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

Paula O'Brien [1] ; Room, Robin [2] ; Anderson-Luxford, Dan [2 1] MELBOURNE LAW SCHOOL, UNIVERSITY OF MELBOURNE, VICTORIA, AUSTRALIA [2] LA TROBE UNIVERSITY, VICTORIA, AUSTRALIA

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

Garde, Amandine [1] ; Cabrera, Oscar A [2 1] UNIVERSITY OF LIVERPOOL, LIVERPOOL, UNITED KINGDOM [2] O'NEIL INSTITUTE FOR NATIONAL AND GLOBAL HEALTH LAW, GEORGETOWN UNIVERSITY, WASHINGTON, DC, USA

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

Ross Daval, C Joseph [1] [1] BRIGHAM AND WOMEN'S HOSPITAL AND HARVARD MEDICAL SCHOOL, BOSTON, MASSACHUSETTS, USA

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

Pomeranz, Jennifer L [1] [1] SCHOOL OF GLOBAL PUBLIC HEALTH, NEW YORK UNIVERSITY, NEW YORK, NY, USA

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

Brandon del Pozo [1] ; Compton, Michael T [2 1] RHODE ISLAND HOSPITAL AND BROWN UNIVERSITY, PROVIDENCE, RI, USA [2] NEW YORK STATE PSYCHIATRIC INSTITUTE AND COLUMBIA UNIVERSITY, NEW YORK, NY, USA

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

Subramanian, Sujitha [1] ; Gokani, Nikhil [2] ; Aneja, Kashish [3] [1] UNIVERSITY OF LIVERPOOL, UNITED KINGDOM [2] UNIVERSITY OF ESSEX, UNITED KINGDOM [3] SUPREME COURT OF INDIA, NEW DELHI, INDIA

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

Rothstein, Mark A [1] [1] UNIVERSITY OF LOUISVILLE SCHOOL OF MEDICINE IN LOUISVILLE, KENTUCKY, USA

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.

AuthorAffiliation

About This Column

Mark A. Rothstein serves as the section editor for Currents in Contemporary Ethics. Professor Rothstein is the Herbert F. Boehl Chair of Law and Medicine and the Director of the Institute for Bioethics, Health Policy and Law at the University of Louisville School of Medicine in Kentucky. (mark.rothstein@louisville.edu)

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Commercial Speech and Unhealthy Food Products: Conceptual Foundations

Constantin, Andrés [1] ; Hevia, Martín [2] ; Cabrera, Oscar A [1 1] GEORGETOWN UNIVERSITY, WASHINGTON, DC, USA [2] TORCUATO DI TELLA UNIVERSITY, BUENOS AIRES, ARGENTINA

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

Aneja, Kashish [1] ; Ginsbach, Katherine [2] ; Gottschalk, Katie [2] ; Halabi, Sam [3] ; Nardi, Francesca [2 1]
O'NEIL INSTITUTE FOR NATIONAL AND GLOBAL HEALTH LAW, GEORGETOWN UNIVERSITY, WASHINGTON, DC, USA; SUPREME COURT OF INDIA, NEW DELHI, INDIA [2] O'NEIL INSTITUTE FOR NATIONAL AND GLOBAL HEALTH LAW, GEORGETOWN UNIVERSITY, WASHINGTON, DC, USA [3] O'NEIL INSTITUTE FOR NATIONAL AND GLOBAL HEALTH LAW, GEORGETOWN UNIVERSITY, WASHINGTON, DC, USA; COLORODO SCHOOL OF PUBLIC HEALTH, COLORADO STATE UNIVERSITY, AURORA, COLORADO, USA

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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.

AuthorAffiliation

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

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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The Influence of the Commercial Speech Doctrine on the Development of Tobacco Control Measures

Melillo, Margherita [1] [1] O'NEILL INSTITUTE FOR NATIONAL AND GLOBAL HEALTH LAW AT GEORGETOWN UNIVERSITY, WASHINGTON, DC, USA

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
Identifier / keyword:	Tobacco; Commercial Speech; Advertising; FCTC; Litigation
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Public Reason, Public Comments, and Public Charge: A Case Study in Moral &Practical Reasoning in Federal Rulemaking

Fabi, Rachel [1] ; Zahn, Lauren [1 1] SUNY UPSTATE MEDICAL UNIVERSITY, SYRACUSE, NY, USA

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.

