THE JOURNAL OF
LAW, MEDICINE & ETHICS

Volume 49:4 • Winter 2021

A Journal of the American Society of Law, Medicine & Ethics • www.aslme.org

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Rethinking the Principle of Justice for Marginalized Populations During COVID-19
Henry Ashworth, Derek Soled, and Michelle Morse

ISSN: 1073-1105

CAMBRIDGE UNIVERSITY PRESS

https://doi.org/10.1017/jme.2021.96 Published online by Cambridge University Press

The Journal of Law, Medicine & Ethics (JLME): Material published in *The Journal of Law, Medicine & Ethics* (JLME) contributes to the educational mission of the American Society of Law, Medicine & Ethics (ASLME), covering public health, health disparities, patient safety and quality of care, and biomedical science and research, and more.

The Journal of Law, Medicine & Ethics is published by Cambridge University Press on behalf of the American Society of Law, Medicine & Ethics.

ISSN: 1073-1105

E-ISSN: 1748-720X

Printed in the USA by The Sheridan Group

Editorial Office
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Letters to the Editors: Comments on articles in the Journal should be addressed to the Editor at the editorial office or emailed to thutchinson@aslme.org

Submission Guidelines: For submission guidelines, please contact the editorial office at thutchinson@aslme.org or go to cambridge.org/jlme/submit

Supplements: Initial inquiries should be directed to the Editor at the editorial office or emailed to thutchinson@aslme.org

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THE JOURNAL OF

LAW, MEDICINE & ETHICS

VOLUME 49:4 • WINTER 2021

Board of Editors

https://doi.org/10.1017/jme.2021.96 Published online by Cambridge University Press

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Reproductive Technologies and Free Speech
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The Supreme Court and lower courts have not articulated a clear or consistent framework for First Amendment analysis of speech restrictions in health care and with respect to abortion. After offering a coherent doctrine for analysis of speech restrictions in the doctor-patient relationship, this piece demonstrates how potential legislation restricting patient access to information from reproductive testing intended to limit "undesirable" reproductive choices would violate the First Amendment.

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Assuming Access to Professional Advice
Claudia E. Haupt

Access to reliable health advice can make the difference between life and death. But good advice is hard to come by. Within the confines of the professional-client or doctor-patient relationship, the First Amendment operates in a way that protects good and sanctions bad advice. Outside of this relationship, however, the traditional protections of the First Amendment prohibit content- and viewpoint discrimination. Good and bad advice are treated as equal. A core assumption of First Amendment theory is the autonomy of speakers and listeners. Another assumption, as this Article demonstrates in the health context, is the availability of access to professional advice. This assumption, however, is erroneous because access to health advice in fact is unevenly distributed.

This Article argues that assuming access to professional advice creates indefensible inequality. Lack of access to expert advice puts some listeners at much higher risk than others. Current First Amendment doctrine is largely unproblematic for those who can afford expert advice and makes expert advice much costlier where health provider access is needed to obtain good advice. Those who lack access must place a higher degree of trust in widely-available information because they have no more reliable alternative. In other words, First Amendment doctrine places a higher burden on those who can least afford expert advice and who are most dependent on experts in public discourse.

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The rise in vaccine hesitancy in high-income countries has led some to recommend that certain vaccinations be made compulsory in states where they are currently voluntary. In contrast, I contend that legal coercion is generally inappropriate to address the complex social and psychological phenomenon of vaccine anxieties. I note that historical experience of mandatory vaccination in the United Kingdom (UK) indicates that coercion may exacerbate such anxieties. I utilise a psycho-social dialectic methodology that the Frankfurt School philosopher, Theodor Adorno, employed within his research into anti-Semitism, to examine the social conditions which have influenced vaccine anxieties. I identify many of the same psychological tricks that Adorno detected within anti-Semitic discourse within anti-vaccination discourse. I contend that education is a preferable policy response than compulsion, but note that education concerning the facts about vaccines may backfire by entrenching vaccine anxieties. I argue that educating people about the psychological reasons why they may invest in anti-vaccination discourse may alleviate such anxieties.

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In most U.S. jurisdictions, clinicians providing informal "curbside" consults are protected from medical malpractice liability due to the absence of a doctor-patient relationship. A recent Minnesota Supreme Court case, *Warren v. Dinter*, offers the opportunity to reassess whether the majority rule is truly serving the best interests of patients. Precluding liability for informal consults may encourage clinicians to be willing to offer them, which in turn may benefit patients through efficient and free access to specialist advice. But this approach may also lead to patient harm if informal consults are provided without due care. Given the lack of evidence that the benefits of informal consults outweigh their risks, we offer two recommendations. First, informal consultants should not currently be granted special legal protections against medical malpractice liability, but rather should be held accountable when their advice foreseeably causes patient harm. Second, empirical research into both the benefits and drawbacks of informal consults, as well as the benefits and drawbacks of different approaches to liability, should be given high priority. The evidence generated from this research should then be used to guide policymakers in crafting the ideal legal response to informal consults going forward.

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In the face of limited resources during the COVID-19 pandemic response, public health experts and ethicists have sought to apply guiding principles in determining how those resources, including vaccines, should be allocated. The application of such principles, however, has further marginalized historically oppressed communities and perpetuated White normative biases. This paper explores the core tenet of justice in medical ethics and proposes an applicative justice framework that prioritizes equity over equality in allocating resources. Critics of this proposed reform may deem it reverse discrimination or unfair to dominant group; however, it justly accounts for the existing and longstanding historical inequities embedded in the current healthcare system. An applicative justice ethical framework provides guidance for the moral imperative of restitution and offers concrete methods to combat these injustices in allocating resources such as vaccines. Through collective action and policy change, the healthcare system can be reoriented towards achieving equity now and in the future.

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https://doi.org/10.1017/jme.2021.96 Published online by Cambridge University Press

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Symposium articles *are solicited by the guest editor for the purposes of creating a comprehensive and definitive collection of articles on a topic relevant to the study of law, medicine and ethics. Each article is peer reviewed.*

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Next Issue:

Health Law and Anti-Racism: Reckoning and Response

A Symposium Guest Edited by Michele Goodwin and Holly Fernandez Lynch

https://doi.org/10.1017/jme.2021.96 Published online by Cambridge University Press

From the Shadows: The Public Health Implications of the Supreme Court's COVID-Free Exercise Cases

Parmet, Wendy E

ABSTRAK (ENGLISH)

This article analyzes the Supreme Court's "shadow docket" Free Exercise cases relating to COVID-19. The paper highlights the decline of deference, the impact of exemptions, and the implications of the new doctrine for vaccine and other public health laws.

TEKS LENGKAP

The relationship between religious liberty and public health has always been fraught. When plagues strike, societies often turn to prayer and communal worship. Frequently they also scapegoat non-believers, heretics, and members of minority faiths.[1] That history should caution courts to be vigilant when pandemic responses target religious minorities and the exercise of religion. Yet, because pathogens do not distinguish between religious and secular activities, governments cannot ignore the risks that religious activities can pose during a pandemic. Since the start of the COVID-19 pandemic, American courts have struggled to reconcile these dueling imperatives.

Early in the pandemic, most courts, including the Supreme Court,[2] rejected challenges to public health emergency orders even when they applied to worship. Then on November 25, 2020, in *Roman Catholic Diocese v. Cuomo*,[3] the Court changed course, offering a strikingly different approach that casts a far more skeptical eye on state health orders that touch upon religious practices, especially in-person worship. Although much remains unclear, the Court's more recent decisions regarding COVID restrictions — all announced from the "shadow docket" without the benefit of argument[4] — forgo both deference to state officials and consideration of public health evidence in the determination of whether the state has regulated religious activities less favorably than comparable secular activities. Now almost any public health law that includes an exemption for some secular activity risks being subject to strict scrutiny in a Free Exercise claim. As a result, the states' capacity to carry out essential public health functions, as well as protect their populations from COVID-19 or other, potentially more lethal, pandemics, is in jeopardy. To ensure that states are not left impotent to protect the public's health, the Court needs to rethink its approach. While deference should not be absolute, states should not be precluded from protecting the public's health.

