational or unexpected compared to their actual risk.

3.risk perception and environmental factors

The multidimensional interaction between genes and other factors such as environment and lifestyle choices (e.g., diet) must be taken into account when determining an individual's predisposition to disease.[80] Additionally, for some genetic conditions, there are a range of mitigating or preventive measures available to lower one's risk of developing disease. For example, women with a positive *BRCA1/2* test result may undergo prophylactic surgery or undertake more frequent cancer screenings. Individuals predisposed to heart disease may alter diet or exercise routines.

At this time, the predictive value of most genetic tests is therefore somewhat limited because they indicate the probability that an individual may develop a disease, and do not yet fully take into account how individual characteristics, prevention, and environment alter the risk. Although science and technology are advancing quickly, the predictive value and clinical utility of genetic tests vary.[81]

Individuals and their healthcare providers, therefore, may evaluate genetic risk differently depending upon how they view the relevance of environmental factors and the interaction with genetic factors. This, in turn, could affect whether and how much insurance an individual chooses to purchase. For example, an individual who learns of a genetic risk factor for heart disease may believe, accurately or not, that their lifestyle exercise and diet choices mitigate this risk enough so additional insurance is not necessary.

B. External Barriers: Not Every Opportunistic Individual Will Be Able to Access Increased Insurance

Insurance purchasing behavior is influenced by more than genetic testing results and an individual's understanding of their genetic risk. Many personal and societal factors weigh on an individual's calculus in deciding whether to purchase insurance. One important factor is the affordability of a plan. Even with a positive genetic test, applicants are unlikely to immediately seek out and purchase maximum coverage if they cannot afford the premiums.

1.financial cost

The average life insurance premium across the countries examined in this paper are instructive. In the United States, the average monthly premium for a healthy 40 year old for a $250,000 term life insurance policy is approximately US$20.[82] A healthy 30-year-old in Canada can expect to pay an average of CAN$13 (US$10.23) per month per $100,000 of coverage.[83] In Australia, a healthy 40-year-old pays about AU$18 (US$13.60) per week for $250,000 in coverage. For women, this rate is cheaper at around AU$11 (US$8.70) per week for $250,000 in coverage.[84] In the UK, the average term life insurance premium is £30 (US$41) monthly. Unsurprisingly, these premiums vary by age and health status but the average premium demonstrates that the expense for just life insurance is one that could have an impact on an individual's or family's budget.

While some individuals or families could absorb these costs through budgeting, many families may not be able to afford additional insurance even if they desired it.[85] For example, one study found that individuals with a self-reported income of less than $49,000 had a higher frequency of Huntington's Disease diagnosis than those of a higher income.[86] One possible explanation for this is the inter-generational wealth effects of having a parent with a genetic illness.[87] Thus, individuals with a predisposition to Huntington's Disease may be less likely to be able to afford the costs of additional insurance. Additionally, even if the cost of a $250,000 life insurance policy could be affordable for many families, increasing this amount to greater coverage could begin to stretch budgets thin.

2.knowledge of a complex system

Further, it is not clear that applicants know enough information from a genetic test to accurately predict the amount of coverage that they may need or want. Applicants may not even know the type of coverage available to them or they may assume that insurance costs are too high for their budget.[88] The impact of anti-selection may be significantly decreased if applicants do not know how to use their genetic test results to their advantage, since one

key element of anti-selection is individuals 'exploiting' their informational asymmetry. Indeed, research in the UK has shown that only as few as 10% of applicants considered more than one life insurance policy while 59% relied on the advice of a broker.[89]

If anything, the taking of a genetic test might initiate a thought process to finally "get around" and obtain an adequate amount of life insurance for the household, as many people currently have insufficient life insurance holdings.[90] For example, Bernheim et al. (2003) argue that an insufficient purchase of life insurance is responsible for two-thirds of poverty among widows and over one-third of poverty among widowers.[91] Individuals may simply procrastinate on life insurance decisions to avoid thinking about the possibility of premature death and the hardship it would impose on the surviving family. Another obstacle encountered in practice is that people may not know how to determine an adequate amount of life insurance and do not feel comfortable taking financial advice. Acting upon the results of a genetic test may help overcome some of these cognitive hurdles and actually help improve the problem of insufficient life insurance holdings.

3.barriers to entry

Applicants also incur opportunity costs to enter the insurance market. There exists a wide array of policy options, coverage types, and payouts that come with varying levels of complexity and work required to gain coverage. Some insurance applications, usually those for higher payouts, are complex and take significant time to complete and be processed.[92] This means that there is real opportunity cost to filling out applications, collecting required disclosure information, undertaking medical exams, and deciding which policy to purchase. Determining the best policy and coverage amount may be more difficult for those with lower financial literacy, a problem in populations across the globe.[93] Some applicants may find that the opportunity costs associated with purchasing insurance as a result of a genetic test are simply too high and forego it altogether.

C. Genetic Dimensions: Genetic Tests Are Complex and Variable

There is no single monolithic genetic test. Different types of genetic tests provide different information about risk. The type of genetic testing one gets, therefore, will greatly alter perceptions of risk and subsequent decisions about insurance purchasing. Many of the studies measuring insurance purchasing behavior focus on predictive genetic test results for adult or late-onset highly penetrant serious monogenic disorders, such as Huntington's disease and hereditary breast and ovarian cancer.[94] Even with these conditions, the situation is much more complex than it seems. For example, even in the case of Huntington's Disease, there is some reason to believe anti-selection would be less of a problem than foretold by insurers due to the rarity of Huntington's disease, the small group of those at-risk who opt for testing, insurer access to family history (in many countries), and the variation in progression and severity of disease.[95]

But not every genetic test is as predictive as these key examples. Modeling should, and often does, take into account a wide variety of genetic conditions in order to understand the potential impact on insurers. Assumptions of insurance purchasing behavior must also consider how individuals with less penetrant or less severe genetic conditions will react.

The field of genetics has evolved at a rapid pace in recent years giving rise to a multitude of tests and testing technologies that include: polygenic risk scores for multifactorial diseases, risk prediction models, whole genome sequencing, recreational genetic testing, low penetrance multifactorial gene panels, epigenetic clock, and pharmacogenetic tests.[96] While some of these technologies and tests appear particularly promising, they are mostly still at the research stage. The health impact of the few that have been translated into the clinic (mostly pharmacogenetic tests) is not sufficiently documented yet to support the conclusion that non-disclosure of results could lead to widespread anti-selection. However, given the fast progression of the discipline, careful monitoring of developments by actuaries and independent experts appears warranted.

It is also important to consider the distinction between diagnostic and predictive genetic testing. While this paper focuses on predictive genetic testing, some laws do also limit insurer use of diagnostic genetic tests. For example, while the UK Code covers predictive genetic testing, the Canadian Genetic Nondiscrimination Act applies to both predictive and diagnostic testing. Diagnostic genetic results serve to confirm or rule out a diagnosis based on

existing symptoms, signs or abnormal non-genetic test results which indicates that the condition in question may be present.[97] Even if individuals who get a positive diagnostic test result were interested in altering their insurance purchasing behavior, the patient would still need to disclose to the insurer some information about the likely disease affecting him. In this case, the benefit to the insurer that can use the information is achieving greater certainty on the specific condition afflicting the applicant.[98] Such added certainty may also sometimes benefit the applicant. The proper premium will be easier to set for the insurer who may, in turn, be more likely to take on the risk and to make an adequate pricing assessment rather than overprice or reject an applicant because of a degree of uncertainty regarding his actual illness. Alternatively, if the insurer is unwilling to take on the risk, they could already identify that risk based on existing symptoms without reliance on the genetic test.

D. System Dimensions

1.timing of purchase

The timing of an individual's genetic test compared to when they purchase insurance also influences anti-selection. Some applicants, for example, already have existing policies that meet their needs well before they consider and take a genetic test. Others specifically choose to purchase an insurance policy directly before receiving a genetic test. Indeed, sometimes genetic counselors or other healthcare professionals recommend securing insurance prior to undergoing testing.[99] Here, the information balance between insurers and applicants who purchase insurance before receiving a genetic test is no different than the information asymmetry between insurers and other applicants —as both would theoretically have access to information about family history and clinical symptoms. This scenario may bypass the anti-selection problem altogether since neither party could use information asymmetry to their advantage.

Sometimes, however, an applicant may know that someone in their family has received a positive genetic test and, depending on the jurisdiction, this information would not automatically come to light in an insurance application. In some jurisdictions disclosure would be required to the insurer, in other jurisdictions it would only be required if the insurer directly asks, in others no disclosure of genetic tests undertaken by family members is required. This may give the individual slightly more information about their risk than the insurer. However, the applicant still does not know her own genetic risk compared to that of the family member.

Timing is likewise important in the context of negative tests. It is not obvious that those who enroll in a life insurance plan before knowing genetic test results suddenly drop their plan once discovering they tested negative. In these scenarios, at the time of application, the individual would appear at higher risk due to family history and would be classified accordingly. Upon receiving a negative test result, some individuals may reapply based on the new information to obtain a lower premium, but others may not (due to the internal and external barriers described above), thus keeping more low risks in the risk pool, to the benefit of insurers.

2.'gaming the system'

When thinking about coverage amounts, there are two distinct pathways. In one, individuals are motivated to take out insurance to meet normal needs. In the other, individuals engage in a financial gamble by taking out abnormally large sums insured. A common approach to determining the amount of insurance to purchase is a needs analysis. For example, in determining the need for coverage for life insurance the applicant or financial planner on her behalf determines cash needs (e.g., funeral costs, installment debts, estate and inheritance taxes), income needs (for children and the surviving spouse during the readjustment and dependency period) and special needs (e.g., mortgage, emergency fund, college education). The total needs are then compared against available sources of recovery (e.g., checking and saving accounts, retirement funds, current group and other life insurance, etc.) to determine the additional amount of life insurance required to cover the gap. None of these calculations is affected if an applicant receives bad news about mortality risk.

Applicants may not always value life insurance as a key asset. A recent survey in the US by the Association of Life Insurance Underwriters reported that of individuals without life insurance only 38% believed they specifically needed the product.[100] Of course not all applicants place equal weight on the value of a life insurance policy, because the perceived need for life insurance depends on family circumstances, such as the number of dependents or existence

of mortgages. For example, not all applicants who carry a life-threatening genetic variant or who know they have a family history of disease will view the need for life insurance policy the same. They will likely contextualize this need based on their family and financial circumstances.

Yet the worry about opportunistic purchasing can be seen in the Howard modeling described above.[101] Howard adduced no direct evidence for the financial-gambling behavior of 'adverse selectors.' However, statements in a document released by the Canadian Institute of Actuaries alongside Howard, and by Howard in evidence before a committee of the Canadian Senate, suggest that these assumptions were motivated by fears that viatical companies, legal in four Canadian provinces, would finance the purchase of policies with large sums insured by individuals with adverse genetic test results, who would then assign the benefits to the companies.[102]

Such activity, known as 'stranger-originated life insurance' (STOLI) did take place in the USA, especially before 2008. However its targets were extremely wealthy elderly persons with relatively short life expectancies.[103] There is no evidence that any population with adverse genetic test results, neither very old nor exceptionally wealthy, and with reduced but by no means negligible life expectancies, would prove profitable for viatical companies.[104] There is no published evidence of STOLI activity linked to genetic tests in the UK, where the Code has been in force for almost 25 years (and viatical companies are legal).

Moreover, if viatical companies were to make egregious profits from genetic tests, they would have to be better than clinical geneticists in discovering persons with deleterious variants, better than epidemiologists in understanding the clinical risk, and better than actuaries in understanding actuarial risk.[105] They would also be betting against any medical advances reducing mortality over several decades. It has been suggested that life insurers in North American have long-standing antipathy towards viatical companies because they are actually concerned with low lapse rates.[106] Current profit calculations assume that individual policyholders will have relatively high lapse rates, but policies purchased by viatical companies will likely not be lapsed —cutting into insurer profits. This, however, is a different matter entirely than problems with STOLIs.

V. What Does This Mean for Concerns about Anti-Selection?

Global discussions about whether insurers should be able to access and use genetic test results are inevitably intertwined with concerns of anti-selection. Different studies and models indicate the possibility for a variety of insurance purchasing behaviors—leading to a significant range in the estimated negative economic impact of any policies limiting insurers' use of genetic test results. If the impact of barring insurer use of genetic test results is so drastic as to significantly impact the insurance market, genetic anti-discrimination laws may face a tough road to enactment or new efforts may be undertaken to amend existing policy in favor of policy that is less restrictive. However, a more limited modelled impact suggests that a slight increase in premiums may be a viable policy choice in order to address fear of discrimination and other social concerns.

In light of these challenges, some alternative strategies to address genetic discrimination and the use of genetic results in insurance merit consideration (in addition to any traditional legislative frameworks), including public-private agreements, public engagement, awareness raising and education, and multidisciplinary dialogue.

A. Use of Alternative or Complementary Strategies

In light of the complexity of the issues arising in this field, the novel nature of the challenges presented and their interdisciplinary nature, and in consideration of the fast pace of scientific and technological advances, it is questionable whether laws alone can adequately address the concerns presented in this area. There is arguably a potential for a lack of understanding of the realities and limitations of advancing genetic science, as well as a lack of awareness of the existence of relevant legal protections, on the part of medical and legal professionals, as well as the general public.[107] This may perpetuate further stigma and negative attitudes towards individuals with certain genetic susceptibilities and intensify the potential for discriminatory and other unfair treatment. Furthermore, legislation can take years to adopt and, once enshrined, can become static due to the difficulty of amending the law. This leads to outdated laws as scientific advance outpace the legislation.

In light of these challenges, some alternative strategies to address genetic discrimination and the use of genetic results in insurance merit consideration (in addition to any traditional legislative frameworks), including public-private

agreements, public engagement, awareness raising and education, and multidisciplinary dialogue.

A multifaceted and well-informed awareness-raising and education campaign is needed, which targets the myriad of stakeholders in this field, as well as the public. Such a campaign should aim to ensure that individuals are aware, not only of the basic elements of genetic science (and the benefits and limitations of genetic testing) but also the potential for misuse of their genetic information (and any legal or other protections in place).[108] Awareness raising campaigns should similarly target scientists and medical professionals, and commercial third parties such as insurance companies and ensure that they are informed about the ethical and legal issues that may arise with use of genetic information, as well as any relevant protections or policies in place.[109] A number of international legal instruments have highlighted the need for such awareness raising and education in this area.[110]

In addition, ongoing multidisciplinary engagement and discussion is required in this area.[111] There is a need for in-depth and focused discussion and consultation with the various stakeholders involved, including scientists, insurance companies (and other third parties), lawyers and policy makers. This discussion is particularly necessary in the insurance industry, in light of the complexity of the issues arising regarding fundamental practices and principles of the industry, and with a view to achieving the correct calibration of competing interests (between the insurer and the customer). In conjunction with such measures, there also needs to be public consultation and engagement on these issues to ensure transparency and to gauge the public's attitude and perception of these issues.[112]

VI. Conclusion/Next Steps

From the insurer's perspective, allowing access to genetic test results for underwriting seems highly logical, maybe even obvious. But society must be concerned if many individuals choose not to undergo testing out of fear of genetic discrimination.[113] The competing interests between the need for insurers to have access to information known to applicants to accurately allocate risk and for applicants to be protected against unfair discrimination by insurers is at the core of regulation in this area. It also requires a deeper inquiry into whether anti-selection is actually as serious a problem as some insurers suggest. As we have laid out in this paper, the actuarial and economic models generally do not suggest wide-spread and severe anti-selection effects related to genetic testing. Further empirical evidence from ELSI researchers regarding individual purchasing and other behaviors following a genetic test will help to provide data for actuarial and economic modeling, as well as provide key research to underline any regulatory or policy response.

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DETAILS

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Harmony between Man and His Environment: Reviewing the Trump Administration's Changes to the National Environmental Policy Act in the Context of Environmental Racism

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ABSTRACT (ENGLISH)

This article aims to show how the changes to NEPA by the Trump Administration are an act of environmental racism, defined as "[i]ntentional or unintentional racial discrimination in environmental policy-making, enforcement of regulations and laws, and targeting of communities for the disposal of toxic waste and siting of polluting industries."

FULL TEXT

In 1970, Congress passed the National Environmental Policy Act ("NEPA") for the purpose of requiring federal agencies to engage in "efforts which will prevent or eliminate damage to the environment and biosphere and stimulate the health and welfare of man."
[1]For over 50 years, NEPA promoted this goal by requiring federal agencies to: (1) take into consideration consequential environmental effects inflicted from large scale projects, (2) foster community engagement and participation in the development of the same, and (3) establish a Council on Environmental Quality (CEQ).[2] In totality, actions under NEPA sought to protect our planet and establish "harmony between man and his environment."[3]
On September 14, 2020, CEQ changes intended to modernize NEPA took effect. The Trump Administration claimed that the changes would "streamline the development of infrastructure projects and promote better decision making by the Federal government."[4] However, environmentalists fear that these changes threaten the heart of NEPA's mission. Though NEPA was not free from criticism prior to the Administration's changes, the Act nonetheless succeeded in its goal to require federal agencies to reflect on their environmental impacts while engaging with the community in the process. Now, the degree to which federal agencies will be required to consider their effects on the environment is more limited, with efforts toward "efficiency" and "modernization" likely resulting in federal agencies bypassing important steps.[5] This is especially worrisome because poor environmental quality often disproportionally affects minority communities, exposing individuals within those communities to more harmful levels of pollution. Should the Trump Administration's changes to NEPA remain in effect, minority communities will suffer.
The goal of this article is to describe the changes the Trump Administration developed for NEPA and illuminate the consequences. Specifically, these changes eliminate important protections, otherwise guaranteed by NEPA, necessary to ensure the safety of communities affected by large-scale, federal projects. Because communities of color are disproportionally affected by damage to the environment, the changes to NEPA will work to perpetuate the suffering of those communities and reinforce environmental racism. Ultimately, the Trump Administration's changes to NEPA are an act of environmental injustice, and the long-term results of these changes will lead to harmful impacts on minority communities around the country.
Because communities of color are disproportionally affected by damage to the environment, the changes to NEPA will work to perpetuate the suffering of those communities and reinforce environmental racism. Ultimately, the Trump

Administration's changes to NEPA are an act of environmental injustice, and the long-term results of these changes will lead to harmful impacts on minority communities around the country.

I. What Is NEPA?

NEPA is legislation that works "to create and maintain conditions under which man and nature can exist in productive harmony, and fulfill the social, economic, and other requirements of present and future generations of Americans."[6] NEPA is procedural in nature; it does not compel federal agencies to make substantive changes to their projects.[7] Nonetheless, enforcing a procedural process that federal agencies must follow to enact major action affects the agency's substantive decisions and guides agencies to make more environmentally-friendly decisions.[8] To fulfill its mission, NEPA: (1) requires federal agencies to consider environmental impacts of major activities, (2) implements procedures to ensure community involvement in such activities, and (3) forms the CEQ.[9]

First, NEPA requires dual action from federal agencies: to consider the long-term environmental impacts of major federal actions before proceeding (a "look before you leap" philosophy), and to act with transparency to the public for such projects before they occur.[10] Examples of major federal actions include establishing government policies or regulations, undertaking federal projects, or issuing federal permits and funds. A "failure to act" also may constitute a major federal action.[11] To ensure transparency, agencies that plan large scale actions are required to draft an Environmental Impact Statement (EIS), which includes information detailing the environmental impact of the proposed action, and the benefits of the plan in relation to unavoidable harm.[12] The information provided must contain an "accurate, scientific analysis, expert agency comments, and public scrutiny."[13] Upon completion of the EIS, agencies will have a comprehensive understanding of the totality of the environmental impacts the proposed project will likely incur.[14] To further ensure the protection of the surrounding environment, agencies must analyze reasonable alternatives[15] to the proposed action, including taking no action.[16] Direct effects,[17] indirect effects,[18] and cumulative impacts[19] to the environment must all be considered.[20] The adequacy of the final EIS is subject to judicial review based on an "arbitrary and capricious" standard.[21] Agency action is "arbitrary or capricious" if an agency has "relied on information that Congress has not intended[,] … entirely failed to consider [an] important aspect of [the] problem, offered explanation for its decision that runs counter to evidence … or is so implausible that it could not be ascribed to … agency expertise."[22] To determine whether an EIS will be required,[23] a federal agency shall draft an Environmental Assessment (EA).[24] If it is found that an EIS will not be necessary[25], the federal agency may file a "Finding of No Significant Impact" (FONSI).[26]

Additionally, NEPA ensures that the public may provide input on large-scale federal actions.[27] To advance its goal of community participation, NEPA requires federal agencies to: (a) diligently offer opportunities for discourse, which may include "provid[ing] public notice of NEPA-related hearings, public meetings, and other opportunities for public involvement," and (b) publicize the drafts and final copies of any EIS reports for the opportunity of public review.[28] The environmental information provided to the public by federal agencies must be made available "*before* decisions are made and *before* actions are taken."[29] By ensuring availability before taking action, NEPA enables the public to be included in decision-making processes before an agency will decide on or enact any projects.[30] Fostering such inclusivity requires federal agencies to publicly consider their potential projects before arriving at a conclusion, creating a positive environment to promote community engagement and facilitating the opportunity for those affected by proposed changes to have a voice.[31]

Finally, NEPA also established the CEQ, the organization responsible for enforcing agency compliance with NEPA[32] and Executive Order 12898, which requires consideration of environmental justice.[33] On a broad scale, the CEQ is responsible for gathering information about the current and prospective conditions of the environment and identifying trends that would adversely affect environmental quality.[34] Specifically, this organization conducts research for federal agencies of ecological systems and environmental quality in and around the community;[35] reviews and appraises Federal Government programs to determine if NEPA goals are being met;[36] and works closely with the President to provide reports of federal agency activities, and guidance on how the government should move forward in order to continue to meet the expectations of NEPA.[37]

II. NEPA and Environmental (In)Justice

The concept of environmental justice first appeared in the United States in 1982, when North Carolina agreed to the implementation of a waste landfill in Warren County, home to a large African American community.[38] The landfill would contain polychloride biphenyls, a man-made chemical that causes cancer in those who are exposed.[39] Public outcry led to the commencement of the "Toxic Waste and Race" Study by the United Church of Christ Commission for Racial Justice (hereinafter "the Study").[40] The Study revealed that "race proved to be the most significant among variables tested in association with the location of commercial hazardous waste facilities."[41] Additionally, the Study determined that "[t]hree out of every five Black and Hispanic Americans lived in communities with uncontrolled toxic waste sites."[42]

After these findings, President Bill Clinton executed Executive Order 12898.[43] The purpose of the order was to ensure that each federal agency "[t]o the greatest extent practicable and permitted by law … [achieve] environmental justice as part of its mission by identifying … disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority populations and low-income populations."[44] The purpose of environmental justice is to combat the social problem of environmental racism, defined as "[i]ntentional or unintentional racial discrimination in environmental policy-making, enforcement of regulations and laws, and targeting of communities for the disposal of toxic waste and siting of polluting industries."[45] It is wishful thinking to believe that environmental justice was served after the passing of Executive Order 12898; environmental racism continues to impact communities of color, as exhibited, for example, by the notorious Flint Water Crisis.[46] However, this is just one current example of how communities of color bear the burden of our environmental shortcomings. Various communities face disproportionate exposure to environmental contaminants; Native American,[47] Black,[48] LatinX,[49] and Asian American[50] communities all carry the burden of pollution in its various forms far more than their white counterparts. NEPA has been used to combat environmental injustice by allowing public participation to educate, to delay harmful government actions, and to require agencies to consider the socioeconomic and health effects of their actions.[51]

Encouraging public participation helps facilitate community education, as NEPA requires federal agencies to disclose "the NEPA documents, any public comments that the agency received on the documents, and any comments that the agency received from other agencies on the documents."[52] Public participation also allows individuals in minority and low-income areas to have a voice in government,[53] offering their unique insights on the effects agency action may have on their communities.[54]

Delaying government action is more controversial. Although the Trump Administration's changes to NEPA (discussed below) attempt to limit delay[55] in projects, sometimes delay can be important, such as when it is a tool to ensure environmental protection and combat environmental racism. Here, delay is the result of taking time to complete adequate work. The necessary time taken by agencies for due diligence under NEPA allows those that will be directly affected the opportunity to organize and inform the government of the potential harms its actions may cause the community.[56] These benefits of NEPA have consistently been seen in multiple cases, including recently. In *Cheyenne River Sioux Tribe v. U.S. Army Corps of Engineers*,[57] the focus was on the installation of the Dakota Access Pipeline, a pipeline that would run through North Dakota, specifically through reservation lands belonging to the Standing Rock Sioux Tribe.[58] The Standing Rock Sioux Tribe has fought against the installation since 2015, arguing that the pipeline poses serious risks to the safety and survival of the tribe due to the possibility of an oil spill contaminating its water supply. A federal judge ordered that the operating pipeline be shut down, citing an inadequate EIS filed by the Army Corps of Engineers.[59] In his ruling, Judge James Boasberg cited NEPA, writing that, "given the seriousness of the Corps' NEPA error, the impossibility of a simple fix, the fact that Dakota Access did assume much of its economic risk knowingly, and the potential harm each day the pipeline operates, the Court is forced to conclude that the flow of oil must cease."[60] The battle over the Dakota Pipeline continues,[61] but it is important to acknowledge that courts have favored upholding NEPA.

Although there is room for improvement, NEPA was on the right track to allow affected parties a voice in government action and to fight against environmental racism. However, the changes the Trump Administration implemented limit NEPA's bite, creating a national danger to the environment and communities of color alike.

III. The Trump Administration's Changes to NEPA

The NEPA revisions enacted by the Trump Administration include a variety of changes, such as: imposing page and time limits for agencies to complete EIS reports, expanding agency authority to delegate work to private entities, and limiting the scope of judicial review for NEPA claims.[62] Although these changes may appear positive, ultimately the speed of the evaluation has less to do with efficiency and more to do with bypassing significant checks that make NEPA a strong tool for environmental preservation.

First, the changes impose page and time limits for agencies completing EIS reports. According to the new rules, "[t]he text of final environmental impact statements … shall be 150 pages or fewer and, for proposals of unusual scope or complexity, shall be 300 pages or fewer."[63] EAs must be prepared "within 1 year … from the date of decision to prepare an environmental assessment to the publication of a final environmental assessment," while EIS statements must be issued "within 2 years … from the date of the issuance of the notice of intent to the date a record of decision is signed."[64] Though these changes have been made for the obvious purpose of expediting the NEPA process, "[t]he Trump Administration does not provide any reliable data supporting the conclusion that requiring one year for completion of any EA and two years for completion of any EIS is either necessary or practicable."[65] Thus, these changes risk that an agency will fail to conduct a thorough investigation should it be pressed to fight against the clock and page limits. Although some delays may extend for an unreasonable period, it is difficult to set a one-size-fits-all approach in legislation. The focus instead should be on quality and comprehensiveness, while moving analysis along efficiently and reasonably. Ultimately, to establish limits in the reviews simply encourages sloppy and incomplete work. Instead of limiting the NEPA investigations, if the Trump Administration actually wanted to expedite work, it would have ensured resources necessary to accomplish that goal were properly allocated to its agencies.

Additionally, the changes suggest that there will be a significant expansion in the use of Categorical Exclusions[66] ("CE") and EAs. Agencies are to identify categories of actions in their agency that "normally do not have a significant effect on the environment."[67] Previously, if an action proved to be an "extraordinary circumstance" that fell outside of the listed categories, then that action would automatically be excluded from being included in a CE.[68] Now, however, a CE may be used for an extraordinary action upon consideration by the agency, where it must determine "whether mitigating circumstances or other conditions are sufficient to avoid significant effects" on the environment.[69] With a broader scope for what may be categorized as a CE, agencies now have considerable discretion in deciding whether or not to fill out an EA or EIS. Significantly, actions filed as CEs do not require public participation. Should more CEs be filed in place of EAs and EISs, there will be less public participation in large-scale federal actions that would have, in the past, needed to be presented to the public. Exclusion of the public will lead to the exclusion of opposing voices, those which may drive change and ensure the protection of the community and the environment.

Even if the agency is required to file an EA or an EIS, there now exists broader discretion for the agency to choose the EA rather than an EIS. Despite both types of reports necessitating agencies to evaluate environmental impacts, the EA is much less thorough than the EIS. For example, the EA has no requirement to consider cumulative effects, which curtails the duty to consider an action's indirect effects.[70] Originally, the effects to be considered were "direct, indirect, and cumulative," but now, agencies need only consider "reasonably foreseeable effects." Specifically, the change threatens the effects that were once considered "cumulative." Though there has never been a specific way to address cumulative impacts, the CEQ has recommended analyzing cumulative impacts in accordance with the following eight principles:

- **Cumulative** [impacts] are caused by the aggregate of past, present, and reasonably foreseeable future actions.

- **Cumulative** [impacts] are the total effect, including both direct and indirect [impacts], on a given resource, ecosystem, and human community of all actions taken, no matter who (federal, non-federal, or private) has taken the actions.

- **Cumulative** [impacts] need to be analyzed in terms of the specific resource, ecosystem, and human community being affected.
- It is not practical to analyze the **cumulative** [impacts] of an action on the universe; the list of environmental [impacts] must focus on those that are truly meaningful.
- **Cumulative** [impacts] on a given resource, ecosystem, or human community are rarely aligned with political or administrative boundaries.
- **Cumulative** [impacts] may result from the accumulation of similar [impacts] or the synergistic interaction of different [impacts].
- **Cumulative** [impacts] may last for many years beyond the life of the action that caused the [impact].
- Each affected resource, ecosystem, and human community must be analyzed in terms of its capacity to accommodate additional [impacts], based on its own time and space parameters.[71]

Exactly what effects are "reasonably foreseeable" have yet to be judicially determined.[72] Though courts may offer interpretations that favor environmental preservation, there is a stronger likelihood that courts will respect the language of the statute as amended, rather than try to interpret it as the Act had been first written. "A 'but for' causal relationship is insufficient to make an agency responsible for a particular effect under NEPA" and, thus, effects that are remote in time, geographically remote, or the product of a lengthy causal chain will generally not be considered.[73] Therefore, though the judiciary has curtailed much of the Trump Administration's efforts to ignore climate change, the federal bench will likely be unable to continue on this path without a cumulative effects analysis, as long-term impact will not be considered by federal agencies.

IV. NEPA Changes and Environmental Injustice

By restricting community participation in large-scale federal projects and dissipating requisite considerations of cumulative impacts, the Trump Administration's changes to NEPA will provoke and exacerbate harm in minority communities across the United States.

Community participation has fostered pathways to provide affected individuals and groups with a voice in federal action. Federal agencies "ought to engage the affected public and regulated community in how best to induce agencies into structuring their programs to accomplish continuous monitoring and adaptation in a manner that preserves sufficient regulatory certainty."[74] Although federal agencies are capable of conducting research, analyzing the findings, and coming to conclusions on how to best act, nothing can substitute the knowledge and experience of those who live within the community. The voices of the public are essential, as no one can speak to the needs of the community better than the community itself. Thus, cutting off community involvement will lead to harmful results. Rather than making public participation more difficult, then, federal policy should do more to assist communities of color in efforts to address environmental injustice. To begin, the minimum public comment period time should be raised from 45 days to 90 days to allow the public a better opportunity to plan and attend hearings. Additionally, there should be meetings held both in-person and virtually to foster greater participation; when meetings are to be held virtually, it should be required that advertisements for these hearings direct individuals to locations that allow for free access to computers and WIFI, such as a local library. Third, public hearings should be held at a variety of times to ensure that all have a fair chance to participate regardless of one's work schedule, family obligations, etc. Beyond supporting public participation, which may be especially challenging for marginalized communities to

engage in, judicial review of agency decisions should prioritize consideration of environmental justice. NEPA should clarify that review of environmental justice *must* be included in NEPA reviews, and that such analysis is reviewable under the Administrative Procedure Act. Further, evidence to be reviewed by the judiciary should challenges be brought should include how much public participation occurred (time spent, how many individuals commented, etc.), and what information on the project was disclosed to the public during these gatherings and time for comment, and whether the information that was disclosed adequately reflects the consequences of the project. Courts having the authority to engage in such reviews will help ensure agency accountability, and bolster the effectiveness of public comment.

After all, how can communities that have experienced extensive racism, generational traumas, poverty, violence, and abuse at the hands of the white establishment be expected to solve systemic issues of environmental injustice without additional resources? Consider the words of Father Paul Abernathy,[75] who, in discussing community development, posed the question: "[A]fter we [people of color] have suffered so much, are we healthy enough to sustain opportunity in our community?"[76] Beyond supporting public participation, which may be especially challenging for marginalized communities to engage in, judicial review of agency decisions should prioritize consideration of environmental justice. This need not necessarily be adverse to government projects. Indeed, so long as environmental well-being may be adequately preserved, proposed projects could provide significant, economic benefit for communities of color.

We depend on policies like those historically advanced by NEPA to remedy the disproportionate harm caused to the environment surrounding minority communities. Thus, the changes to NEPA will only further endanger communities of color and force them to continue to carry the burden of environmental injustice. Ultimately, these changes must be reversed for the safety, well-being, and survival of communities across the country.

Additionally, by not considering cumulative results, the long-term effects of potentially harmful federal action will be dismissed. Examining cumulative effects is vital for ensuring the well-being of minority communities. We know that communities of color are disproportionately affected by environmental damage. For example, the statistics regarding Black Americans are staggering:

Sixty-eight percent of African Americans live within 30 miles of a coal-fired power plant. Black children are nearly twice as likely to suffer from asthma, compared to the national average. People of color make up 76 percent of the population living within three miles of the 12 dirtiest coal power plants in the country, and African Americans are more likely to live in environmentally hazardous areas than any other racial demographic.[77]

In addition, scholars have argued that "policymakers embarking on highway development and redevelopment projects should engage in a systematic, comprehensive, and holistic review of how racial and ethnic groups will be impacted by the project," in order to protect minority groups from significant harm.[78] Limiting the review of NEPA reports, and no longer requiring a hard look at cumulative effects, will prevent federal agencies from engaging in such a comprehensive review, leading communities of color to face even greater harms as a result of inadequate environmental regulation.

NEPA's changes will also affect the Hispanic and LatinX community. The Trump Administration, prior to enacting its NEPA rollbacks, enabled the Department of Homeland Security to waive certain parts of NEPA in order to build the wall at the Southern border,[79] in addition to the circumvention of 26 regulations, including the Clean Air Act, the Safe Drinking Water Act, and the Solid Waste Disposal Act.[80] In bypassing regulations protecting those who live along the border, the Administration showed disregard to whether those at the border have access to the necessities of life, valuing political gains over ensuring the health and well-being of American and Mexican citizens and others. This has been more than an act of disregard; it is an act of callousness targeted against Hispanic and LatinX

communities.