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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

Shah, Seema K [1] ; Gross, Marielle [2] ; Nebeker, Camille [3 1] LURIE CHILDREN'S HOSPITAL AND DEPARTMENT OF PEDIATRICS, NORTHWESTERN UNIVERSITY, CHICAGO, ILLINOIS, USA [2] DEPARTMENT OF OBSTETRICS, GYNECOLOGY, AND REPRODUCTIVE SCIENCES, UNIVERSITY OF PITTSBURGH SCHOOL OF MEDICINE, PITTSBURGH, PENNSYLVANIA, USA [3] SCHOOL OF PUBLIC HEALTH AND UC SAN DIEGO RESEARCH ETHICS PROGRAM, UNIVERSITY OF CALIFORNIA, SAN DIEGO, LA JOLLA, CALIFORNIA, USA

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

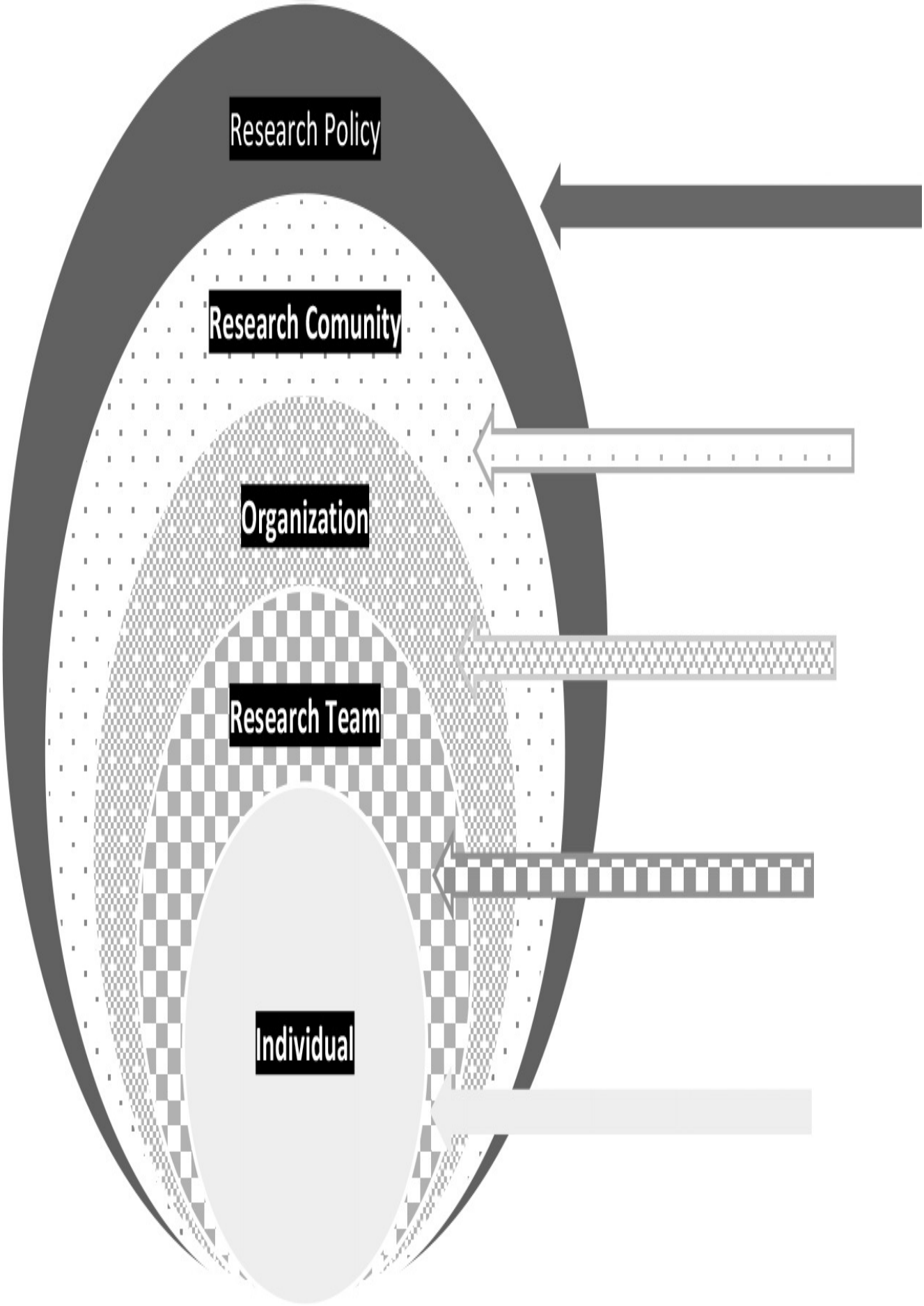
Conducting research on substance use disorder is ethically challenging,[1] particularly when studying the effects of substance use during pregnancy on neonatal and childhood development. As part of a broader effort to