This paper develops these arguments. Part One briefly reviews the nation's failed response to COVID and the state orders that have impacted worship. Part Two summarizes the application of the Free Exercise law to public health measures prior to and early in the pandemic. Part Three surveys the Supreme Court's changing approach. Part Four interrogates the new approach, noting its most important features and highlighting areas of uncertainty. The Conclusion considers the potential impact of the COVID-cases on vaccine mandates and other public health laws post-pandemic.

Part One: A Patchwork of Orders

There is little question that the U.S. response to COVID-19 has been catastrophic. Although the U.S. does not have the highest per capita death rate in the world, more than 750,000 Americans had died from COVID-19 by November 3, 2021.[5] Millions more have been seriously ill, and thousands are long-haulers who face long-term health problems.[6] Communities of color and immigrants have been especially hard hit, both by the disease and its economic and

social fallouts.[7]

Part One briefly reviews the nation's failed response to COVID and the state orders that have impacted worship. Part Two summarizes the application of the Free Exercise law to public health measures prior to and early in the pandemic. Part Three surveys the Supreme Court's changing approach. Part Four interrogates the new approach, noting its most important features and highlighting areas of uncertainty. The Conclusion considers the potential impact of the COVID-cases on public health law post-pandemic.

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Many factors impeded the nation's response to COVID-19.[8] For present purposes, three appear especially relevant. First, is political polarization. Although there was bipartisan consensus for the initial round of emergency orders issued in March 2020, it quickly faded.[9] By April 2020, the pandemic had taken on a distinctly political hue, with Republicans less concerned about the coronavirus and less supportive of state emergency orders than Democrats.[10] That political divide continued during a presidential campaign in which one candidate (then President Trump) minimized the pandemic and the other (now President Biden) made it his number one priority.[11] Given the pre-existing political alignment between religiosity and party affiliation,[12] not to mention President Trump's emphasis on re-opening church services, partisan differences over the pandemic easily converted into a divide between religiosity and secularism.[13]

Second, was the lack of a coordinated, federal response. Under the Constitution, states have primary responsibility for public health protection.[14] Nevertheless, pandemics cross state lines and necessitate a level of national coordination that has been largely absent during the pandemic.[15] As a result, states were largely left to go their own way as they tried contain the pandemic while mitigating its economic and social effects.[16] This led to a confounding and often incoherent patchwork of orders.[17]

Third, was insufficient economic support to buffer the economic fallout from pandemic-control measures.[18] As public health scholars have noted, the provision of economic (and other forms) of support can be critical to obtaining compliance with public health advice.[19] People are more likely to stay home following potential exposure to a contagious disease if they do not have to worry about losing their job. Likewise, businesses are more likely to support public health measures if they know they can avoid economic catastrophe. During a pandemic, economic relief can be a critical tool for disease mitigation.

Congress did provide significant support through the CARES[20] and the Families First Coronavirus Response Acts[21] in the spring of 2020. The December 2020 Coronavirus Response and Relief Supplemental Appropriations Act of 2021 offered additional aid,[22] as did the American Rescue Plan Act that President Biden signed into law in March 2021.[23] The support that these acts offered, however, did not reach everyone, and the delay in enacting further relief in the late summer and fall of 2020 added to the challenge that states faced as they tried to balance human and economic health.[24] The results were not pretty. Initially, most states issued a series of emergency orders that shuttered some, but not all businesses, and limited many, but not all, social gatherings. Then, as pandemic fatigue, economic stress, and partisan divisions grew, states began to "reopen."[25] Once cases re-surged in winter 2020-2021, some governors re-imposed some, but not all, of the restrictions.[26]

This less-than-coherent approach extended to religious worship. Early on, it became clear that religious worship and gatherings could serve as super-spreader events.[27] South Korea's initial outbreak, for example, was tied to services in a charismatic religious community.[28] In March 2020, an Arkansas church service was associated with 61 cases and four deaths.[29] As 2020 progressed, evidence accumulated that indoor activities where people are close to one another for an extended period, especially where there is singing or loud talking, are especially risky.[30] Nevertheless, the CDC did not recommend restrictions on worship, noting that millions of Americans "embrace worship as an essential part of life."[31]

In spring 2020, when COVID-restrictions were at their most stringent, most states exempted religious services from orders that shuttered mass gatherings.[32] According to the Pew Research Center, only 10 states barred in-person religious services in April 2020.[33] About one-third of states placed no caps at all on in-person religious gatherings.[34]

Three states deemed religious worship to be “essential services.”[35] Still, religious services did not escape regulation. In April 2020, 22 states limited religious gatherings to 10 or fewer persons.[36] Some states had even stricter and some had looser requirements.[37]

In the summer and fall of 2020, even as infections surged, more states “opened up,” lifting restrictions on religious worship, as well as other activities.[38] Other states, including New York and California, maintained significant restrictions.[39] As the discussion below shows, challenges to these laws helped to reshape the Court’s understanding of how the Free Exercise Clause applies to public health laws.

Part Two: Doctrinal Roots and the Early COVID Cases

Prior to COVID-19, the application of the Free Exercise clause to communicable disease laws was relatively stable, if under-theorized. Three cases formed the foundation for the analysis: *Jacobson v. Massachusetts,*[40] *Employment Division v. Smith*,[41] and *Church of the Lukumi Babalu Aye v. Hialeah*.[42]

Strictly speaking, *Jacobson* was not a Free Exercise case. The 1905 decision concerned a Cambridge, Massachusetts law requiring all residents to be vaccinated against smallpox or pay a $5 fine. The defendant, Henning Jacobson, was a Lutheran pastor who had both religious and secular objections to vaccination.[43] Yet, because the Supreme Court had yet to apply the Free Exercise Clause to the states,[44] he based his challenged on the due process clause, not the Free Exercise clause.[45]

In a complex and multi-faceted opinion by Justice Harlan, the Court rejected Jacobson’s contentions, emphasizing that a community has the “right to protect itself against an epidemic of disease which threatens the safety of its members.”[46] This did not mean that communicable disease laws were wholly beyond judicial review. Rather, the Court recognized that the police power extended only to “reasonable regulations, as the safety of the general public may demand,”[47] and that courts should step in when public health laws have “no real or substantial relation” to their “objects,” or are “beyond all question, a plain, palpable invasion of rights secured by the fundamental law.”[48] The Court also noted that some regulations might be “so arbitrary and oppressive in particular cases, as to justify the interference of the courts.”[49] Still, *Jacobson* provided strong support for the principle that states can limit individual liberty to prevent the spread of communicable diseases, and that courts should provide considerable deference to the elected branches, and the health officials to whom they delegate power, to determine what steps are needed to stop an epidemic.[50]

For more than 100 years, *Jacobson* remained the Court’s leading infectious disease case, and primary authority for the constitutionality of vaccine mandates (even in the absence of an epidemic).[51] Moreover, although *Jacobson* was not a Free Exercise case, the Court cited it in several notable religious liberty cases. For example, the Court referenced it in *Prince v. Massachusetts* while rejecting a religious liberty challenge to a child labor law.[52] The Court also cited *Jacobson* in *Sherbert v. Verner*,[53] which held that the denial of unemployment benefits to a Seventh-Day Adventist who refused to work on her Sabbath violated the Free Exercise Clause, for the proposition that the Constitution does not require accommodations to laws that regulate actions that “pose[] some substantial threat to public safety, peace or order.”[54]

Smith overruled *Sherbert,* but in doing so, the Court did not reject the point that *Sherbert* drew from *Jacobson.* Rather, Justice Scalia’s opinion in *Smith* ruled that all generally applicable regulations of conduct, and not simply those that seek to prevent a substantial threat to public safety, peace or order, were subject to rational basis review, even if they burdened someone’s exercise of religion.[55]

Lukumi added an important limitation to *Smith.*[56] In *Lukumi,* the Court clarified that laws that were facially neutral, but targeted religion, were subject to strict scrutiny, and were constitutional only if they were narrowly tailored to a compelling state interest.[57] In *Masterpiece Cakeshop v. Colorado Civil Rights Commissio*n, the Court relied on *Lukumi* to hold that the Colorado Civil Rights Commission violated the Free Exercise Clause because it acted with hostility toward the religious beliefs of a baker who refused to decorate a cake celebrating a same-sex marriage.[58] Tellingly, Justice Gorsuch, in a concurring opinion, wrote “*Smith* remains controversial in many quarters.”[59] However, he did not call for overruling *Smith.* Instead, he argued that the state had failed to act with neutrality in applying an intent requirement to the state’s civil rights laws to bakeshops that refused service.[60]

Gorsuch's focus on the state's perceived lack of neutrality in *Masterpiece Cake* echoed Justice Alito's 2016 dissent in *Stormans, Inc. v. Wiseman*[61] *Stormans* challenged a Washington State law that required pharmacists to sell contraceptives, including Plan B. Relying on *Smith* and *Lakumi,* the Ninth Circuit concluded that because the state's rule was neutral and generally applicable, strict scrutiny was not required.[62]

In a dissent from the Court's denial of certiorari, Justice Alito, joined by the Chief Justice and Justice Thomas, argued that because the Washington allowed pharmacies to refuse to fill prescriptions when they did not accept the customer's insurance it was neither neutral nor generally applicable; hence strict scrutiny was required.[63] This analysis suggested — or foretold — that the existence of *any* secular exemption from a regulation that also implicated a religious practice would trigger strict scrutiny.