Further, Native Americans continuously struggle against the government's adverse effects on the environment. As discussed above, pipelines, in particular, have been recent threats to the Native American community.[81] Not only do pipelines damage sacred land, they threaten to pollute and destroy the water supply for Native Americans.[82] In addition to the Trump Administration's actions in limiting public discourse overall through NEPA, state legislation has been proposed, typically by Republican lawmakers[83], targeting protests against the installment of the pipelines.[84] This is evidence of the influence and importance of hearing the voice of the community and reflects the danger of the Trump Administration's efforts to silence those who are in need of being heard.

Asian Americans[85] are also confronted with the devastating results of environmental racism. Environmental advocate Andrea Chu has explained that harmful stereotypes, such as the "model minority" myth, often push Asian Americans out of the discussion of environmental racism.[86] However, the reality is that this community faces a disproportionate burden of pollution, too — particularly, exposure to harmful toxins in the soil.[87] Chu's work has revealed that "[m]any Asian immigrant families harvest and eat produce from their homelands, but may find that their adopted soil is chemically toxic due to the industrialization of these lower income Asian American communities," leaving these families with harmful toxins in their gardens and, ultimately, food.[88] Additionally, like those in the African American and LatinX communities, "Asians and Pacific Islanders also live near Superfund sites and factories that spew thousands of tons of toxins into the air,"[89] which leaves them vulnerable.

Ultimately, communities of color already face significant harm because those in power, including the federal government, fail to care for our environment by considering the consequences of their actions and planning with the health of the community and Earth in mind. These systemic issues lead to irreversible damages to the mind and body. We depend on policies like those historically advanced by NEPA to remedy the disproportionate harm caused to the environment surrounding minority communities. Thus, the changes to NEPA will only further endanger communities of color and force them to continue to carry the burden of environmental injustice. Ultimately, these changes must be reversed for the safety, well-being, and survival of communities across the country.

V. NEPA's Future

For decades, NEPA has proclaimed a two-fold purpose: to work towards a cleaner environment and ensure environmental justice. The changes brought forth by the Trump Administration, however, threaten to destroy key elements of what makes NEPA effective. By loosening guidelines for agencies, the new NEPA closes the door on the community and restricts those affected by major federal projects from having a voice in how those projects should or should not alter the community. Looking forward, President Biden has already taken some remedial steps by revoking Executive Order 13807, which imposed 2-year deadlines on EIS reports,[90] and Executive Order 13783,[91] which eliminated CEQ's guidance on greenhouse gas emissions and directed federal agencies to rescind parts of their review that impeded energy production, as well as implementing Executive Order 13990, which states:

In light of the alleged legal deficiencies underlying the program, including the inadequacy of the environmental review required by the National Environmental Policy Act, the Secretary of the Interior shall, as appropriate and consistent with applicable law, place a temporary moratorium on all activities of the Federal Government relating to the implementation of the Coastal Plain Oil and Gas Leasing Program … The Secretary shall review the program and … conduct a new, comprehensive analysis of the potential environmental impacts of the oil and gas program.[92]

Additionally, President Biden has continued to promote environmental justice efforts in his Infrastructure Plan[93] through the establishment of Justice40, which promises that 40 percent of the overall benefits from Federal investments in climate and clean energy will be directed to disadvantaged communities.[94] Only time will tell what the effects of the Infrastructure Plan will have on environmental justice, but environmentalists[95] seem hopeful that these

are positive steps to ensuring a clean environment, getting us all the closer to establishing true harmony between us and our environment.

Note

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DETAILS

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Applying Civil Rights Law to Clinical Research: Title VI's Equal Access Mandate

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ABSTRACT (ENGLISH)

Title VI of the Civil Rights Act of 1964 and its implementing regulations prohibit federally-funded educational institutions and healthcare centers from engaging in disparate impact discrimination "on the ground of race, color, or national origin" in all of their operations.

FULL TEXT

Minority communities have long faced both limited opportunities to enroll in cutting edge clinical research and concerns about whether their rights as research subjects are adequately respected.[1] A recent examination of vaccine clinical trials from 2011 to 2020 found Black and African American individuals were underrepresented by 2-3 percentage points and Hispanic and Latino individuals by more than 5 percentage points, compared to the U.S. population.[2] Data from the FDA found Black and African American participation was even lower, making up only 8 percent of clinical trial enrollment for new molecular entities and therapeutic biologics approved in 2020.[3] Both the National Institutes of Health (NIH) and Food and Drug Administration (FDA) have, in recent years, strongly encouraged the inclusion of racial and ethnic minorities in clinical research, and both require the submission of

certain breakdowns of data by race and other variables.[4] For example, in response to the COVID-19 pandemic, NIH launched the "Rapid Acceleration of Diagnostics (RADx)" program and specifically the "RADx- Underserved Populations (RADx-UP)" initiative with the goal of understanding disparities in the morbidity and mortality of COVID-19, establishing community research sites, encouraging collaboration, and evaluating novel testing strategies."[5] The FDA's "Enhance EQUITY Initiative" shares similar goals.[6] Encouraging access across diverse individuals creates participation opportunities for marginalized communities and improves the generalizability of research results. However, the Department of Health and Human Services (HHS), of which NIH is a constituent part, has not used the full arsenal of legal and policy tools at its disposal to push for equal access. In particular, we argue that Title VI of the Civil Rights Act of 1964, which is enforced by HHS's Office for Civil Rights (OCR), obligates institutions that receive Federal financial assistance and host clinical research to provide equal access to participation in clinical trials to racial and ethnic minority communities. We first consider the ban on discrimination that Title VI created, including the scope of its application. We next discuss the unique challenges of applying Title VI in the clinical research context and how those challenges may be overcome. Finally, we discuss questions of implementation and enforcement.

The Department of Health and Human Services (HHS), of which NIH is a constituent part, has not used the full arsenal of legal and policy tools at its disposal to push for equal access. In particular, we argue that Title VI of the Civil Rights Act of 1964, which is enforced by HHS's Office for Civil Rights (OCR), obligates institutions that receive Federal financial assistance and host clinical research to provide equal access to participation in clinical trials to racial and ethnic minority communities.

Title VI's Scope of Application

Title VI bans discrimination by recipients of certain government funding on the basis of race, color, and national origin. HHS regulations have extended this ban to cover disparate impact discrimination, including the unintentional mistreatment of individuals of differing racial and ethnic backgrounds. Congress has made clear that Title VI applies quite broadly, especially in the health care context, to all operations of hospitals and universities.

Title VI prohibits recipients of Federal financial assistance from conducting activities that have a disparate impact on those of any particular race, color, or national origin. Section 601 of Title VI prohibits intentional discrimination "on the ground of race, color, or national origin …under any program or activity receiving Federal financial assistance."[7] While intentional discrimination can be difficult to prove,[8] Section 602 of Title VI permits agencies authorized to administer grants to issue regulations to "effectuate the provisions" of Section 601.[9] HHS used its Section 602 authority to prohibit recipients of Federal financial assistance from "utilize[ing] criteria or methods of administration which have the effect of subjecting individuals to discrimination because of their race, color, or national origin."[10] The Department of Justice (DOJ) and HHS OCR wrote in recent guidance that "[d]isparate impact discrimination focuses on the consequences of a recipient's practices rather than the motivation, and occurs when a recipient has an otherwise neutral policy or practice that has a disproportionate and adverse effect on individuals of a certain race, color, or national origin …. "[11] The Supreme Court, since the 1970s, has recognized the effect of HHS's regulations prohibiting disparate impact discrimination.[12]

Importantly, while individuals may bring claims under Section 601, only the government may bring disparate impact claims. In *Alexander v. Sandoval*, the Supreme Court held that a class of non-English speakers could not bring, under DOJ's regulations implementing Section 602, a challenge to Alabama's decision to administer state driver's license examinations only in English; DOJ's regulations, like those from HHS, prohibit disparate impact discrimination.[13] The practical result of this decision is that nearly all Title VI enforcement requires government action, as "few federally funded programs are overtly discriminatory and, as a result, intentional race and national origin discrimination have become increasingly difficult to prove."[14]

Congress has made clear that Title VI applies to all of the operations of many entities, such as hospitals and universities, that receive Federal financial assistance and, thus, to the conduct of their clinical trials. As originally passed, Title VI applied to "any program or activity receiving Federal financial assistance."[15] In response to a 1984 Supreme Court ruling holding that similar language in Title IX applied only to the portion of the institution that receives federal funding,[16] Congress, in the Civil Rights Restoration Act of 1987 (CRRA), amended Title VI to clarify

that it applies to all the activities of an institution receiving Federal financial assistance.[17] Congress defined "program or activity" broadly to include "all the operations of …a college, university, or other postsecondary institution" and "all the operations of …an entire corporation, partnership or other private organization …which is principally engaged in the business of providing education [or] health care …. "[18] HHS later added that definition to its regulations implementing the CRRA.[19]

Congress has defined Federal financial assistance broadly to include assistance provided "by way of grant, loan, or contract other than a contract of insurance or guaranty …"[20] That definition sweeps in Medicare Part A (primarily inpatient Medicare spending), Medicaid, and NIH grants, meaning that nearly every hospital and research university must comply with Title VI.[21] In its regulations implementing the CRRA, HHS explained that, "if a college or university receives Federal financial assistance from the Department to support medical research, all of the operations of the college or university are covered, not solely the operations of the component performing the medical research."[22] Similarly, all of the operations of a private hospital receiving Federal financial assistance are covered.[23] Further, recent rulemaking implementing Section 1557 of the Affordable Care Act (ACA) has mirrored the CRRA's language.[24] However, Title VI's protections would not extend to an entity that conducts research only on behalf of private industry, although industry-funded trials at healthcare organizations would still be subject to Title VI through enforcement against the hospital. Thus, if a healthcare provider at a community hospital with Medicare-covered patients conducted a clinical trial without any external funding, her research would still be subject to Title VI.

HHS regulations and NIH guidance require NIH grant recipients to comply with Title VI as a condition of receiving grant funding, a contract-like compliance mechanism. HHS regulations require that potential awardees of Federal financial assistance provide a one-time assurance of compliance with Title VI,[25] known as Form HHS 690.[26] While the form specifies only that the applicant will comply with Title VI for "any program or activity for which the Applicant receives Federal financial assistance from the Department,"[27] it is "filed for the organization and is not required for each application," according to NIH,[28] suggesting its institution-wide reach. Much like other NIH assurances, this is a contract-like document that federal officials interpret as imposing obligations upon the signatory to "comply with: Title VI of the Civil Rights Act of 1964 …. "[29]

In summary, Title VI prohibits intentional discrimination, and HHS has used its authority under Section 602 of Title VI to prohibit disparate impact discrimination. Congress has made clear that Title VI's reach is extensive, covering all operations of many hospitals, community health centers, and universities, at which a substantial portion of domestic clinical research occurs. However, both researchers and government officials have paid little attention to how Title VI applies in the research context. It is to these implementation issues that we now turn.

Implementation Issues in the Clinical Trial Context

Congress designed Title VI to provide expansive protections that mandate equal access to participation in programs established by federally-funded entities. However, only the government may enforce disparate impact discrimination claims, and Title VI and HHS's implementing regulations permit justified deviations from equal access; courts and the DOJ evaluate such issues under a burden-shifting framework borrowed from Title VII employment discrimination cases.[30] Further, a lack of enforcement has, to date, blunted the effectiveness of Title VI in the research context.

One may argue that clinical trials testing interventions in clinical equipoise provide no anticipated clinical benefit to participants, and, thus, failing to provide equal access to clinical trials does not harm affected individuals. However, Title VI, itself, provides a response. Title VI separately specifies that individuals may neither "be excluded from participation in," nor "be denied the benefits of" any "program or activity receiving Federal financial assistance."[31] Understanding the phrase "participation in" narrowly –so as to mandate that individuals receive Title VI protection only if they actually benefit from the service they receive –would render the phrase "participation in" superfluous; courts generally reject the idea that Congress includes surplus language in its laws.[32] This so-called rule against superfluity is so common that even its detractors have admitted it is "widely recognized."[33]

Further, clinical trials often provide direct benefits. A patient suffering from cancer or a rare genetic condition may be able to receive cutting edge treatments only through participation in such trials, creating direct –and perhaps substantial –benefits for those who have failed other treatments or when no treatment exists. Individuals derive

additional benefits from contributing to scientific knowledge and from assisting future generations or others in their communities. Of note, Title VI provides no right to participate in any particular clinical trial; rather, once an institution elects to offer a clinical trial, the institution must offer the opportunity to participate in the study on equal terms, protecting against disparate impact on individuals of differing racial and ethnic backgrounds.

By way of example, Title VI prohibits selecting sites at which recipients of Federal financial assistance offer programs, such as clinical services, so as to impact disparately protected classes.[34] DOJ's *Title VI Legal Manual* explains that "[m]any Title VI cases involve challenges to site selection decisions, such as the locations selected for construction of highways or facilities that will have negative consequences for the surrounding community. Site selection cases can also involve challenges to the closure or relocation of desirable facilities, such as schools or hospitals."[35] In the clinical research context, deciding to offer a clinical trial in only one location, when multiple potential sites are qualified and available, may, even inadvertently, make it harder for certain racial or ethnic communities to participate.

Title VI's prohibition on disparate impact discrimination, while expansive, is not absolute; courts use a burden-shifting framework to determine whether a recipient of federal funds may justifiably adopt a policy or practice that unintentionally disfavors certain racial or ethnic groups. The government must first make the "prima facie showing" that "the adverse effect of the policy or practice disproportionately affect[s]" members of a particular racial or ethnic group; the funding recipient may then "demonstrate the existence of a substantial legitimate justification for the policy or practice"; and the government may then respond that "the justification …was pretextual" by showing that a less-discriminatory "alternative that would achieve the same legitimate objective" exists.[36] Cases decided prior to *Sandoval* borrowed this burden-shifting framework from Title VII disparate impact cases in the employment context, and at least one case after *Sandoval* applied it to an analogous state law.[37]

This burden-shifting framework is not applied mechanically. For example, courts faced with site selection questions have merged the requirement that funding recipients assert a substantial, legitimate justification with the government's obligation to consider whether less discriminatory alternatives exist.[38] In one case, according to the *Title VI Manual*, although a court said plaintiffs could show that building a new highway on a particular location had a disparate impact on minority communities, the funding recipients provided a substantial, legitimate justification by demonstrating that "the recipients had selected the final freeway location 'so as to minimize impacts upon minority neighborhoods' …. "[39] By this logic, sponsoring institutions would need to demonstrate that they purposely considered access to the opportunity to participate in clinical trials when evaluating the feasibility of potential study sites.

NIH has taken civil rights obligations seriously, releasing guidance in 2015 that explains obligations to "provide equal access to the opportunity to participate in NIH supported research, programs, conferences and other activities."[40] However, in that same document, NIH articulates substantial researcher discretion in administering clinical trials that may, if very broadly construed, come into conflict with Title VI requirements. In particular, NIH stated that "[r]esearch projects are often limited in scope for many reasons, such as the principal investigator's scientific interest, funding limitations, recruitment requirements and other non-discriminatory considerations. Thus, criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health of the subjects, the scientific study design, or the purpose of the research. It is not anticipated that civil rights protections should alter the fundamental manner in which research projects are designed, conducted, or funded."[41] While several of the reasons NIH articulates —such as the health of the subject —offer clear "substantial legitimate justifications," others —such as the investigator's scientific interest —could, if interpreted broadly, easily perpetuate existing biases or, at worst, serve as mere pretext for discrimination. For example, if researchers elect to focus research on predominately English-speaking populations so as to avoid translation costs, other communities would effectively lose equal access to the opportunity to participate in clinical trials.[42]

Many in the research and enforcement communities may not fully appreciate that Title VI, correctly construed, mandates that qualified individuals receive equal access to participate in clinical research, even if participation

cannot be said to render the possibility of direct clinical benefit. A significant reason so little attention has been paid to the impact of Title VI on clinical research is likely the lack of enforcement. As of June 2021, of the more than 50 recent civil rights resolution agreements and compliance reviews that OCR listed on its website, none of the summaries explicitly cited violations by those engaged in clinical research, though several academic medical centers were among the institutions subject to resolution agreements and compliance reviews.[43] Further, of the "Enforcement Success Stories" listed on OCR's website for complaints related to individuals with limited English proficiency, none of the twenty-five referred to researchers or NIH grant awardees.[44] While OCR has opined on equal access to clinical research on the basis of gender and disability in the context of Section 1557 enforcement, its guidance does not speak to discrimination on the basis of race.[45] The *Sandoval* prohibition on private disparate impact enforcement makes the lack of public enforcement all the more notable.

It is worth noting here that the vast majority of researchers do not intentionally discriminate based on race, color, or national origin. Rather, it is the accumulation of subtle, often unconscious, biases or multiple barriers to research participation that may have significant effects.[46] Further, we recognize that disparate impact cases are difficult to prove, especially where study protocols and inclusion criteria differ substantially across studies. The next section provides our recommendations for the type of institutional enforcement that may prove effective in this context.

Recommendations to Support Enforcement

Improved awareness of and compliance with Title VI would both increase equity in access to clinical trials and improve the representativeness of data collected. NIH and HHS OCR each have the authority to promote compliance with Title VI, by making clear to regulated parties how Title VI applies to the clinical research context.

It is within NIH's power and remit to provide updated guidance that makes clear to researchers and research institutions their obligations under Title VI. The *NIH Grants Policy Statement*, which outlines the obligations of NIH research grant awardees, provides detailed guidance on policies such as animal welfare requirements and ClinicalTrials.Gov registration; however, it provides only two sentences regarding the entire Civil Rights Act of 1964, with limited additional information on individuals with limited English proficiency.[47] While animal welfare protection and clinical trial reporting are fundamental to an ethical research enterprise, Title VI protections against racial and ethnic discrimination would appear, at the very least, equally important. NIH could, for example, borrow from the FDA's 2020 guidance on "Enhancing the Diversity of Clinical Trial Populations," which warns against using "eligibility criteria [that] have become commonly accepted over time …as a template" and explains that eligibility criteria should ensure "a representative sample of the population for whom the drug has been developed …. "[48] As discussed above, NIH has, to date, provided researchers with substantial flexibility in adopting study designs that may result in disparate treatment of study participants. Yet based on overarching concerns of equity in the allocation of clinical research services, NIH, as a primary and influential federal funder of clinical trials, should provide clear instruction to and guidelines for researchers on disparate impact discrimination against clinical trial participants, outlining steps researchers should take to comply with Title VI. For example, if normal laboratory values differ by race and ethnicity, [49] researchers that establish uniform trial exclusion criteria may unintentionally create a disparate impact on more heavily-excluded minority communities. NIH guidance encouraging researcher awareness of such concerns could help address disparate impact discrimination.

HHS OCR could take a more active role in enforcing Title VI in the clinical research context, and, given the increased attention that COVID-19 has brought to health disparities, one should expect that such enforcement may be forthcoming. There appear to be no reported examples of Title VI enforcement directly in the clinical research context. While researchers and research sponsors can gain substantial scientific and moral value from adopting inclusive study designs,[50] the reality of NIH-funded research in the modern era is that universities and academic medical centers focus their often under-funded research support and compliance efforts on government enforcement priorities. The specter of real enforcement would provide a justification for healthcare organizations to direct resources to track —and to then create programs to address —disparities in access to clinical research. In trying to understand where enforcement in this area might begin, one may consider, by way of example, a phase 3 study with an eligibility criterion that includes English language requirements.

More comprehensive data collection here can give evidence of possible unintentional but real discriminatory results in clinical research. So that enforcement and guidance efforts can be well calibrated and targeted toward the most serious cases, HHS OCR could require that entities to which Title VI applies collect racial, ethnic, and other demographic data for all clinical trials and report those results to HHS OCR. According to the DOJ's *Title VI Manual*, "Title VI regulations provide agencies with a clear mandate to collect the data necessary to ensure compliance with their Title VI disparate impact regulations."[51] Indeed, HHS already reserves such data collection authorities, and it mandates reporting by NIH grant applicants.[52] While neither Title VI nor HHS's current regulations obligate HHS to engage in data collection for monitoring purposes,[53] the *Title VI Manual* and at least one court case strongly suggest that HHS has the authority to do so.[54] In organizing its data collection, HHS OCR might borrow data reporting guidance from the FDA, which already requires sub-reporting by race and gender, and attempt to leverage existing data sources.[55] Having data on clinical trial participation would allow HHS OCR meaningfully and effectively to enforce Title VI in the clinical trial context, while giving institutions a better sense of their blind spots in this regard. HHS OCR should provide enforcement guidance, prophylactic instructions, and clear case examples so that the regulated community is enabled to meet its legal obligations. HHS has, in analogous circumstances, pursued enforcement in particularly egregious cases, an approach that research institutions might expect HHS OCR to pursue here. However, engagement with the research community will be essential, since implementation will present numerous challenges.

However, data collection cannot and should not replace community members and researchers who might spontaneously raise questions with IRBs or administrators about unequal access. Recognizing such concerns and elevating them through the institutional compliance process will be important in the ethical conduct of research, as well as in Title VI compliance.

In our view, HHS OCR should provide enforcement guidance, prophylactic instructions, and clear case examples so that the regulated community is enabled to meet its legal obligations. HHS has, in analogous circumstances, pursued enforcement in particularly egregious cases, an approach that research institutions might expect HHS OCR to pursue here. However, engagement with the research community will be essential, since implementation will present numerous challenges. As just one example, if a researcher employed by a health care system generally only provides patient care at one clinical site, it is unclear whether the system would need to require the clinician (or a collaborator employed by the health care system) to enroll across or recruit at other sites serving different patient populations.

Conclusion

Title VI of the Civil Rights Act prohibits all programs or activities of universities and medical centers receiving Federal financial assistance from discriminating on the basis of race, color, or national origin. HHS has, through regulation, extended this prohibition to include policies creating a disparate impact, even if the discrimination is not intentional. Furthermore, Title VI prohibits discrimination in both the benefits of and participation in such programs and activities. Thus, Title VI requires that clinical researchers at universities, academic medical centers, hospitals, and community health centers take affirmative steps to ensure that all individuals have an equal opportunity to participate in clinical research.

However, following *Sandoval*, government enforcement is essential to ensuring that potential research participants receive the benefit of these protections. To date, NIH has offered only ambiguous guidance that fails to explain what inclusive clinical trial participation requires; and HHS OCR has not taken action to enforce Title VI protections in the clinical research context. Both agencies should communicate the intention and effect of Title VI to the research community more clearly, explaining, for example, what considerations should enter research site selection decisions, among others. As with any regulatory and enforcement regime, the informed participation of the regulated community will be essential to a successful outcome. In fact, researchers have already begun carefully to explore issues related to bias in research,[56] and we urge government officials to review that literature in crafting policies. Ultimately, government enforcement of anti-discrimination protections in clear and egregious cases should be anticipated, and, if undertaken prudently, could promote awareness and compliance in the larger research

community. More representative trials will yield better, more representative research results, make more opportunities available to under-represented and historically marginalized communities, and nudge research institutions to think critically about previously unrecognized impacts of their study design and conduct decisions. These steps offer promise of improving the lives of participants and the quality, impact, and trustworthiness of clinical research.

Note

Mr. Liss reports that, at the time he worked on this article, he worked for a large international law firm, which represents many clients that would be affected by these legal issues. Mr. Peloquin and Mr. Barnes work for Ropes &Gray LLP.

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Advancing Legal Preparedness through the Global Health Security Agenda

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ABSTRACT (ENGLISH)

The Global Health Security Agenda (GHSA) is a multilateral, multisectoral partnership comprised of more than 70 countries, international organizations, foundations, and businesses to strengthen global health security.

FULL TEXT

The Global Health Security Agenda (GHSA) is one of the most important global platforms in galvanizing stakeholders around the world to strengthen countries' capacities to prevent, prepare for, detect, and respond to global health emergencies today.[1] With the backdrop of the 2009 H1N1 pandemic, the 2012 MERS-CoV outbreak, and the 2014 Ebola outbreak in West Africa, the launch of GHSA in February 2014 tightened the relationship between global health law (specifically, the International Health Regulations [IHR] [2005]) and country-level capacity building and implementation for greater health security.[2] Yet until 2021, none of GHSA's "Action Packages" (the groups driving GHSA's technical work) had explicitly focused on the role of law in strengthening global health security. This column introduces GHSA's newest Action Package, focused specifically on advancing public health emergency legal preparedness as a critical capacity for health security, explaining the essential role that the Action Package can play in promoting and developing technical tools on legal preparedness to prevent, prepare for, and respond to public health emergencies, including pandemic influenza.

Learning from the experiences of past outbreaks and COVID-19, there is a need to reach a common understanding in the definition and importance of public health emergency legal preparedness and to build a foundation from which to develop and disseminate legal resources that can support countries' legal preparedness in future emergencies.[3] The COVID-19 pandemic and other past public health emergencies have highlighted a range of legal challenges that arise during a response, including, but not limited to, the need for emergency laws to trigger the operationalization of public health measures (e.g., quarantine, isolation, masking policies, border control measures); crisis standards of care; access to personal protective equipment (PPE); and research, development, manufacturing, procurement, and distribution of medical countermeasures.[4] This column will first provide an overview of the Legal Preparedness Action Package, including background and strategic objectives. It will then discuss the priorities of the Action Package that include defining legal preparedness, identifying a methodology that will serve as a mapping strategy, the creation of a legal framework, and the legal mapping analyses across issue areas. This column concludes by reinforcing the role of law in public health emergency.

Informed by cross-cutting lessons learned from the COVID-19 pandemic and other emergencies, the Legal Preparedness Action Package will help advance GHSA's mission and goals to leverage the COVID-19 experience to better support countries around the world to improve capacity building for preparedness. The Action Package will set

a foundation for public health emergency legal preparedness by developing technical tools and approaches to guide and support countries in building their legal preparedness capacity.

The GHSA Legal Preparedness Action Package

GHSA is a multilateral, multisectoral partnership comprised of more than 70 countries, international organizations, foundations, and businesses to strengthen global health security. It integrates into its partnership international organizations like the World Health Organization, Food and Agricultural Organization, and World Organization for Animal Health. This approach necessitates multiple sectors, such as foreign affairs and defense; as well as non-governmental partners including private sector and civil society.[5] Therefore, GHSA is well-positioned to serve as a foundation for promoting legal preparedness globally as it seeks to build capacity at the country level to support and achieve greater global health security.[6] As a multilateral and multisectoral initiative that works at policy and technical levels, GHSA can trigger action to address gaps in global health security.[7] Together with WHO, GHSA promotes the Joint External Evaluation (JEE), a voluntary monitoring and evaluation tool that involves a collaborative, multisectoral process to assess country capacities across a wide range of technical areas to prevent, detect, and respond to a wide range of public health emergencies; track their progress; and incentivize their long-term strengthening.[8] While the JEE includes a legal technical area, there is a clear need to better define the capacity and understand how countries can become better prepared legally, especially considering the legal challenges observed during the COVID-19 pandemic.[9]

Given the need for clearer understanding and guidance on legal preparedness, GHSA's ability to bring together a diverse set of experts and garner political support at a global level gave way to the creation of the Legal Preparedness Action Package. In June 2021, Argentina, Georgetown Law's O'Neill Institute for National and Global Health Law, and the United States formally presented a proposal before GHSA leadership to create the Action Package. The proposal was approved in August 2021 and already has the support of numerous countries, international organizations, and civil society organizations that recognized the importance of coming together to promote and advance legal preparedness as a critical capacity for health security. The working group of the Legal Preparedness Action Package consists of global health legal experts, international organizations, and government officials from around the world who are working collaboratively to define legal preparedness, identify and advocate the use of existing tools relevant to legal preparedness, and develop needed guidance and capacity building tools to support countries in achieving greater legal preparedness.[10]

Informed by cross-cutting lessons learned from the COVID-19 pandemic and other emergencies, the Legal Preparedness Action Package will help advance GHSA's mission and goals to leverage the COVID-19 experience to better support countries around the world to improve capacity building for preparedness. The Action Package will set a foundation for public health emergency legal preparedness by developing technical tools and approaches to guide and support countries in building their legal preparedness capacity. The strategic objectives will focus on:

- *Outreach and Advocacy* – focusing on identifying and using political and technical fora as well as engaging relevant stakeholders across multiple sectors and geographic regions to raise wide-ranging awareness and support for public health emergency legal preparedness as a critical public health capacity.

- *Guidance Tools* – establishing a foundation and greater understanding by defining legal preparedness, its relation to other health security capacities, and the importance of sub-national, national, regional, and global legal preparedness to achieve global health security outcomes.[11] This will include building technical tools and leveraging existing resources to guide countries in improving their overall legal preparedness.

- *Capacity Building* – developing and promoting training approaches to build country capacity, creating a network of experts, incorporating standardized legal benchmarks, and facilitating progress toward legal preparedness for countries that can support implementation of priority activities identified in their National Action Plan for Health Security.

Defining “Public Health Emergency Legal Preparedness”

The first major challenge for the Action Package is developing a definition of “public health emergency legal preparedness” that both reflects current evidence and practice and serves as a unifying point of research and analysis given the diversity of stakeholders. There are few efforts to define the term, even though the role of law in health security has circulated conceptually in global health academic and policy communities for a decade or more. Some scholars and policy analysts point to gaps in legal capacity, but it is rare that they specifically recognize it as such, much less provide a definition. Where definitions of “legal preparedness” are proposed, the focus is primarily general public health and not public health emergencies — this is seen even in literature explicitly focused on public health emergencies. Additionally, available definitions of “public health emergency legal preparedness” are formulated based on limited, often anecdotal contexts and do not take into account complex global dimensions of public health emergency legal preparedness. As such, there is a clear need to define “public health emergency legal preparedness” in a universal way that can be understood and used by all.

In the context of public health emergencies, legal preparedness requires the recognition that law plays a critical role in supporting public health capacities that are essential to all phases of an emergency — from prevention to recovery. Legal preparedness involves the identification of legal approaches that could impact a public health response, and the strategic development of legal instruments to facilitate the implementation of public health capacities needed for a response, with supporting policy instruments that interpret and provide greater guidance on the implementation of such legal instruments.[12] Legal preparedness encourages the development and review of systems and infrastructure to allow for rapid corrective action.

Based upon the definition of “public health emergency preparedness”[13] and after a thorough literature review, conversations with Action Package members and external experts, the Legal Preparedness Action Package has adopted, on a preliminary basis, the following formulation:

Public health emergency legal preparedness is the capability to understand, map, individuate and anticipate, develop, refine, and utilize legal instruments and related committed authorities that enable the implementation of public health capacities, including strategies to prevent, protect against, respond to, and recover from public health.[14] Public health emergency legal preparedness aims to facilitate efficient and effective coordination among relevant multi-sectoral stakeholders and support the overall continuous process of preparing for and responding to public health emergencies.[15]

Leveraging and Complementing Existing Resources

In addition to defining “legal preparedness,” the Action Package is working to develop a methodology that will serve as a mapping strategy for identifying existing resources for legal preparedness and creating a living library of those resources that will continue to grow over time. Building from methodologies developed by members of the Action Package in past research efforts, the O’Neill Institute for National and Global Health Law and the Global Health Law Consortium are working to analyze the resources, in consultation with their respective GHSA Legal Preparedness Action Package leads. This analysis will identify the relevant aspects of existing resources and classify them under the priority areas identified by the Legal Preparedness Working Group (LPWG) to guide the Action Package’s workstreams. Through this work, the Action Package will provide an important service to the global community by centralizing and promoting these resources into a single, accessible location; avoid needless duplication of existing efforts; and provide a starting point for analysis of the priority legal areas to be addressed by the Action Package.

Legal Framework

After defining legal preparedness and identifying existing resources that will inform a centralized research and

analysis starting point, the resulting research and information will necessarily need to comport with the legally appropriate framework. To better support the prevention, preparedness, detection, and response to public health emergencies, a legal framework is needed. A legal framework is made up of binding legal instruments that formally establish and integrate a country's legal preparedness and response activities, setting a legal foundation for the infrastructure needed to respond to a public health emergency. A country's legal framework may include, but is not limited to, constitutions, legislation, arrêtés, decrees, regulations, administrative requirements, and applicable international agreements. This framework, in turn, may vary internally, for example by principles of federalism or local competence, and externally, by bilateral and multilateral arrangements, agreements, and organizations.

The Action Package members are keenly aware, and are broadly representative, of national and regional contextual differences relevant to this legal analysis. Therefore, the work developed will require careful scoping to develop useful guidance and capacity building tools.

Legal Mapping

One of the first priorities of the Legal Preparedness Action Package will be legal mapping analyses across issue areas. Legal mapping helps to understand a country's legal infrastructure and approach to developing legal instruments. Such mapping provides an overview of legal instruments across and within jurisdictions to understand how public health risks are addressed. It also involves the review and documentation of what legal authorities exist and what those authorities do and do not provide.

As such, legal mapping can help in the assessment of those instruments for clarity and functionality; the development of legal authorities where necessary; and the incorporation and promotion of international legal standards (e.g., IHR [2005]) at the country level to ensure an efficient and effective coordinated, multisectoral response.[16]

Conclusion

The GHSA Legal Preparedness Action Package represents a truly global and diverse acknowledgement of the need to be prepared legally to prevent, detect, and respond to public health emergencies. Over the next two years, the Action Package aims to provide guidance on a range of issues to help countries address a wide gap that requires urgent attention. The GHSA Legal Preparedness Action Package emerged from the legal struggles experienced in dealing with the COVID-19 pandemic and the widely shared understanding that much more must be done to recognize the role of law in public health emergencies, that legal preparedness must be strengthened before the next global health security threat, and that the GHSA is a well-positioned body to do so.

Note

The views expressed are the author's own and do not reflect the views of the United States Government or the U.S. Department of Health and Human Services. The authors have no conflicts of interest to disclose.

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About This Column
Lawrence O. Gostin and Benjamin Mason Meier serve as the section editors for Global Health Law. Professor Gostin is University Professor at Georgetown University and the Founding Linda D. &Timothy J. O'Neill Professor of Global Health Law at Georgetown University Law Center and Director of the World Health Organization Collaborating Center on National and Global Health Law. Professor Meier is a Professor of Global Health Policy at the University of North Carolina at Chapel Hill and a Scholar at the O'Neill Institute for National and Global Health Law. This column will feature timely analyses and perspectives on law, policy, and justice in global health.

DETAILS

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Involuntary Commitment as “Carceral-Health Service”: From Healthcare-to-Prison Pipeline to a Public Health Abolition Praxis

Wahbi, Rafik; Beletsky, Leo

ABSTRACT (ENGLISH)

Involuntary commitment links the healthcare, public health, and legislative systems to act as a “carceral health-service.” While masquerading as more humane and medicalized, such coercive modalities nevertheless further reinforce the systems, structures, practices, and policies of structural oppression and white supremacy. We argue that due to involuntary commitment’s inextricable connection to the carceral system, and a longer history of violent social control, this legal framework cannot and must not be held out as a viable alternative to the criminal legal system responses to behavioral and mental health challenges. Instead, this article proposes true alternatives to incarceration that are centered on liberation that seeks to shrink the carceral system’s grasp on individuals’ and communities’ lives. In this, we draw inspiration from street-level praxis and action theory emanating from grassroots organizations and community organizers across the country under a Public Health Abolition framework.