address the opioid epidemic, the National Institutes of Health (NIH) funded a network 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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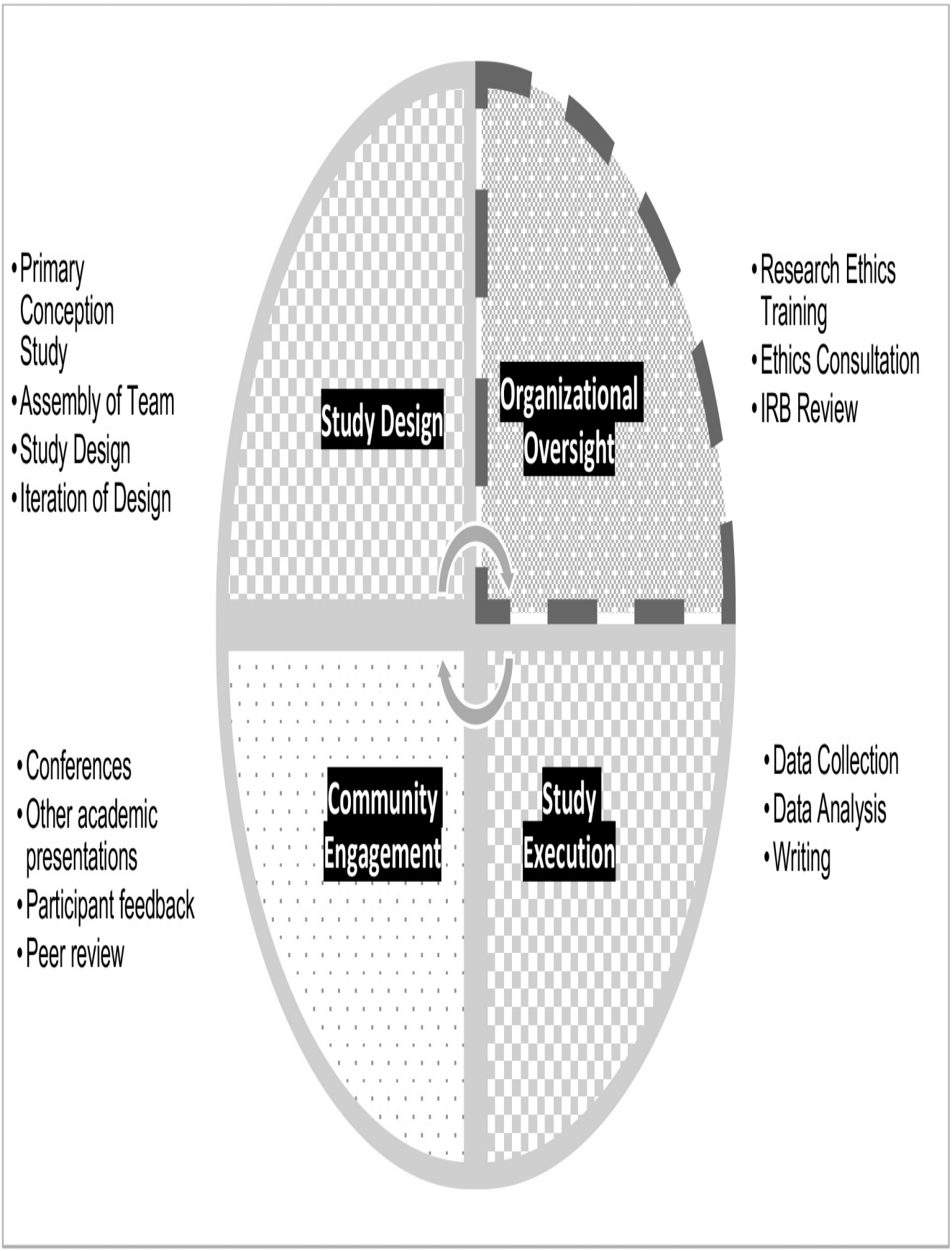
Perhaps more importantly, mere compliance with regulations is not sufficient to ensure research is conducted ethically. The current system of ethical oversight in the U.S. was vividly described by Carol Levine as “born in

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

Tessema, Frazer A [1] ; Sarpatwari, Ameet [1] ; Rand, Leah Z [1] ; Kesselheim, Aaron S [1] [1] PROGRAM ON REGULATION, THERAPEUTICS, AND LAW (PORTAL), DIVISION OF PHARMACOEPIDEMIOLOGY AND PHARMACOECONOMICS, DEPARTMENT OF MEDICINE, BRIGHAM AND WOMEN'S HOSPITAL AND HARVARD MEDICAL SCHOOL, BOSTON, MA, USA

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.