The interest among some justices in narrowing *Smith* was also evident by the Court's February 2020 decision to grant certiorari in *Fulton v. City of Philadelphia*.[64] In *Fulton,* a Catholic foster care agency challenged Philadelphia's refusal to enter into new contracts with the agency due to its refusal to place children with same-sex couples. The Third Circuit had found that the city's policy was a generally applicable law, subject under *Smith*, to rational basis review.[65] The grant of certiorari included the question whether *Smith* should be overruled.[66]

Despite these forewarnings, until COVID-19, lower courts usually upheld communicable disease laws against Free Exercise claims. This was especially apparent with regard to state vaccine laws.[67] For example, even after California and New York repealed religious exemptions for school-based mandates, courts relied on *Smith* and/or *Jacobson* to reject Free Exercise challenges.[68] The existence of other exemptions — for example, for medical reasons — did not change the conclusion.

In the spring and summer of 2020, most lower courts followed past practice and rejected Free Exercise challenges to public health orders regarding COVID-19.[69] Although they used different approaches to reconcile *Jacobson* with contemporary Free Exercise cases, courts generally read *Jacobson* as requiring them to grant substantial deference to public health emergency orders.[70] Most courts also relied on *Smith* to conclude that strict scrutiny was inapplicable because the state had restricted a range of comparable secular activities, and hence acted in a manner that was neutral toward religion.[71]

Still, the heated political debates over the treatment of religious services, combined with the fact that all states included multiple exemptions to their emergency orders, created anger and constitutional peril. On April 14, 2020, Attorney General William Barr warned that "government may not impose special restrictions on religious activity that do not also apply to similar nonreligious activity … Religious institutions must not be singled out for special burdens."[72]

Some courts agreed. For example, in *Maryville Baptist Church v. Beshear,* the Sixth Circuit held that orders by Kentucky Governor Beshear prohibiting drive-in services "by name" while allowing secular, "'life-sustaining' businesses [including] law firms, laundromats, liquor stores, and gun shops to continue to operate so long as they follow social-distancing and other health-related precautions" were likely unconstitutional.[73] The court stated:

Assuming all of the same precautions are taken, why is it safe to wait in a car for a liquor store to open but dangerous to wait in a car to hear morning prayers? Why can someone safely walk down a grocery store aisle but not a pew? And why can someone safely interact with a brave deliverywoman but not with a stoic minister? The Commonwealth has no good answers.

While the law may take periodic naps during a pandemic, we will not let it sleep through one.[74]

A few days later, the same panel in *Roberts v. Neace* enjoined the Governor's ban on in-door services.[75] The Sixth Circuit's decisions pointed to the dilemma that courts faced during the pandemic. In the absence of federal coordination, inadequate financial support, and changing epidemiological and political conditions, state officials imposed orders that often appeared perplexing. Why exempt liquor stores but not churches? Laundromats but not worship? An epidemiologist might answer that because worship brings many people together for an extended period, with singing and chanting, it creates a greater risk than retail stores or laundromats. The Sixth Circuit, however, did not consider public health evidence, relying instead on its own assessment of risks. Soon the Supreme Court would do likewise.

Part Three: The Supreme Court Steps InThe Court's Early COVID Cases:

Between May and November 2020, the composition of the Supreme Court changed. So, too, did its approach to Free Exercise challenges to COVID orders. As the views of the justices who were initially in the dissent became those of the majority, the Court established a new doctrinal framework that devalued public health evidence and could subject almost any public health law to strict scrutiny.

Between May and November 2020, the composition of the Supreme Court changed. So, too, did its approach to Free Exercise challenges to COVID orders. As the views of the justices who were initially in the dissent became those of the majority, the Court established a new doctrinal framework that devalued public health evidence and could subject almost any public health law to strict scrutiny.

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On May 22, 2020, the Supreme Court issued its first decision regarding a COVID-restriction in *South Bay United Pentecostal Church v. Newsom (South Bay I)*.[76] Like the other COVID-cases that the Court would hear, *South Bay I* was an emergency petition decided from the "shadow docket,"[77] without the benefit of argument or full briefing. The issue before the Court was California Governor Gavin Newsom's order limiting attendance at places of worship to 25% of capacity or a maximum of 100 attendees.[78] Many other secular activities, including lecture halls, concerts, movie theaters, and sports events faced similar limits, but others, including retail stores, restaurants, and hair salons faced less strict limits.[79]

By a 5-4 vote, the Court rejected the emergency petition without issuing an opinion. Concurring, Chief Justice Roberts explained that the order appeared to treat religious worship similarly to "comparable secular gatherings … where large groups of people gather in close proximity for extended periods of time."[80] Citing *Jacobson*, he explained that the Constitution "principally entrusts" health and safety to"'politically accountable officials,'"[81] and that courts should be reluctant to second-guess officials when they "'undertake[] to act in areas fraught with medical and scientific uncertainties.'"[82] This reluctance, he added, was particularly appropriate in deciding an emergency petition.[83]

In a strongly worded dissent, Justice Kavanaugh, joined by Justices Thomas and Gorsuch, argued that California had not imposed the identical occupancy limit on "comparable secular businesses."[84] Tellingly, he pointed to no evidence to support the conclusion that exempt businesses were "comparable" to religious services. Nor did he explain how courts should determine the relevant comparators.

The Court's second COVID case, *Calvary Chapel Dayton Valley v. Sisolak*, *c*oncerned Nevada's 50-person cap on religious services; certain other activities, including gaming, were allowed to admit 50% of their maximum occupancy.[85] By another 5-4 vote, again from the shadow docket and without an opinion, the majority rejected an emergency petition to enjoin the occupancy limit. Justices Alito, Gorsuch, and Kavanaugh published three separate dissents previewing the arguments that the majority would later adopt.

In his dissent, Alito, joined by Thomas and Kavanaugh, argued that the petitioner was likely to succeed on the merits of its Free Exercise claim because the state had "made no effort" to show that the religious services were riskier than activities that were permitted, such as "going to the gym" or "what goes on in casinos."[86] Thus like Kavanaugh in *South Bay,* Alito appeared to assume that the state bore the burden of establishing that the services were not comparable to the exempted activities.[87] He added that because *Jacobson* was not a First Amendment case it was not relevant, and that "a public health emergency does not give Governors and other public officials *carte blanche* to disregard the Constitution for as long as the medical problem exists."[88]

In his own dissent, Kavanaugh pinpointed the problem presented by the juxtaposition of restrictions and exemptions: "when a law on its face favors or exempts some secular organizations as opposed to religious organizations, a court … must determine whether the State has sufficiently justified the basis for the distinction."[89] Recognizing that states were "struggling" to balance economic and health risks, he stated, "The Constitution does not tolerate discrimination against religion merely because religious services do not yield a profit."[90] He added,

This Court's history is littered with unfortunate examples of overly broad judicial deference to the government when

the government has invoked emergency powers … The court of history has rejected those jurisprudential mistakes and cautions us against an unduly deferential judicial approach, especially when questions of racial discrimination, religious discrimination, or free speech are at stake.[91]

A New Approach:

Two months later, Justice Ruth Bader Ginsburg, who had voted with the majority in *South Bay I* and *Calvary Chapel* , died.[92] On October, 26, 2020 President Trump's nominee, Amy Coney Barrett, was confirmed to the Supreme Court.[93] One month later, in *Roman Catholic Diocese of Brooklyn (RCD),* the approach of the dissenters in *South Bay I* and *Calvary Christian* became that of the majority. [94]

RCD concerned New York Governor Cuomo's order barring more than 10 persons from attending religious services in "red-zones" (areas identified as COVID-19 "hotspots") and more than 25 persons from attending services in "orange zones" (areas adjacent to red zones)."[95] By the time the case had reached the Supreme Court, the Governor had reclassified the areas where the plaintiffs were located, enabling them to hold services at 50% of capacity.[96]

Despite the fact that the plaintiffs were no longer subject to the order at issue, the Court took up the emergency appeal and by a 5-4 vote, in a short *per curiam* opinion, concluded that the plaintiffs had "made a strong showing that the challenged restrictions violate 'the minimum requirement of neutrality' to religion."[97] In support of its claim, the plaintiff Agudath Israel of America had referenced statements by Cuomo that could be construed as targeting Orthodox Jews.[98] The Court could have rested on those facts.[99] Such a decision would have signaled that the deference that Roberts commended in *South Bay I* did not extend to orders when there was evidence of animus toward a religious group, perhaps especially a religious minority.

The majority, however, did not rely on extra-textual evidence of animus. Rather, it found that discrimination existed because certain secular activities, including "acupuncture facilities, camp grounds, garages, as well as many whose services are not limited to those that can be regarded as essential," were subject to less onerous restrictions.[100] From this, and the fact that the restrictions specified religious services by name, the majority concluded, without pointing to any public health evidence, that the contested orders were not of general applicability. In effect, as in the *South Bay I* and *Christian Calvary* dissents, the majority relied on its own intuition to determine which activities were comparable to the religious services that were restricted. The majority also appeared, without stating, to treat the state as having the burden of persuasion on that threshold issue.

Applying strict scrutiny, the majority held that the regulations were not narrowly tailored to the compelling state interest of preventing the transmission of COVID-19. In so doing, the Court noted that many other "hard-hit" jurisdictions had less onerous restrictions, showing how the variation among states that had come to characterize the pandemic response could be used to establish a lack of narrow tailoring.[101] The Court also pointed out that there were no reported outbreaks of COVID-19 at plaintiffs' services, suggesting that states could not act to prevent the transmission of the virus until a super-spreader event at a particular religious facility was documented.[102]

Both Gorsuch and Kavanaugh added strongly worded concurring opinions. In his, Gorsuch derided governors who "[A]t the flick of a pen, … have asserted the right to privilege restaurants, marijuana dispensaries and casinos over churches, mosques, and temples."[103] He also criticized the Chief Justice's concurrence in *South Bay I* for relying on *Jacobson,* which he termed a "modest" decision that applied to a different set of facts and a different constitutional claim.[104] He warned that while the impulse for courts to "stay out of the way in times of crisis … may be understandable or even admirable in other circumstances, we may not shelter in place when the Constitution is under attack. Things never go well when we do."[105]

In his concurrence, Kavanaugh accepted that the Constitution "'principally entrusts the safety and health of the people to the politically accountable officials of the States,'" but explained that "judicial deference in an emergency or a crisis does not mean wholesale judicial abdication, especially when important questions of religious discrimination, racial discrimination, free speech, or the like are raised."[106] He added that "once a state creates a favored class of businesses … the State must justify why houses of worship are excluded from that favored class."[107] He did not explain, however, how the Court should determine which favored "classes of businesses" were comparable to

worship.

In dissent, Justice Sotomayor warned of the potential danger of this approach: “Justices of this Court play a deadly game in second guessing the expert judgment of health officials about the environment in which a contagious virus, now infecting a million Americans each week, spreads most easily.”[108] In the three months that followed the Court’s decision, approximately 250,000 more Americans died from COVID-19.[109] Still, on its own, *RCD* might have been read as a limited decision, motivated by the draconian nature of Governor Cuomo’s order, and serving to remind officials to tread carefully when restricting worship.

That was not to be. In the weeks and months that followed, the Supreme Court issued a series of decisions relating to the Free Exercise clause.[110] Among the more interesting was *South Bay United Pentecostal Church v. Newsom (South Bay II).*[111] In a short, unsigned opinion, once again from the shadow docket, a six justice majority (including Roberts, Thomas, Alito, Gorsuch, Kavanaugh, and Barrett) blocked California’s ban on indoor services, but left in place a 25% capacity limit plus a ban on singing and chanting.[112]

Although the majority agreed to enjoin part of the state’s order, the separate opinions of the justices in the majority showed continuing disagreement. Now stating that deference had its “limits,” Roberts supported enjoining the orders restricting worship, but would have kept in place the ban on singing, noting that he saw no basis for “overriding that aspect of the state public health framework.”[113] In contrast, Gorsuch, joined by Thomas and Alito, argued that the state had targeted religion, and that as a result, strict scrutiny was required.[114] Regarding the ban on chanting, Gorsuch noted, “California’s powerful entertainment industry has won an exemption. So once more we appear to have a State playing favorites during a pandemic …”[115] In a separate statement, Alito indicated that he would stay the injunction on capacity limits and singing and chanting for 30 days, to be lifted unless the state “demonstrates clearly that nothing short of those measures will reduce the community spread of COVID-19 at indoor religious gatherings to the same extent as do the restrictions the State enforces with respect to other activities it classifies as essential.”[116]

In contrast, Barrett, joined by Kavanaugh, agreed that the capacity limits should also be blocked, but was content to accept the state’s limits on singing and chanting.[117] In reaching that conclusion, the newest justice stated that the petitioners did not “carry their burden,” suggesting that she thought they had the burden of establishing that they were entitled to relief from that ban.[118] In contrast, in her dissent, Justices Kagan, joined by Breyer and Sotomayor, lamented the majority’s failure to credit the state’s scientific evidence and hoped that the Court’s decision would not “worsen the Nation’s COVID crisis.”[119]

Despite the absence of a majority opinion in *South Bay II,* on February 26, 2021, by a six-three vote, the Court in *Gateway City Church v. Newsom,*[120] granted emergency relief to a church contesting restrictions on indoor gatherings.[121] Although the restrictions in *Gateway City Church* were quite unlike the ones in the earlier cases in that they applied to all indoor gatherings and did not specify worship, the Court ruled that the outcome was “dictated by this Court’s decision” in *South Bay II.*[122]

Then on April 9, the Court, by a 5-4 vote — again from the shadow docket — issued its most far-reaching COVID decision in *Tandon v. Newsom*.[123] *Tandon* challenged the application of California’s limits on the number of people from separate households who could gather in private homes.[124] The plaintiffs claimed that the restrictions violated their rights under the Free Exercise Clause to conduct prayer meetings in homes because the state permitted more people to gather for secular purposes in certain public spaces, such as train stations and shopping malls.[125] The Ninth Circuit panel, by a vote of 2-1, disagreed, finding that such public settings were not comparable to in-home gatherings “in terms of risk to public health or reasonable safety measures to address that risk.”[126] The Appeals Court explained:

[T]he district court found that the State reasonably concluded that when people gather in social settings, their interactions are likely to be longer than they would be in a commercial setting; that participants in a social gathering are more likely to be involved in prolonged conversations; that private houses are typically smaller and less ventilated than commercial establishments; and that social distancing and mask-wearing are less likely in private settings and enforcement is more difficult.[127]

Having rejected the analogy to gatherings in public spaces, the Ninth Circuit concluded that the state's restriction on private gatherings was a neutral law of general applicability, and not subject to strict scrutiny.[128]

The Supreme Court disagreed. In a *per curiam* opinion, the Court held that the restrictions on in-home gatherings were neither neutral nor generally applicable.[129] In reaching its conclusion, the Court stated, "it is no answer that a State treats some comparable secular businesses or other activities as poorly as or even less favorably than the religious exercise at issue."[130] The Court then explained that comparability "must be judged against the asserted government interest that justifies the regulation at issue," and that comparability is concerned "with the risks various activities pose, not the reasons why people gather."[131]