FULL TEXT

“Yea, the guilty is oftentimes the victim of the injured,
And still more often the condemned is the burden bearer for the guiltless and unblamed”
-Kahlil Gibran, *The Prophet*, 1923

“The call for social justice is ‘an implicit call for solutions, a call for remedies, a call for action’ (Coates, 2004). As we have seen, the call for social justice cannot rely on civil justice or macro-level remedies alone; law has been the handmaiden of what hooks (1992) has termed ‘the white supremacist capitalist patriarchy’ in the ever-evolving political and economic exploitation of persons of color. To paraphrase Bell (1992), the 14th Amendment cannot save us. The call for social justice requires more.”
-Rose M. Brewer and Nancy A. Heitzeg

Introduction

On April 23, 2011, a North Carolina Police officer killed Ronald Armstrong (Armstrong), a 43-year-old Black man with bipolar disorder and paranoid schizophrenia, shortly after the police department finalized an involuntary commitment, which was ordered by a physician.[1] The previous week, Armstrong had been off his medication for five days for unknown reasons. His sister Jinia Lopez saw that Armstrong had been self-harming, and so she talked with her brother, and they agreed together that they would go to the hospital. While he was being checked in and evaluated into the hospital, Armstrong became nervous and frightened by the environment, so he ran away. The physician examining Armstrong concluded that he was a danger to himself and began issuing an involuntary commitment order, which under North Carolina law, and laws across the country, is within his power as a physician. The doctor made this conclusion based on Armstrong’s flight from the hospital, and the “odd behavior” that was noted from earlier in the week. Police officers were immediately called as soon as Armstrong left the hospital. When they found him, not too far from the hospital, the involuntary commitment order had not been fully processed yet, so the officers began talking with Armstrong. They had found him wandering around a roadside and convinced him to come to the sidewalk. Armstrong then began to eat grass and dandelions and continued to self-injure himself. As

soon as the officers were alerted that the commitment order was processed, they began to approach Armstrong. Seeing the officers quickly approach him, Armstrong sat down on the floor, and wrapped himself around a four-by-four post near a stop sign. The officers attempted to pry Armstrong from the pole. The court notes detail that Armstrong was "anchored to the base of a stop signpost…in defiance of the [commitment] order." By this point, two hospital security guards and 3 police officers arrived, with his sister, who was pleading with Armstrong to come back to the hospital. With five law enforcement officers present, this did not last long —only 30 seconds passed after the court order was finalized that Lieutenant McDonald instructed Officer Gatling to tase Armstrong. Armstrong said, "I ain't got to go." Armstrong clung to the post. Over the next two minutes, Officer Gatling tased Armstrong five separate times. When Armstrong did not respond to the tasing, the five officers in total, pulled Armstrong off the post and pinned him down. Armstrong exclaimed that he was being choked and could not breathe. After the officers applied the handcuffs and stood up to "collect themselves," they began to walk away. Armstrong's sister noticed that he was unresponsive and pleaded with the officers to check on him. By the time the officers returned to Armstrong, he was not breathing. The police had just murdered Armstrong. The police report states that it was a total of six-and-a-half minutes between when the involuntary commitment order was finalized and when the EMS was radioed. Six-and-a-half minutes.

We propose to follow a public health abolition framework that disrupts, dismantles, and abolishes carceral-health services, and shifts from modes and systems of punishment and cages to models of community public health. Grassroots organizations, activists, and community organizers across the country are currently resisting carceral logics and services and instead are embodying a public health abolition politic by demanding real investments in alternatives to incarceration, instead of relying on punishment tactics like involuntary commitment. Beyond demanding these alternative systems of care, these movements are actively working and building programs and spaces to safeguard and heal community members.

In *Armstrong v. Village of Pinehurst*, later known as the "Taser case," the court considered whether use of the taser repeatedly was considered excessive force. The Fourth Circuit ruled that the officers did indeed use excessive force but were still protected by qualified immunity.[2] The ethics, effectiveness, or existence of the involuntary commitment order were not questioned in this case at all. Involuntary commitment laws are based on the state's *parens patrei* power, which is the power for the state to act as a guardian or "parent" for those who are unable to care for themselves, including children and those with substance use disorders and disabilities.[3] States across the country have various standards for involuntary commitment in terms of what classifies as "dangerous," or if dangerousness is even a standard (see Delaware and Iowa).[4] Armstrong's story is not uncommon in the United States. The data and evidence are clear: law enforcement kill Black men with mental illness at significantly greater rates than white men.[5] In cases where law enforcement do not kill the individual during apprehension, involuntary commitment cases involve individuals with serious mental health issues or substance use disorders. After being violently restrained individuals are committed to so-called treatment centers for "rehabilitation," but these sites are far from treatment or rehabilitation, but rather another form of prison or jail.[6] And yet since its inception, the law has consistently been shown to be ineffective, unethical, and racist.[7] Some keenly assert that involuntary commitment is worse than punishment, and is also in violation of the United States Constitution.[8] And yet, involuntary commitment not only continues to be used nationally, it's use is increasing significantly.[9] The question remains, why?

This paper attempts to answer the following question: given that involuntary commitment is neither ethical nor effective at accomplishing its purported goals of "treatment" and "rehabilitation," why is it still a regularly practiced law? Drawing from critical race theory, and a feminist abolition praxis, we will explain how involuntary commitment links the criminal legal, health care, public health, and legislative systems to act as a "carceral-health service" (based off of the concept of "carceral-service" introduced by Richie and Martensen in the field of social work).[10] We will answer this question by situating involuntary commitment within a social and historical analysis of the U.S. Prison Industrial Complex (PIC). In this way, we aim to re-frame involuntary commitment as a carceral-health service, not an alternative of the carceral system, but as part of a larger socio-political system of racial and class control. Involuntary commitment acts as one public health/medical to prison pipeline. For example, emergency

departments/rooms can be sites for carceral reach and control, with police officers frequently working with physicians and medical personal to conduct their searches.[11] By situating involuntary commitment within a racially conscious history, we aim to follow the wisdom of Dr. Helena Hansen et al. to "detect and represent power relations that are not transparent, have been forcibly erased, and exist only in traces."[12] Thus, we argue that due to involuntary commitment's inextricable connection to the carceral system, it is not a reformable law and must be abolished under a larger framework of police and prison abolition, while in it's stead, building and supporting systems of community care, utilizing evidence-based treatments and approaches. We propose to follow a public health abolition praxis that disrupts, dismantles, and abolishes carceral-health services, and shifts from modes and systems of punishment and cages to models of community public health.[13] Grassroots organizations, activists, and community organizers across the country are currently resisting carceral logics and services and instead are embodying a public health abolition politic by demanding real investments in alternatives to incarceration, instead of relying on punishment tactics like involuntary commitment. Beyond demanding these alternative systems of care, these movements are actively working and building programs and spaces to safeguard and heal community members.

Critical Race Theory and Involuntary Commitment

Critical race theory (CRT) can be defined as "a framework that can be used to theorize, examine and challenge the ways race and racism implicitly and explicitly impact on social structures, practices, and discourses."[14] In other words, CRT is an orientation to address observed racial stratification, viewing racism as a central component to understanding how people of different races have variable social positions in society and are given access to different rights and privileges,[15] thus resulting in harm, violence, or premature death.[16] Professor Kimberlee Crenshaw explains how critical race scholarship is centered around two primary ideas:

The first is to understand how a regime of white supremacy and its subordination of people of color have been created and maintained in America, and, in particular, to examine the relationship between that social structure and professed ideals such as "the rule of law" and "equal protection." The second is a desire not merely to understand the vexed bond between law and racial power but to *change* it.[17]

In the context of involuntary commitment, CRT will be used as a framework to theorize and understand the racial logics that are used to maintain the existence of an unethical and ineffective health law such as involuntary commitment.

While much of disparities research seeks to compare non-white groups to white groups and eliminate risk or reward with regards to an intervention or negative exposure/outcome, in this paper we will be considering the concept of racial arithmetic, described by sociologist Dr. Michael Rodriquez-Muniz. Racial arithmetic is how ethnoracial statistics are used by various political actors to make decisions regarding treatment, distribution of resources, or policy.[18] In the context of involuntary commitment, it applies to how ethnoracial statistics have historically been used to justify or even uphold the use of involuntary commitment. So while Black individuals are "disproportionately" involuntarily committed, the goal is not to bring the ratio of being involuntarily committed between Black and White groups to one. In this case, there is no such thing as a proportionate amount of involuntary commitment. The racial stratification of involuntary commitment doesn't reveal a deficiency in how the law or practice is enacted, but rather are a reflection of a society and mental health system founded on settler colonialism, white supremacy, and ableism.[19] The racialization of involuntary commitment is a feature not an error of the law.

Involuntary Commitment as a Carceral-Health Service

To understand involuntary commitment as an extension of the carceral system, we need to situate it within the larger history of social, racial, and class control of the earliest penal systems. Michel Foucault's analysis of the earliest "reforms" of the 16th century French penal system explained how the "criticism of the reformers was directed not so much at the weakness or cruelty of those in authority, as at a bad economy of power." This "bad economy of power" refers to the ways in which the early penal system made unilateral decisions with regards to criminal doctrine, procedure, and punishment, etc. Since the earliest reforms of the punishment and penal system (prisons and jails), the goal has been to disperse the "bad economy of power," not to eliminate it or transform it. Reforming the penal, or

criminal justice system, as it is commonly referred to today, has never been to provide more “humane” treatment, but rather as

a strategy for the rearrangement of the power to punish, according to modalities that render it more regular, more effective, more constant, and more detailed in its effects; in short, which increase its effects while diminishing its economic cost (that is to say, by dissociating it from the system of property, of buying and selling, of corruption in obtaining not only offices, but the decisions themselves) and its political cost (by dissociating it form the arbitrariness of monarchical power). The new juridical theory of penality corresponds in fact to a new ‘political economy’ of the power to punish.[20]

This dispersal of power can be seen not just from one system to the next (carceral to medicine) but must be understood relationally. That is, power is not merely an object given from one system or individual to the next, but instead it describes sets of relationships. In the case of involuntary commitment, we must not view it just as a health law that has power to “treat” individuals with serious mental health issues or SUDs, but to examine the power relationships and this new “political economy of the power to punish.” This includes the relationships between various actors (family members, medical staff, law enforcement, etc.), as well as the power relationships between the various systems that govern or maintain these actors (e.g., public health, healthcare, the carceral system).

In order to understand how to examine such power relations between the various actors involved in involuntary commitment, we look to the work of sociologist and disability studies scholar Liat Ben-Moshe, who argues that since its earliest conceptions, the project of social control by the state, through the penal system, was connected to the targeted control and elimination of those with disabilities, including psychiatric, developmental, and physical.[21] But it is not strictly in the form of “incarcerating” an individual in a criminal jail or prison; rather, she contends that disability has “always been central to diverse practices of incarceration, alongside and interlocking with other forms of stratification.” She explains that the “diverse practices of incarceration” produce “diverse sites of confinement.”[22]

While these sites of confinement might not be traditionally regarded as jails or prisons, or even arrests, we can see how involuntary commitment serves the same purpose as incarceration, when these “sites of confinement” are compared with regards to whom they target and confine, and the way in which they do it. Foucault explains that to understand the logic and history behind these diverse sites of confinement the “form of rationality at stake” must be questioned. He continues,

The criticism of power wielded over the mentally sick or mad cannot be restricted to psychiatric institutions; nor can those questioning the power to punish be content with denouncing prisons as total institutions. The question is: how are such relations of power rationalized? Asking this is the only way to avoid other institutions, with the same objectives and the same effects, taking from their stead.[23]

Involuntary commitment is not treatment for the sake of public safety, but rather a “form of rationality” that takes on from its “stead,” the penal system. If the goals of the penal system are to punish through violence, then involuntary commitment’s goals will be relationally connected to commit such violence on people and bodies that are deemed deviant.

In order to understand how involuntary commitment has continued to grow, despite its failed results, we will connect it to the larger prison industrial complex.[24] We will use the concept of the “carceral state” or “carceral expansion” interchangeably, which refers to “the ways that ideology, economic policy, and legal/legislative initiatives have supported the growth of legal apparatuses associated with punishment.”[25] Richie and Martensen explain the expanding carceral state has three characteristics:

(1) that carceral expansion is not related to crime rates, (2) that the investment in punishment is directly related to divestment in other aspects of society that create equitable opportunity, and (3) that it is targeted toward the literal capture and metaphorical containment of black and other people of color, Indigenous peoples, transgender and gender-non-conforming people, young people from poor communities, people with mental health issues, and other groups who are disadvantaged by institutionalized oppression, and as such, it is an artifact of social control and exclusion.[26]

In the field of social work, and in particular feminist social work, recent attention has been given to how social

services frequently adopt carceral logics and create partnerships with the carceral system. Richie and Martensen identify these types of services as “carceral services” that “replicate the control, surveillance, and punishment of the Prison Nation, and thus, punitive and social services can become indistinguishable.”[27] Similar to how there are carceral services in social work, we argue that involuntary commitment laws act as one of many “carceral-health services” in health related fields.

Involuntary commitment can be seen as a carceral-health service very vividly through the various power relations and dynamics in the killing of Ronald Armstrong. The hospital that intimidated and frightened Armstrong, the physician that called the involuntary commitment order, the two hospital security guards, and the three law enforcement officers. Together these actors were following the law by executing Armstrong for resisting the commitment order.

A Public Health Abolition Praxis: Abolishing Carceral-Health Services

Black and Brown led resistance against prisons and police in the United States have a long history.[28] But many draw the beginnings of the current movement to abolish prisons and police to the 1998 international conference titled: *Critical Resistance: Beyond the Prison Industrial Complex*.[29] Together, they came to “address the alarming growth of the prison system, popularize the idea of the ‘prison industrial complex’ (PIC), and make ‘abolition’ a practical theory of change.”[30] Abolitionist scholars explains how the theories, practices, writings, and strategies of the modern prison abolition movement can be found throughout the academic literature, as well as in the mass media and art.[31]

Mariame Kaba, an abolitionist educator and organizer based in New York City, explains how prison industrial complex (PIC) abolition is

“a political vision, a structural analysis of oppression, and a practical organizing strategy. While some people might think of abolition as primarily a negative project —“let’s tear everything down tomorrow and hope for the best” —PIC abolition is a vision of a restructured society in a world where we have everything we need food shelter, education, health, art, beauty, clean water, and more things that are foundation to our personal and community safety …PIC abolition is a positive project that focuses, in part, on building a society where it is possible to address harm without relying on structural forms of oppression or the violent systems that increase it.”[32]

The relationship between public health and abolition is not new and others have begun to recognize that “Public Health is strategy for Abolition,” as critical resistance and other public health organizers and professionals expressed in an American Public Health Association (APHA) statement in 2018.[33] Recently, the statement was fully adopted by the APHA and affirms moving towards “the abolition of carceral systems and building in their stead just and equitable structures that advance the public’s health.”[34] PIC abolition, according to Kaba, is much more than just eliminating laws such as involuntary commitment, or getting rid of armed officers that respond to mental health crises. It is about preventing further harm and violence from happening, and when it does occur, to not respond with more violence. A public health abolition praxis must follow what Mariame Kaba describes as the “positive project” of abolition. The positive project in public health abolition is to support existing systems of care, as well as creating new systems of care for those who use drugs or who have mental health crises. These alternative systems are not just often underfunded, many are just not funded at all. The existence of laws like involuntary commitment creates legislative and legal boundaries around who and how a community can intervene for those with substance use disorders or serious mental health issues. To prevent further harm, one must recognize that carceral-health services and health equity cannot co-exist. The PIC and health equity cannot co-exist. In an article published in *BMJ Global Health*, the authors emphasized how police violence and the larger carceral system extends beyond the U.S.[35] Additionally, an abolitionist public health is defined as “work directed towards at the dissolution of the Prison Industrial Complex, recognition of its discriminatory roots, and the implantation of interventions that tackle the social economic and political determinants of health at the root of societal problems, thus making policing obsolete.”[36]

With regards to involuntary commitment, an integrated evidence-based health and social service model in tandem with non-carceral community-based emergency and crisis response teams has the potential to respond to the wide range of crises that individuals can be in. By responding with compassion and practices that do not further harm the individual (punishment and incarceration), these alternative approaches exceed involuntary commitment because

they actually address the issues, instead of caging them away.

Utilizing a public health abolition framework, we contend that involuntary commitment must be abolished, along with all other carceral-health services, which are the conduits of the public health/healthcare to prison pipeline. Involuntary commitment and other carceral-health services will continue to exist in our public health system unless organized action is taken. We call on the fields of health law, public health, medicine, and all health-related fields to adopt a public health abolition praxis. With regards to involuntary commitment, an integrated evidence-based health and social service model in tandem with non-carceral community-based emergency and crisis response teams has the potential to respond to the wide range of crises that individuals can be in. By responding with compassion and practices that do not further harm the individual (punishment and incarceration), these alternative approaches exceed involuntary commitment because they actually address the issues, instead of caging them away.

In Los Angeles, grassroots organizations, organizers, and those directly impacted by the carceral system are a clear example of an abolitionist public health framework. In 2017 several community-based organizations in Los Angeles formed JusticeLA to collectively work toward shifting the city's dollars and investment away from police and prisons and into community-based systems of care.[37] In November of 2020, Los Angeles County voters approved the historic Measure J, which would dedicate 10% of the County's unrestricted budget, to fund alternatives to incarceration.[38] Through this coalition, and others like Re-imagine LA,[39] the LA County Alternatives to Incarceration (ATI) Workgroup report was produced to create a roadmap for how the county can be begin to fund the services and programs it needs to better respond to substance use or mental health related crises.[40] The recommendations in the ATI report include increasing non-carceral crisis mobile response teams, creating an alternate crisis response system (988 number), funding harm reduction services, supervised consumption sites, expanding access to medication for addiction treatment, and much more.

Conclusion

For far too long the fields of public health, medicine, and law have engaged in carceral-health services, that have shown to be harm and death producing, and not reducing. Carceral-health services disperse carceral power, reifying systems of punishment under the auspices of "treatment." Carceral-health services co-opt terms like "treatment" "rehabilitation," in order to maintain their power. Advocates are beginning to push back against the expanding carceral state, by resisting these carceral logics, and specifically seeking true alternatives to systems of punishment, including carceral-health services like involuntary commitment. In North Carolina, mental health and community health advocates point to how the carceral system and hospital emergency departments act as safety nets for all social ills, including those that result in anxiety, suicide, depression and substance use disorders. But they also express concern over the 91% increase in use of involuntary commitment in their state. One advocate explained how their grassroots efforts to provide mental health care that "is shifting from authoritative approaches to more responsive ones that engage individuals more effectively and with greater safety."[41] Advocates and organizers in North Carolina, Los Angeles, and around the world are continuing to resist and abolish carceral-health services and laws such as involuntary commitment. The work of the JusticeLA and Reimagine LA coalitions shows that an abolitionist public health framework works to dismantle systems and sites of oppression, and instead builds and reinforces systems and sites of care that address the root causes of violence and harm. Ronald Armstrong needed care and support. Involuntary commitment is unreformable and incapable of addressing crises. For this reason, involuntary commitment and all public health and medical partnerships with the carceral system should be abolished.

Note

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DETAILS

Subject:	Action theory; White supremacy; Excessive force; Law enforcement; Grass roots movement; Praxis; Social control; Hospitals; Legal system; Rehabilitation; Community; Police; Prisons; Substance use disorder; State laws; State court decisions; Public health; Social justice; Racism; Critical race theory; Mental health; Imprisonment; Drug use; Health services; Oppression; Activism; Race; Murders &murder attempts; Federal court decisions
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“We Who Champion the Unborn”: Racial Poisons, Eugenics, and the Campaign for Prohibition

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ABSTRACT (ENGLISH)

Dr. Caleb Williams Saleeby was the author of *Parenthood and Race Culture*, one of the first monographs on eugenics and the book that popularized the term “racial poison.” The goal of eradicating the racial poisons and the harm they caused — particularly infant morbidity and mortality — provided common ground for early 20th century reformers, and their concerns fed the growing support for legal prohibition of alcohol.

FULL TEXT

Introduction

In 1920, the 18th amendment to the United States Constitution, commonly known as the “Prohibition Amendment,” became effective. Its provisions outlawed “the manufacture, sale or transportation of intoxicating liquors.” Williams Jennings Bryan, three-time candidate for president and secretary of state under Woodrow Wilson, was one of the most prominent advocates for Prohibition. Bryan highlighted the importance of a scientific argument that bolstered

the case for abolishing the liquor trade in an article published several years after the amendment had passed. “The most frightful warning” against alcohol, Bryan said, “was furnished by the study of eugenics. It was found that alcohol travels in the blood and curses, even before their birth, the children of drinking parents.” Bryan reserved “special praise” for the “noble women who banded together under the name of the Woman’s Christian Temperance Union” and spread the eugenic message of alcohol toxicity “to the students in schools” and distributed to the public “the results of scientific research” on the alcohol question.[1] The most important proponent of that eugenic explanation of the dangers of alcohol was Scottish physician Caleb Williams Saleeby.

A growing body of scholarship describes the American legal experience with eugenics, which provided justification for dozens of state laws such as the statutes that mandated sexual sterilization or prohibited interracial marriage.[2] There is also a considerable literature about the only federal statute passed with the support of open lobbying by eugenic leaders: the 1924 Immigration Restriction Act.[3] But the most important source of law for the United States is the Constitution, and little has been published about how 20th century eugenic concerns were an important factor in passage of a major constitutional amendment. In this article I will explain how the Prohibition Amendment received support from one of the founders of the eugenics movement, who began his work not in the U.S., but in Great Britain.

My specific focus is Caleb Saleeby, who is regularly mentioned in books on eugenics,[4] and whose campaign in favor of prohibition was described decades ago,[5] but who otherwise has received little attention, despite his major role in mounting an international coalition against alcohol, in the name of eugenics. Saleeby provided language and concepts that amplified fears of alcohol and publicized the importance of adopting laws that would prohibit its manufacture, sale, and use. His efforts were directly aligned with individuals, such as Bryan, and organizations like the Anti-Saloon League and the Woman’s Christian Temperance Union, which led the campaign that eventually resulted in the U.S. Prohibition amendment. Saleeby linked alcohol to the societal maladies of crime, disease, poverty, and welfare dependence, putting him in the mainstream among eugenists who prescribed medical and scientific solutions to social problems.

Saleeby earns our attention not only because he was so important to the success of Prohibition in the U.S., but also because his activism gives us insight into what eugenics meant to many of its earliest adherents. His drive to dramatize the danger of the “racial poisons,” like alcohol, shows how concerns that people had about environmental toxins could be fit into the broader field of eugenics.[6] He provides a bridge between people who became medical eugenists in the 19th century, such as John H. Kellogg, who emphasized “biologic living,”[7] public health leader W.A. Evans,[8] or Harvey Wiley, father of the Food and Drug Administration.[9] Those men embodied the transition between sentiments commonly described as “Lamarckian,” which argued that traits acquired during a parent’s life would be passed down to children, and those who later put much less emphasis on environmental factors and explained anatomy, morbidity, temperament, and the character of children via a theory of “hard heredity.”[10]

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Caleb Saleeby

Caleb Williams Saleeby was born 1878. He graduated with honors in medicine from Edinburgh University and practiced in a maternity hospital briefly before taking a position as a resident officer at the York City Dispensary, where he observed obstetrics from the other side of the Atlantic. He moved to England in 1901, settling in London to do postgraduate medical work. After only a short time as a physician, Saleeby left medical practice to be a journalist and author. He eventually wrote sixteen books, and he published regularly on a variety of issues for popular magazines like *Pearson’s Weekly* and *Harpers,* while contributing numerous articles to professional and technical journals.

A turning point in Saleeby’s career came soon after he had received his medical degree.[11] In May 1904, he attended the meeting of the Sociological Society at the University of London, at which Francis Galton delivered a now famous

lecture on eugenics. Galton's lecture was entitled: "Eugenics, its definition, scope and aims," and it quickly drew the attention of the press both in England, and within days in the United States as well. One American newspaper announced Galton's talk with the dramatic headline: "Doctor invents science."[12] The lecture was soon published in an American journal, further alerting the academic world to its significance.[13]

Galton's lecture was fateful for Saleeby, who would claim a spot in the leadership of a new movement by coining terms such as "eugenist," to describe like-minded advocates, "positive and negative eugenics," to distinguish among eugenic policies,[14] and "eugenic feminism," his designation for women in the movement.[15]

Saleeby was eventually credited as "the outstanding propagandist for eugenics."[16] In 1907 he put his skills as a publicist to use when he helped found the Eugenics Education Society, described by one commentator as "the intellectual heart of English Eugenics."[17] Others saw him not only as "an evangelizing eugenicist and acolyte of Francis Galton" but also an "eccentric."[18] That eccentricity, and his heated attacks on the work of Galton protégé and biographer Karl Pearson, led to an early break with the Eugenics Education Society and formal eugenics establishment in England,[19] but did nothing to prevent the public from identifying Saleeby as an early and prominent spokesman for the new movement.

Saleeby was extensively involved in governmental commissions and voluntary organizations. He held positions on the National Conference on Infantile Mortality, the National Birth Rate Commission, the Divorce Law Reform Union, the National Temperance League, and the National Council of Public Morals.[20] Five times between 1907 and 1924 he was designated as Royal Institution Lecturer on eugenics, and he was a founder and Chairman of the Sunlight League.[21]

He lobbied for initiating a ministry of health as part of the war effort in World War I and worked to perfect the design of body armor for soldiers, winning significant attention for his advocacy for, and invention of, the steel helmet.[22] His greatest contribution to the prohibition effort was the idea that some substances or conditions to which people might commonly be exposed constituted a eugenic threat. To characterize the biologic nature of this threat, Saleeby coined the term "racial poison."[23]

Some racial poisons were diseases — like syphilis or gonorrhea — that could kill off a population by causing sterility. The phrase also encompassed environmental toxins like lead, nicotine, and alcohol. Saleeby's coinage became shorthand for factors that simultaneously poisoned individuals, inhibiting their growth and healthy functioning, and their "germ plasm," the cellular repository of heredity. Eugenists like Saleeby knew that alcohol lowered moral inhibitions and provided a gateway for familial destruction through interpersonal violence, promiscuous sex, and subsequent disease. As Saleeby said, drinking was like "the germinal tissues of years … soaking in alcohol."[24] Its effects cascaded from users to their mates, ultimately leading to more "ill-born" children.

The goal of eradicating the racial poisons and the harm they caused provided common ground for early 20th century reformers, linking the movements for social hygiene, public health, and temperance. In the United States, the phrase "racial poison" became a rallying cry for eugenic enthusiasts fearful of decreasing fertility among the "better classes" which they condemned as "race suicide." Their concerns fed the growing support for legal prohibition of alcohol. When Prohibition became law in the U.S., Saleeby called it America's "Great Experiment in Eugenics."[25]

Parenthood and Race Culture

Galton's original definition of eugenics appeared in 1883,[26] but 25 years passed before anyone else attempted to write a complete book on the topic. Saleeby filled that gap in1909, with *Parenthood and Race Culture*, in which he confidently claimed to "survey and define the whole field of eugenics"[27] and announced dramatically: "eugenics is going to save the world."[28]

Saleeby's book and other writing received extensive publicity. The *New York Times* published advertisements [29] and followed up with several feature articles by Saleeby.[30] Saleeby's focus on the "racial poisons" immediately caught on among those who were selling alcohol cures, as well as among those who advocated for prohibition of strong drink.[31]

The goal of eugenics, said Saleeby, "is a better race." First, the right kind of parents must be encouraged to reproduce. Then, we must "take care of those selected" to be parents, which included protecting "the expectant mother from alcohol, lead or syphilis." "That," said Saleeby, "is strict eugenics by any definition worth a moment's

notice."[32]

Reminding his reader that he had coined the term "eugenist," "which is now the accepted term," Saleeby echoed Galton, asserting that eugenics is "at once a science and a religion."[33]

We have to consider the parental environment of the children we desire, as well as their innate quality. Thus, positive eugenics must largely take the form, at present, of removing such disabilities as now weigh upon the desirable members of the community, especially of the more prudent sort.[34]

But Saleeby also saw another side to the eugenics equation: "The proportion of the mentally defective in Great Britain is now 0.83 per cent.: and it is doubtless rising yearly. Only by the recognition and application of negative eugenics can this evil be cured."[35]

Saleeby's attention was drawn to environmental factors that might have an impact on prospective parents, and he had developed the phrase "racial poisons" to identify those factors. Did this put him into the camp of the Lamarckians, who believed that acquired characteristics could be inherited? In his early work, he made his position on Lamarckism clear. He was entirely familiar with the controversy surrounding the Lamarckians and August Weissmann's work emphasizing the impossibility of acquiring parental characteristics. Weismann had attacked the premise of Lamarck in an experiment. He cut off the tails of rats, rebreeding them generation by generation, and then noting that each new generation still had a tail.[36]

Saleeby admitted that the semantics of "acquiring" were confusing, but, he said, the failure to take into account the fetal environment only added to the confusion.

Said Saleeby:

An acquirement is an acquirement, whether it be acquired five minutes or months before, or five minutes or months after, the change in environment which we call birth. Thus a character may be congenital — that is, present at birth — but not inherent or germinal, not inborn at the real birth, which was the union of the maternal and paternal germ-cells at conception. Such congenital characteristics are really acquirements, and — poisonings apart — are not transmissible.[37]

On Lamarkism, Saleeby said specifically: "This doctrine of the transmission of acquired characters by heredity, as we have seen, is, at the present day, repudiated by biologists." Nevertheless, he emphasized that "the inherited potentialities of the germ are only potentialities; no more. They are entirely at the mercy of the environment."[38] He later insisted: "Heredity or no heredity, we cannot desire to have children born into the alcoholic home; heredity or no heredity, we cannot desire to have children born into the criminal environment."[39] His last word on Lamarck: "The controversy between Lamarck and Weismann has *absolutely nothing to do with the question*."[40]

In *Parenthood and Race Culture* Saleeby trained his sights on alcohol, which he considered the most destructive racial poison.

The term racial poisons teaches us to distinguish, amongst substances known to be poisonous to the individual, those which injure the germ-plasm: and amongst substances poisonous to the expectant mother herself, we must distinguish those which may also poison her unborn child.[41]

Alcohol was, insisted Saleeby, "pre-eminently the racial poison," which was "the most important aspect of the whole alcohol question."[42] He linked alcoholism as both the cause and the result of feeblemindedness, and said that the children of alcoholic, feebleminded women "are not only doomed by the very nature of their germplasm, but they will actually be many times intoxicated not merely in their cradles but before their birth."[43] Defective women inhabited a vicious cycle. Their germ plasm made them defective at birth, the alcohol ingested by their mothers provided additional poisoning as they nursed, then they were condemned to live in a home polluted by alcohol. Most "chronic inebriates" were feebleminded and so were their progeny. Therefore, he concluded, "the chronic inebriate must not become a parent."[44]

Saleeby had written a memorandum for the Eugenics Education Society that he included in *Parenthood*. "It perhaps fairly sums up, in the briefest possible space," he concluded, "the indisputable relations between alcohol and parenthood." He argued that three factors insured that the "children of the drunkard" were "less capable of citizenship" than other children:

•1. The inheritance of nervous defect inherent in the parent. (defective germ plasm),

•2. Intra-uterine alcoholic poisoning in cases where the mother is an inebriate. (prenatal environment),

•3. Neglect, ill-feeding, accidents, blows, etc., which are responsible on the one hand for much infant mortality, and combined with the possible causes before mentioned, for the ultimate production of adults defective both in body and mind. (family environment).

Restraining the drunkard was imperative, he claimed, lest "a defective race" emerge that would pose "a grave financial burden upon the sober portion of the community, to say nothing of higher considerations."[45]

Saleeby's argument about the effects of alcohol was hardly novel. Francis Galton had focused on the hereditary inclinations that fostered a "craving for alcohol" in 1865, as did his precursors throughout the 19th century.[46] One of those authors had been Saleeby's own grandfather, who made similar arguments in 1856.[47] Saleeby's writing came long after the career of "habitual drunkard" Jane Cakebread had been thoroughly chronicled in the British press. She held the record for most arrests "for drunkenness and rowdyism," and made her 300th visit to the prison in 1895.[48] Her notoriety prompted some to propose abolition of criminal sentences for drunkenness, in favor of commitment to an asylum or other efforts at reform.[49] Immoral women were often the group to blame as a font of evil following drink.[50]

Trends in birth rates added to general concerns about the toxicity of alcohol to women. The national birth-rate began to decline in Great Britain in the mid-1870s, and by 1901 births had dropped by twenty-one percent, falling most dramatically among the middle classes. Studies in England and Wales showed nearly one in six babies died by their first birthday.[51]

Saleeby supported the Notification of Births Act, which Parliament passed in 1907. It enabled local health authorities to keep track of newborn babies, monitor their progress, and provided more substance to what before then had often been speculative concerns.[52] Alcohol was thought to be a significant factor in the failure of some pregnancies to yield a live birth, as well as the difficulties that infants faced in their first year of life.

The birth rate fell an additional 13 percent by the time World War I started in 1914 and continued in decline until the War's end. Some statistical analyses showed a decrease of as much as 37 percent during the same period,[53] a time when Saleeby held a leadership role on the National Birth Rate Commission. In 1916 he contributed to the report on the *Declining Birth Rate*, where he noted that "… alcohol is also a racial poison of large importance, causing direct blastophthoria, which may often lead to failure of conception or ante-natal death affecting the birth-rate and survival rate."[54]

At the time *Parenthood* was published, Saleeby sat on the executive committee of the National Conference on Infantile Mortality. Speaking at that group's 1908 annual meeting on "The Human Mother," he argued that: "If certain influences, such as alcohol and some few diseases, have been in operation, the babies may be already doomed" at birth.[55] To remedy infant mortality, Saleeby urged "the principles of maternalism: There is no State womb, there are no State breasts, there is no real substitute for the beautiful reality of individual motherhood."[56]

Saleeby was quick to enlist the government as the agency to enforce his eugenic prescription. He proposed a four-point program on motherhood that put the government in charge of all things maternal, making childbirth a public health issue.

•1. All motherhood to be regarded as a first charge on the resources of a nation.

•2. Government authority to look after maternity.

•3. The handing over of all maternity cases, regardless of wealth or social conditions, to the public health authority.