US gene therapy prices have recently reached from $475,000 to over $2 million for one-time use.[15] 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.

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.

AuthorAffiliation

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

Jaime O'Brien [1] ; Vinarcsik, Lou [2] ; Wilson, Yolonda [2] [1] NORTH CAROLINA, USA [2] SAINT LOUIS UNIVERSITY, ST. LOUIS, MISSORI, USA

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

Campbell, Marcelo [1] [1] SCHOOL OF LAW AND SOCIAL JUSTICE, UNIVERSITY OF LIVERPOOL, UNITED KINGDOM

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

Ross, Heather M [1] ; Bowman, Diana M [1] ; Wani, Jessica M [1 1] ARIZONA STATE UNIVERSITY, PHOENIX, ARIZONA, USA

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

Dzehtsiarou, Kanstantsin [1] ; Garde, Amandine [1] [1] UNIVERSITY OF LIVERPOOL, UNITED KINGDOM

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

Etilé, Fabrice [1] [1] FRENCH NATIONAL RESEARCH INSTITUTE FOR AGRICULTURE, FOOD AND THE ENVIRONMENT (INRAE) AND THE PARIS SCHOOL OF ECONOMICS, PARIS, FRANCE

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

Hodge, James G, Jr [1] ; Piatt, Jennifer L [1] ; Barraza, Leila [2] ; White, Erica N [1] [1] SANDRA DAY O'CONNOR COLLEGE OF LAW, ARIZONA STATE UNIVERSITY, PHOENIX, ARIZONA, USA [2] MEL AND ENID ZUCKERMAN COLLGE OF PUBLIC HEALTH, UNIVERSITY OF ARIZONA, TUCSON, ARIZONA, USA

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.

AuthorAffiliation

About This Column

James G. Hodge, Jr., J.D., LL.M., serves as the section editor for Public Health and the Law. He is the Peter Kiewit Foundation Professor of Law and Director, Center for Public Health Law and Policy, Sandra Day O’Connor College of Law, Arizona State University (ASU).

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

Case of Barbados and Jamaica

Lake, Shajoe J [1] ; Benjamin, Kimberley E [1] ; Foster, Nicole D [2 1] O'NEILL INSTITUTE FOR NATIONAL AND GLOBAL HEALTH LAW AT GEORGETOWN UNIVERSITY, WASHINGTON, DC, USA [2] FACULTY OF LAW, UNIVERSITY OF THE WEST INDIES, CAVE HILL, BARBADOS

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

Barbosa, Isabel [1] ; Leite, Fábio [2] ; Britto, Carla [3] [1] GEORGETOWN UNIVERSITY, WASHINGTON, DC, USA [2] PONTIFÍCIA UNIVERSIDADE CATÓLICA DO RIO DE JANEIRO, RIO DE JANEIRO, BRAZIL; PLEB – PESQUISA SOBRE LIBERDADE DE EXPRESSÃO NO BRASIL, RIO DE JANEIRO, BRAZIL [3] PLEB – PESQUISA SOBRE LIBERDADE DE EXPRESSÃO NO BRASIL, RIO DE JANEIRO, BRAZIL

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

Silvia Serrano Guzmán [1] ; Ariadna Tovar Ramírez [1] ; Cabrera, Oscar A [1] [1] O'NEILL INSTITUTE FOR NATIONAL AND GLOBAL HEALTH LAW, GEORGETOWN UNIVERSITY, WASHINGTON, DC, USA

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.

DETAILS

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

Kruger, Petronell [1] ; Mafuyeka, Mikateko [1] ; Karim, Safura Abdool [1 1] SOUTH AFRICAN MEDICAL RESEARCH COUNCIL/ WITS CENTRE FOR HEALTH ECONOMICS AND DECISION SCIENCE UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG, SOUTH AFRICA

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

Cinà, Margherita M [1] ; Nardi, Francesca E [1 1] O'NEILL INSTITUTE FOR NATIONAL AND GLOBAL HEALTH LAW AT GEORGETOWN UNIVERSITY, WASHINGTON, DC, USA

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

Friant-Perrot, Marine [1] ; Garde, Amandine [2] [1] UNIVERSITY OF NANTES, FRANCE [2] UNIVERSITY OF LIVERPOOL, UNITED KINGDOM

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]

DETAILS

Subject:	Digital media; Case law; Marketing; Regulation; Communication; Professional advertising; Amendments; Viral marketing; Public health; Tobacco; Alcohol; Beverages; Digital broadcasting; Provisions; Alcoholic beverages
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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