Applying those principles, the Court determined that strict scrutiny was required, and that the restrictions could not pass that high bar. In reaching that decision, the Court overlooked the testimony that was offered by the state's experts, and pointed again to the exemptions the state offered for some secular activities, stating that the state "cannot 'assume the worst when people go to worship but assume the best when people go to work.'"[132] In effect, the very factors that led the Court to conclude that strict scrutiny was required led it to find that the order was not narrowly tailored, and hence failed strict scrutiny. The Court added that the fact that the state had changed its policy after the petition for certiorari was filed made no difference, stating that "officials with a track record of 'moving the goalposts' retain authority to reinstate those heightened restrictions at any time."[133]

In dissent, Kagan, who was joined by Breyer and Sotomayor, argued that because the state had adopted a "blanket restriction on at-home gatherings of all kind, religious and secular alike," it had not treated religious activity less favorably than comparable secular activities.[134] The First Amendment, she claimed, does not demand "that the State equally treat apples and watermelons."[135] She added that the majority had ignored the lower courts' factual findings that in-home gatherings posed a greater risk than the commercial activities that were less stringently regulated in other ways.[136] She concluded by lamenting that the Court "once more commands California 'to ignore its experts' scientific findings,'" thereby weakening its ability to address the health emergency.[137] Less than three weeks later, the Court issued its third order in the *South Bay* litigation, this time vacating without an opinion the Ninth Circuit's judgment.[138]

Out from the Shadows:

On June 17, 2021, the Court emerged from its shadow docket and released its long-awaited decision in *Fulton v. City of Philadelphia*.[139] By a unanimous vote, the Court held that Philadelphia had violated the Free Exercise clause. However, in his opinion for the Court, which never cited the COVID cases, Roberts declined to overrule *Smith,* finding instead that Philadelphia's policy was not neutral and generally applicable because the City's contract with foster care agencies contained a provision granting it the sole discretion to create exceptions to its anti-discrimination requirement.[140] The Court also held that it need not decide if the City's anti-discrimination law violated the Free Exercise clause because the agency plaintiff was not a public accommodation.[141]

In concurring opinions, however, five justices expressed dissatisfaction with *Smith.* Barrett, who was joined by Kavanaugh, stated that the "textual and structural arguments against *Smith* are more compelling" than those supporting it.[142] Nevertheless, she noted that overruling *Smith* would raise a host of difficult questions that the Court need not answer for the reasons explained in the majority's decision.

Alito felt no such compunctions. In a lengthy concurring opinion that Gorsuch and Thomas joined, he argued that an originalist interpretation of the First Amendment compelled the Court to overrule *Smith* and apply strict scrutiny to all laws that burden the exercise of religion.[143] Although he did not rely on the COVID cases, he pointed to them to demonstrate that the Court's current approach under *Smith* in determining comparability was unworkable.[144] This point was echoed in Gorsuch's concurrence, which Alito and Thomas joined.[145]

Part Four: Themes and Questions

The protection of the public's health, especially but not solely from outbreaks of communicable disease, has long been considered a core component of the states' police power.[146] The Court's most recent COVID-Free Exercise cases portend a fundamental change in the Court's assessment of such laws, and raise many questions about the state's ability to protect public health in the years to come.

A. The Decline of Deference

At the start of the pandemic, most courts, usually citing *Jacobson*, granted substantial deference to state health officials in deciding whether restrictions on religious worship violated the Free Exercise Clause.[147] In his concurring opinion in *South Bay I,* Roberts signaled that such deference was appropriate; the dissenters disagreed.[148]

Once the dissenters became the majority, deference diminished.[149] Starting with *RCD,* the majority has not cited *Jacobson;* nor has it offered any deference to state health officials. Even the Chief Justice appears to have changed his tone, noting in *South Bay II* that, while courts "owe significant deference to politically accountable officials," deference has its "limits."[150] Those limits, it now appears, extend not only to the deference granted to health officials. As Kagan suggested in *Tandon,* the Court now also seems unwilling to defer to the factual findings — based on public health evidence — of the lower courts.[151]

Critically, the Court has not replaced deference to public health officials or trial courts with a searching or even casual review of the scientific evidence. Instead, starting with *RCD,* the Court has ignored the public health evidence in the record. In its place, the Court seems to be relying on the justices' own intuition as to what secular activities pose risks that are comparable to the activities that the petitioners seek to have exempt. Thus the Court assumes that retail establishments, casinos, and acupuncture are comparable in terms of risk to in-person worship, but at least in *South Bay II*, some justices appeared to accept that in-person singing and chanting are more dangerous.[152] The justices offered no evidence in support of these distinctions.

The Court has also not addressed the critical question of which party has the burden of persuasion in establishing what secular activities present the appropriate comparator for the religious exercise that has been burdened. Although the state clearly has the burden of proof once strict scrutiny is found to be applicable, the plaintiff should have had the burden of establishing comparability, as it is a necessary element for invoking strict scrutiny.[153] In *RCD,* the Court hinted that the plaintiffs had that burden, pointing to their "strong showing" on the issue of comparability.[154] In later cases, however, the Court failed to point to any evidence produced by the plaintiffs to establish comparability. In effect, the Court appeared to assume (without explicitly saying) that the state has the burden of showing that the secular activities it regulated more lightly were not comparable to the religious activities that were subject to stricter regulations. Interestingly, the state appears to have this burden even when plaintiffs are seeking emergency petitions to stay refusals by the lower courts to enjoin state laws.[155]

B. The Dangers of Exemptions

Since *RCD,* the existence of exemptions, as in Justice Alito's *Stormans*' dissent, has proven critical to the Court's Free Exercise analysis.[156] In *Fulton*, the Court held that strict scrutiny was required because a provision in the City's contract with foster care agencies gave it discretion to offer individualized exemptions.[157] The fact that the City had no intention of granting such exemptions was, according to the Court, irrelevant.[158]

The impact of that analysis to public health laws remains unclear. Few public health laws include the type of contractual provision at issue in *Fulton.* On the other hand, many of the emergency powers laws used during the pandemic grant executive officials broad discretion to determine the type and level of restrictions imposed on different activities.[159] Other public health laws, such as quarantine laws, have typically been applied on an individualized basis; inevitably officials use their discretion in determining when to issue orders. Under *Fulton*, a religious litigant challenging any of these laws could potentially argue that the mere existence of discretion and the possibility (in some cases) of an individualized analysis demands strict scrutiny.

The Court, however, may not and should not read *Fulton* as holding that any broad grant of discretion to executive officials — including discretion over enforcement — compels strict scrutiny. Doing so would eviscerate the ability of all administrative agencies to exercise discretion over their enforcement priorities. It would also make it difficult for officials to impose just the type of carefully tailored and measured responses that strict scrutiny theoretically favors. The Court, therefore, should limit *Fulton's* reach to the type of contractual grant of discretion at issue in that case. Even so, the COVID cases show that the mere existence of exemptions from public health laws can trigger strict scrutiny.

In the COVID-cases, the key issue was comparability: whether the secular activities that were regulated less strictly

were comparable to the religious practices that were regulated more strictly. As noted above, the Court appeared to rely on its own intuition, rather than deference or an evaluation of the public health evidence, in making the comparability determination.[160] The approach creates enormous uncertainty and risk for states that seek to implement non-pharmaceutical interventions during a public health emergency, forcing them to choose between implausibly restricting all activities or providing religious objectors "most-favored nation status."[161]

Critically, states cannot avoid the problem by offering no exemptions. Shuttering everything is simply not possible. People need health care, especially in a pandemic. They also need food and medicine, and the people who work in health care and food distribution need access to transportation and often childcare. Yet, by granting these necessary exemptions, states treat some secular activities more favorably than some religious activities (in-person worship). This sets a comparability trap, in which the state has to show — apparently without the benefit of deference — that none of the exempted activities is comparable to the religious activity asserted by the plaintiff.

Prior to *Tandon*, Caroline Corbin argued that comparability should be based on two factors: the dangerousness of the activity and its essentiality.[162] If that were the case, a court might conclude emergency rooms are not comparable to in-home prayer meetings because the former are more critical to society writ large during a pandemic than the latter. In *Tandon,* however, the Court insisted that comparability depends solely on the "risks various activities pose, not the reasons why people gather."[163] That approach allows the Court to avoid deriding the exercise of religion as "non-essential." It also means that as long as hospitals pose as a great a risk of transmission as in-person worship (a likely assumption early in a pandemic), a court might treat the two activities as comparable, requiring the state to defend, subject to strict scrutiny, its decision to allow the former but not the latter.