•4. The establishment of maternity centers, both per-natal and post-natal, throughout the country.[57]

"All this," said Saleeby, "is fundamental eugenics, and is far more feasible than any question of breeding for genius or of deciding who shall marry whom and who shall not marry whom."[58]

His interest in eugenics was directly related to his work as a physician, but Saleeby's focus on infant mortality and the declining birth rate also fed into the concerns of other groups, like the American Association for the Prevention of Infant Mortality, which also had a eugenics section.[59] Increased infant mortality led to fewer babies, and highlighted growing fear of what became known as "race suicide," the concern that a demographic Armageddon would end with extinction of the white, Anglo Saxon population. At the time of *The Declining Birth Rate* in 1916 this had become a constant trope in the U.S., as it had in Europe,[60] and played a large part in the immigration restriction debate of that time.

Saleeby did not support the idea, sometimes prevalent in eugenic circles, that some infant mortality had a positive impact.

The causes of infant mortality destroy many children inherently unfit, diseased or weakly. But we are not justified in keeping up our infant mortality, if we find, as we do, that for every diseased child whom they destroy they kill many who were healthy at birth and damage for life many more.…[61]

Finally, said Saleeby, "The opponent of infant mortality and the eugenist appeal to the same principle and avow the same creed: that parenthood is sacred, that it must not be casually undertaken."[62]

Racial Poisons and Alcohol: The Eugenic Context

Saleeby's emphasis on the "racial poisons" fit neatly into the larger eugenics movement. The two most well-known eugenic problem families were the Jukes, described in Richard Dugdale's 19th century treatise, and the Kallikak family, the saga of Deborah Kallikak by psychologist Henry Goddard. Both studies highlighted the dangers of alcohol. Dugdale included dozens of tables and charts in *The Jukes*, showing the study subjects classified in groups that reflected the hereditary effects of habitual drunkenness as a cause of family degradation and community degeneracy.[63]

The problems of Martin Kallikak, described in Goddard's blockbuster text, *The Kallikak Family*,[64] were directly related to his encounter with the so-called "feebleminded tavern wench." That single alcohol drenched dalliance led to "hundreds of the lowest types of human beings."[65] Students of eugenics in the U.S. trained at the Eugenics Record Office (ERO) read those books and learned to list the telltale signs of degeneration and decay in pedigrees, with alcohol listed as the alphabetically first and key consideration in compiling a heredity chart.[66]

The Woman's Christian Temperance Movement in the Campaign for Prohibition

The eugenic connection between alcohol, infant morbidity and mortality was taken up by advocates for Prohibition. They spoke of social degeneration linked to the presence of alcohol, and regularly blamed increases in crime and demographic decay on the liquor trade. It was the policy of the Woman's Christian Temperance Movement (WCTU) that such social problems were amenable to eugenic reforms.

The WCTU was founded in 1874, with the purpose of creating a "sober and pure world" by abstinence, purity, and evangelical Christianity.[67] The constitution of the WCTU called for "the entire prohibition of the manufacture and sale of intoxicating liquors as a beverage."[68]

The WCTU also engaged in numerous other reform activities, including the improvement of labor conditions, the abolition of prostitution, the funding of sanitation and public health, and advocacy for women's suffrage and international peace.

By 1879 the movement for “scientific temperance” had become a focal point of the WCTU campaign against alcohol. That year Mary Hunt spoke to the WCTU’s national convention on “Scientific Temperance Instruction.” She urged the adoption of “text-book study of Scientific Temperance in public schools as a preventive against intemperance.” The following year the WCTU established a Department of Scientific Temperance Instruction in Schools and Colleges through which Hunt and her colleagues pressured state and national legislators to mandate temperance education. Instruction, said Hunt: “should give clear and emphatic utterance to the solemn warnings of science on this subject.”[69] Congress adopted a federal law in 1886, and by 1900, every state had a law requiring students to receive anti-alcohol education.[70]

The eugenic marriage laws, which required medical examinations before marriage, provided an overlapping area of interest between eugenics and the WCTU.[71] Tying together the burgeoning popularity of those laws, with their insistence on premarital health examinations, Mrs. Frances W. Leiter, head of the WCTU health department, heralded the coming “eugenic woman with her correct poise of both mind and body.… The eugenic young woman will make certain demands before the sacred ceremony at the altar of matrimony — the certificate of health.”[72] As time passed the fervor for eugenic marriage laws spread from coast to coast.[73] Before long eugenics took a regular position on the program of WCTU meetings and conventions, and the arguments against liquor also benefited from a eugenic gloss.[74] When Cornell University began to provide instruction in eugenics and alcohol[75] as part of the “first regular course on this subject in the world,” the organization responded: “We rejoice.”[76]

In time prominent leaders within the WCTU allied themselves with the eugenics movement in support of the abolition of alcohol. Mary Teats, “national purity evangelist” of the WCTU Christian Temperance Union later founded the Chicago Correspondence School of Gospel and Scientific Eugenics.[77] Her embrace of eugenics was intended to eradicate prostitution as well as prohibit strong drink. She condemned “habits of life” such as sexual excess and the alcohol consumption that marred parental bodies and worked to “curse their offspring.”[78]

Edith Smith Davis was the Superintendent of the Scientific Temperance Department of the WCTU when she compiled a *Compendium of Temperance Truth*, a series of essays that were written by WCTU temperance counselors and instructors.[79] The book had a whole chapter on alcohol and eugenics, deemed by Davis “this great field of scientific study” and included the Biblical curse of generational guilt often repeated by eugenists: “That there is nothing new under the sun receives confirmation in the fact that the law of Moses is the law of Eugenics—that the sins of the fathers shall be visited upon the children unto the third and fourth generation.”[80]

Some prominent educators criticized the expansive overreach of the WCTU, whose insistence on making the anti-prohibition message a mandatory feature of the curriculum threatened to crowd out other scientific study in high schools.[81] But the WCTU had built a national campaign using the rhetoric of “poison” to describe alcohol, regardless of the amount or form in which it was ingested. Though scientific support for this position was often weak, for years it remained a key feature of the campaign for “scientific” temperance. In 1910, a publication by Saleeby’s rivals at the Galton Laboratory in London posed a challenge to the WCTU’s teachings.

As a member of the Eugenics Education Society, Saleeby engaged in the “running feud” with London’s Eugenics Laboratory, founded by Francis Galton and the home of pioneering biometrician Karl Pearson.[82] Pearson supported the position that hereditary defects in children — what he termed “inherent worthlessness” — led to early death, thus infant mortality represented an efficient elimination of those unfit to live.[83] From that perspective, campaigns of social amelioration were counterproductive, and they interfered with “natural selection.”

Saleeby argued that heredity was important to “health, vitality and longevity,” but it was not “all important.” He was pointedly critical of Pearson’s interpretation of “natural selection.” “Conditions initiated in the slums are not natural,” said Saleeby, “they are hideously unnatural.” Saleeby catalogued the conditions to which pregnant women were

exposed, saying that it was crucial not to forget “prenatal influences due to environment” and that “nurture was playing on heredity” during the entire term of a pregnancy. Saleeby also drew notoriety for disagreeing with the “better off dead” school of eugenics, which claimed that high infant mortality signaled a eugenic benefit.[84] Saleeby’s brand of eugenics condemned any attempts at infanticide or neglect after birth. He also spoke energetically against abortion, as did most eugenists at the time, and listed himself among those “who champion the unborn.” Saleeby supported curbs on parenthood among those he judged “unfit.” But he also did “entirely deny the right of the eugenic idea to any voice or place as to the fate of children *once they have come into being*.”[85]

Ethel Elderton and her colleague Karl Pearson at London’s Galton Laboratory focused their research on how degeneracy or defect was passed down in a family. They claimed in a series of publications that people who had a dangerous impulse to drink were themselves possessed of hereditary weakness. It was that defect that led to their alcoholism, not alcohol that caused the defect. Consequently, they concluded, most people who drank to no serious ill effect were not a threat to future generations.[86]

Leaders of the WCTU linked the problems of “race suicide” with alcoholism, as Saleeby had, claiming that the increase in infant mortality and the falling birth rate were fueled by alcohol consumption. One headline captured the WCTU position. The temperance organization, it said, “Upholds Eugenics.” After prohibition had become law in America, one commentator in the WCTU’s *Union Signal* looked to the future, predicting that “world prohibition will be an ideal which we may work towards.”

Saleeby and his colleagues at the Eugenics Education Society took exception to the Galton Laboratory contention. Their campaign against alcohol rested on the designation of alcohol as a racial poison that posed a danger not only to the current, but also to future generations. Both Saleeby and the WCTU *Scientific Temperance Journal* quickly issued critiques of the Galton Laboratory’s work.[87] As the debate between the eugenists persisted, the WCTU was caught up in the controversy, raising questions about which directions future efforts toward “scientific temperance” education would take.

Part of the educational work of the WCTU involved drafting short leaflets on important topics. A “leading scientist” reviewed tracts on “eugenics” and “inheritance” before approving them for distribution. When a pamphlet on “alcoholism and heredity” was submitted for vetting, reviewers noted that “the status of the question has not been definitely determined.”[88] Temperance advocates found the comments of Henry Goddard, an early stalwart of the eugenics movement, particularly troubling. He underlined the lack of consensus in the field as to the actual effects of alcohol on “germ plasm,” the factor that transmitted heredity. Goddard targeted “unfounded statements” that asserted a link between drinking in parents and feeble-mindedness in children. His own position as author both of the best-selling book *The Kallikak Family*[89] and *Feeble-Mindedness—Its Cause and Consequences*,[90] a study that summarized data from three hundred cases, provided adequate credibility to his observations. Goddard was unwilling to conclude that “strong and incontrovertible evidence existed connecting alcohol as the cause of feeble-mindedness.”[91]

This debate raged for years, but by the time the Prohibition campaign was over, *The Union Signal* newspaper, “official organ of the WCTU,” had sided with Saleeby. Galton Laboratory scientists had downplayed the effects of parental alcoholism on children, said Cora Stoddard, leader of the WCTU Scientific Temperance Federation. This study was often “exploited” according to Stoddard, as “would-be evidence” of the “claim that drinking by parents makes no difference with the children.”[92] By then, the WCTU was clearly in the Saleeby eugenics camp. Saleeby had described the Elderton/Pearson paper as a “terrible blow to eugenics”[93] and Stoddard quoted directly from the Saleeby article that had condemned the Elderton/Pearson research.

Sarah E. Wise, head of the Moral Education branch of the WCTU, said:

The need of the education of parents along lines of eugenics, of heredity, of prenatal influences, alcoholic or emotional, of self-control, of child nature and child psychology becomes every day more urgent and more apparent. The character and condition of the parents determines the character of the child.

Again echoing Salleby, Wise added: "Parents need to be taught the close inter-relationship between the physical, the mental and the moral natures … We know that certain poisons in the body mean definite defects in the brain."[94] Just as Cora Stoddard had said: alcoholic drinks "by their effects on the germ-plasm … curse the unborn child."[95] Leaders of the WCTU linked the problems of "race suicide" with alcoholism, as Saleeby had, claiming that the increase in infant mortality and the falling birth rate were fueled by alcohol consumption. One headline captured the WCTU position. The temperance organization, it said, "Upholds Eugenics."[96] After prohibition had become law in America, one commentator in the WCTU's *Union Signal* looked to the future, predicting that "world prohibition will be an ideal which we may work towards." He suggested that soon "eugenics and sex hygiene" might be addressed by the Scientific Temperance department, though religious leaders cautioned that it might be premature to initiate "Sunday school instruction" in such topics.[97]

Passing Prohibition

The prohibition Amendment was introduced in Congress in December 1917 with a seven-year deadline for passage. Pundits and politicians predicted that it would pass easily, and their optimism was confirmed when Nebraska endorsed ratification in 1919, providing the two-thirds margin needed within little over a year.[98] The clock began to tick toward enforcement measures that would begin on January 20, 1920.

Newspapers reported a plan that had been announced by the Anti-Saloon league to bring European speakers to America so that they could learn the value of prohibition first-hand. Then those thought leaders could speak for themselves to their European counterparts in the fight for worldwide prohibition.

To help launch the international campaign Saleeby traveled to the U.S. in spring 1919 for a convention of the Anti-Saloon League. It was a several-week meeting that brought together delegates from every continent in five different cities in North America. On June 5, international delegates including Saleeby assembled in Washington, DC; two days later they signed a constitution for the new World League against Alcoholism. The next day, Saleeby was joined on the dais by William Jennings Bryan and Dr. Howard Hyde Russell, who had founded the Anti-Saloon League in 1893 and was numbered among the "prophets of the anti-liquor movement."[99] All three addressed the mass meeting. Saleeby's talk reiterated his beliefs about the role of alcohol as a "racial poison." He reminded the crowd of his long-standing conviction that "we eugenists would never succeed in purging mankind of its defective elements if we merely confined ourselves to the task of segregating the feeble-minded, etc., of the present generation," but he had undertaken the equally pressing task to "protect parenthood against the racial poisons."[100] Saleeby would join Russell in leadership positions for the World League against Alcoholism as a member of the General Council, the Executive Committee and Permanent International Committee, where he served as the representative of England. He was later elected as Chairman, and also toured in this role in New York, Pennsylvania, and Ohio. He called Prohibition "the greatest health measure in history."[101]

As the effective date for Prohibition approached, Saleeby embarked on the Anti-Saloon League speaking tour in support of the coming regime. But the headlines that announced the tour inevitably gave first billing to another more famous prohibition champion. William Jennings Bryan is well remembered for his political career, but is also known today as the opponent of Clarence Darrow in the famous Scopes 1925 "Monkey Trial," which challenged the use of a textbook that taught both evolution and eugenics. Because of that role, Bryan is often portrayed as an opponent of eugenics. Bryan clashed with eugenic popularist Albert Wiggam, and his undelivered "Last Speech" meant for the Scopes trial railed against Wiggam's *New Decalogue of Science*, which praised the "beneficent hand of natural

selection." [102] Bryan's opposition to evolution also prompted a response from eugenic leader Charles Davenport.[103] But the assessment of Bryan as "implacably opposed to Social Darwinism and eugenics,"[104] ignores the distinction between attitudes characterized as "Social Darwinism," a phrase used by philosopher Herbert Spencer and later popularized decades after Bryan,[105] the actual statements of Darwin in books like *Origin of Species* (1859) and *Descent of Man* (1871), and everything else that one might identify with eugenics. In *The Descent of Man* Darwin described some of the attitudes later expressed by many eugenic enthusiasts, arguing against asylums, hospitals and relief for the poor, and seemingly applauding the social benefit of deaths among those suffering from disease or disability. Bryan condemned this recitation of the "cruel law by which the strong kill off the weak," saying, "Can you imagine anything so brutal?"[106]

Bryan's quarrel with Darwinism, by his own account, began during his college years in the 1870s when he "became confused by the different theories of creation,"[107] before Galton's theory of eugenics even had a name. Bryan's rejection of Darwin's theory, even then, was focused on his understanding of natural selection: "The Darwinian theory represents man as reaching his present perfection by the operation of the law of hate—the merciless law by which the strong crowd out and kill off the weak."[108] He disavowed the idea of a dog-eat-dog process of natural selection and was unsettled by many questions about the origins of life that Darwin's theory left unanswered. Bryan eventually committed these conclusions to paper in a famous speech, "The Prince of Peace," which he gave regularly starting in 1904.[109] When Bryan's views on evolution were taking shape, Galton's ideas about eugenics were all but unknown among most Americans. While there are many features of "survival of the fittest," a phrase first used by Spencer, that were echoed by people who embraced eugenics, there were others, like Saleeby, who rejected those implications of "natural selection."[110] It was the "better off dead" faction of eugenists that drew objection from both Bryan and Saleeby.

Bryan made no blanket condemnation of eugenics, and readily allied himself with several other famous eugenists in the liquor fight. While Bryan was collaborating with Saleeby, he was also an officer in the National Dry Federation with eugenics booster and Kansas Senator Arthur Capper, who supplied the bronze "Capper Medal" given to winners of the American Eugenics Society's Fitter Family Contests.[111] Richmond Pearson Hobson was among the first congressmen to support a prohibition amendment. His failed bills in 1911 and 1914 set the stage for the 18th amendment.[112] Hobson also named Saleeby's work as a key to his decision in introducing early prohibition legislation.[113]

The Bryan/Saleeby/Russell tour traveled through Tennessee, then North Carolina. The two main speakers often appeared as part of a coordinated program, where Bryan spoke at one church, and was followed by Saleeby, who had already spoken at a second church nearby. Russell joined them to make a trio.

Bryan's wife, the attorney Mary Baird Bryan, was herself an official in the WCTU. She championed the National Society for the Promotion of Practical Eugenics along with Ellen Axson Wilson, wife of the President, and Antoinette Hughes, wife of Supreme Court Justice Charles Evans Hughes. That organization campaigned for mandatory health certificates and tests for syphilis as part of a eugenic marriage law.[114] Its members quoted the leaders of the eugenics movement, and endorsed immigration restriction, prohibition of marriage among those with disabilities or others "living on charity or receiving state assistance," while applauding sterilization "for the good of the community," and generally supporting measures "to make the stock better."[115] It is highly unlikely that the woman who "managed his correspondence, helped prepare his speeches, edited his articles, and on occasion even negotiated with his fellow politicians," whom he described as "my faithful helpmate"[116] would have publicly endorsed such a breadth of eugenic policies, had Bryan objected.

Bryan's own comments on eugenics were a regular part of stump speeches on the lecture circuit. In 1912

newspapers reported that “Mr. Bryan discussed eugenics for a time during his address,” tracing “some of the faults of men” to “hereditary influences which were hard to overcome.”[117] Later, Bryan, the anti-evolutionist, joined Saleeby, the eugenicist, in fighting for Prohibition, even though Saleeby had publicly endorsed radical reforms like eugenic sterilization.[118] One scholar of the Scopes trial has concluded that “there is no evidence in Bryan’s writings on evolution (or in his available correspondence and papers) to suggest that he was particularly concerned with eugenics.”[119] We also know that attorney Clarence Darrow, Bryan’s opponent in the Scopes case, made arguments in favor of evolution and those arguments were not merely a part of his legal advocacy for Scopes. Darrow felt so strongly about the supporting the teaching of evolution that for the only time in his career, he volunteered his services for the Scopes case.[120] Why would Darrow, who publicly condemned eugenics in published essays such as widely popular “The Eugenics Cult”[121] if he thought it was the same thing as evolution? Darrow embraced evolution while he rejected eugenics. In contrast, Bryan was happy to give public credit to eugenics if it led to Prohibition, but he rejected the monkey-to-man account of evolution and the cruelties he associated with natural selection.

Prohibition and Eugenics: Bryan and Saleeby on the Road

The Bryan/Saleeby/Russell tour traveled through Tennessee, then North Carolina. The two main speakers often appeared as part of a coordinated program, where Bryan spoke at one church, and was followed by Saleeby, who had already spoken at a second church nearby. Russell joined them to make a trio.

Bryan’s leading role was clear. “There was not the least doubt, … but that William Jennings Bryan is looked upon by the Anti-Saloon League Leaders as being possessed with 100 percent views on all prohibition subjects.”[122] Although his profile could not compete with “the great Commoner” and famed orator, Saleeby’s hand in the work of the World League against Alcohol was important, but more subtle. Its constitution, adopted in June 1919, incorporated a eugenic argument that could have been taken from Saleeby’s texts. The League planned

- 1. To educate mankind regarding alcoholism, which is the poisoning of body, germ-plasm, mind, conduct and society, produced by the consumption of alcoholic beverages.

- 2. To secure by legislation the suppression of the manufacture and sale of alcoholic beverages throughout the world.[123]

Bryan, Saleeby, and Russell all came to Washington, DC in September 1920 for a meeting of the World League against Alcohol. Both Bryan and Saleeby appeared several times on the program, and Russell was a member of the National Honorary Committee and an official Delegate to the Congress. Bryan addressed the delegates with stories about the long march of the prohibition movement. “Nearly half a century ago,” he said, “the Woman’s Christian Temperance Union was organized” in Ohio. Approximately twenty-five years later, Ohio also “gave birth to the Anti-Saloon League.” Both groups were “born in prayer,” noted Bryan, as he gave both organizations credit in “winning of this victory” for prohibition. But while he pointed to “conscience” as a critical factor in the campaign, he was quick to add a comment on the role of science. It “has taught us that even a moderate use of intoxicating liquor is harmful … [and] … that the alcohol habit fastened on man or woman does not stop with the one who drinks, but goes on and on, and curses children unborn.” He credited Saleeby directly for this insight:

… we have before us as one of the delegates from Great Britain, perhaps the most distinguished of all the authorities on eugenics, and by the study of this science they’ve learned that little children come into the world with their eyes closed to life’s possibilities before they could have a chance to see the light of day. My friends, I can’t think of anything more terrible than that a father or mother, for the pleasure of drinking, should thus injure their own flesh and blood — those who come into the world at their call.

Later in his address to the conference Bryan again quoted Saleeby, who had repeated during the Temperance tour

a year earlier:

The saloon is not only an evil in itself, but it is the gateway to all other evils; and when we took away alcohol we took away the things that followed in the wake of alcohol; and our boys set an example in cleanliness of life and in freedom from the diseases that are attributable to immorality.[124]

Just as he had praised the WCTU for its eugenic message,[125] Bryan echoed warnings about the eugenic dangers of diseases like syphilis, another of Saleeby's "racial poisons." "Eugenics furnishes us with a strong inducement to restrain against immorality," he said, evoking "the child that is wrecked in the very dawn of its life by the inherited effects of immorality."[126] Bryan did not always agree with the eugenists, particularly when he discussed evolution, and he proclaimed that "scientific breeding as if man were an animal is a false doctrine."[127] But in the battle for Prohibition, the eugenist idea of alcohol as a "racial poison" was one of his most potent weapons.

After Prohibition had been in place for several years, Congressional hearings probed its effectiveness, providing an occasion for others to comment on the messages that had impact in advocating for original passage. A representative of a state constituent group of the WCTU again recounted the work of that organization and its ongoing efforts to enforce the law. She also reminded lawmakers of the role of the WCTU in education during the run-up to the prohibition campaign, and included a reference to Saleeby's key concept — alcohol as racial poison:

The National Woman's Christian Temperance Union is mobilizing a half million women for law observance and law enforcement. This organization laid the foundation for the passage of the eighteenth amendment by teaching in the schools of this Nation the fact that alcohol is a racial poison and educated the present generation which gave to us the eighteenth amendment. We continue to affirm this truth and will also continue this education of our youth.[128]

Yale Professor Irving Fisher, President of the Eugenics Research Association the year that prohibition went into effect, said that it was the "mission of the eugenics movement to discover and set itself against racial poisons" such as alcohol.[129] He also invoked the name of Saleeby in Congressional Hearings: "… prohibition has come in, and the people who have worked for prohibition have done more than all the doctors and all the medicines in the world against the deadliest and most horrible of all diseases."[130]

Another person who testified to Congress also echoed Saleeby's "racial poison" argument, saying:

The advocates of the complete abolition and destruction of the liquor traffic have been persuaded that the eradication of this nefarious industry was the only remedy against alcoholism. The strongest argument for such a contention is that alcohol is a narcotic, a habit-forming drug, and a racial poison which, like lead and syphilis destroys the protoplasm and in that way injures the generations to come.[131]

It is clear that many identified the language of "racial poison" as a eugenic message point and that most credited Saleeby as a key voice that swayed major advocates in advocacy for the prohibition amendment.

Conclusion

After 10 years, prohibition in American proved a social and legal failure. As the momentum built toward repeal, Anti Saloon League advocate Atticus Webb joined Texas Senator Morris Sheppard, author of the Prohibition Amendment, in publishing *Dry America*, a pamphlet distributed to churches and Sunday schools. It was meant to marshal arguments against repeal, and its cover declared Saleeby's message: "alcohol must be branded a racial poison."[132] But while speakers at the International Congress of Eugenics in 1932 continued to condemn alcohol as a racial poison, most eugenic organizations took no position on the momentum that was building for legal repeal of prohibition.[133] They realized that the law did not prevent many people from drinking. New proposals for "gin marriage" laws began to appear[134] that mirrored early attempts to regulate marriage with a eugenic motive. By requiring a 30-day waiting period for marriages, they would prevent risky, drunken, last minute weddings. As the gin marriage laws were adopted in several states over 10 years, proposals also proliferated to push a federal law

regulating marriage.[135] Other eugenicists, ignoring the coming demise of prohibition, attempted to address the degenerate alcoholic with sterilization — a legal remedy that was already available in most states.[136]

After more than 10 years of a “dry” regime in the U.S., in late 1932, Senator John Blaine of Wisconsin submitted a resolution to the Senate that would lead to the repeal of Prohibition. The 21st Amendment to the Constitution reversed the anti-alcohol law on December 5, 1933.

Less than 10 years later, Caleb Saleeby died. Some journalists seemed surprised that a person of such renown left only a very modest estate,[137] and was remembered primarily as the person who advocated for steel helmets for British troops during WWI. Saleeby began his career arguing for prenatal care for pregnant women, and the children they would bear. One eulogist reminded readers that his proudest declaration was: “I am counsel for the unborn.”[138] Yet the obituaries made no mention of Saleeby’s role as a champion of eugenic prohibition or of his famous tour with Bryan, and the term “racial poison” disappeared from the headlines.[139] Bryan’s alliance with the eugenist was forgotten, and his “rejection of modern biology” was erroneously equated with hostility to eugenics.[140] As the history of Prohibition was written, Saleeby and his crusade against alcohol as the most dangerous racial poison all but vanished.

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Note

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An Inter–professional Antiracist Curriculum Is Paramount to Addressing Racial Health Inequities

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ABSTRACT (ENGLISH)

Legal, medical, and public health professionals have been complicit in creating and maintaining systems that drive health inequities. To ameliorate this, current and future leaders in law, medicine, and public health must learn about racism and its impact along the life course trajectory and how to engage in antiracist practice and health equity work.

FULL TEXT

To fight racism and its inextricable link to health, health care professionals must recognize, name, understand, and talk about racism competently.[1]

Racial disparities in health date beyond our country's founding.[2] Black people fare worse than white people across a range of health outcomes, including birth outcomes, chronic conditions, and mortality.[3] In 2019, Black Americans were expected to live an average of 4.1 years fewer than their white counterparts.[4] Preliminary data show that the COVID-19 pandemic may have widened the disparity to an astonishing 6 years.[5] COVID-19's disparate impact and recent social unrest following police killings of Black people had fueled growing demands for curricula in law, medicine, and public health to critically examine health inequities and teach antiracism.[6]

As law, medical, and public health schools across the country endeavor to create more opportunities to educate about racism and its impacts on health inequities, we share some examples of how Loyola University Chicago students and faculty are utilizing interprofessional and experiential curricular and volunteer opportunities to educate students on the health implications of racism and develop skills to create and sustain antiracist practices.[7] While we acknowledge that racism and discrimination have impacted the health of many racial and ethnic groups demanding attention in our curricula,[8] this article intentionally focuses on racism and its effect on the health of Black people.

In this article, we: (1) acknowledge the complicity of our disciplines in contributing to structural racism and health inequities; (2) outline calls for incorporating antiracist education and interprofessional training into our curricula; (3) share examples from our institution of interprofessional didactic, experiential, and volunteer opportunities in antiracism and health equity; and (4) discuss challenges and opportunities in integrating antiracist and interprofessional training into our curriculum.

Section I: Law, Medicine and Public Health Are Complicit in perpetuating Racism &Health Disparities

Still, the inescapable reality is that law and medicine have been symbiotic actors in creating health disparities since America began, and they remain inextricably linked to any meaningful solution to health inequality.[9]

Our legal, medical, and public health systems have contributed to health disparities by creating and sustaining structural racism. For future professionals to dismantle structural racism and advance health equity, they must know the often-untold racist histories of their professions.

The U.S. legal system has fomented and bolstered systemic racial health inequities since its inception. Its laws enabled "genocide, enslavement, oppression, and 'redlining'… which remain forceful predictors of health and well-being."[10] During the gruesomely inhumane period of enslavement, the law required only the most minimal provision of "food, shelter, and medical care" to enslaved Africans to the extent "necessary to protect [enslavers'] financial investment" in slave labor."[11] The law also permitted the bodies of enslaved people to be exploited and dehumanized

in the name of medicine.

In the 1857 *Dred Scott* case, the U.S. Supreme Court infamously ruled that Black people were unworthy of citizenship[12] and that Black people were "so far inferior, that they had no rights which the white man was bound to respect."[13] The first printed copy of *Dred Scott* included an appendix by Dr. Samuel A. Cartwright,[14] wherein he offered medical opinions that Black people were anatomically, culturally and religiously destined to be inferior.[15] This linked the Supreme Court's ruling to the racist medically adopted principles of the time. Four decades later, the Supreme Court decided *Plessy v. Ferguson*, holding that separate-but-equal policies were constitutionally valid exercises of state police powers.[16] *Plessy*'s validation of "separate-but-equal" laws paved the way for segregated hospital systems, de jure or de facto.[17] These segregated hospital systems were far from equal and resulted in under-resourced hospitals and inferior care for patients served at hospitals designated for Black people.[18] This problem persists. As of June 2021, higher COVID-19 mortality in Black communities was traced to modern-day segregated hospitals.[19]

Laws serve as a determinant of health. Ideally, laws set forth policies that "enable everyone to lead safe, healthy lives."[20] The practice of law shaped the most celebrated 20th century public health achievements in the U.S., such as the control of infectious diseases.[21] Laws pertaining to Medicaid, Medicare and nutrition assistance programs are premised on supporting the health of vulnerable populations.[22] Yet, racially biased laws, policies and practices, in areas, such as housing, employment, and criminality, have underpinned a system of continuous racial health disparities.[23] Moreover, anti-discrimination laws, like Title VI of the Civil Rights Act, provide insufficient ammunition to combat health inequities resulting from biased laws and policies.[24.] Title VI prohibits racial discrimination by institutions that receive "federal financial assistance," like hospitals. Title VI, however, has limited applicability, namely because: (i) it cannot be enforced to address discriminatory practices of individual physicians; (ii) it does not address disparities in the quality of care received in hospitals serving majority Black communities and those that predominantly serve white patients; and (iii) a 2001 U.S. Supreme Court ruling barred private Title VI lawsuits challenging practices having only disparate impact."[25]

The field of medicine similarly contributed to health inequities. Physicians actively supported the slave trade by opining on the health and strength of enslaved Africans at auctions and by enabling medical neglect, mistreatment, and torture by withholding treatment and failing to meet the basic human needs of enslaved people.[26]

Physicians also tortured and experimented on Black people, without consent, to develop new medical procedures. Notably, J. Marion Sims, hailed as "the father of obstetrics and gynecology," practiced gynecological surgical procedures on enslaved Black women without anesthetics and forced them to hold each other down for repeated experimentation.[27]

There are many other examples of medical abuse of Black people and their bodies without informed consent. In her book "Medical Apartheid," Harriet A. Washington detailed the 1961 account of a surgeon performing an unconsented hysterectomy on civil rights trailblazer Fannie Lou Hamer, after she went to the hospital to have only a (likely benign) fibroid tumor removed.[28] This occurred a mere sixty years ago. At the time, the instances of Black women being forcibly sterilized "to reduce the Black population, was so widespread it was dubbed a 'Mississippi appendectomy.'"[29]

Ideally, laws set forth policies that "enable everyone to lead safe, healthy lives." The practice of law shaped the most celebrated 20th century public health achievements in the U.S., such as the control of infectious diseases. Laws pertaining to Medicaid, Medicare and nutrition assistance programs are premised on supporting the health of vulnerable populations. Yet, racially biased laws, policies and practices, in areas, such as housing, employment, and criminality, have underpinned a system of continuous racial health disparities. Moreover, anti-discrimination laws, like Title VI of the Civil Rights Act, provide insufficient ammunition to combat health inequities resulting from biased laws and policies.

From the early development of medical science through the 20th century, physicians promoted notions of biological inferiority and 'physical peculiarities' of Black people.[30] Such 'peculiarities' included thicker skulls, less sensitive nervous systems, and diseases inherent in dark skin."[31] In 2016, a study reported that 50% of medical students and residents surveyed held false beliefs about biological differences in how Black and white people experience pain.[32]

The authors reflected, “[i]t demonstrates that beliefs about biological differences between blacks and whites —beliefs dating back to slavery —are associated with the perception that black people feel less pain than do white people and with inadequate treatment recommendations for black patients’ pain.”[33] These misperceptions and biases negatively impact equitable access to medical care and health outcomes today.

Public health has a relatively recent history of examining the deleterious effects of social determinants and racism on health, advocating for elimination of racial disparities in health, and working toward health equity. However, it, too, is implicated in racist actions resulting in long-term negative consequences. Perhaps most notably was the Tuskegee experiment developed by the U.S. Public Health Service (USPHS) in 1932 in Macon County, Alabama.[34] The study was designed to record the natural history of syphilis in Black men, but participants were told that they would be treated for “bad blood.” A total of 600 Black men (399 with syphilis) were lured with the promise of free medical and survivor’s insurance. Although penicillin became the standard treatment for syphilis and widely available in the 1950s, the medicine was withheld from the men without their knowledge or consent. The study continued until 1972 when the national press revealed its existence to the general public. By then, 128 participants had died of syphilis or from related complications, 40 spouses were diagnosed with syphilis, and 19 children were infected at birth.[35] In 1997, President Clinton finally issued a formal apology to the survivors and descendants of the Tuskegee experiment.[36]

The lingering harms of the Tuskegee experiment, coupled with medical racism and social mistreatment of Black people, has facilitated racial inequities in health[37] and a deep mistrust of public health officials, doctors, and vaccines including vaccines for COVID-19.[38]

Section 2: Curriculum Gaps and Calls for Action

There is a growing call for antiracist curriculum requirements in law, medical, and public health schools. As a result, schools have been more intentional in developing antiracist curricula.

Many law schools are working to incorporate antiracist teachings and critical race theory into their curriculum.[39] Currently, antiracist curriculum is not required by the law school accrediting body, the American Bar Association (ABA), however, there are growing demands to rectify this. In July 2020, 150 law school deans asked the ABA to “require, or at least consider requiring, that every law school provide training and education around bias, cultural competence, and antiracism.”[40] Additionally, the Society for American Law Teachers[41] and the Clinical Legal Education Association have also requested changes to the curriculum.[42] In August 2021, the ABA’s Standards Committee approved recommendations to change law school accreditation standards to require antiracism and bias training.[43]

Similarly, students, scholars, and medical school faculty and staff are asking to include antiracist and health equity curriculum in medical education. In early 2021, the Association of American Medical Colleges called on medical schools to immediately embark on addressing their institutions’ educational curricula and policies to end racism in medical education.[44] There have also been demands for the inclusion of antiracist training in medical schools from students, scholars, and medical school faculty and staff.[45] Some schools have already initiated the process, including the four Massachusetts medical schools: Tufts, Harvard, Boston University, and the University of Massachusetts, in partnership with the state Medical Society and Department of Public Health.[46]

In public health, the accrediting body of public health schools and programs requires foundational knowledge and competencies related to understanding the role of racism in creating and perpetuating health inequities, as well as challenging students to advocate for policies and programs that improve the health of diverse populations.[47] However, schools of public health are working to further incorporate antiracist teaching and competencies related specifically to antiracism.[48] For instance, University of Michigan faculty are developing an online course titled “Health Equity via Antiracist Teaching” to help instructors learn how to implement antiracist principles and practices into their courses.[49] Also, faculty at the University of Washington have developed and implemented their own school-wide competency.[50] These are all promising initiatives and are a step toward our programs and schools becoming antiracist institutions.