Importantly, the COVID cases show that states cannot escape the trap by treating religious activities more favorably than many other secular activities. Indeed, by singling out some types of religious activity (e.g. worship), and treating it more favorably than some types of secular activity (e.g. entertainment venues), the state may be found to have targeted religion. According to Sotomayor, this is precisely what happened in *RCD.*[164] The state regulated worship more strictly than some secular activities, but less strictly than others that the state deemed comparable. Still, the majority saw the state as impermissibly discriminating against religious activities.[165]

Theoretically, strict scrutiny need not doom a public health measure. Indeed, it may well be that although the Court will require strict scrutiny in most Free Exercise cases, that test will not always prove to be "fatal in fact."[166] In his concurrence in *Fulton,* Alito argued that certain peace and public safety laws, recognized at the time of the founding, should survive strict scrutiny.[167] He did not include public health laws in that category, even though courts in the ante-bellum period accepted restraints on religion that related to health.[168] He also pointed to some potential laws, including bans on circumcision that could be defended on public health grounds, as examples of anti-religious measures that warranted strict scrutiny.[169] It therefore seems possible that Alito and the justices who joined his concurrence might not endorse a more relaxed approach to strict scrutiny for public health laws. Nor did the majority in the COVID cases seem willing to apply a less-than-fatal form of strict scrutiny. Indeed, *Tandon* suggests that the very fact that a comparable secular activity faces less stringent restrictions can serve to establish that the state has less restrictive means of protecting the public's health.[170]

More chilling, in a dissent to a later case in which the majority refused, without opinion, to block a COVID vaccine mandate for health care workers, Gorsuch, who was joined by Thomas and Alito, suggested that preventing deaths from COVID-19 may not remain a compelling state interest.[171] If so, no public health law that implicates religion could survive strict scrutiny.

Undoubtedly, the Court's approach to comparability in the COVID cases responded at least in part to the messy and often quite questionable mix of laws and exemptions that characterized the state response to the pandemic.[172] In the absence of a uniform national approach to pandemic mitigation, states adopted, rescinded, and re-imposed a dizzying array of restrictions. Given the inconstancies between jurisdictions, and the ever-changing orders within jurisdictions (some due to new evidence and the virus' shifting epidemiology and some due to political and economic pressures), it is not surprising that the Court questioned the application of strict measures to religious worship.[173]

Still, it is difficult to see how states can protect the public from disease threats without granting officials substantial

discretion, and implementing some distinctions between activities. Moreover, in the early days of a new pandemic, when the science is still evolving, the exercise of discretion will invariably be messy. Officials will make mistakes, and measures that appear to be necessary at one point of time may later be shown to be either unnecessary or ineffective. If we want officials to be able to save lives in the early stages of a pandemic, we need to give them some leeway. The Court, however, seems to be in an unforgiving mood.

C. Beyond Worship

One of the unusual features of the Supreme Court's initial COVID-Free Exercise cases is that in each instance, the challengers claimed that the state regulation burdened their ability to worship. As a result, the Court did not have to consider the impact of its less deferential and changing stance to public health laws that regulated other exercises of religion.

Many other Free Exercise cases, however, focus on laws that burden religion without regulating worship. In *Fulton,* for example, the Court accepted that the city's policy burdened the plaintiff's religious exercise "by putting it to the choice of curtailing its mission or approving relationships inconsistent with its belief."[174] Although the religious activity infringed upon was not worship, the Court insisted that the plaintiff's assertion that the law restricted its religious beliefs should be accepted.[175] This is the typical approach.[176]

What happens when the Court's well-established deferential stance to determining what constitutes a burden on religion meets its new less deferential approach to public health laws? Will the mere existence of exemptions (or per *Fulton,* the mere possibility of exemptions) mean that any religious litigant can demand an exemption to any public health law, even if it restricts practices that most people would regard as purely secular. This is the issue that has arisen in litigation that has challenged COVID-vaccine mandates, but it is not limited to such cases.

Tandon and *Fulton* raised the issue. The law in *Tandon*, for example did not regulate worship qua worship, it simply impacted worship by regulating in-home gatherings. Other public health laws may implicate other activities that individuals may feel are related to their exercise of religion. Consider for example, an outbreak of a deadly gastrointestinal disease that seems to be spreading unchecked in restaurants. Early in the outbreak, health officials have little information about the specific practices that are spreading the disease. They only know that several fatal outbreaks have been associated with restaurants; and that the death toll is climbing quickly. To slow the spread, they shutter restaurants, but allow food services to continue in hospitals and congregate care facilities.

Bad facts make bad law. There is no doubt that the facts during the pandemic have been awful. The ever-changing and inconsistent patchwork of regulations and exemptions that tried to balance health and economic imperatives were often hard to fathom and difficult to explain. The sense of anger and grievance that much of the country felt regarding the COVID-restrictions, some of it justified and much of it stoked by President Trump and his allies, certainly added to the perception that state restrictions were motivated by animus and bigotry towards the faith-based community.

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Now imagine that a restaurant owner — Plaintiff X — claims that her religion compels her to cook and serve meals to strangers. She claims that the order shuttering restaurants burdens her ability to exercise her religion. She points to the fact that hospitals and nursing homes are permitted to remain open. They too could spread the disease. The state, she claims, has not treated comparable secular activities comparably to her religious practice of running her restaurant.

How would the Court decide such a case? Would the fact that restaurants are not typically thought of as a religious activity result in the Court giving greater weight to the testimony of health officials than it did in the cases concerning the regulation of worship? In other words, would the Court, perhaps without saying so, be more willing to defer to health officials when reviewing claims that do not fall within the justices' own pre-existing assumptions as to what constitutes a religious activity? Would the Court instead rely on its own intuition to decide that even if restaurants are a religious activity, they are simply not comparable to hospital cafeterias and nursing home dining rooms? Or, would the Court follow the logic of the COVID cases and apply strict scrutiny? Unfortunately, the COVID-cases offer little

basis for answering those questions.

The possibility that courts would strike down public health orders that do not touch upon commonly recognized forms of worship or religious activity is not far-fetched. Indeed, the uncertainty as to what Tandon and Fulton may require has already spawned a wave of litigation challenging COVID-vaccine mandates on Free Exercise grounds. Although many courts have rejected such challenges, ruling that the mandates are neutral laws of general applicability,[176] others have held that by offering medical but not religious exemptions, the mandates violate the Free Exercise clause.[177]

To date, the Supreme Court has not ruled on this issue. On October 29, 2021, however, the court rejected an emergency appeal in case denying a Free Exercise challenge to Maine's requirement that health care workers be vaccinated against COVID-19.[178] The majority did not write an opinion. In a brief concurring opinion, Barrett, who was joined by Kavanaugh, stated that the Court should not use its discretion to take the case without benefit of "full briefing and oral argument."[179] In a heated dissent, Justice Gorsuch, who was joined by Thomas and Alito, argued that medical exemptions are comparable to religious exemptions and that strict scrutiny was required.[180]

To date, it is not clear whether the Court will take another vaccine case, or how it will resolve one should it do so. What is certain is that *Fulton* plus the COVID cases suggests that the Court does not mean to cabin its approach to laws that regulate worship qua worship.[181] Nor should the Court do so. Those whose practice their faith by selling food or educating students should not be given less protection than those who practice their faith by attending church on Sunday.

The problem is that when the appropriately expansive notion of what constitutes a religious practice is combined with the less deferential approach to comparability, all laws that seek to preserve the safety and well-being of society — during a pandemic and otherwise — are threatened. Any law can burden *someone's* religious practice; and all laws have exemptions. Yet, freed from deference, and unconcerned with empirical facts, the Court is left with little but its own intuition to determine which secular activities pose health risks that are comparable to the regulated activities that the plaintiff sincerely views as religious. The result may be a Free Exercise jurisprudence that dramatically limits the states' ability to protect public health, except when the Justices' intuition tells them that the religious activity at issue is not comparable to the exempt secular activities. Judicial intuition, however, seems a thin reed upon which to rest the public's health.

Conclusion

Bad facts make bad law. There is no doubt that the facts during the pandemic have been awful. The ever-changing and inconsistent patchwork of regulations and exemptions that tried to balance health and economic imperatives were often hard to fathom and difficult to explain. The sense of anger and grievance that much of the country felt regarding the COVID-restrictions, some of it justified and much of it stoked by President Trump and his allies, certainly added to the perception that state restrictions were motivated by animus and bigotry towards the faith-based community.

Still, by dispensing with deference, disregarding public health evidence, and limiting the determination of comparability to the risks posed by activities without any consideration of their benefits, the Court opened a Pandora's Box that threatens to undermine the public's health. While punting on the question of *Smith*'s fate, *Fulton* did little to close that box. Rather it has invited more litigation on the impact of broad grants of discretion.

As a result, all public health laws now face uncertainty. This cloud extends to vaccine mandates, not only for COVID, but also for measles, mumps, rubella, and other long-required vaccinations. As noted above, for more than a century, courts looked to *Jacobson* to affirm the state's right to mandate vaccination.[182] *Smith* provided further support.[183] Now, with the majority ignoring *Jacobson*, and five justices questioning *Smith,* these laws face new dangers. Most ominously, the Court's analysis of exemptions in both *Fulton* and the COVID cases raises the question whether vaccine mandates that include any exemptions, as all do,[184] are subject to strict scrutiny.[185]

Further, a decision by a state to mandate vaccination in some employment settings — say nursing homes — but not others — say prisons — could also fall victim to the comparability trap. Of course, a court might find that nursing homes are not comparable to prisons, or that vaccine mandates for nursing home workers can survive strict scrutiny.

The problem is that the outcome of all of such questions seems now to depend on judicial intuition more than public health evidence.

Future social distancing laws may also be at risk. COVID-19 will not be the last pandemic. When the next one strikes, the protection of the public may once again require the imposition of some forms of social distancing measures until a vaccine or treatment is developed. Ideally, those measures will be more carefully crafted and more consistently applied than they have been during the COVID-19 pandemic. Nevertheless, the Court's new jurisprudence suggests that the existence of any exemptions may lead to strict scrutiny, and that the state's careful reliance on public health evidence may prove to be of little help to the state.

Also imperiled are day-to-day laws and regulations that protect population health. Fire safety laws, food inspection laws, and tobacco control laws, to name just a few examples, may face new challenges by individuals who claim that compliance burdens their exercise of religion. Will all such laws be subject to strict scrutiny as long as a litigant can show that officials have broad discretion, or that the laws are under-inclusive? Will we have anything more than judicial intuition to ensure that the mass of laws that keep us safe are not toppled?

Perhaps, after the pandemic is over, the Supreme Court's eagerness to police public health orders through its shadow docket will diminish. Importantly, Justices Barrett and Kavanaugh have voiced their concerns about ruling on vaccine mandates without the benefit of full briefing and argument.[186] Hopefully, when the Court next speaks, it will not be from the shadow docket, and the justices will provide us with an opinion that relies less on the rage and intuition that seemed to propel the Court's COVID-cases and offer instead a more thoughtful and nuanced analysis of how to reconcile the Constitution's protections for religious liberty with the protection of public health. Such an approach might accept a narrowed *Smith*, but might also make clear that public health evidence matters in the determination of comparability and the application of strict scrutiny. It might also accept that states should be able to consider not only the risk of an activity subject to regulation, but also its benefits. By offering such an approach, the Court could continue the important task of policing anti-religious animus, especially aimed at religious minorities, without subjecting all public health laws to the comparability trap.

COVID-19 has stressed our society and our jurisprudence in a multitude of ways. Unfortunately, the next pandemic may be more lethal. It is also likely to have a different epidemiological profile, and require a very different mix of interventions than those that states used in 2020. To guide us through the inevitable clashes between religious liberty and public health that will then arise, we need a Free Exercise doctrine that takes both the science and the potentially adverse consequences of religious liberty more seriously than the opinions from the shadow docket.

Acknowledgements

Many thanks to Claudia Haupt. Jeremy Paul, and Dorit Rubinstein Reiss for their comments on an earlier draft of this paper and to Emily Kaiser and Riley Grinkis for their outstanding research assistance.

Note

Prof. Parmet reports after completing the manuscript, but prior to its publication, she was awarded a subgrant to a grant from the Robert Wood Johnson Foundation to ChangeLabs to work on a project relating to public health authorities, which may turn out to relate to some of the issues discussed in this paper. In addition, also after the manuscript was submitted, Parmet signed onto an amicus brief in two cases before the Supreme Court on some of the issues discussed in the paper.

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DETAIL

Subjek:	Public health; COVID-19; Supreme courts; Politics; Judicial reviews; Pandemics; Epidemics; Election results; Religion; Presidential elections; American Rescue Plan Act 2021-US; Coronaviruses; State laws; Subordination; Government mandates; Disease transmission
Ketentuan indeks bisnis:	Subjek: American Rescue Plan Act 2021-US
Lokasi:	United States--US; Massachusetts
Orang:	Trump, Donald J; Biden, Joseph R Jr
Pengidentifikasi/kata kunci:	COVID-19; Supreme court; Deference; COVID-19; Exemption; Public health; Free Exercise; Public Health Law; First Amendment
Judul:	From the Shadows: The Public Health Implications of the Supreme Court’s COVID-Free Exercise Cases
Pengarang:	Parmet, Wendy E
Judul publikasi:	The Journal of Law, Medicine &Ethics; Boston
Volume:	49
Edisi:	4
Detail sumber:	First Amendment Values in Health Care
Halaman:	564-579
Tahun publikasi:	2021

Tanggal publikasi:	Winter 2021
Bagian:	Symposium Articles
Penerbit:	Cambridge University Press
Tempat publikasi:	Boston
Negara publikasi:	United Kingdom, Boston
Subjek publikasi:	Law, Medical Sciences
ISSN:	10731105
e-ISSN:	1748720X
Jenis sumber:	Jurnal Akademik
Bahasa publikasi:	English
Jenis dokumen:	Journal Article
DOI:	https://doi.org/10.1017/jme.2021.80
ID dokumen ProQuest:	2730847778
URL Dokumen:	https://www.proquest.com/scholarly-journals/shadows-public-health-implications-supreme-court/docview/2730847778/se-2?accountid=211160
Hak cipta:	© 2021 The Author(s)
Terakhir diperbarui:	2023-11-28
Basis data:	Public Health Database

Vaccine Confidence and the Importance of an Interdisciplinary Approach

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ABSTRAK (ENGLISH)

Parental confidence in vaccines is waning. To sustain and improve childhood vaccine coverage rates, insights from multiple disciplines are needed to understand and address the socio-cultural factors contributing to decreased vaccine confidence and uptake.

TEKS LENGKAP

Vaccination is the safest and most effective means to prevent communicable disease.[1] Not only are serious adverse events after vaccination extremely rare,[2] but the benefits are also immense: children vaccinated against 13 diseases will experience an estimated 20 million fewer cases of those diseases and 42,000 fewer early deaths during their lifetimes.[3] In part due to the safety and effectiveness of vaccines, childhood vaccination programs have been remarkably successful. In the US, vaccination coverage levels for many vaccines in 2019 were ≥90%.[4] In the UK, the percentage of children who had received the routinely recommended vaccines by their first or second birthday in 2019-20 was ≥90%.[5] Globally, nearly two-thirds of all countries have reached the Global Vaccine Action Plan 2011–2020 target of ≥90% national coverage with the third dose of a diphtheria and tetanus toxoids and pertussis-containing vaccine and the first dose of a measles-containing vaccine.[6]

This success, however, is increasingly tenuous. As Benbow[7] implies, the success of childhood vaccination programs is threatened by several socio-cultural factors that have the potential to undermine confidence in the science and truths that are foundational to vaccination programs. It is worth emphasizing two such factors: the democratization of scientific and medical knowledge — a contributor to the "dizziness of freedom" — as well as the embrace of a postmodern medical paradigm among anti-vaccine advocates. These factors are synergistic. Health information is increasingly exchanged through social media sites without the involvement of "traditional gatekeepers such as health professionals and organizations" such that "anyone can contribute, easily and often quasi-anonymously."[8] This openness, in turn, can elucidate the complexity and uncertainty in the state of the science around medical interventions, like vaccinations (and it is worth noting that this complexity and uncertainty can also be perpetuated by conventional media, such as when, for instance, new theories regarding vaccine safety are featured before there is scientific consensus on their validity). It is this complexity and uncertainty that is leveraged to advance an agenda designed to locate truth outside of objective, scientific evidence. Whereas the focus of past anti-vaccine movements had been to undermine the role of scientific experts in making decisions about health,[9] the current anti-vaccine movement has intensified this focus to question the legitimacy of science and the biomedical enterprise itself.[10]