Section 3: Opportunities to Educate Students on Antiracism and Engage in Health Equity Work

It is critical that educational institutions provide opportunities for law, medicine, and public health students to learn interprofessionally how to collaborate to address racist harms and change future practices through health equity work. Interprofessional collaboration is critical to improving health outcomes and addressing structural racism.[51] In this section, we share examples from Loyola University Chicago faculty and student efforts to engage in antiracist learning and practice.

A. Health Justice Lab: Race and Health Equity Course

In Spring 2021, Loyola faculty introduced a new course called Health Justice Lab: Race and Health Equity. This interprofessional three-credit course grappled with the relationship between racism, law, medicine, and public health. Students studied how structural racism manifests itself in the practices of medicine and public health, all with the imprimatur of the legal system —perpetuating centuries of health inequities for Black populations.

Ten JD students and ten MD/MPH and MPH students enrolled in the class taught by faculty of law and public health and an interprofessional and diverse panel of guest speakers and community partners. Students were led through discussions, case studies, community outreach, and advocacy work to understand the impact of racism on health and to address health inequities. Topics included medical experimentation on Black people, environmental justice, maternal mortality disparities, epigenetics, and the health impacts of inequities in policing and education. Other course materials included a mix of readings, podcasts, films, TED Talks, webinars, and articles from local and national sources with an intentional focus on Black authors and scholars.

One component of the course was a community-focused health equity advocacy project. Students were divided into interprofessional teams and partnered with a community leader to address issues impacting the community such as water affordability, youth suicide, COVID-19 vaccine access, and contaminated soil concerns. These projects allowed students to hone their advocacy skills, practice community-based work, and address health equity issues identified by community partners.

One student who reflected on the course said, “This has been the first class I have ever taken where we actually learned about the intricacies of health and racism which [go] deeper than many people may initially think.” Another remarked, “This course has shown how systemic racism in our healthcare system harms at every level …I gained a deeper understanding of how the U.S. healthcare system was not built with every person in mind, rather it was built on a foundation of racism and meant to continue to perpetuate inequalities.” Yet another said, “I studied history in college, but still I didn’t know 1/50 of what I learned in this course.”

B. Engaging Students in Health Equity and Antiracism Work

While a dedicated interprofessional course focused on antiracism and health equity is a critically important tool for educating future health practitioners, there are other methods of engaging students in healthy equity work through volunteer, student-led advocacy, and clinical experiences. Here are some examples of such opportunities offered at our institution.

i.cercl

The COVID Equity Response Collaborative Loyola (CERCL) is a team of public health, medicine, nursing, law, and social work students and professionals working in partnership with community leaders and public health officials to minimize the negative impact from COVID-19 in Black and Latinx communities in Chicago’s near western suburbs. CERCL, founded in April 2020, works to increase testing and vaccine access, support contact tracing efforts, provide social and legal support, and offer opportunities to engage in research.[52]

This interprofessional collaborative has been driven by the ~100 students who have volunteered or interned with CERCL. As of late summer 2021, the collaborative has provided free COVID-19 testing to more than 1,200 residents, trained more than 65 individuals on contact tracing, screened ~800 residents on their social and legal needs, and facilitated vaccination for more than 200 residents.

ii.health justice project clinic

Medical legal partnership (MLP) clinics like Loyola’s Chicago’s Health Justice Project (HJP) offer opportunities for direct advocacy to address racism as a social determinant of health. As articulated by MLP scholar Medha Makhlouf, MLPs can address racism by educating health care providers and students on inequitable power formations,

providing opportunities to evaluate patient/client experiences through a lens of understanding how race, racism, and systems of oppression have impacted the client, fostering the identification of oppressive policies and practices, and providing opportunities for multidisciplinary approaches to understanding health disparities.[53]

The HJP offers law, medical, public health, and social work students an opportunity to serve vulnerable, predominantly Black and Latinx, patients in collaboration with health providers by addressing health harming legal needs and engaging in upstream policy advocacy. The HJP's corresponding seminar courses and provider trainings address racism and health equity, cultural sensitivity, trauma-informed practice, and upstream practice, all with intentional content related to racism as a structural and social determinant of health. Acknowledgement of the impact of race and racism is built into analysis of individual client cases and advocacy at the systemic level, offering students an opportunity to put their knowledge into practice.

iii.white coats for black lives

Students at Loyola Chicago's Stritch School of Medicine (SSOM) founded a White Coats for Black Lives (WC4BL) chapter of the national WC4BL student-led organization, following the national outcry for justice following the murder of George Floyd in Minneapolis, MN, on May 25, 2020.[54] The WC4BL Chapter at Loyola aims to eliminate racism in the practice of medicine, foster crucial conversations aimed at recognizing that racism is a public health crisis, and prepare future physicians to treat all patients with equal dignity and respect.[55] Since its founding, WC4BL SSOM has engaged in student and university education and critical advocacy work.

In July 2020, Mercy Hospital and Medical Center located in Chicago's Southside, was on the verge of becoming yet another closed safety net hospital thereby causing detrimental access effects on marginalized populations.[56] WC4BL joined with Chicago Health Equity Coalition and the Kenwood Oakland Community Organization to protest the closure, joining other Chicago area physicians, advocates, residents and medical students by attending rallies, press conferences, calling the Governor and Mayor and testifying at The Illinois Health Facilities and Services Review Board hearings. In March 2021, the Illinois HFSRB approved the sale of Mercy Hospital for $1 to Insight Chicago, an Illinois not-for-profit.[57]

Section 4: Challenges and Opportunities

The momentum around calls to incorporate antiracist, anti-bias, and health equity curricula into medical, law, and public health programs has created opportunities for programs to include competencies, learning objectives, course offerings, and experiential opportunities for students. Given the historical complicity of the law, medicine, and public health in creating health inequities, these programs have a unique opportunity to work collaboratively to develop these curricular offerings. Creation of these programs and offerings present opportunities and challenges.

The COVID-19 pandemic and shift to online learning for graduate students allows broader opportunities to develop interprofessional curricular offerings online, which can bridge geographic and programmatic barriers. For example, Loyola Chicago's health sciences campus is located 45 minutes from its law school. Further, mainstreaming online learning platforms facilitated the creation of the Health Justice Lab course, allowing online public health and MD/MPH students to participate with law students who would otherwise have been attending in person courses miles away.

There are, however, challenges to creating interprofessional course offerings, including the need to navigate variations in curricular offerings (i.e., medical and public health curricula must include interprofessional offerings while law schools have no such mandate), varying space for elective course offerings for students, different academic calendars, resource issues related to assigning faculty across multiple programs. The key to overcoming these logistical challenges was flexibility. For the Health Justice Lab course, we worked around conflicting semester start and end dates and divergent spring breaks. Use of asynchronous activities allowed us to accommodate conflicting schedules and delivering the course in the evenings allowed public health students, many of whom work full time, to enroll. Listing two separate courses in the law school and the school of public health also assisted with administrative challenges, including faculty courseload assignments and variable tuition costs.

There are also challenges in developing course offerings and materials on antiracism and health equity. Some faculty may feel ill equipped, as integrating it requires buy-in, time (to develop material, learn and engage

communities), and commitment at all levels. Loyola University Chicago has offered training to assist faculty in developing these skills and has created faculty positions to assist in developing antiracism and critical race theory curriculum. Other associations, such as the Society of American Law Teachers and the American Association of Law Schools, have also offered training and support to faculty seeking to transform their teaching. This institutional and association aide is critical to supporting faculty in integrating antiracism content throughout the curriculum. There also may be backlash against faculty and courses that cover racism, bias, and antiracism. For instance, courses that address privilege and racism, generally, are rated more negatively by students.[58] There has also been significant backlash against efforts to incorporate critical race theory ("CRT") into curricula. Since 2020, lawmakers in several states have prepared bills targeting CRT and seeking to ban any teaching that connects the U.S. to its racist past.[59] Those against CRT "have begun using it as a catch-all term to refer to… teaching about racism or LGBTQ-inclusive policies."[60] As of June 2021, dozens of federal and state bills have been proposed to ban teaching on racism and inequity.[61] Though discouraging, these efforts may provide opportunities for solidarity and advocacy among faculty and students.

Conclusion

Our professions are compelled to teach about the intersection of racism and health and to provide antiracist and health equity advocacy tools to our students. These professions have perpetuated structural racism and continue to be complicit in creating and maintaining systems and structures that result in extreme health inequities. Lawyers engaged in health law practice, physicians, and public health professionals should therefore work to combat racism by employing antiracism tools in their professions to transform systems and reduce health disparities. We should provide tools to our students to understand clients, patients, and communities in the context of racism. There are a number of models of courses and activities, clinical, experiential and student volunteer and organizational activities that can further these goals. Our communities, our students, our patients, our clients, and our colleagues are rightfully demanding this. It is long overdue.

Note

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DETAILS

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FOREWORD The American Society of Law, Medicine &Ethics and Anti-Racism

Hutchinson, Ted

ABSTRACT (ENGLISH)

This foreword explores the history of the American Society of Law, Medicine &Ethics and its role in promoting access to care and antiracism.

FULL TEXT

The parent organization of the *Journal of Law, Medicine &Ethics*, The American Society of Law, Medicine &Ethics (ASLME), has long been concerned with health and social justice. From our founding in 1911 as the Massachusetts Society of Examining Physicians to our re-branding in the late 1960s as the Massachusetts Society of Law &Medicine (which was subsequently and almost immediately changed to the American Society of Law &Medicine), our founders have written about and explored issues around access-to-care.

In 1992, the Society's educational mission was formally detailed and disseminated for the first time, with a focus on racial and economic Health Disparities as one of four key areas of study, in addition to Public Health, Patient Safety,

and Biomedical Science and Research. That mission plainly states that

Racial, ethnic, and economic disparities in health status and access to health care represent areas of enormous concern that justify an ongoing an intensive organizational focus for ASLME. Through research, meetings, and publications, ASLME aims to encourage a continuing examination of the factors that underlie disparities, the extent to which the organization and structure of the health care system itself contributes to disparities, and the proper role of law, public policy, and government in reducing health disparities.[1]

More recently, ASLME's Board of Directors embarked on several new anti-racism initiatives. First, beginning in 2021, ASLME committed to organizing a health law and anti-racism track at our flagship annual Health Law Professors conference, with plans to continue this track each year. Our 2021 conference, hosted online by our friends at Northeastern University School of Law, due to COVID-19, featured a successful rollout of the anti-racism track. We hope to see this track go live, along with the rest of our conference, in 2022 and beyond.

Second, ASLME launched a new graduate student writing competition focused on issues at the intersection of health law and anti-racism to support emerging scholars in any field interested in engaging in this work. The winner of the inaugural edition of this writing competition was Duquesne University School of Law student Gabrielle M. Kolencik. Her terrific article appears in this issue.[2]

In the third tier of our initiatives, ASLME also plans to enhance scholarly discourse by creating both an Expanding Perspectives Column in *JLME* and an Expanding Perspectives Fellowship, designed to expand awareness of how specific issues related to law, medicine, and ethics impact individuals with a diverse set of backgrounds and experiences. The Expanding Perspectives Column and Fellowship are planned to launch in 2022.

Finally, in addition to these initiatives, ASLME and our partners at the University of Pennsylvania Law School, University of Pennsylvania Perelman School of Medicine —Department of Medical Ethics and Health Policy, and the University of California Irvine School of Law all supported this special issue of the *Journal of Law, Medicine &Ethics*, as well as a public conference at Penn, to continue the conversation. We thank all of the contributors to this special issue, all of the attendees and speakers at the conference, and especially our great friends Michele Goodwin and Holly Fernandez Lynch for guest-editing this issue, for co-hosting the conference, and for inspiring us all with the work we do.

Everyone at the *Journal* is grateful and proud to publish such an import issue on the occasion of our fiftieth anniversary. We thank all of you, our members and readers, for loyally standing by us all these many years. We hope you enjoy this very special collection of papers.

Note

The author does not have any conflicts of interest to disclose.

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An Antiracist Health Equity Agenda for Education

González, Thalia; Etow, Alexis; De La Vega, Cesar

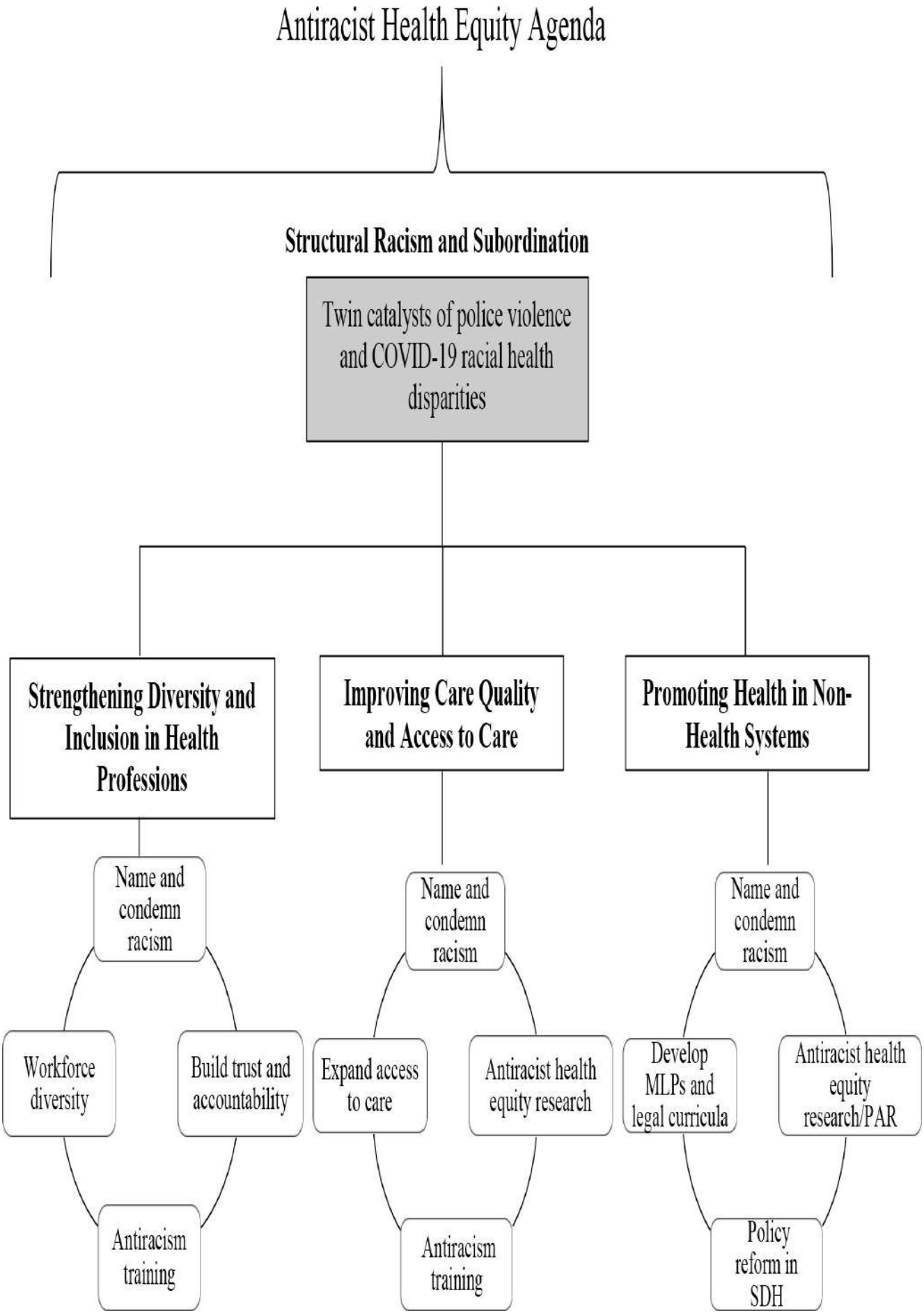
ABSTRACT (ENGLISH)

With growing public health and health equity challenges brought to the forefront — following racialized health inequities resulting from COVID-19 and a national reckoning around the deaths of unarmed Black victims at the hands of police — an antiracist health equity agenda has emerged naming racism a public health crisis.

FULL TEXT

Antiracism and Public Health

Research and policy advocacy has increasingly elevated the negative influence of structural discrimination (e.g., racism, sexism, classism, ableism) on health. While not new discourse,[1] national protests against police killings and violence against Black people, coupled with stark health disparities of COVID-19 in BIPOC communities,[2] have generated intense scrutiny of racism —as the most significant operant force of structural discrimination —and its invidious influence within all U.S. institutions and systems.[3] From this confluence of social, political, legal, and public health contexts a broad movement has emerged that we name an *antiracist health equity agenda*. The agenda is multi-pronged, cross-sectoral, and transdisciplinary and marked by an overarching aim to: (1) identify and elevate racism as a fundamental driver of health inequities; (2) engage in antiracist reform of health determinant institutions and systems; and (3) eliminate racial health disparities (Figure 1). As an agenda rooted in an antiracist health equity vision, it is both evolving and grounded in prior critical race-conscious work.[4]



Enlarge this image.

As Figure 1 illustrates, the agenda assumes a wide variety of forms and targets a range of health-impacting systems and actors. A systematic landscape analysis of medical, public health, and legal literature reveals key areas of focus

across several lines: equity-focused and antiracist training in health and related professions; research (e.g., methodologies and designs promoting and embodying racial equity); access to care and care quality; and workforce diversity in health professions. At the forefront of the agenda is a solutions-driven orientation that centralizes racial equity across the social determinants of health.

However, the agenda is not limited to academic attention and action. It is also reflected in a broader public discourse and movement inclusive of policy statements and declarations, issue briefs, toolkits, opinion pieces, and action plans at community, county, and state-levels by stakeholders from frontline impacted communities, and health and legal organizations across the country. Within the public sphere of the agenda, a central element includes formal declarations that racism a public health crisis. Since 2017, the American Public Health Association has cataloged more than two hundred resolutions with a significant surge occurring in 2020.[5] These declarations serve a key first step as they not only acknowledge the relationship between racism and health but, as importantly, establish a governmental duty to dismantle racist systems.[6] Additionally, they function to engage new stakeholders in public dialogues on the necessity to define and respond to racism as a public health crisis.

Confronting Racism in Discipline and Policing as a Public Health Imperative

Despite more rigorous attention on the centrality of racism to the field of public health, there has been little to no focus on school policies and practices deeply rooted in structural discrimination, and more specifically racism as drivers of health disparities. This article aims to alter this pathway and urges the public health community to take action as part of holistic race-conscious approaches to health equity and address the long-standing disparities in school disciplinary actions. The time has come for public health and health law professionals to join with frontline communities and civil rights and educational justice advocates working to reduce health risks for BIPOC students.

The social control and subordination of Black people vis-à-vis education is not a new phenomenon. Historical evidence is clear that schools regularly employed violent policing and discipline rooted in racism and anti-Blackness.[7] Laws and policies at the federal, state, and school district levels —grounded in structural discrimination —have operated for decades to formalize the legacy of racism through discipline and policing practices.[8] For example, in the 1960s in response to desegregation, local and state-level policies and laws gave teachers, administrators, and law enforcement authority to identify students as “pre-delinquent,” giving rise to the contemporary school-to-prison pipeline.[9] The disproportionate impact of these laws and policies was, and continues to be, felt most significantly by BIPOC students.

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Inequities across race and gender in discipline and policing have been the subject of research by academics and advocates for decades. And contemporary data affirms the persistence of the disparate use of discipline and policing against BIPOC students. When compared to their white peers, longitudinal data is clear that BIPOC students are punished and policed at higher rates than their white classmates. For example, in 2016, the Department of Education Office for Civil Rights found that Black preschoolers are 3.6 times as likely to receive 1 or more out-of-school suspension as their white peers.[10] In 2020, analysis of U.S. Department of Education data revealed an upward trend in discipline disparities for Black girls across all categories, who have the highest rate of overrepresentation compared to white youth of any other race and gender group.[11] The downstream consequences of racialized and gendered discipline are far-reaching and include school pushout and entry into the criminal justice system.

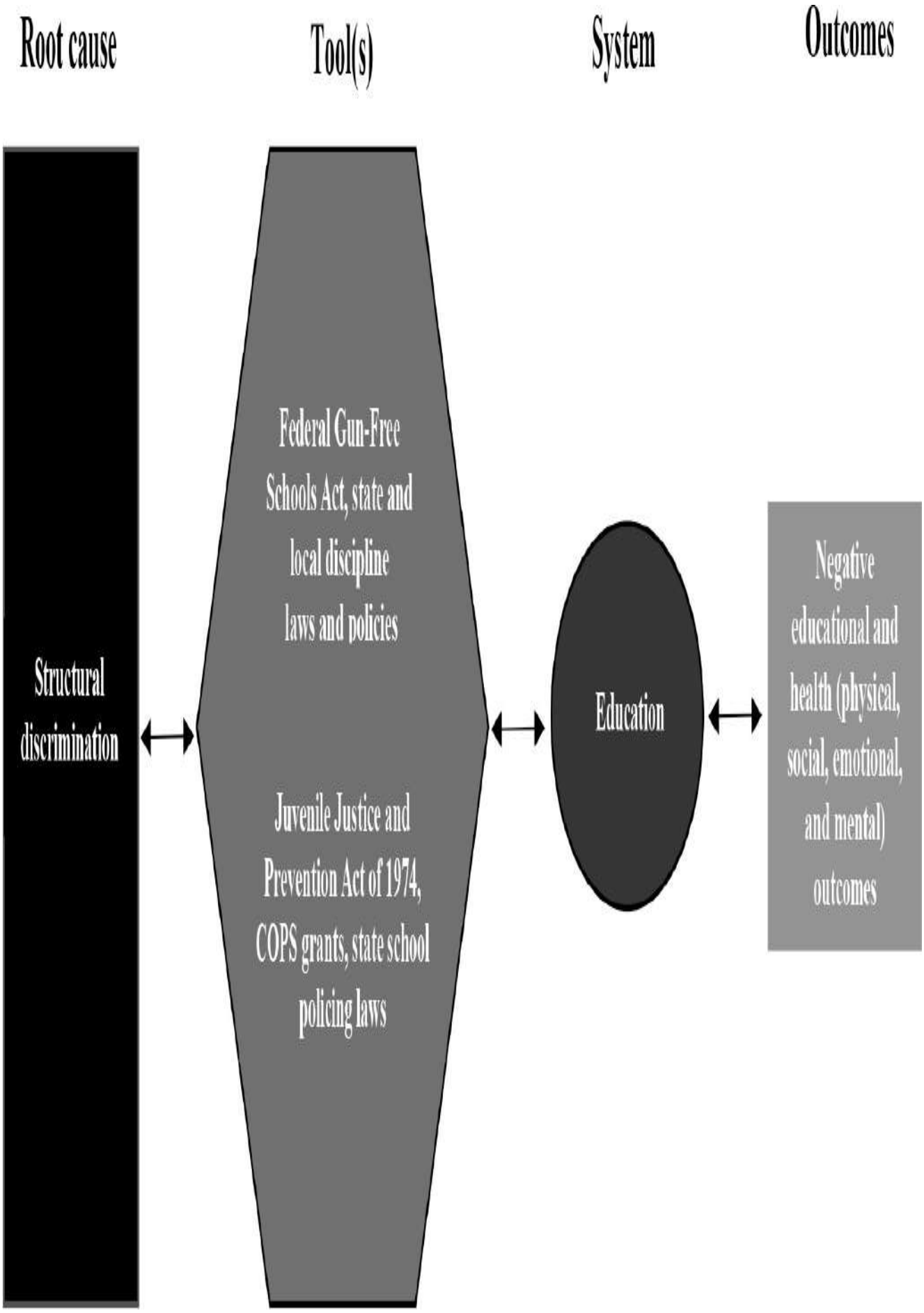
The Relevance of Education Policies to Public Health

The co-influential nature of health and education —education creates opportunities for better health and poor health puts educational attainment at risk —is well accepted.[12] As a significant social determinant of health (SDH)

education functions as a strong predictor of both positive and negative health outcomes at individual- and community-levels including disease, disability, mental health, substance abuse, morbidity, and mortality.[13] By age 25 individuals with a high school degree can expect to live over 10 years longer than those without one.[14] One additional year of schooling is associated with 6.85 percentage points (pp) reduction in poor health and 3.8 pp and 4.6 pp reduction in difficulty completing activities of daily living (i.e., bathing, dressing, eating, getting in and out of bed, and walking across a room) and instrumental activities of daily living (i.e., making meals, shopping, making phone calls, taking medications, and managing money), respectively.[15] Research affirms that education is a predictor of social and economic stability, community wellbeing, and risk for incarceration.[16] The relationship between school environments and health also includes protective health factors, such as school connectedness, peer connectedness, and positive school climate. Individually, and as importantly cumulatively, each of these factors serve to diminish risks of health-harming behaviors for youth (e.g., early sexual initiation, drug use, emotional distress, suicide ideation and attempts, and violence).[17]

Positioning Discipline and Policing in the Antiracist Health Equity Agenda

To illustrate the centrality of discipline and policing within the antiracist health equity agenda, we apply the revised SDH framework developed by public health law scholar Ruqaiijah Yearby.[18] By mapping discipline and policing onto the revised SDH framework, the urgency for an antiracist health response within education becomes evident (Figure 2).



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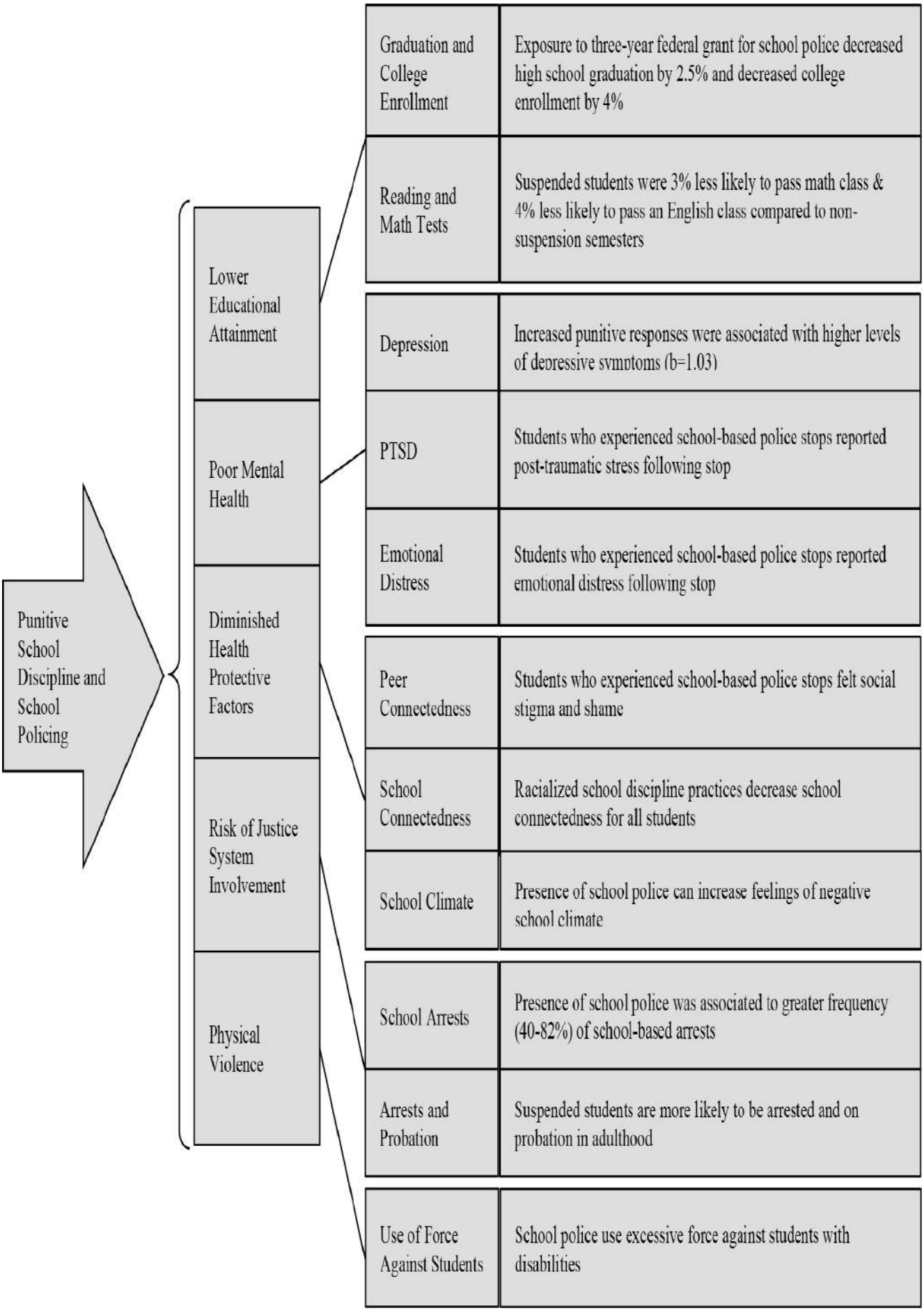
As Figure 2 illustrates, there are several reasons that education policies and practices must be interrogated through a race-conscious framework. First, racism is the foundation of punitive and zero tolerance laws and policies.

Second, discipline and policing are experienced in a disparate manner when comparing peer groups. Third, these policies and practices operate at multiple independent and overlapping levels of influence *within* schools and are reinforced by discrimination *outside* of schools. And fourth, discipline and policing directly impacts the health status of BIPOC students across multiple domains and produces a downstream risk for entry into health-harming systems (Figure 3).



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Given the lack of data, a challenge exists to understanding the short- and long-term effects of discipline and policing on individual or population health outcomes in BIPOC communities. We hypothesize that their impacts are likely

farther reaching than just students who have experienced these health-harming practices. They may, for example, create unknown levels of emotional and psychological stress on peers, families, and communities. Further, it is significant that the potential proximate health effects of discipline and policing does not occur in isolation from contemporary and historic social contexts —all of which are grounded in ideologies, norms, and structures of subordination and racism. School-based practices and policies exist against and within community conditions with disproportionately high levels of stress,[21] complex trauma,[22] and adverse childhood experiences,[23] all of which negatively influence health. For BIPOC students who are exposed to community violence, especially at the hands of police, such experiences can amplify the cumulative influences of early-life adversities on their physical and mental health in adulthood.[24] As a result, the health consequences of discipline and policing may operate to compound pre-existing health disparities for BIPOC students whose experience with racism[25] outside school is also coupled with disproportionality of harms associated with COVID-19.[26] This is a dangerous potential dose-response effect.

Roadmap for Action

The overlooked and understudied health impacts of discipline and policing offer key points of intervention for public health professionals, researchers, and students committed to race-conscious approaches to achieving health justice. Below we offer initial steps for action, focusing on three key pathways: research, policy and advocacy, and teaching and training. To reform the policies and practices that impact education, we urge reforms centered on prevention, intervention, and health promotion.

Research

There is an emerging body of academic and public discourse beginning to shed light on discipline practices and policing as an urgent matter of public health that drives racial health inequities.[27] Yet, as discussed above, there exists a research gap examining the range of pervasive and persistent health inequities stemming from racialized educational practices and policies. There is also a limited body of scholarship exploring the health associations between school-based interventions, including restorative justice practices and trauma-informed approaches. These omissions from the evidence base provides an ideal opportunity for public health researchers and practitioners, utilizing methodologies such as legal epidemiology and community-based participatory research,[28] to extend the antiracist health equity agenda to an overlooked population: BIPOC students.

Advocacy and Policy Reform

Health law professionals can also provide decision-makers with critical insights into how laws and policies shape social determinant systems and drive health inequities while centering the voices of those most impacted by health-harming systems. For example, they are well positioned to expand the antiracist health equity agenda through policy reports, legislative analyses, and law review articles —all aimed at dismantling the deeply-rooted disciplinary inequities experienced by BIPOC students. Additionally, they can leverage institutional and philanthropic resources to hold symposia and roundtables centering community expertise. Further, there is much-needed attention to state law reform. Analysis of the current legal scheme of health-harming laws (e.g., punitive school discipline)[29] and health-promoting laws (e.g., school-based restorative justice, social and emotional learning, trauma-informed approaches, and mental health supports and services) reveals significant inconsistency.[30] Yet another opportunity is examining actionable ways to operationalize the over 200 declarations issued to date declaring racism a public health crisis. Despite evidence of the intrinsic links between education and health, less than ten of such declarations address racism in education, and more specifically racialized disparities in education policies and practices.[31]

An additional pathway for action lies in developing public health responses to community-based demands for dismantling the school-to-prison pipeline, including school police reform, with opportunities for development and implementation of systemic reviews, analysis of phase out plans, and recommendations for budget reallocations.[32] Moreover, public health and medical communities (including local health departments), well-versed in the negative impacts of racism and childhood trauma on healthy development, have an important role to play as critical partners in expanding school-based policies and providing guidance on COVID-19 school operating plans with specific attention to the physical, social, and emotional needs of staff, students, and families.

Training the Next Generation

Coupled with direct systemic reforms, faculty within public health programs and law schools are well situated to train and educate the next generation of antiracist health equity leaders. One such model is medical-legal partnerships (MLPs).[33] In addition to providing on-the-ground training for the next generation of health law leaders, MLPs fill a critical gap by facilitating multidisciplinary partnerships to holistically support marginalized youth and their families. Though presently overlooked in the context of discipline and policing, MLPs provide a key avenue for addressing the health harms of these racialized policies through direct services (e.g., legal assistance and social support), research (e.g., health effects of discipline or policing), and policy reform (e.g., legislative testimony and drafting model codes). There is also an opportunity for interdisciplinary collaboration across education, medicine, civil rights, and Critical Race Theory to create courses and curriculum specific to education laws and policies as well as advance new training in legal epidemiology, Antiracist Health Praxis, and other methodologies.

Conclusion

This article aims to serve as a catalyst and roadmap for cross-disciplinary collaborations and commitments to generate new evidence on the relationship between education policies and differential health outcomes, craft new legal responses to racism in education, and train the future generation of scholars, advocates, and practitioners. As BIPOC students continue to face steep health, mental health, and structural challenges amidst the ongoing COVID-19 pandemic, the work of antiracist health equity approaches in education are vital. Within the movement to disrupt the pathways that lead to racial health inequities, ending discriminatory discipline and school-based policing policies is a concrete, and fundamental, next step. As public health professionals, we have an opportunity —and responsibility —to uproot and redress racialized policies that have long-harmed our most important asset: our children.

Note

The authors have no conflicts to disclose.

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Attorneys as Healthcare Advocates: The Argument for Attorney-Prepared Advance Healthcare Directives

Orsatti, Grace W

ABSTRACT (ENGLISH)

Attorneys regularly prepare advance healthcare directives for their clients. However, attorneys, lacking medical knowledge, are often considered ill-equipped to prepare such documents. While recognizing and respecting the fact that advance healthcare directives pertain to decisions about medical care, this article proposes that attorneys who prepare advance healthcare directives nevertheless provide a valuable service.

FULL TEXT

I. Introduction

Advance healthcare planning documents allow individuals to preemptively make and record end-of-life healthcare decisions. Frequently, such advance care planning documents are prepared not by doctors but by attorneys.[1] In fact, individuals may be more likely to discuss their end-of-life healthcare plans with an attorney than with a physician.[2] Critics, however, object to attorney-prepared advance directives, arguing that they are a service "which only a clinician can provide."[3] This article will address how attorneys who provide advance healthcare planning services can and do provide value to their clients.

Critics of attorney-prepared advance healthcare documents argue that "[s]oliciting the advice of a lawyer to complete what is fundamentally a medical directive is like getting advice from your doctor about completing your taxes," on grounds that attorneys lack the medical knowledge to properly complete such documents and therefore may fail to properly reflect the client's end-of-life healthcare preferences and needs.[4] However, clinician-prepared advance directives receive similar criticism for failing to accurately predict future patient needs and ensure that patients receive desired healthcare treatment at the end-of-life.[5] Advance healthcare directives are inherently speculative in nature. Whether prepared by an attorney or a physician, such documents attempt to plan for an uncertain future and may not accurately reflect the client's desires or be suited to the client's specific medical circumstances when relied upon. Specific treatments selected in the document may ultimately be incompatible with each other, unavailable, or medically impossible to follow.[6] Moreover, clinicians may disregard such instructions entirely in the face of family objections, or the patient's end-of-life healthcare instructions may not be adequately entered into the patient's medical record.[7]

Nevertheless, some form of advance healthcare planning continues to be viewed as valuable. Such planning provides an opportunity for patients and families to reflect on their values and goals, before a medical crisis. Patients who engage in such planning report greater satisfaction with their care and it may improve the relationship between the patient and their family at the end-of-life.[8] Moreover, where advance care planning occurs, surrogate decisionmakers as well as clinicians report a decrease in distress when making end-of-life healthcare decisions for the incapacitated principal.[9] Attorneys can help to inform and engage the public in end life healthcare preparation, and increase accessibility to advance healthcare planning, providing a valuable service to their communities

II. The Value of Attorney-Facilitated Advance Healthcare Planning

Various planning methods exist to prepare for end-of-life healthcare. However, advance care planning of the type often ascribed to attorneys is of a type that emphasizes the completion of documents and forms. This has been disparaged as a "legal approach" that is "disappointingly ineffective in improving the care people near the end-of-life receive and in ensuring that this care accords with their informed preferences."[10] Despite such shortcomings, however, attorneys who prepare advance healthcare directives can and do provide value to the clients whom they serve by: (a) assisting the client in selecting the healthcare agent best suited to the task of promoting the client's wishes; (b) ensuring that the client shares and discusses their wishes with their agent, family, and physician, to

increase the likelihood of the clients end of life wishes being followed; and (c) ensuring that advance care planning documents comply with applicable law to protect clients against the possibility of the documents being ineffective when needed most.

Attorneys are well suited for the task of helping the client select the best agent to advocate for and protect the client's interests. Selection of an effective agent requires consideration of multiple factors including the availability and reliability of the agent. In addition, the agent must be able to understand medical information provided, and act upon that knowledge accordingly. The agent must be able to communicate with the client's medical team and family members, and manage the emotional toll that comes with making medical decisions for a loved one. Selecting the right agent requires a careful balancing and weighing of the client's interpersonal relationships and family dynamics.

A. The Value of Attorney-Facilitated Advance Healthcare Planning: Selection of the Healthcare Agent

Even those who challenge the utility of written advance healthcare directive forms acknowledge the critical importance of selecting a healthcare agent and documenting that agent choice in a written advance directive.[11] Advance directives in which the patient selects an agent help clinicians to clearly and easily identify the person responsible for making decisions for an incapacitated patient. A clearly identified agent with decision-making power can adapt to changing medical circumstances, and reevaluate decisions depending on the patient's condition as the patient's medical needs change.[12] Moreover, the appointment of an agent can curtail arguments and power struggles among family members in a time of crisis by making clear who holds decision-making authority. Indeed, at least one court has admonished attorneys to ensure that their clients select "a responsible and trustworthy individual to serve as an agent" noting "an all-too-familiar scenario playing out in guardianship courts, as disgruntled siblings are challenging with greater and greater frequency advance directives on the basis of an alleged breach of fiduciary duty on the part of the family member designated as attorney-in-fact."[13]

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Attorneys routinely dedicate hours to each individual client, through exhaustive conversations and detailed inquiries that yield such information about the patient's particular relationships and socio-economic circumstances.[14] Clinicians, however, may not have the time to dedicate to such in-depth inquiry of each individual patient's life circumstances to help the patient identify the most appropriate healthcare agent. Yet as a standard practice, attorneys, particularly those providing estate planning services, who regularly draft advance healthcare directives, necessarily obtain from their clients detailed information about family relationships and family structure before preparing any estate documents. The conscientious estate planning attorney must delicately inquire, in detail, into the client's personal life to prepare an estate plan distributing the client's assets upon their death. The purpose of such intrusion into the client's personal life is to understand all the dynamics of the family in order to employ the most appropriate estate planning tools whether that be a will, trust documents, or otherwise.

In order to proficiently prepare an estate plan, the attorney learns which family members are trustworthy, dependable, organized, financially responsible, or improvident. The attorney learns where the client's parents and children live, their occupations and lifestyle, and how close or distant they are to the client — geographically and emotionally. Existing or potential family tensions and conflicts are identified. The attorney learns which family members relate well to each other, and who cannot work together, and about the mental and physical wellbeing of the client's family members, including which family members may have special needs or disabilities, or which family members may have drug or gambling addictions that must be accounted for. In reliance on this information, the attorney can prepare special needs trusts or spendthrift trusts, or make decisions about how to preserve a client's eligibility for certain government health benefits, through re-titling or redistribution of the client's assets. Moreover, in addition to the client's family and financial circumstances, the attorney also learns about the client's religious

preferences, as well as precise funeral and burial wishes, down to details such as the name of the funeral home, house of worship, or cemetery in which the client wishes to be laid to rest.

Comprehensive information of this sort is necessary to counsel the client about how to best protect and distribute their assets in an estate plan and to ensure that the client's wishes are honored. Information of this sort is equally important for a client when selecting a healthcare agent who must be ready, able, and available to make crucial healthcare decisions at a critical time. For example, a healthcare agent who lives too far away may be unreachable in a time of medical crisis. An unreliable or indecisive relative, even though that relative may have a close personal relationship with the client, may prove ineffective, unable make decisions when needed. A family member inclined to dispute with others may make it difficult to reach consensus and resolution when end-of-life decisions must be made, leading to the increased possibility of court involvement. Equipped with thorough information about the client and their family at the outset, the attorney is well-placed to help the client identify the healthcare agent best suited to advocate for the client who cannot do so on their own.

B. The Value of Attorney-Facilitated Advance Healthcare Planning: Planning across the Adult Lifespan

Advance healthcare planning is considered most beneficial when it occurs multiple times over the course of the client's life.[15] The Institute of Medicine Report, *Dying in America* advocates for such a "life cycle model" of advance care planning as most effective, given that decisions one makes in early adulthood or good health may differ drastically from decisions made at an older age or in sickness. [16] Under such a "life cycle model", in which individuals engage in advance care planning discussions multiple times over the course of their life, the danger of an outdated advance care planning that is not conducive to the client's evolving circumstances is reduced. Moreover, this "life cycle" approach helps to "normalize" such discussions to "avoid the emotional burden sometimes experienced by patients, families, and loved ones who have not adequately prepared for making end of life care decisions."[17]

Such regular review of end-of-life plans over the client's adulthood already occurs as a standard legal practice among attorneys in the field. It is customary for estate planning attorneys to advise clients to return and update their estate plans upon the occurrence of any significant life event such as marriage or divorce, birth of a child, a medical diagnosis, death of a spouse or other family member, or an out-of-state move. Each of these "milestone" life events can impact the client's end-of-life healthcare choices in addition to their overall estate plan.[18] These life events present an opportunity for the attorney to reconnect with the client and fully revisit the entire estate plan and advance care documents in light of the progress of time and changed circumstances. For example, with respect to clients who move or retire out-of-state, state-specific requirements for witnessing or notarizing may apply, or the death of a spouse may raise questions about which of the client's children will assume the role of healthcare agent(s).[19] The ability of attorneys to encounter clients at these regular life intervals allows for advance healthcare planning to be conducted early and often throughout the stages of adulthood.[20]

C. The Value of Attorney-Facilitated Advance Healthcare Planning: Compliance with Applicable Law

State statutes often impose obligations and restrictions on the healthcare agent's exercise of decision-making authority for an incapacitated patient. The advice and counsel of an informed attorney can be crucial for ensuring that advance directives are compliant with applicable law. For example, in Alaska an agent cannot withhold or withdraw life sustaining procedures unless "clearly expressed" in a writing or, where no writing to the contrary exits, such a decision is in the patient's best interests.[21] In Pennsylvania, the absence of written authorization to withhold or withdraw artificial nutrition and hydration "may be overcome by previously expressed wishes of the principal to the contrary" or if, after consideration of the agent's "values and preferences," the agent concludes the principal clearly would not want such treatment.[22]

The assistance of an attorney to explain such statutory requirements can provide context for the client when emphasizing the importance of clearly expressing their wishes, preferences, and goals to those tasked with making end-of-life healthcare decisions in uncertain or unforeseen circumstances. A well-prepared healthcare agent with knowledge of the client's goals and objectives, is better able to support the client at the end-of-life, and can adapt more readily to the reality of the patient's medical circumstances as they change in a manner that a static advance

directive form alone cannot.[23]

Attorneys are also well-positioned to help the client understand the ramifications of failing to prepare advance directives including, for example, the application of default state surrogacy laws that may apply if the client chooses not to select a healthcare agent. The attorney can clarify the effect of divorce on agent selection, plan for multiple agents, children, or blended families to participate in the end-of-life decisions of an incapacitated parent, and prepare for the unavailability of the agent through selection of alternate agents. Moreover, the attorney can inform the client about the nature of intrusive guardianship proceedings that can occur as a result of intractable end-of-life family disputes, which can cause "embarrassment, hurt and feelings of indignity as well as the loss of power and control over … person or property."[24]

In addition to the foregoing services, the estate planning attorney ensures that the client has the requisite level of capacity to complete advance directive documents, to forestall any legal challenges of that nature. Ensuring that the client has the requisite capacity to complete the advance directive document at the time it is signed, can help to avoid any assertions that the patient lacked the capacity to complete the document, or that the client was the subject of undue influence at the time the document was drafted.[25] Finally, the attorney is also responsible for proper execution of the documents in accordance with state statutory requirements which may require a witness and notary, given that improper execution of advance directive documents risks rendering them invalid.[26]

III. Attorney-Facilitated Advance Healthcare Planning: Potential Areas for Improvement

Although attorneys offer benefits to clients seeking advance healthcare planning, some areas of improvement may exist. Attorneys, for example, must take care not to reduce advance care planning to simply the preparation of written documents without engaging the client in broader goal setting and conversation with family. Rather, taking steps to ensure that the agent and family are informed of the client's plans, and are equipped to act on the client's behalf when needed, protects the client's interests. Training to prepare attorneys to provide effective advance healthcare planning, along with increased collaboration with medical professionals may have the to potential to improve such deficiencies, and enhance advance healthcare planning legal services

A. Overreliance on Written Documents

End-of-life planning conducted by an attorney differs in its objectives, to some degree, when compared to advance care planning conducted by a physician. Both professions seek to ensure quality end-of-life care and surrogate decision making that accords with the patient's medical needs and goals. Attorneys seek also to protect and safeguard their client's legal interests at the end-of-life, reduce the likelihood of family conflict, and avoid the need for guardianship proceedings. For attorneys, the written legal document in the form of an advance directive is viewed as critical to protect those interests.[27]

However, attorney-facilitated advance care planning is criticized for overemphasis on the written document rather than on encouraging clients to explore and discuss end-of-life objectives, and set general goals for end-of-life healthcare treatment.[28] Specifically, the type of attorney-facilitated advance care planning that is criticized consists of a single client meeting which is terminated — in many cases, prematurely — with the execution of the written advance directive document.[29] Once the client's wishes have been memorialized in writing, the advance care planning process is considered complete. The client then leaves with their documents, only to store them in a file cabinet with other legal paperwork until the time of need arrives. No subsequent discussion of the documents occurs between the client and agent, physician, family, or trusted friends. Indeed, they may all be unaware that the advance healthcare directive even exists. They may have no knowledge of their loved one's overall goals, preferences, or motivations, all of which have been ostensibly captured in a cold, static document that lacks the warmth and depth that human interaction and conversation affords.[30]

Moreover, attorney-prepared documents are criticized for overly-complicated language that may be difficult to interpret by the clinician, client, and agent.[31] In addition, advance directives prepared by attorneys who lask medical knowledge, risk devolving into checklists from which the client simply selects from an assortment of treatment preferences. Without consultation with a medical professional to provide context and consideration of what the patient's existing or future health circumstances might warrant, treatment choices selected may be incompatible with

each other and with the patient's needs.[32]

Nevertheless, for attorneys, the written document itself does serve an important purpose. The written advance directive document, when drafted well, provides a physical, portable record that can be referred to in any subsequent dispute. It can "facilitate communication among members of the health care team."[33] It continues to be available when the client becomes unable to make or communicate decisions, and it can provide guidance, reassurance, and support for the difficult decisions the agent and the clinician must make. The written document allows the client to grant an agent the legal authority to make decisions on the patient's behalf. It encapsulates and provides a tangible record which can be referenced in the event of disagreement. It is relied upon in legal proceedings to determine who bears decision making authority for an incapacitated patient.[34] Finally, when drafted in a manner that complies with constitutional requirements and state statutes, the written document can prevent court involvement in the nature of guardianship or conservatorship actions, or other governmental intrusion into healthcare decisions.[35] Yet, written advance directives alone do not comport with evolving advance care planning methodologies which encourage discussion of the client's goals and values with others. Rather, to be most effective, the client must involve family members and others in an ongoing conversation about the client's end-of-life values and preferences.[36]

B. Involving the Healthcare Agent, Family and Others in the Planning Process

End-of-life healthcare planning conducted by attorneys is criticized for involving only the client and for not integrating broader conversations with the agent, family and loved ones.[37] The perception persists that "although most lawyers urge clients to share documents with family and health care providers, few have routine practices designed to assist clients in doing so."[38] Engaging the client's loved ones offers "opportunities to create shared meaning and strengthen relationships."[39] Absent these broader and recurring conversations, attorney-prepared documents on their own may fail to integrate the client's specific medical need and the client's relationships into the overall care plan.

The manner in which attorneys provide advance care planning services is well suited to promote family involvement and discussions with loved ones, as standard practice. Estate and end-of-life planning conducted by attorneys usually occurs as a series of conversations and meetings. From the first client meeting, the attorney is well-positioned to encourage the client to commit to discussing their end-of-life healthcare goals with family, caregivers, friends, as well as their physician, as a prerequisite to completion of the document.

For clients who commit to having such conversations with loved ones before the written directive is ultimately prepared by the attorney, the attorney can provide direction, support, and resources to help the client conduct such conversations. Initiating such conversations with family members can be difficult for clients, and family members may be unwilling to discuss their loved one's death. Preparing the client with information, resources, and tools to help the client broach the subject of their end-of-life goals and preferences with their family and others may help to ease discomfort.[40] Throughout this process, recognition of and sensitivity to the client's religious, cultural, and spiritual values, is imperative for the advance care plan to respect and reflect each individual client's needs.

To support the client in this process of engaging their family and friends in end-of-life conversations, the attorney can direct the client to any of the ubiquitous, evidence-based internet resources available to help facilitate such conversations with family.[41] Websites which promote reflection and encourage engagement in selecting care preferences are valuable resources. However, the experience of completing an advance directive form on the internet can seem impersonal. The support of and interaction with an attorney-facilitator can counter a sense of detachment and isolation that may accompany the experience of completing end-of-life care documents online, alone, on a computer screen.

The client, supported by their attorney and equipped with resources, can engage third-party stakeholders such as family members as well as the physician in the advance healthcare conversations. If the client consents, and keeping confidentiality obligations in mind, the attorney can involve the agent and family members in the attorney-client advance care planning meetings. Whether or not the attorney is present when such conversations with loved ones occurs, and even if the conversations are not ultimately documented in an advance directive, such reflection and conversation with family in advance, is beneficial. It may ease some of the shock and distress that can later

arise when end-of-life has never been discussed and is only considered at a loved one's deathbed for the very first time. "[W]hile it is never too soon to initiate these conversations, putting off these conversations until days before patients' deaths is inhumane and distressing to the dying and their families."[42]

After the client has shared and discussed their goals with their family as well as their physician, the attorney is in a better a position to pursue the next step of preparing an advance directive document to memorialize the client's healthcare wishes. Thereafter, and over the course of the client's lifetime, the attorney can continue to meet with the client to review and update the document, as the client's circumstance change. Recognizing once again that attorneys are not clinicians, specific medical treatment choices are best left to medical professionals within whose bailiwick related end of life documents such as the POLST form and in-hospital resuscitation orders also fall. Attorneys and their clients must be clear that the attorney-prepared advance directive document serves as a basis for ongoing discussion with a medical professional, and must instruct the client to regularly review the document with their physician, in order to reflect the client's particular medical circumstances and needs.

C. Distributing the Advance Healthcare Directive Documents

Critics of attorney-drafted advance care directive forms contend that such paperwork does not find its way to the client's physician or healthcare agent, and rather than being made part of client's medical record, the document is instead filed and forgotten once the client leaves the law office. Such attorney-prepared documents fail to fulfil their intended purpose because they are never exchanged with agents and medical providers and therefore may be unavailable when needed.[43] For this reason, some recommend instead that these documents be completed exclusively in a healthcare setting, so that they can be immediately made part of the patient's file.[44] However, the failure to properly include an individual's healthcare wishes in the medical record, is not a problem unique to attorneys. Even when advance healthcare planning occurs in a medical setting, the patients' directives may not be entered into the patient's medical record.[45] Healthcare facilities, clinicians and lawyers alike must all take steps to better ensure that such documents are adequately included in the medical record and relied upon when needed.

As already emphasized, as a first step, attorneys must instruct their clients to discuss their advance healthcare wishes with a physician before recording them in an advance directive. Clients and attorneys must then ensure that the documents are shared with the client's physician, agent, family and friends. Of course, simply because the attorney directs the client to provide the advance directive document to their physician and discuss it with their agent and family does not mean the client will do so. "Even if lawyers encourage patients to discuss the documents with clinicians and family members, such engagement may not happen."[46]

For attorneys, an option may be to mail or otherwise distribute copies of the completed advance directive document directly to the medical records office and/or to the client's physician, if the client consents. Assistance by the attorney in this way ensures that the client or their agent is not solely responsible for making certain that the document is included in the client's record. Similarly, the attorney can also provide copies of the advance directive directly to the healthcare agent, with the client's consent, including instructions as to their use, when they are to take effect, and explanation of the duties of the healthcare agent. Taking steps to provide the document directly to the relevant parties may decrease the likelihood of the document not being utilized if the client forgets or neglects to share the document on their own.

D. Attorney Training and Skill Development

Medical professionals, commendable for their candor, have concluded that physicians very often "lack training, communication skills, and confidence regarding the initiation of end-of-life conversations," and have, "poor skills in conducting advance directives discussions."[47] Physicians and medical students report "feeling unprepared or uncomfortable with broaching the topic of death with their patients and families" and uncertain about "how to initiate or proceed with these discussions."[48] If physicians struggle with lack of preparedness to discuss death, it can only be expected that attorneys experience similar difficulty when drafting living wills or other advance directives for clients struggling to make future healthcare decisions in light of uncertain diagnoses and myriad treatment options.

The struggles that physicians encounter in conducting end-of-life conversations have been attributed, in part, to an inadequacy in medical education in preparing physicians for such conversations. In medical education "dealing with

death is not uniformly considered a basic medical skill."[49] The medical profession has thus identified a clear need for and commitment to investment in training, in an effort to improve the efficacy of advance healthcare planning.[50]

In the same manner that physicians struggle with lack of preparedness in this domain, it can only be expected that lawyers preparing advance healthcare directives experience similar difficulty discussing end-of-life healthcare decisions with a client. Just as medical schools have not adequately prepared doctors to hold end-of-life conversations and more training is required, law schools may not be adequately preparing lawyers for the reality of end-of-life planning. Such skills are likely to only be developed by attorneys on-the-job, through trial and error, in a piecemeal fashion. For the many students who enter the ever-popular practice of estate planning, the legal profession may need to better equip them as future practitioners for the reality that they are expected to prepare clients for healthcare decisions at the end-of-life.

"[S]tudies have established that physicians can be taught the communication skills needed to provide good end of life care."[51] Attorneys seeking to help clients document these healthcare decisions in advance directives may similarly benefit from additional, profession-specific skills training to most effectively assist clients who wish to memorialize their end-of-life decisions, and to guide clients through the process of advance care planning. Facilitator trainings that have been considered helpful for improving advance care planning effectiveness in the healthcare setting include intensive small group trainings, simulations, and classroom modules "focused on achieving competency in facilitating [advance care planning] conversations through video demonstration, instructor role modeling, role-play exercises, and feedback on competency."[52]

While trained attorney facilitators cannot and should not usurp the role of medical and other professionals, they can serve as a valuable resource to those seeking to prepare for end of life. Although various approaches exist to encourage individuals to conduct end-of-life planning, successful interventions include those that incorporate "direct interactions" between the patient and the professional facilitating the conversation.[53] Some scholarship indicates that when such direct interactions occur over multiple visits and where the advance care planning facilitator is trained, improvement in the documentation of advance care plans results.[54] Studies that showcase the effectiveness of direct facilitated end-of-life discussions have utilized clinicians, nurses, social workers, and hospital chaplains among others, as advance care planning facilitators.[55] Future studies about the effectiveness of direct attorney-facilitated interactions may help to improve the role of the lawyer as facilitator.

End-of-life conversations that are poorly conducted by uninformed facilitators run the risk of hindering the client's goals, obstructing medical treatment, and escalating family conflict. The assistance of trained, skilled, and informed attorney-facilitators may reduce the likelihood of legal documents that, when needed, may be ineffective at best, or obstructive at worst, with respect to accomplishing the client's goals. To help lawyers engaged in advance care planning improve their skills, the American Bar Association has created guidelines for lawyers to utilize in practice. The ABA Advance Directives Counselling Guide for Lawyers, created by a multidisciplinary team of medical and legal professionals, seeks to "assist lawyers and health care professionals in formulating end-of-life health decision plans that are clearly written and effective."[56] The document provides important guidance and resources to attorneys preparing advance healthcare directives. The extent to which the document is utilized in practice by estate planning attorneys however, remains unknown, and further research as to the use and effectiveness of the document in improving attorney-facilitated end-of-life conversations might prove insightful.

IV. Opportunities for Medical-Legal Partnership

Advance healthcare directives fulfil their intended purpose when the client's decisions are honored after the client becomes incapacitated. However, attorneys who prepare advance directives may never know if the documents served their intended purpose when the client is dying. The attorney does not join the client at the bedside. Our legal system affirms and respects the fact that end-of-life healthcare choices should be left to patients, their families, and their physicians.[57] Although attorneys are not physically present at the bedside, their representation continues, however, through the advance directive document drafted by the attorney to protect the interests of the individual who no longer has the capacity to protect their interests on their own.

Clinicians complain, however, that "legal advance directives are often incomprehensible, are too lengthy, or contain

specific treatment wishes which are not pertinent to the clinical situation at hand."[58] If clinicians struggle to interpret and implement perplexing instructions in attorney-prepared advance directives, patient goals may be impeded. Yet if the attorney-drafted document is unclear, the attorney who drafted it may never know. If physicians or the healthcare agent struggle to interpret, or fail to apply the document because of gaps, errors, or inadequacies in the language, or family arguments erupt about its meaning, the deficiencies in the advance directive document may never come to the attention of the attorney who drafted it. Rather, such disputes are often resolved through internal protocols within healthcare facilities which may include medical team meetings, family meetings, social worker consultations, or the intervention of clinical ethicists and hospital ethics committees. Such internal dispute-resolution is likely to occur without the attorney ever realizing that a disagreement is occurring or that the dispute is exacerbated by the attorney's own ineffectiveness as an advance care planning facilitator. Only if court proceedings are ultimately initiated might the attorney who prepared the advance directive become involved in the ensuing guardianship proceedings.

Thus, if an advance directive fails to achieve its desired purpose, the attorney who prepared the document is often deprived of the opportunity to learn from and improve their advance planning methods to better serve future clients. The fact that internal dispute-resolution exists in hospitals and nursing homes to resolve end-of-life disagreements without court intervention does not absolve attorneys from the obligation to conduct effective advance care planning documents that clinicians can rely upon.

"To ensure that [advance care planning] efforts are effective, evidence-based, and legally recognized, it is important that the medical and legal communities engage with one another to align their approaches."[59] Collaboration with medical professionals may help attorneys better understand how to draft meaningful and effective documents. Legal professionals working together with medical professionals to address deficiencies and better understand the needs of each profession in the preparation of advance directives offers "potential to improve practice among lawyers and clinicians by establishing a shared understanding of the goals of [advance care planning] and to clarify the appropriate role of lawyers and clinicians."[60]

Medical-legal collaborations and training programs have the capacity to benefit the legal profession and the public by informing attorneys about which advance care planning practices are most helpful to patients and clinicians, thereby improving the efficacy of attorney-facilitated advance care plans. Similarly, through such partnerships, healthcare professionals may gain from the expertise that legal professionals offer. Medical students, clinicians, and healthcare professionals who rely on advance health care directives may benefit from information about attendant legal requirements and obligations, as well as the constitutional and statutory rights of the patient and healthcare provider, and the possible legal outcomes where advance directives fail or do not exist.[61] Medical-legal partnerships have the capacity to help both professions enhance their knowledge, skill, and understanding with respect to the preparation, documentation, interpretation, and application of advance care planning documents.

Advance healthcare directives allow individuals to identify trusted, capable, and informed advocates to act as healthcare agents and protect their interests. They reduce the likelihood of individuals falling to the mercy of default surrogate decisionmaker statutes or court-appointed guardianships. They offer a means to avoid inter-family disputes that can spill over into legal proceedings leaving vulnerable clients at the mercy of the judicial system. Competent, well-trained professionals working together to provide advance care planning services through interdisciplinary partnerships can help to promote end-of-life health care that accords with client wishes.

V. Attorneys as Healthcare Advocates

A. Increasing Public Awareness about Advance Care Planning

Although advance directives are widely considered beneficial, only every third American has completed an advance directive.[62] Access to knowledgeable, informed lawyers trained to draft advance directive documents can serve to increase availability of and public access to end-of-life planning services. Certainly, advance healthcare directive documents can be prepared exclusively with a clinician or online. Yet even among these and other advance care planning alternatives, the individualized service of an attorney — who can act as a full-service facilitator, and who can ensure that the client engages all the appropriate parties, including the agent and the physician, in the advance

care planning process — remains a viable option.

As advocates for advance care planning, attorneys can encourage the public to document, share, and discuss end-of-life goals and preferences. However, in so doing, attorneys must be cognizant of and responsive to the fact that their professional skills differ from those provided by medical professionals, and ensure that each client consults with a qualified medical professional to further discuss and develop their advance healthcare plans. Nevertheless, by helping to “normalize” advance care discussions, by making advance care planning more widely available, and by offering an alternative means by which individuals can begin to engage in end-of-life healthcare conversations and prepare documents, attorneys provide value.[63]

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B. Attorneys as Catalysts for Health Care Equity: The Example of Law School Clinics

The COVID-19 pandemic has highlighted healthcare disparities that disproportionately affect minority and low-income populations.[64] A clear need exists for all individuals, but particularly those who are most vulnerable, to identify a healthcare agent of one’s own choosing and discuss end-of-life treatment goals in the event of a medical crisis.[65] Advance directives serve as a means to empower individuals to retain some degree of autonomy and have a voice in their own healthcare treatment. A well-informed healthcare agent serves as an advocate on behalf the patient who cannot represent themselves — an advocate who understands and can honor personal and family needs and deeply-held values, traditions, and beliefs to best promote and protect the patient’s goals.

Economically vulnerable and minority populations are less likely to have completed advance directives with the result that “poorer, younger, less-educated, and minority individuals are not having timely [end-of-life] conversations with their physicians, and as a result are dying in places and ways that do not reflect their wishes.”[66] A need exists for greater outreach to communities with low rates of advance healthcare planning. One potential opportunity to reach underserved populations is through law school clinical programs that provide legal services to the public. Such programs can help to address disparities in end-of-life healthcare planning among vulnerable and disadvantaged populations by making advance care planning services more readily available as a *pro bono* offering.

Clinics offering medical-legal services or estate planning services are a particularly popular offering at law schools. These educational and service programs often provide — as part of their services — preparation of advance healthcare directives for the clients they serve. Such clinics increase access and availability to advance healthcare planning, by offering free services to underserved populations. Law school clinics also offer an opportunity to train the next generation of attorneys to help clients prepare effective end of life plans. Through law school clinics, with careful supervision and instruction, students work alongside professionals to provide direct client services, allowing the student to observe best practices, learn from experience, and develop their skills as future practitioners, while at the same time serving the public.[67]

Law school clinical programs integrate into the curriculum instruction about the applicable law, but also instruction about effective client communication, discussions about public policy and notions of justice, and the role of an attorney as an instrument of that justice.[68] “[C]linics are the law school sites within which the cognitive, skills and civic dimensions are purportedly iterative and integrated, where students learn and deploy legal skills and encounter the real-life ethical challenges of working directly with clients to diagnose and treat their legal problems.”[69] Law school clinics, which often serve culturally diverse, underserved populations as well as economically disadvantaged clients, incorporate examination and reflection of cultural, moral, and religious considerations inherent in the practice of law.[70] By integrating instructive and reflective exercises into the curriculum throughout the course of the clinical program, clinics seek to nurture and promote respect, awareness, and sensitivity to the diversity of client

experiences.

Law school clinics additionally offer an opportunity for interdisciplinary collaboration through partnerships with other university departments. Such partnerships with other professional schools such as medicine or nursing programs, have the potential to improve the skill of the next generation of advance care planning professionals. “By recognizing lawyers as powerful allies in addressing some of the root causes of systemic health inequities, medical legal partnerships can expand institutional and professional boundaries and help students learn new ways to practice law and medicine together. … Working together to overcome potential barriers to serving health-and justice-related interests not only improves teamwork but also teaches students how much they have in common with each other.”[71] Such partnerships offering advance healthcare planning training, supervision, and education have the potential to improve the skills of advance care planning of future professionals, who learn and implement best-practices for providing advance care planning services to the public. In addition, they have the potential to empower vulnerable populations by encouraging preparation for end-of-life care well before a medical crisis occurs, and offer a resource to underserved populations seeking to receive advance care planning services.

VI. Conclusion

Discussions of end-of-life meet at the intersection of medicine, law, ethics, religion, social work, and philosophy. The breadth of the domains that end-of-life conversations encompass is reflective of the profoundness of the subject matter. Advance care planning must be conducted with awareness and respect for the human dignity of the individual facing profound questions about their own mortality. Attorneys must be prepared to effectively and compassionately respond to each client’s needs in a manner receptive and responsive to the cultural and spiritual values of the client.

Attorneys can and do play an important role in providing such end-of-life healthcare counsel, a service that is an integral part of any comprehensive estate plan. Through an advance healthcare directive, the agent can authorize admission of the client to a nursing home or hospice facility, or support the client’s wish to remain at home. The agent can prevent the need for judicial proceedings and court-appointed guardians to provide external oversight. Healthcare directives are more than a mere ‘add-on’ to wills, trusts, financial powers of attorney, and the various asset protection tools that estate planners employ. Various components of the estate plan as a whole are reliant on the health status of the client and on the permissions granted in the healthcare directive. Advance directives govern fundamental decisions about the healthcare of the person on whose life the estate is based, and around whom the entire estate plan is centered.

Critics of advance care directives often point to the fact that most people do not prepare them as a reason warranting their abandonment.[72] However, comparably few U.S. adults prepare any type of estate plan including a last will and testament, trust documents, or financial power of attorney.[73] The fact that low numbers of adults prepare any estate planning documents, including advance healthcare directives, is not reason enough to abandon their use. Skilled and informed attorneys who provide estate planning and advance directive services provide value by increasing the availability of such documents and encouraging clients to at least begin to consider the end-of-life healthcare wishes.

Advance healthcare planning involves “a complex inter-play” between patients, surrogates, communities, clinicians, health systems, and policy.”74 The role and value of legal professionals who empower individuals to advocate for themselves through an advance healthcare plan, cannot be discounted. Attorneys who provide facilitated advance care planning services in keeping with evolving best practices provide value to the healthcare profession, to families, and to the clients whom they serve. Even among the many options available for preparation of advance healthcare plans, attorneys who offer facilitated advance care planning assistance can deliver a trusted and meaningful service.

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The Racialized Marketing of Unhealthy Foods and Beverages: Perspectives and Potential Remedies

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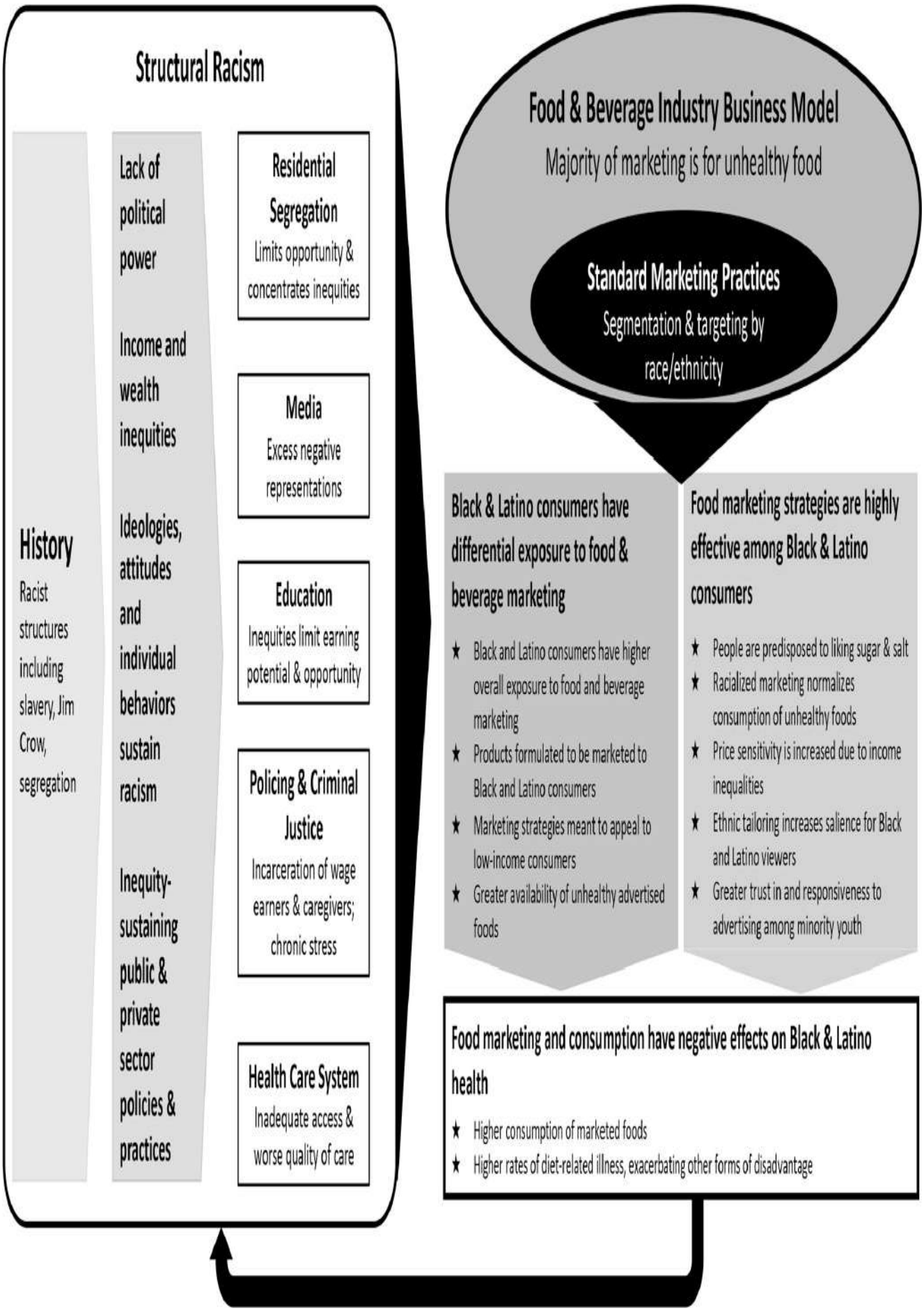
ABSTRACT (ENGLISH)

We propose that marketing of unhealthy foods and beverages to Black and Latino consumers results from the intersection of a business model in which profits come primarily from marketing an unhealthy mix of products, standard targeted marketing strategies, and societal forces of structural racism, and contributes to health disparities.

FULL TEXT

We are in a time of national reckoning with racial inequity in the United States. Part of this is understanding structural racism effects on health risks and outcomes, including obesity and diet-related chronic diseases, which affect Black/African American and Hispanic/Latino children and adults disproportionately.[1] In this article, we consider the marketing of unhealthy foods and beverages to Black and Latino children and adults in the United States through this lens. Here, “unhealthy foods” refers to foods or beverages high in fat (saturated or trans fat), salt, or sugar (HFSS).[2] We build on prior work[3] and propose that there are patterns of *racialized food marketing* resulting from the intersection of three factors (see Figure 1): (1) the business model in which profits come primarily from marketing an unhealthy mix of foods, (2) the standard marketing strategies of segmenting, targeting and positioning products to appeal to individuals and groups, including racial or ethnic groups; and (3) structural racism as a force in the background of all societal processes —including the marketplace. This racialized food marketing contributes to

health disparities and requires race-conscious, structural solutions.



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Racialized Food Marketing

Unhealthy dietary patterns are the leading risk factor for deaths in most countries.[4] But the profit-making model of large food and beverage companies is not aligned with the public health goal of shifting eating patterns in healthier directions. Food and beverage company profits come primarily from the sale of shelf-stable, packaged foods and beverages.[5] Such foods are convenient and can be critical for food and nutrition security for certain markets.[6] However, a 2018 report found that 70% of a sample of products (n=6,469) from the 10 largest U.S. food and beverage manufacturers failed to meet the bar set for healthy products.[7] This mix of products (along with other HFSS food, e.g. fast food) contributes to the high rates of diet-related diseases observed across demographic groups in the United States, and the significant rates seen globally.[8]

Black and Latino consumers experience a disproportionate level of exposure to marketing of HFSS foods, which contributes to higher morbidity and mortality from diet-related diseases. Structural racism shapes the environments in which people live and shapes their access to healthy and unhealthy food, and it shapes the marketing practices that create and support food environments. These food environments and marketing practices in turn shape people's food choices.

This generally problematic model of food marketing sets the stage for racialized marketing as a structural racism issue.[9] Marketing involves an integrated system with standard practices that divide consumers into segments defined by various characteristics, including geographic characteristics and demographic characteristics such as race and ethnicity or income. As a result of these marketing practices, and the ways in which they operate against a background of structural racism, Black and Latino consumers experience a disproportionate level of exposure to marketing of HFSS foods, which contributes to higher morbidity and mortality from diet-related diseases.[10] Structural racism shapes the environments in which people live and shapes their access to healthy and unhealthy food, and it shapes the marketing practices that create and support food environments. These food environments and marketing practices in turn shape people's food choices.[11]

Marketing strives for synergy across four dimensions: Product, Price, Place, and Promotion.[12] Here we identify racialized aspects of each dimension.

Promotion: *Group-level targeting results in greater exposure to food marketing among Black and Latino groups. "* Promotion" refers to advertising and other promotional activities. Group-level targeting has historically meant that Black and Latino audiences, like other groups, were distinguished from "mainstream" audiences and specific efforts made to reach and appeal to these audiences. This includes promotions through Black and Latino media, including TV channels and programs with high Black and Latino viewership, and Black and Latino-oriented social media. In combination with higher media consumption, this results in Black and Latino consumers having greater total exposure to HFSS food advertising across media types.[13]

Ethnically tailored content increases the impact of food marketing. Some food marketing has ethnically tailored content.[14] Research suggests that Black and Latino youth are more interested in, and respond more positively to, marketing that contains ethnic cues and features spokespersons or characters of similar ethnicity.[15] The dearth of positive role models and cultural symbols, and more generally a lack of positive representation in the media[16] may render Black and Latino youth more in need of and responsive to marketing that contains positive representations.[17]

Digitally targeted marketing is increasingly sophisticated and combines group-level targeting with individually-tailored content based on geographic and other information gathered from mobile devices and online tracking.[18] Food, beverage and restaurant marketers are leaders in targeting communities of color via digital advertising.[19]

Place: *Unhealthy foods are relatively more available in Black and Latino communities.* Black and Latino people are more likely to experience higher availability of fast food and lower access to healthier foods in their neighborhoods;[20] this is enabled by residential segregation,[21] a product of past housing discrimination and other factors.[22]

Marketing by geographic area also results in higher exposure of Black and Latino consumers to HFSS advertising and promotions. Geographic marketing strategies include outdoor advertising, the placement of products within retail food outlets in Black and Latino neighborhoods, and sponsorship (for example, a company sponsoring a playground

or an event). For all of these strategies, there is evidence that the food industry intentionally targets Black and Latino consumers.[23] Sponsorship may be welcomed by low-resource Black and Latino communities and contribute to product or brand loyalty. However, this should be understood against the backdrop of structural racism that has contributed to concentrated poverty in these communities. Lack of resources makes sponsorships from private companies valuable and attractive. Digital targeted advertising intersects with place-based strategies and the background of structural racism, including segregation and income inequality, resulting in greater exposure to advertising for fast food for residents of neighborhoods with many fast food restaurants.[24]

Product: *Some products formulated to be marketed to Black and Latino consumers are less healthy.* Food products are formulated to appeal to specific tastes, and marketers claim that their products fulfill consumers' specific preferences. For example, Kraft Foods' Latino-targeted Kool-Aid "Mandarina Tangerine" flavor, packaged in English and Spanish, marked the first "broad and complete approach to developing and marketing a product to the Hispanic market" in 1998.[25] But products formulated to be marketed to Black and Latino consumers are generally less healthy (e.g., sweeter or higher in fat and sodium) than those marketed to the "mainstream" (e.g., white) population.[26] These products are then advertised to Black and Latino groups, and priced attractively to encourage purchase and cement the racialized preference. In this way, the racialized marketing of foods is analogous to the marketing of menthol-flavored cigarettes marketed to Black consumers.[27]

Price: *Pricing strategies capitalize on the price-sensitivity of low-income consumers*. For example, promotions of sugary beverages are timed to coincide with the receipt of food assistance benefits, and there are volume discounts on unhealthy products pricing.[28] Because Black and Latino consumers are disproportionately poor relative to white consumers[29] (a reflection of structural racism), strategies meant to appeal to low-income groups are another way that food marketing is racialized.

Effects of Racialized Food Marketing

A 2013 review found that children's exposure to advertising of sugar-sweetened beverages, presweetened cereal, candy, snacks, and fast foods was linked to increased snacking, energy consumption, and lower healthy food consumption; subsequent research confirmed these relationships.[30] There is also experimental evidence that positive attitudes toward food marketing (i.e., receptivity to food marketing) are associated with higher consumption of sugary beverages and fast food, and with obesity.[31] Thus greater exposure to marketing of HFSS foods and more positive attitudes towards food marketing —two aspects of racialized food marketing —likely contribute to higher consumption of HFSS foods among Black and Latino consumers.[32]

Promoting a Racially Equitable Marketplace

On our analysis, racialized food marketing results from marketers' strategic decisions (e.g., segmenting by race/ethnicity or tailoring marketing strategies to price-sensitive consumers) as well as the disparate effects that marketing practices have against a background of structural racism. Of note, while marketers create racially- or ethnically-specific marketing strategies, this is not an unusual marketing practice, nor need it be motivated by any discriminatory intent. Nonetheless, these standard marketing practices leverage the processes and outcomes of structural racism and, in so doing, exacerbate health disadvantage.

The example of racialized food marketing demonstrates a point made by RIM (Race in the Marketplace) scholars: some have historically argued that the marketplace is a neutral force and will naturally counter racism, because racism is an inefficiency that the market's competitive pressure will eliminate; however, the marketplace does not hang free from structural racism,[33] and can amplify racial inequity. Given this, a racially equitable marketplace requires more than the absence of discriminatory intent. It requires identifying the relationships between the marketplace, on the one hand, and different forms of racial inequity and manifestations of structural racism, on the other, and then actively pursuing marketplace activity that advances rather than undermines racial equity. In doing this, it is important to recognize that these relationships are complex. This can be seen in the divergent reactions within the Black community to food marketing, with some seeing it as a cause of diet-related health disparities, others seeing themselves marketed to as a sign that they are valued in the marketplace,[34] and still others seeing food marketing as a positive force for Black entrepreneurship and communities' economic development and

advancement.

Jou (2017) describes some of the relevant history. Starting in the 1960s, U.S. federal policy, including loans from the Small Business Administration (SBA) led to a proliferation of fast-food restaurants, with major outreach targeting African-American entrepreneurs. This was apparently a politically-motivated, expedient strategy to address poverty and economic disparities. It was also seen as a potential way to avoid civil unrest by improving the business climate in Black communities and leveraging other appealing aspects of fast food (e.g., convenience and low prices). Black franchise owners were seen to benefit from the corporate umbrella and the overall profitability of this model.[35] In this way, Black ownership of fast food franchises can be seen as a dimension of racial equity. Analogously, some have argued that receipt of food and beverage advertising by Black-owned media companies is a dimension of racial equity.[36]

The history of racialized marketing practices by beverage companies is another instructive example. Coca-Cola marketing was originally oriented to white communities and influenced by racist perceptions of Black people. Pepsi, as a competitor to Coca-Cola, initially used a proactive racialized approach to develop a “Negro market” and salesforce for its product.[37] This targeted advertising of Pepsi was a positive form of recognition and arguably a step in a more racially equitable direction, as was job creation in the Black community. Fast forward to today, however, and sugary drink consumption is significantly higher among Black people, is the largest source of added sugar in the diet, and is a significant contributor to excess energy intake, weight gain, diet-related illness and accordingly, health disparities. [38] Together, these examples demonstrate a pitfall of the racialized marketplace: mitigating one dimension of racial inequity (economic disparities in Black business ownership, or exclusion of Black consumers from the marketplace) can exacerbate another (Black consumers are disproportionately exposed to unhealthy food marketing). What we should strive for instead are approaches that advance racial equity along multiple dimensions without undermining it along any.

Addressing Racialized Food Marketing

Addressing racialized food marketing requires that companies consider the differential effects of their products on communities of color when formulating their business models, creating products, and designing marketing practices. However, a recent survey of 15 food and beverage companies, restaurant brands, and retailers found that some donate money to racial justice causes or public health efforts, or have food security initiatives, but “many companies did not directly address how their existing business models might perpetuate and exacerbate racial disparities. Instead, they seemed to fall back on philanthropic and diversity initiatives that did not address the underlying systemic issues.”[39] One concrete step forward would be for food and beverage companies to conduct racial equity audits and share their results.[40]

Greater exposure to marketing of HFSS foods and more positive attitudes towards food marketing —two aspects of racialized food marketing —likely contribute to higher consumption of HFSS foods among Black and Latino consumers.

Public policy and regulation can also do more to address racialized food marketing. Reducing overall exposure to unhealthy food advertising may seem like an obvious move, but regulating advertising has been an uphill battle. The First Amendment to the U.S. Constitution forbids government from making a law “abridging the freedom of speech.” [41] Traditionally, free speech protections were given primarily to political, religious and artistic speech,[42] but starting with *Virginia State Board of Pharmacy* in 1976, the U.S. Supreme Court extended First Amendment protections to the marketing of commercial products.[43] Over the ensuing 40 years, large corporations successfully mustered the commercial speech doctrine as a defense against government intervention in commercial activity;[44] current court decisions support this business-friendly definition of the First Amendment. However, alliances of reformers and social movements have changed public opinion and then court decisions on such contested topics as legal segregation and marriage equality. If public health advocates work now to de-normalize the acceptance of marketing of unhealthy products —such as building on the Children’s Online Privacy Protection Act (COPPA) —they can set the stage for future changes to the law.

Another regulatory approach is to curb business conduct, thereby indirectly regulating marketing, rather than directly

regulating the marketing itself. Examples include warning labels, policies requiring that healthy foods accompany toy give-aways, product placement regulations, taxes, healthy zoning, and setting nutrition standards for foods sold in schools and on government property. A yet untested strategy —Performance-Based Regulations already used to improve public education and address climate change[45] —is also worth considering. This strategy would set dietary outcome sales targets for the nation and/or for specific population groups (for example, aggregate reductions of 25 percent sales in sugar, salt and saturated fat) to which individual regulated enterprises would be held. The regulated enterprises themselves, not the government , would decide, behind-the-scenes, how to achieve sales targets to match the dietary targets in the most efficient way. Failure to achieve their regulatory targets would subject them to substantial financial penalties.

Another way to respond to racialized food marketing is with targeted social marketing (including counter-marketing) and efforts to improve marketing literacy. In the past, critics of racially targeted marketing of unhealthy products led community campaigns using social marketing to counteract industry advertising. In some cases, these campaigns have appealed to racial identity to reject the claims of industry marketers. In the 1990s, often led by Black church groups, communities mobilized to challenge alcohol advertising messages and to limit the placement of ads.[46] Similarly, Black health and community organizations have challenged tobacco marketing to Black communities, demanding the right for communities to have a voice in determining the messages on tobacco their children received.[47] More recently, groups in Oakland, California, New York City, and elsewhere have launched unhealthy food counter-marketing campaigns urging communities of color to reject the claims of fast food, sugary beverage, and snack food marketers.[48] Such social marketing campaigns could be adopted by community organizations, as well as governments; however, Grier and Schaller (2020) find some hesitancy among policy actors to adopt racially targeted interventions.[49]

Conclusion

Structural racism means that some individuals, families and communities have fewer resources and options and have more stress in their everyday lives, and thus especially need food products that improve rather than complicate their life circumstances. Were food and beverage companies to market a range of affordable, convenient and appealing products that help consumers achieve good health and well-being, this would be an advance for racial equity —a way of mitigating the harms of structural racism rather than amplifying them. Based on the experience of recent decades, such a change will require some mix of government regulation, community mobilization, and the willingness of at least some food and beverage companies to take up the challenge of minimizing food marketing's amplification of structural racism.

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Note

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Raqeeb, Haastrup, and Evans: Seeking Consistency through a Distributive Justice-Based Approach to Limitation of Treatment in the Context of Dispute

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ABSTRACT (ENGLISH)

When is life-sustaining treatment not in the best interests of a minimally conscious child? This is an extremely difficult question that incites seemingly intractable debate. And yet, it is the question courts in England and Wales have set out to answer in disputes about appropriate medical treatment for children.

FULL TEXT

1. Introduction

A number of recent high profile court cases in the United Kingdom involving mechanical ventilation of critically ill children highlight the challenges of asking courts to identify a child's best interests. Courts sometimes struggle to identify the child's 'best interests.' As a result, they may reach inconsistent conclusions. There have been recent proposals to change the law applying to disputes about treatment.[1] We argue that such changes are not necessarily required, but defend a different approach to the ethical basis for decision-making and the role of the court.

We will draw on the recent case of *Tafida Raqeeb v Barts NHS Foundation Trust*. We argue that the apparent inconsistency between this decision and other recent cases highlights the subjectivity and formidable ethical

challenge of determining the best interests of a minimally conscious young child. Moreover, we argue that the decision in this case ignored a central and relevant ethical consideration: resource allocation and distributive justice. Decisions in the NHS must be made to ensure limited medical resources are allocated ethically, efficiently and effectively.[2] This must inform decision making.

We argue that rather than turning to the courts to identify what is in a child's best interests, hospitals should make decisions about when it is appropriate to provide mechanical ventilation under conditions of distributive justice. If a hospital determines mechanical ventilation would not be an appropriate use of resources, parents may seek judicial review of whether this decision is lawful or they may privately fund treatment elsewhere. If the hospital is concerned that treatment arranged by the parents would cause significant harm to the child, they should apply to the court for a care order or a supervision order. We contend that this approach better reflects the role and expertise of the relevant parties. It would also prevent the courts from relying on an outdated concept that a judge (acting in the role previously fulfilled by the monarch as the wise parent) is well placed to objectively identify the best interests of a child and whether it is in the child's best interests to die.[3]

2. Tafida Raqeeb

The recent case of *Raqeeb* involved a five-year-old girl, Tafida Raqeeb, who suffered bleeding on her brain that resulted in extensive and irreversible brain damage.[4] After six months, Tafida remained in a minimally conscious but medically stable state. Tafida's doctors concluded that although she could be kept alive on mechanical ventilation, this would be of no benefit to her and treatment should be withdrawn. Tafida's parents did not accept this opinion. They found doctors in Italy who were willing to continue to provide mechanical ventilation and who were also prepared to undertake a tracheostomy to allow Tafida to receive home ventilation. They believed that there was a possibility of some neurological improvement over the next year, but could not say whether this would be better for Tafida.[5]

When Tafida's parents requested that Tafida be transferred to Italy for further treatment, the NHS Trust refused. Tafida's parents made an application seeking judicial review of the Trust's decision not to agree to the transfer of Tafida. The Trust, meanwhile, sought a declaration that it would be lawful to withdraw life sustaining treatment from Tafida. Justice MacDonald held that the Trust's decision to refuse transfer was unlawful, because they failed to consider Tafida's right to free movement in the European Union. However, the judge acknowledged that if the Trust had considered Tafida's Article 56 rights, it would have reached the same conclusion (that the request should be declined pending review by the court).[6] Of greater consequence was Justice MacDonald's decision that ongoing ventilation was in Tafida's best interests and that she must be provided with mechanical ventilation.[7] What was acknowledged, but not addressed, was that once long term mechanical ventilation was established in Italy, Tafida's parents could choose to transfer her back to England and at that point English doctors may be placed in a position of continuing treatment that they do not believe is in Tafida's best interests.

Justice MacDonald came to the conclusion that mechanical ventilation was in Tafida's best interests based on a number of factors.[8] Tafida was minimally conscious and whilst there was little prospect of improvement, she was not considered to be in pain. The burden of treatment was considered to be low. There was a responsible body of medical opinion suggesting she should continue to receive treatment and that this could eventually occur at home with a loving and devoted family. Further, Justice MacDonald heard evidence that children in England in a similar position have received long term mechanical ventilation, that Tafida could be safely transferred to Italy and that there was private funding available to allow this to occur. Of note, Justice MacDonald considered the Islamic religious beliefs of the parents and of 5-year-old Tafida as a relevant consideration in deciding whether it was in her best interests to die. In previous cases, the courts have rejected the relevance of parents' religious beliefs, "[a]n objective balancing of [the child's] own best interests cannot be affected by whether a parent happens to adhere to one particular belief or another, or none."[9] Yet despite accepting that Tafida could not have developed a sufficient understanding of Islam and of life and death to hold a view on her present position, Justice MacDonald still held that the religious tenets by which Tafida was raised should be given weight in the balancing exercise.[10]

In the months following the case, Tafida was transferred to Italy and the family has reported improvements in the

form of reduced reliance on ventilation.[11] There does not, however, appear to have been a substantial improvement in Tafida's neurological condition and she will continue to require constant care. English and Italian clinicians agreed during the hearing that improvement was possible for Tafida and that this may allow her to go home, but the English clinicians questioned whether this was a substantial improvement.[12] The difference was not about what was medically possible, but whether this existence was in Tafida's interests and clearly Tafida's parents and the Italian doctors continue to believe it is.

3. Potential Inconsistency with Previous Cases

Tafida's parents had identified doctors willing to provide ongoing treatment to her and appeared able to fund this treatment. Although there were few benefits that could be identified in the provision of long-term ventilation, it was also found that she was not experiencing any pain. As a result, Justice MacDonald understandably erred on the side of maintaining Tafida's life and allowing the parents to raise their child in accordance with their beliefs. However, the conclusions in Tafida's case contrast with other recent high-profile cases, in which the benefits and burdens of life do not appear to have been weighed in the same way.

The case of *Evans* involved a 21-month-old child, Alfie Evans, with a neurodegenerative condition that had left him in a "semi-vegetative state" and unresponsive to stimuli.[13] As Alfie's doctors had determined ongoing mechanical ventilation was not appropriate, Alfie's parents had found doctors in Rome willing to provide treatment. Justice Hayden held that ongoing ventilation was not in Alfie's best interests and that he should not be transferred to Rome.[14] Justice Hayden came to this conclusion on the basis that, since there was no prospect of improvement, ongoing ventilation was futile.[15] Justice Hayden further identified the risks of transferring Alfie, such as a risk of infection, and noted that it was undesirable for Alfie to die in transit.[16] Justice Hayden concluded that Alfie should not be taken to Rome because the risks were not justified given there was little prospect of Alfie benefiting from treatment.[17] However, it is unclear that the risks to Alfie of transfer were any different to those affecting Tafida Raqeeb and all experts agreed that there was also no prospect of Tafida recovering any more than minimal awareness.[18]

These three cases illustrate the difficulty of identifying the best interests of a minimally conscious child. Relevant considerations include the pleasure and suffering the child is able to derive from life, but in many of these cases, this is likely to lead to an impasse. As the child is minimally conscious, they are likely to experience few pleasures from life, but also little suffering, though we cannot be certain of either. Given their minimal awareness of anything, it is often difficult to identify whether the child has any interests in anything. This leads to consideration of even more difficult questions, such as what is inherently valuable in human life? Or, what is the value of a peaceful death?

The case of *Haastrup* is also comparable.[19] The case involved an 11-month-old child, Isaiah, who had suffered severe hypoxic ischemic brain damage at birth. There was a consensus view from medical practitioners that there was no evidence Isaiah could interpret or interact with the outside world and so no evidence he was suffering.[20] Doctors believed that it was in Isaiah's best interests to withdraw mechanical ventilation and allow him to die. Isaiah's parents disagreed with the doctor's prognosis and conclusion about treatment. Justice MacDonald held that mechanical ventilation should be withdrawn as 'in cases where the end of life is in issue, for many the concept of human dignity becomes encapsulated by the idea of a "peaceful" or "good" death.[21] Like Tafida, it was recognized Isaiah was not experiencing any suffering and could have been kept alive by mechanical ventilation for years. But rather than focusing on the absence of suffering, Justice MacDonald focused on the absence of benefits available to Isaiah and the likely manner of his death if treatment was continued.[22]

These cases highlight the challenges of determining the best interests of the child and the extent to which different values inform how evidence is interpreted and applied, as well as different evaluations of probabilities. The different evaluations of suffering appear to potentially reflect an inconsistency in the interpretation of evidence rather than a difference in the cases. All three children had severe neurological damage and were all unlikely to experience very much if anything at all, although in each case it was impossible to prove the absence of painful experience. In *Raqeeb*, ventilation was considered inherently beneficial because it would maintain life and life was viewed as sacred.[23] In *Evans* and *Haastrup*, by contrast, if ventilation would not provide some additional benefit beyond merely maintaining life, this was seen as an unjustifiable assault on the child's dignity.[24] These differing conclusions

highlight that the benefits and burdens of any medical treatment are necessarily understood through a value system and this may vary depending on which judge hears the case.

4. Identifying a Minimally Conscious Child's Best Interests

These three cases illustrate the difficulty of identifying the best interests of a minimally conscious child. Relevant considerations include the pleasure and suffering the child is able to derive from life, but in many of these cases, this is likely to lead to an impasse. As the child is minimally conscious, they are likely to experience few pleasures from life, but also little suffering, though we cannot be certain of either. Given their minimal awareness of anything, it is often difficult to identify whether the child has any interests in anything. This leads to consideration of even more difficult questions, such as what is inherently valuable in human life? Or, what is the value of a peaceful death? Or, what impact should respect for human dignity have on the provision of invasive medical treatments? Or what is the value of a small chance of a small improvement?

The challenge of assessing the best interests of an unconscious, or barely conscious, person were highlighted in *Airedale NHS Trust v Bland*.[25] In the Court of Appeal, Lord Justice Hoffman held it was fallacious to suggest a person only has interests in things in which they may consciously experience and people have an interest in a dignified death, even though they may not experience this.[26] This view, however, assumes a partly non-experiential account of well-being or interests, which is at least contestable. Indeed, in the House of Lords, both Lord Mustill and Lord Keith rejected Hoffman's argument, suggesting when or how Bland died was of no consequence to him because he had no awareness of anything.[27] Despite citing these arguments, in *Raqeeb* Justice MacDonald returned to the argument of Lord Justice Hoffman and held that it is wrong to suggest a child who experiences nothing or very little can derive no benefit from being kept alive.[28]

These questions (of the value of life and the nature of human dignity) are ones that the greatest philosophers such as Aristotle, Plato, Bentham, Nietzsche and others have struggled with for thousands of years, and unsurprisingly judges have not been able to resolve them either. As the child is barely cognisant of their existence, it is difficult to identify relevant interests of the child that favour either the provision or withdrawal of treatment. As Gillon argues, in some cases both the position of the parents and the position of the doctors may be morally justifiable.[29] Foster has argued that given the strong presumption in favour of maintaining life in English law and the lack of certainty about the best interests of a person in a persistent vegetative state or minimally conscious state, it is always unlawful to withdraw life sustaining treatment from a person in such a state.[30] This is because it is difficult to identify any harms in maintaining life that are strong enough to overcome the presumption. While this suggestion is extreme and provocative, it highlights the challenge of claiming that it is in an unconscious or minimally conscious person's interests to die.

5. Why Are the Courts Making These Decisions?

The court generally decides these matters under its *parens patriae* jurisdiction, which gives the court jurisdiction to protect the interests of those who cannot take care of themselves.[31] Although the court often also simultaneously invokes its jurisdiction under the *Children Act 1989*.[32] As Lord Esher MR described the *parens patriae* jurisdiction, "The Court is placed in a position by reason of the prerogative of the Crown to act as supreme parent of children, and must exercise that jurisdiction in the manner in which a wise, affectionate, and careful parent would act for the welfare of the child."[33] Lord Donaldson MR described the inherent powers of the court exercising its *parens patriae* jurisdiction as "theoretically limitless" and suggested "they certainly extend beyond the powers of a natural parent," although others have described a more limited power.[34] This power is now generally exercised through the use of declarations about what would be lawful in an individual case.

In exercising its *parens patriae* jurisdiction, the court must make a decision about what is objectively in the child's best interests.[35] The relevant interests extend beyond medical interests, and must include other interests such as emotional, sensory, and instinctive.[36] The views of the child and the parents (about the child's interests) must be considered; however, the parents' own interests are taken to be of no relevance.[37] There must always be a strong presumption in favour of preserving life.[38] Beyond this, courts have taken different approaches to the most appropriate way of determining best interests. Some judges purport to be making the decision the child would make

if they were able to and consider determination of the child's best interests to be a form of substitute decision making.[39] Others are of the view that they are required to make an objective decision about the welfare of the child and embrace the paternalistic nature of the jurisdiction.[40] Courts have rejected attempts to define or refine the best interests approach. In *Wyatt v Portsmouth Hospital NHS Trust*, Lord Justice Wall held that in considering best interests "the forensic debate should, in our judgment, be unfettered by any potentially contentious glosses on the best interests test which are likely to either inappropriately shift the focus of the debate, or to restrict the broad exercise of the judicial discretion."[41] Lord Justice Wall cited an earlier case in which it was recognized "[t]he infinite variety of the human condition never ceases to surprise and it is that fact that defeats any attempt to be more precise in a definition of best interests."[42]

Yet, it is arguable that court involvement in these cases is not strictly necessary. In *Raqeeb*, Justice MacDonald suggested it was necessary to seek a determination from the court in cases in which hospitals and parents disagreed about whether or not life sustaining treatment was appropriate for an unconscious child.[43] However, this proposition is questionable for a number of reasons. At a fundamental level, given the remedy provided is a declaration, a court application cannot be necessary before doctors proceed. A declaration is a remedy that allows a judge to advise on the lawfulness of the proposed course of action.[44] If a court declares withdrawal of treatment to be lawful, this withdrawal must be a lawful act. The court's declaration does not make this the case. The judge cannot make an action that would otherwise be unlawful lawful through a declaration.[45] So in the case of *Evans*, for example, the declaration did not make the withdrawal of treatment lawful, the declaration was an advisory statement that the doctors' proposed course of action was lawful. The court's involvement was not necessary for the doctors to proceed, it merely provided comfort to the parties.

Justice MacDonald suggested a declaration from the courts is necessary because if parents do not consent to the withdrawal of treatment, there would be "a void in relation to consent."[46] This mischaracterises the role of consent. Parents must consent to the provision of (non-emergency) treatment because otherwise it would be an unlawful invasion of the child's bodily integrity.[47] However, consent is not required for the non-provision of treatment.[48] Whether a failure to provide treatment is lawful will be assessed under the law of negligence or criminally negligent homicide, not battery.

Regardless of the accuracy of Justice MacDonald's statement, at a practical level, hospitals are understandably concerned to act lawfully, and given the consequences of a decision to withdraw life-sustaining treatment, they appear to prefer to seek the comfort of a declaration that this would be lawful prior to proceeding. Decisions to withdraw life-sustaining treatment are common in intensive care unit. A Canadian study of neonatal intensive care units found that 84% of deaths followed a decision to withdraw treatment.[49] The difficulty arises when parents do not agree with these decisions and threaten litigation. This leaves hospitals with a choice between seeking a prospective declaration their proposed course of action is lawful or proceeding and risking being sued or even criminal investigation. Unsurprisingly, hospitals often seek a prospective declaration from the court that the course of action would be in the child's best interests.

6. The Ignored Relevant Consideration

The elephant in the room in these disputes about long-term mechanical ventilation of children is the question of limited resources. When these matters have come before the court, judges have concluded that their paramount concern must be the best interests of the child.[50] Yet, this limits the extent to which the court may consider the broader context of the child's care.

Long-term mechanical ventilation is the paradigm example of highly expensive potentially life-long treatment. One analysis of the cost of long-term home ventilation found that the average cost was £350,000 per year.[51] Compared with £150,000 per year if patients were cared for in a paediatric ward, and £630,000 if patients received care in an intensive care unit.[52] The standard cost limit for treatment in the UK is £30,000 per Quality Adjusted Life Year (QALY). Home ventilation vastly exceeds this. At this cost, long-term mechanical ventilation could not be cost-effective based on standard thresholds.

While the question of whether treatment was in the best interests of the children in the cases discussed is extremely

difficult, the decisions by the NHS Trusts not to offer long-term mechanical ventilation appears much more clear-cut when viewed in terms of resources. Long-term ventilation for these children would be vastly outside the conventional cost-effectiveness threshold applied to medical treatments. At best, the benefits to the child in providing long-term mechanical ventilation are marginal —the child's life may be maintained but there was little else that could be achieved. Long-term mechanical ventilation at home is very expensive, and this will inevitably mean that other costs elsewhere in the health system cannot be met. Even more crucially, intensive care beds (and carers in the community able to support home ventilation) are a *scarce* resource. Placing a child in a minimally conscious state on long-term ventilation is highly likely to mean that other children (possibly with much greater potential to benefit) are unable to be admitted to intensive care, or unable to receive vital specialized nursing support at home.

In the case of Raqeeb, the family elected to move Tafida to the Italian hospital. However, the court decision in Raqeeb would have potentially obliged clinicians to continue treatment in the UK intensive care unit had the family chosen to stay. Moreover, should she return to the UK, clinicians may feel compelled to continue life-sustaining treatment.[53] There may have been a shift over the last three decades in the court's willingness to intervene in such cases. In *Re J (A minor),* Lord Donaldson MR noted 'The court when considering what course to adopt in relation to a particular child has no knowledge of competing claims to a health authority's resources and is in no position to express any view as to how it should elect to deploy them'.[54] In the same case Lord Justice Balcombe went even further, suggesting there were no situations in which the court should make orders that would even indirectly require doctors to treat a child contrary to their clinical judgment.[55] The decision in Raqeeb appears to conflict with that statement.

7. An Alternative Approach

Although everyone in these cases is undoubtedly aware that treatment was being provided in a system with limited resources, the requirement to make decisions in the child's best interests prevents explicit consideration of this. This was exemplified in *Raqeeb*, in which Justice MacDonald referred to the parents' capacity to fund the treatment themselves eight times but did not explain how this was relevant.[56] The case of *R v Cambridge Health Authority, Ex parte B* demonstrates how decisions could be made and what the role of the courts would be in making these decisions.[57] The case involved a 10-year-old child with cancer, for whom previous treatments had been unsuccessful and whose parents were seeking two phases of treatments that each had around a 10% chance of success and would cost £75,000. The Health Authority had determined it would not fund the treatment. As the decision was made on the basis of funding, the matter was heard as a judicial review of an administrative decision, providing more defined grounds for court involvement.

7.1 Decision Making in Hospitals

Clinical Commissioning Groups (CCGs) are responsible for the purchasing of health services in the NHS and should determine when mechanical ventilation is affordable. A CCG is required to exercise its functions "effectively, efficiently and economically."[58] And "health authorities of all kinds are constantly pressed to make ends meet …Difficult and agonising judgments have to be made as to how a limited budget is best allocated to the maximum advantage of the maximum number of patients."[59]

Our claim is that if and when there is a clear and defensible decision that continued mechanical ventilation is not appropriate, that this would then allow a different approach to disagreement. Changing the locus and ethical basis for decision making about treatment in the context of disputes would be valuable in a number of important ways. If there had been a clear process for identifying whether long-term ventilation for *Raqeeb*, *Evans* and *Haastrup* was appropriate —that may have changed the nature of the disagreement.

In the NHS, CCGs determine the broad categories of health services that will be purchased and NHS Trusts provide those services in accordance with the agreed standards.[60] In purchasing appropriate services, there is not an absolute duty to provide particular services, and the CCG is "entitled to have regard to the resources available to it."[61] At present, CCGs have not set standards or conditions on long-term ventilation. However, they could create standards about when it is appropriate to provide treatment such as mechanical ventilation. Such standards could place limits on the amount of time it is appropriate to provide mechanical ventilation or other limits based on the

likely outcome of mechanical ventilation. These decisions would be made at a population level and based on the likely benefit derived from the resources expended, rather than on a case by case basis. These decisions could be facilitated by “big data” and artificial intelligence, to apply standard cost-effectiveness thresholds typically used for drugs to all medical interventions, taking account of relevant patient specific variables.[62] This could be called “Precision Justice,” mirroring the advance of precision medicine.

If CCGs are unwilling to make these decisions at a regional level, they may also be made at a national level or through a nationally applicable process. Standards could be developed at a national level through NICE guidance, which could establish criteria for when it would be appropriate to provide long-term ventilation.[63] If it proves too difficult to articulate criteria or guidelines that could be applicable in the range of clinical circumstances when long-term ventilation may be sought, it might be possible or preferable to establish a clear *process* for such decisions to be made. That could be through the establishment of a treatment review panel or drawing on the existing resource of “individual funding review panels.”[64]

It is not the aim of this paper to definitively identify how resources like long-term ventilation should be allocated. We have elsewhere outlined some elements of an ethical approach,[65] as have others.[66] Rather, our claim is that if and when there is a clear and defensible decision that continued mechanical ventilation is not appropriate, that this would then allow a different approach to disagreement. Changing the locus and ethical basis for decision making about treatment in the context of disputes would be valuable in a number of important ways. If there had been a clear process for identifying whether long-term ventilation for *Raqeeb*, *Evans* and *Haastrup* was appropriate —that may have changed the nature of the disagreement. Clinicians would no longer have been placed in a position of disagreeing with parents about what would be ‘best’ for the child —instead, the medical team would have been making a clear and defensible judgement that such treatment was not *appropriate* in the context of the limited resources of the healthcare system.

7.2 Role of the Courts

If a body, such as a CCG, declined to provide treatment on the basis of resource allocation, parents may accept this decision or they may seek judicial review. As this is an administrative decision by a public body, the court would have jurisdiction but this review would proceed very differently to a case under the *parens patriae* jurisdiction. In a case of judicial review, the role of the court is not to assess how resources should be allocated (or what would be best for the child), rather it is to determine whether the decision of the CCG was lawfully made.[67] This would be assessed on administrative law grounds. For example, a decision may be unlawful if it is so unreasonable that no reasonable CCG could have made the decision.[68] The grounds to find the decision of the CCG unlawful would be much more limited than the court’s discretion under the *parens patriae* jurisdiction.

Any policy or decision would also need to comply with the *Human Rights Act 1998*.[69] Again though, this would not allow the courts to simply make a decision about what they thought was best in the circumstances. CCGs have a wide discretion to make decisions about the allocation of resources, and doing so will not necessarily constitute an interference in the rights of an individual who is denied treatment because of such a policy.[70] It is acceptable for a CCG not to fund clinically indicated treatment if there are broader policy reasons not to do so, such as the appropriate use of limited resources.[71]

8. Why Is a Distributive Justice Approach Preferable?

8.1 A More Ethically Defensible Approach

In cases involving critically ill children for whom ongoing treatment may arguably provide marginal benefit but at great expense, a distributive justice approach provides the most appropriate and equitable way of making decisions. In a diverse society, arguments about the best interests of such a child are intractable. A distributive justice approach offers a way out of this quagmire. Resource allocation decisions are made across health services every day and treatments are withheld on the basis they would not be a reasonable use of limited resources. There is no reason decisions about long-term mechanical ventilation should not be made on the same basis. Decisions about the best interests of a child appear to be made in a vacuum, a distributive justice approach recognizes the context in which treatment decisions are made.

An advantage of a distributive justice approach is that decisions about minimally conscious children do not need to be made on notions like the intrinsic value of human life or when life is worth living. It may be recognized that every human life is intrinsically valuable, but this does not mean that it is always just and fair to maintain human life. Instead, competing demands on limited resources mean that difficult decisions need to be made. It is only reasonable that a limited medical resource should be used where it will have the greatest possible benefit. If mechanical ventilation may provide a child with an opportunity to recover and lead a full life, it seems only reasonable to prefer that child's treatment over treatment for another child who will remain minimally conscious.

It is extraordinarily difficult, if possible at all, to describe the criteria that make life not worth living. Substantial pain and suffering seem at least necessary conditions, though these were arguably absent in all three cases above. It is less controversial to compare the value of lives: a longer life is better than a shorter life. A life of less pain is better than a life of more pain. And so on. In this way, distributive justice arguments may be more tractable by comparing in relative terms the value of life, rather than in absolute terms of whether a life is worth living.

8.2 A More Suitable Role for the Courts

A distributive justice approach not only provides a way out of the quagmire created by the best interests approach in a diverse society, it also gives the courts a more suitable role through administrative law. Administrative law provides a suitable basis for assessing the appropriateness of decisions by public bodies. As the courts have identified in administrative law cases involving the provision of treatment, "Were we to express opinions as to the likelihood of the effectiveness of medical treatment, or as to the merits of medical judgment, then we should be far from the sphere which under our constitution is accorded to us."[72] This does not mean the court cannot "submit the decision making process to rigorous scrutiny."[73] But this scrutiny should be on the basis of whether or not the decision was lawful, rather than second guessing medical opinions, making contestable value judgements, or acting as a "wise, affectionate, and careful parent."[74]

The use of the *parens patriae* jurisdiction is often called for in the context of disputes relating to children because of the significance and irreversibility of the decisions being made. These are important decisions, but they must be considered in the context of the many important decisions that are made in hospitals every day. Just because a decision involves death, this should not necessitate court involvement. Even if courts make every effort to expedite such decisions, a court case will invariably delay decision making. During this time, the status quo must be maintained. The case of *Gard* is instructive. That case involved an 8-month-old child with a rare mitochondrial disease who was minimally conscious and whose parents wanted to take him to the US for experimental treatment.[75] In the six months it took for the case to be resolved through the courts, he was left on a mechanical ventilator. During this period he could have been provided with the experimental treatment his parents sought. Instead, the child spent months on mechanical ventilation waiting for the court process to be resolved. Although the court process is described as a safeguard, the practical outcome is that children are left in limbo, sometimes for months, waiting for a decision.

The other important consideration is the cost of the court process. Whilst resource arguments often focus on the costs of medical treatments, taking a matter through the courts is also a considerable expense for the state. The NHS Trust must obtain legal advice and representation, doctors must provide reports and give evidence, and holding hearings is also expensive. The cost of conducting court hearings is rarely considered in discussion of limited resources available for medical treatment, but ultimately all these costs must be covered by public funds. The administration of justice is an important public service, but this does not mean court cases are always the most effective use of public funds.

9. Hospital Intervention in Parental Attempts to Seek Treatment Elsewhere

Focusing on the appropriate use of resources may change the process according to which hospitals may intervene in parental decisions to seek treatment elsewhere. The distributive justice approach would recognize that the resources available to an NHS Trust are limited and that it may not be appropriate to expend these on long term mechanical ventilation of a child who experiences no apparent enjoyment from life. But this alternative approach may also clarify that if the parents are able to find an alternative means of accessing mechanical ventilation, there

may no longer be a strong reason to prevent the child from accessing it through the *parens patriae* jurisdiction. As George identifies, the *Children Act 1989* was enacted to govern decision making for children and provides a framework for interfering in parental decisions focused on preventing significant harm.[76]

On appeal in the case of *Gard*, it was argued on behalf of the parents that in order to intervene to prevent the parents from taking their child overseas, significant harm would need to be demonstrated as this is the standard in the *Children Act 1989* for intervening in parental decisions.[77] This argument was rejected on the basis the hospital could apply under the court's inherent jurisdiction for a declaration about treatment, at which point the court must make a determination of the child's best interests and not a determination about whether the parent's preferred course of action was appropriate.[78]

In the wake of the Gard case, there have been proposals for legal change to introduce a "significant harm" test for situations where parents seek treatment by other health professionals.[79] To date, these proposals have not yet been introduced to parliament, and it is unclear whether they would be passed. However, under the proposed distributive justice approach described in this paper, such a change may be unnecessary. If a hospital had already determined that treatment was not appropriate because of resources, it is not clear it could then apply for a determination about whether treatment should be provided because it is in the child's best interests. As an administrative decision would already have been made, there would be no live dispute about whether medical treatment should be provided. If the NHS Trust wished to prevent the transfer of a child arranged by parents, an application would need to be made under the *Children Act 1989* for a care order or a supervision order to prevent 'significant harm' to the child in being taken overseas.[80] It is unclear, however, whether the court would still allow an application under the *parens patriae* jurisdiction or require this higher threshold to be met.

The "significant harm" threshold for court intervention is appropriate and, in our view, is preferable to the court making a best interests judgement.[81] As discussed above, it is not clear why the court should simply be substituting its own decisions about what it thinks is best. The revised test would not allow parents to make harmful decisions for their child, nor would it allow health professionals (whether in the UK or elsewhere) to provide or continue harmful medical treatment. However, if parents' pursuit of medical treatment would *not* be significantly harmful (and there are no relevant resource-based concerns), then it is difficult to see what possible ethical basis there could be for initiating costly and potentially distressing court proceedings.

10. Practical Implications of a Distributive Justice Approach

A distributive justice approach could have considerably altered the three cases discussed above. In each of the cases, the initial decision by the NHS Trust not to provide ongoing long-term mechanical ventilation may well have been appropriate if there had been a clear and fair decision not to allocate publicly funded resources for that purpose. But in some of the cases the parents were able to secure alternative funding for treatment and an alternative location for treatment. In such cases, the NHS Trust should only interfere in the parents' decision to move their child overseas if the child would suffer significant harm as a result of the parents' decision. Given the decisions about whether or not treatment of these children was in their best interests appeared to be so finely balanced, it may be that courts would not have concluded that the children would have been significantly harmed by the decision. That depends on how harm is conceived though and what level of harm is considered to be significant enough to warrant intervention.[82]

A shift from 'best interests' to 'significant harm' may not necessarily alter the outcome of some of the cases. For example, in the *Gard* case Justice MacFarlane suggested this would not have made a difference, as the parents' proposed course would cause significant harm.[83] However, others have argued that it is hard to see how Gard's parents were exposing him to significant harm to attempt a trial of experimental treatment provided by the world's expert in his condition at a world leading institution.[84] The alternative approach suggested here would mean judges were not just considering the application of different wording, but a different question. Under the *parens patriae* jurisdiction the courts are required to determine whether medical treatment is in the child's best interests. If treatment is withheld on the basis of available resources and parents identify available treatment elsewhere, the question for the court should be whether state intervention is warranted to prevent parents causing significant harm

to their child. Although it is unclear whether this different context would alter the outcome of cases, theoretically it sets a higher threshold for intervention and requires courts to justify the appropriateness of intervention.

The alternative approach suggested would also allow more economically sustainable decisions. In the case of *Raqeeb*, Justice MacDonald suggested it was appropriate to provide Tafida with mechanical ventilation because other children in England in a similar situation had been provided with treatment.[85] To suggest that just because a treatment was made available elsewhere it should be made available by the current NHS Trust fails to account of the constraints on the particular CCG and Trust. A distributive justice approach would not apply such a high standard and would instead assess whether any reasonable CCG and Trust could have made the same decision. This avoids the difficulty of suggesting that because a treatment is provided somewhere, it must be provided everywhere. Indeed, it may be that it is unjust that mechanical ventilation is being provided in some of these other cases.

In cases such as *Evans* and *Raqeeb,* consideration would also need to be given to the long-term plans for care. In *Raqeeb*, the parents had secured sufficient funding to take their daughter to Italy and for a tracheostomy that would allow home ventilation. The parents suggested they could then return to England. What was not addressed was who would support home ventilation. Given the Italian doctors suggested Tafida could be maintained on ventilation for 10-20 years, this could be very expensive, in the range of millions of pounds. Even if such children experience a normal quality of life (value 1.0) home ventilation would still fall outside the standard threshold, since it costs over £300,000 per year. The quality of life of Tafida is potentially closer to zero, rendering the intervention even less cost-effective. A distributive justice approach would allow consideration of this question and a more practical discussion about the long-term care of children on home ventilation.

11. Limitations of a Distributive Justice Approach

A distributive justice approach would not solve the problem that these remain extremely difficult and emotional decisions. It may be seen to simply push these decisions back to CCGs (or other resource allocation bodies) and hospitals. The distributive justice approach clearly places the burden of ethical decision making on CCGs and hospitals, but this is consistent with their role and the range of difficult decisions they are already required to make. Hospitals, perhaps assisted by clinical ethics processes, are also in a much better position to make these decisions than the courts. Hospitals have an understanding of the science, but also of their budgets and competing demands. We have criticized the best interests approach applied by the courts under the *parens patriae* jurisdiction on the basis that attempting to identify the best interests of the child was subjective and potentially inconsistent. It may be argued that focusing on appropriate resource allocation gives rise to similar issues. The key difference is that there are existing frameworks for assessing the cost effectiveness of treatments, which are already broadly applied in health systems. These may be challenged, and there will always be borderline cases, but they are arguably more robust than judicial determinations of a child's best interests. Moreover, such judgements are relative not absolute, as we have argued. Similar arguments may be made about the difficulty of identifying significant harm to the child. But these are also based on a well-established threshold that is applied consistently across family law.

12. Conclusion

Decisions about the long-term ventilation or other life-prolonging medical treatment of critically ill infants and children will always be difficult and there is no approach that will resolve this complexity. This complexity should not be an invitation for judicial intervention though. Instead, the courts should exercise restraint. This restraint could be encouraged by hospitals making clear and transparent decisions about why they are not offering mechanical ventilation. If a hospital plainly states that mechanical ventilation will not be provided because the resources could be more effectively utilised elsewhere, the courts may review this decision but are limited in the extent to which they may do so. Judicial review is a more appropriate role for the courts, who have no understanding of the resource limitations on hospitals and a very limited understanding of the clinical considerations for the child.

This approach would mean that in cases like *Haastrup*, *Evans* and *Raqeeb*, the hospitals may decide not to offer long-term ventilation and may implement that decision without the long delay caused by court involvement. If parents opposed the decision, the extent to which the courts could intervene would be limited. But it would also mean the

parents were free to pursue other options for treatment. If the health professionals wished to prevent parents from accessing treatment elsewhere, they may do so if that treatment would pose a risk of significant harm. In cases of children in minimally conscious states, whether courts would intervene to prevent treatment elsewhere would depend on how they interpreted harm and whether this was considered significant enough to warrant state intervention.[86] This approach would recognize the value pluralism in our society and that there may be more than one view about a child's best interests. This approach would also recognize the context in which all treatment decisions must be made and allow those best placed to understand this context to make decisions. While it is beyond the scope of this paper, this shift in approach may also be relevant to disputes about treatment for adult patients.

We should move to a distributive justice based, rather than primarily interest based, justification for limitation of life-prolonging mechanical ventilation in children.

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68. R v Ministry of Defence ex p Smith [1996] QB 517, 554E; The Queen on the application of Ann Marie Rogers v Swindon NHS Primary Care Trust [2006] EWCA Civ 392, [55]-[60]
69. Human Rights Act 1998, (UK), s 6.
70. R (Condliff) v North Staffordshire Primary Care Trust [2011] EWCA Civ 910, [30]
71. D. Lock and H. Gibbs, NHS Law and Practice (LAG Education and Services: London, 2018): at 11.

72. R v Cambridge Health Authority, supra note 66.
73. The Queen on the application of Colin Ross v West Sussex Primary Care Trust [2008] EWHC 2252 (Admin), [36].
74. R. George, “The Legal Basis of the Court’s Jurisdiction to Authorise Medical Treatment of Children,” in Goold, et al., supra note 1.
75. Great Ormond Street Hospital v Constance Gard, Chris Gard &Charles Gard (A child, by his guardian ad litem) [2017] EWHC 972 (Fam).
76. George, supra note 73.
77. Constance Yates &Christopher Gard v Great Ormond Street Hospital for Children NHS Foundation Trust [2017] EWCA Civ 410, [56]-[71].
78. Id., at [89]-[109].
79. See, for example, The Charlie Gard Foundation, available at <https://www.thecharliegardfoundation.org/charlies-law/ >(last visited November 4, 2021).
80. Children Act 1989, s 31.
81. D. Wilkinson, “In Defence of a Conditional Harm Threshold Test for Paediatric Decision-Making,” in Goold, et al., supra note 1.
82. Id., at 102-105.
83. Id., at 103.
84. J. Savulescu and P. Singer, “Unpicking What We Mean by Best Interests in Light of Charlie Gard,” August 2, 2017, BMJ Opinion, available at <https://blogs.bmj.com/bmj/2017/08/02/unpicking-what-we-mean-by-best-interests-in-light-of-charlie-gard/ >(last visited November 4, 2021).
85. Tafida Raqeeb, supra note 10, at [168].
86. Wilkinson, supra note 80, at 102-105.

DETAILS

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Paula O'Brien, Room, R., & Anderson-Luxford, D. (2022). Commercial advertising of alcohol: Using law to challenge public health regulation. The Journal of Law, Medicine & Ethics, 50(2), 240-249. doi:https://doi.org/10.1017/jme.2022.48

In most countries, the alcohol industry enjoys considerable freedom to market its products. Where government regulation is proposed or enacted, the alcohol industry has often deployed legal arguments and used legal forums to challenge regulation. Governments considering marketing regulation must be cognizant of relevant legal constraints and be prepared to defend their policies against industry legal challenges.

Garde, A., & Cabrera, O. A. (2022). INTRODUCTION commercial speech and the commercial determinants of health. The Journal of Law, Medicine & Ethics, 50(2), 212-215. doi:https://doi.org/10.1017/jme.2022.44

This article introduces a symposium that aims to identify and critically assess the legal strategies of the tobacco, alcohol, and food and beverage industries which rest on freedom of expression arguments.

Ross Daval, C. J. (2022). Immigration law, public health, and the future of public charge policymaking. The Journal of Law, Medicine & Ethics, 50(2), 336-338. doi:https://doi.org/10.1017/jme.2022.60

U.S. immigration law has excluded noncitizens likely to become a "public charge" since 1882. When the Trump administration proposed a new Rule expanding the interpretation of that exclusion in 2018, over 55,000 people wrote public comments. These comments, overwhelmingly opposed to the change, are the subject of Rachel Fabi and Lauren Zahn's insightful article in this issue of The Journal of Law, Medicine, and Ethics. The themes they identify resonate with the history of the public charge exclusion, which has always reflected a tension between two aims of American governance — to provide for those in need of assistance, and to shape the nation's citizenry according to ideals of self-sufficiency.

Hutchinson, T. (2022). Letter from the editor. The Journal of Law, Medicine & Ethics, 50(2), 205. doi:https://doi.org/10.1017/jme.2022.43

Pomeranz, J. L. (2022). United states: Protecting commercial speech under the first amendment. The Journal of Law, Medicine & Ethics, 50(2), 265-275. doi:https://doi.org/10.1017/jme.2022.51

The First Amendment to the US Constitution protects commercial speech from government interference. Commercial speech has been defined by the US Supreme Court as speech that proposes a commercial transaction, such as marketing and labeling. Companies that produce products associated with public health harms, such as alcohol, tobacco, and food, thus have a constitutional right to market these products to consumers. This article will examine the evolution of US law related to the protection of commercial speech, often at the expense of public health. It will then identify outstanding questions related to the commercial speech doctrine and the few remaining avenues available in the United States to regulate commercial speech including the use of government speech and addressing deceptive and misleading commercial speech.

Brandon, d. P., & Compton, M. T. (2022). Voluntary registries: Filling the critical information gap in first response to mental health crises. The Journal of Law, Medicine & Ethics, 50(2), 364-367. doi:https://doi.org/10.1017/jme.2022.63

We argue that voluntary mental health registries integrated into the 9-1-1 system, where patients and caregivers can establish a repository of this information, will help fill this information gap by enabling first responders to quickly understand the context of a call for service with a mental health component, and to make better informed decisions. Despite valid concerns about privacy, stigma, and the potential misuse of protected health information, such registries, if carefully designed and administered, can improve the health outcomes of 9-1-1 calls for service involving mental health-related crises.

Subramanian, S., Gokani, N., & Aneja, K. (2022). Right to commercial speech in india: Construing constitutional provisions harmoniously in favor of public health. The Journal of Law, Medicine & Ethics, 50(2), 284-290. doi:https://doi.org/10.1017/jme.2022.53

This article examines the right to commercial speech that has been read into the right to freedom of speech and expression under Article 19(1)(a) of the Constitution of India. Restrictions on this right are only permitted if they come within the ambit of the exhaustive list of reasonable restrictions under Article 19(2), under which public health is notably absent. Nevertheless, through the doctrine of harmonious construction, the Indian judiciary have adopted a purposive interpretation to circumvent the omission of public health by carving up freedom of commercial speech into two parts: protected speech which furthers public interest and unprotected speech which is purely commercial. Moreover, the Indian courts have construed these provisions in light of the right to life under Article 21 and the health-related Directive Principles of State Policy under Part IV of the Constitution. This article concludes that judicial creativity in India has consistently been used in favor of protecting public health.

Rothstein, M. A. (2022). The OSHA COVID-19 case and the scope of the occupational safety and health act. The Journal of Law, Medicine & Ethics, 50(2), 368-374. doi:https://doi.org/10.1017/jme.2022.64

The Occupational Safety and Health Administration (OSHA) issued an emergency temporary standard (ETS) for COVID-19 applicable to private sector employers with 100 or more employees. Among other things, the ETS required employers either to mandate employee vaccination or weekly testing and wearing masks.

Constantin, A., Hevia, M., & Cabrera, O. A. (2022). Commercial speech and unhealthy food products: Conceptual foundations. The Journal of Law, Medicine & Ethics, 50(2), 216-220. doi:https://doi.org/10.1017/jme.2022.45

This article provides a critical and philosophical assessment of arguments invoked for and against the constitutional protection of commercial expression and the regulation of commercial speech with a focus on the commercialization of unhealthy food products.

Aneja, K., Ginsbach, K., Gottschalk, K., Halabi, S., & Nardi, F. (2022). COVID-19 law lab: Building strong legal evidence. The Journal of Law, Medicine & Ethics, 50(2), 385-389. doi:https://doi.org/10.1017/jme.2022.67

The COVID-19 Law Lab platform enables quantitative representation of epidemic law and policies in a given country for multiple years, enabling governments and researchers to compare countries, and learn about the impacts and drivers of policy choices. The Law Lab initiative is designed to address the urgent need for quality legal information to support the study of how law and policy can be used to effectively manage this, and future, pandemic(s).

Melillo, M. (2022). The influence of the commercial speech doctrine on the development of tobacco control measures. The Journal of Law, Medicine & Ethics, 50(2), 233-239. doi:https://doi.org/10.1017/jme.2022.47

Among the attempts to oppose tobacco control legislation, the tobacco industry has alleged violations of its right to commercial speech. While the disputes that took place in some jurisdictions like the United States (US), Canada, or the European Union (EU) have been already analyzed, much less is known about how, globally, this doctrine has influenced the adoption of tobacco control measures. This article contributes to filling this gap by illustrating how the commercial speech doctrine influenced the negotiations of the Framework Convention on Tobacco Control (FCTC). Moreover, using the Tobacco Control Database of Campaign for Tobacco-Free Kids, it shows that arguments on commercial speech have been used to challenge tobacco control measures in an increasing number of countries.

Fabi, R., & Zahn, L. (2022). Public reason, public comments, and public charge: A case study in moral & practical reasoning in federal rulemaking. The Journal of Law, Medicine & Ethics, 50(2), 322-335. doi:https://doi.org/10.1017/jme.2022.59

The “public charge” rule is a long-standing immigration policy that seeks to determine the likelihood that a prospective immigrant will become dependent on the government for subsistence. When the Trump administration sought to expand the criteria that would count against an applicant for permanent residency to include public

benefits historically excluded from the calculation, thousands of commenters wrote to oppose or support the proposed changes. This paper explores the moral and practical reasons commenters provided for their position on the public charge rule and considers the value of the public comment process for immigration, health, and social policy.

Shah, S. K., Gross, M., & Nebeker, C. (2022). Optimizing ethics engagement in research: Learning from the ethical complexities of studying opioid use in pregnancy. The Journal of Law, Medicine & Ethics, 50(2), 339-347. doi:https://doi.org/10.1017/jme.2022.61

Research on opioid use in pregnancy is critically important to understand how the opioid epidemic has affected a generation of children, but also raises significant ethical and legal challenges. Embedded ethicists can help to fill the gaps in ethics oversight for such research, but further guidance is needed to help strike the balance between integration and independence.

Tessema, F. A., Sarpatwari, A., Rand, L. Z., & Kesselheim, A. S. (2022). High-priced sickle cell gene therapies threaten to exacerbate US health disparities and establish new pricing precedents for molecular medicine. The Journal of Law, Medicine & Ethics, 50(2), 380-384. doi:https://doi.org/10.1017/jme.2022.66

Gene therapies to treat sickle cell disease are in development and are expected to have high costs. The large eligible population size — by far, the largest for a gene therapy — poses daunting budget challenges and threatens to exacerbate health disparities for Black patients, who make up the vast majority of American sickle cell patients.

Jaime O'Brien, Vinarcsik, L., & Wilson, Y. (2022). For the common good: Philosophical foundations of research ethics by alex john london. The Journal of Law, Medicine & Ethics, 50(2), 390-391. doi:https://doi.org/10.1017/jme.2022.68

Written in response to what he recognizes as the problematic philosophical underpinnings of "orthodox research ethics," Alex John London's For the Common Good reimagines what is called for in any effort to create a better system of oversight and regulation in biomedical research. London weaves a common thread — justice — through this historical and critical account of the practice of research ethics and its organization of stakeholders, institutions and regulations. By introducing the idea of "a common good" London reframes the narrative and responsibilities of the research ethics field to demonstrate that scientific research and regard for the rights and welfare of individuals are not mutually exclusive. This impressive monograph encourages its readers to push past the limitations of traditional research ethics to consider the context in which the discipline is embedded. That is, rather than settling for analysis at the level of researchers and research participants alone, London encourages us to expand our inquiry to encompass a wider array of stakeholders who co-labor in the social undertaking of biomedical knowledge production. London accomplishes the difficult task of upstream analysis — turning his attention to the conditions and assumptions which create ethical dilemmas rather than applying a retrospective ethical salve to injuries near-guaranteed by a broken system. As opposed to the limited domain of orthodox research ethics (researchers, participants, and the institutional bodies which regulate interaction between the two) London also considers the role and contributions of affected communities, pharmaceutical firms, philanthropic organizations, and journal editors among others.

Campbell, M. (2022). Chile: Front-of-package warning labels and food marketing. The Journal of Law, Medicine & Ethics, 50(2), 298-303. doi:https://doi.org/10.1017/jme.2022.55

This Article aims to show how the food industry has instrumentalized the right to freedom of expression to oppose innovative laws in Chile aimed at creating healthier food environments.

Ross, H. M., Bowman, D. M., & Wani, J. M. (2022). Voluntary registries to support improved interaction between police and people living with dementia. The Journal of Law, Medicine & Ethics, 50(2), 348-363. doi:https://doi.org/10.1017/jme.2022.62

This paper provides an overview of the societal impact of a rising dementia population and examines the legal and ethical implications posed by voluntary registries as a community-oriented solution to improve interactions between law enforcement and individuals with dementia. It provides a survey of active voluntary registries across the United States, with a focus on Arizona, which has the highest projected growth for individuals living with dementia in the country.

Dzehtsiarou, K., & Garde, A. (2022). Freedom of commercial expression and public health protection at the european court of human rights. The Journal of Law, Medicine & Ethics, 50(2), 250-258. doi:https://doi.org/10.1017/jme.2022.49

This contribution considers the case law of European Court of Human Rights (ECtHR) and focuses on the extent to which the Contracting Parties to the European Convention on Human Rights (ECHR) can regulate the tobacco, alcohol, and food industries in a manner compatible with their ECHR obligations. After briefly presenting the two key cases dealing specifically with tobacco advertising, this contribution considers the main factors that the ECtHR takes into account when balancing competing concerns, and in particular freedom of commercial expression and public health protection. It concludes that none of these factors is absolute, as the Court considers the strength of each one of them on the facts of each case. Nevertheless, it is clear from its case law that States have a wide margin of appreciation to regulate marketing practices that are inimical to public health and the prevention of non-communicable diseases more specifically, to the extent that even extensive advertising restrictions can be compatible with Article 10 of the ECHR.

Etilé, F. (2022). Economic perspectives on food choices, marketing, and consumer welfare. The Journal of Law, Medicine & Ethics, 50(2), 221-232. doi:https://doi.org/10.1017/jme.2022.46

This contribution reviews the main normative and positive arguments that can used in the assessment of the costs and benefits of food marketing restrictions, focusing specifically on theoretical and empirical developments in the economics of advertising, consumer behaviour and industrial organization since the 70s.

Hodge,James G.,,Jr, Piatt, J. L., Barraza, L., & White, E. N. (2022). Regressive federalism, rights reversals, and the Public's health. The Journal of Law, Medicine & Ethics, 50(2), 375-379. doi:https://doi.org/10.1017/jme.2022.65

As the United States emerges from the worst public health threat it has ever experienced, the Supreme Court is poised to reconsider constitutional principles from bygone eras. Judicial proposals to roll back rights under a federalism infrastructure grounded in states' interests threaten the nation's legal fabric at a precarious time. This column explores judicial shifts in 3 key public health contexts — reproductive rights, vaccinations, and national security — and their repercussions.

Lake, S. J., Benjamin, K. E., & Foster, N. D. (2022). Public health protection vs. freedom of commercial expression in the commonwealth caribbean: The case of barbados and jamaica. The Journal of Law, Medicine & Ethics, 50(2), 304-311. doi:https://doi.org/10.1017/jme.2022.56

This chapter explores the tension between public health protection and the freedom of commercial expression from a Commonwealth Caribbean perspective, using Barbados and Jamaica as case studies. First, it assesses the scope of the right to freedom of expression. Second, it discusses the extent to which public health protection may be invoked to restrict the right. The authors conclude that Commonwealth Caribbean states can justifiably restrict commercial speech about tobacco products and unhealthy food and beverages.

Barbosa, I., Leite, F., & Britto, C. (2022). Restricting unhealthy food and beverage advertising in brazil: Challenges and opportunities. The Journal of Law, Medicine & Ethics, 50(2), 291-297. doi:https://doi.org/10.1017/jme.2022.54

In Brazil, the normative landscape around advertising is complex, not the least because of limitations inherent to dispute resolution mechanisms. Focusing on unhealthy food and beverages, this case study identifies some challenges and opportunities around advertising restrictions, including in relation to freedom of speech.

Silvia Serrano Guzmán, Ariadna Tovar Ramírez, & Cabrera, O. A. (2022). Commercial speech and the prohibition of tobacco advertising: The colombian constitutional court approach. The Journal of Law, Medicine & Ethics, 50(2), 259-264. doi:https://doi.org/10.1017/jme.2022.50

This article argues that the decision by the Columbian high court to totally ban the advertising and promotion of tobacco products is sound and could indeed be applied to other types of harmful products.

Kruger, P., Mafuyeka, M., & Karim, S. A. (2022). The right to free commercial speech in south africa and its tension with public health interventions. The Journal of Law, Medicine & Ethics, 50(2), 317-321. doi:https://doi.org/10.1017/jme.2022.58

Marketing restrictions to promote public health invoke competing rights, including the right to free commercial speech which for-profit entities use to protect their freedom to market products without undue regulation. The right to free commercial speech in South Africa has been developed through case law since the adoption of the first democratic constitution in South Africa in 1996. This article examines the impact of this recent judgment and the lessons for policy makers to ensure effective regulation of marketing practices in South Africa.

Cinà, M.,M., & Nardi, F. E. (2022). Balancing the scales: The role of the canadian supreme court in weighing commercial speech and public health. The Journal of Law, Medicine & Ethics, 50(2), 276-283. doi:https://doi.org/10.1017/jme.2022.52

The Supreme Court of Canada has established that commercial speech is protected under the Canadian Charter of Rights and Freedoms and that commercial speech exists along a continuum of utility and value, which is balanced against objectives such as public health. This article examines jurisprudence to determine when infringements on commercial speech are acceptable, analyzing considerations of evidence, rational connections between policies and outcomes, proportionality, and minimal impairment.

Friant-Perrot, M., & Garde, A. (2022). The regulation of alcohol marketing in france: The loi evin at thirty. The Journal of Law, Medicine & Ethics, 50(2), 312-316. doi:https://doi.org/10.1017/jme.2022.57

When adopted in 1991, the French Loi Evin was pioneering as one of the first in the world to regulate alcohol marketing as extensively. This short contribution assesses whether it remains fit for purpose over 30 years later. To this effect, it assesses its main provisions, considers the legislative amendments that have ensued as well as the extensive interpretation French courts have given of its scope, before concluding that the prospects for its revisions are limited in the near future.

Hutchinson, T. (2022). Letter from the editor. The Journal of Law, Medicine & Ethics, 50(1), 1. doi:https://doi.org/10.1017/jme.2022.1