Concerning trends in the acceptance of childhood vaccines have consequently emerged. The proportion of 19-35 month old US children who received no vaccinations nearly doubled from 2013 to 2017.[11] Among UK adults surveyed, 55% agreed with or were undecided about the statement "Vaccines are not needed for diseases that are not common anymore."[12] Perhaps most concerning is a growing uncertainty about what constitutes the truth. Nearly one-third of UK adults surveyed do not think the information they receive above vaccines is reliable and trustworthy.[13] Among US adults, 15% of 18-29 year-olds don't trust medical scientists to provide full and accurate information on the health effects of the measles-mumps-rubella vaccine, compared to only 6% of ≥65 year-olds.[14]

Given this landscape, it is increasingly apparent that vaccination strategies informed by the disciplines of vaccinology, public health, medicine, law and epidemiology — the disciplines that have been most responsible for the progress to date in sustaining and improving vaccine uptake — are no longer sufficient.[15] Rather, vaccination strategies need to incorporate expertise from disciplines such as anthropology, ethics, behavioral economics, history, and political science. These disciplines are critical to understanding and addressing socio-cultural factors that challenge acceptance of childhood vaccines. Indeed, the World Health Organization has recommended that a post-2020 immunization strategy must have "greater collaboration and integration within and beyond the health sector," should promote a "wide-ranging view of collaboration and integration, at all levels and across all functions," and needs to include "the use of implementation science, operational research, delivery science, behavioral and social research, and data science to develop, pilot and evaluate improvements to national programs."[16]

Whereas the focus of past anti-vaccine movements had been to undermine the role of scientific experts in making decisions about health, the current anti-vaccine movement has intensified this focus to question the legitimacy of science and the biomedical enterprise itself.

The article by Benbow appeals to this type of interdisciplinary approach and illustrates the need to ground it in empirical research. We cannot simply be content with arguments for one strategy to promote and sustain vaccine uptake over another. We must ultimately ground the vaccination strategies we pursue on data supporting their effectiveness. In this way, though Benbow may be right that educating the public about the verbal maneuvers used within anti-vaccination discourse will be effective in making them less prone to their influence, this is only a hypothesis that must be tested.

The article by Benbow is also a cue to the importance of trust in the vaccine enterprise. A study of vaccine mis- and dis-information is, in essence, a study of trust.[17] After all, we can't achieve vaccine confidence without trust: between the public and the scientists that develop vaccines, between the public and pharmaceutical companies that produce vaccines, between the public and federal agencies that approve vaccines, and between patients and their clinicians who recommend and deliver vaccines.[18] Mis- and dis-information thrive where trust in these relationships have deteriorated.

The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic has reminded us of the importance of trust in these relationships. The politicization of the processes to develop and approve a SARS-CoV-2 vaccine exposed the fragility of these processes and the agencies that endorse them,[19] compromising public trust and confidence.[20] The pandemic was also yet another reminder that the social contract is not reciprocal for many in society.[21] The success in producing a vaccine as a medical countermeasure within months of the start of the pandemic has been diminished by the failure to fulfill the social and moral values central to ethics and global health, such as prioritizing the disadvantaged.

Over the last two decades, the field of vaccine confidence has produced incredible insights into what motivates people to get vaccinated and how to leverage those motivations to improve vaccine uptake. To continue these advances, researchers in the field must move beyond working in parallel and seek to integrate disciplinary skills and perspectives. And researchers must seek the development and evaluation of new strategies to address long-standing issues such as trust and equity. Post-pandemic, these are not simply opportunities, but responsibilities.

Note

Dr. Larson reports grants and other from GSK, grants from Merck, outside the submitted work. Dr. Opel reports grants from US National Institutes of Health, outside the submitted work.

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DETAIL

Subjek:	Confidence; Vaccines; Collaboration; Science; Success; Severe acute respiratory syndrome coronavirus 2; Mortality; Immunization; Pandemics; Interdisciplinary aspects; Measles; Morbidity; Postmodernism; Ethics; Pediatrics; Childhood; Drug dosages
Lokasi:	United States--US; United Kingdom--UK
Pengidentifikasi/kata kunci:	Public Health; Vaccine; Preventive Medicine; Pediatrics; Interdisciplinary Research; Vaccines
Judul:	Vaccine Confidence and the Importance of an Interdisciplinary Approach
Pengarang:	Opel, Douglas J; Larson, Heidi J

Judul publikasi:	The Journal of Law, Medicine &Ethics; Boston
Volume:	49
Edisi:	4
Detail sumber:	First Amendment Values in Health Care
Halaman:	596-598
Tahun publikasi:	2021
Tanggal publikasi:	Winter 2021
Bagian:	Independent Articles: Commentary
Penerbit:	Cambridge University Press
Tempat publikasi:	Boston
Negara publikasi:	United Kingdom, Boston
Subjek publikasi:	Law, Medical Sciences
ISSN:	10731105
e-ISSN:	1748720X
Jenis sumber:	Jurnal Akademik
Bahasa publikasi:	English
Jenis dokumen:	Commentary
DOI:	https://doi.org/10.1017/jme.2021.82
ID dokumen ProQuest:	2730847777
URL Dokumen:	https://www.proquest.com/scholarly-journals/vaccine-confidence-importance-interdisciplinary/docview/2730847777/se-2?accountid=211160
Hak cipta:	© 2021 The Author(s)
Terakhir diperbarui:	2023-11-28
Basis data:	Public Health Database

The Dizziness of Freedom: Understanding and Responding to Vaccine Anxieties

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ABSTRAK (ENGLISH)

The rise in vaccine hesitancy in high-income countries has led some to recommend that certain vaccinations be made compulsory in states where they are currently voluntary. In contrast, I contend that legal coercion is generally inappropriate to address the complex social and psychological phenomenon of vaccine anxieties.

TEKS LENGKAP

Introduction

The attitudes that people have concerning vaccines are infused with politics, social values, and cultural norms.[1] There has been a rise in the proportion of the population that is sceptical about vaccines in high-income countries.[2] Vaccination uptake was stagnating or declining in many states[3] prior to the COVID-19 pandemic. For example, a decline was reported in the uptake of all recommended pre-school vaccines[4] within England in 2019.[5] Similarly, between 2009 and 2018, 27 of the 50 United States (US) states experienced a drop in the percentage of vaccinated kindergarten age children.[6] The World Health Organization (WHO) declared vaccine hesitancy to be a global health threat in 2019.[7] The influence of anti-vaccination ideology and access and delivery issues have been identified as possible explanations for declines in vaccination uptake.[8] In respect of the former, conspiracy theories, including anti-vaccination sentiment, have proliferated during the COVID-19 pandemic.[9] I evaluate several potential policy responses which are available to governments to address vaccine anxieties. I argue that legal coercion is generally inappropriate to address the complex social and psychological phenomenon of vaccine anxieties. The historical experience of compulsory vaccination in the United Kingdom (UK), in the nineteenth century (which was enforced via fines), indicates that such coercion may backfire, as compulsion galvanised the anti-vaccination movement.[10]

I adopt a novel approach, within this article, by employing a psycho-social dialectic methodology, derived from the Frankfurt School philosopher Theodor Adorno's research into anti-Semitism, to examine the broad social and psychological factors which have influenced contemporary anxieties about vaccines. I contend that some of these factors, such as neo-liberal ideology and aspects of postmodern philosophy, ought to be resisted and challenged, as they have influenced an over emphasis on individual autonomy, resulting in the relational principles of biomedical ethics being neglected,[11] thereby undermining the solidarity which underpins vaccination systems. Adorno believed that making people aware of the numerous psychological tricks that he identified within anti-Semitic discourse,[12] was a means of countering racial prejudice. I identify many of the same psychological tricks, which Adorno detected within anti-Semitic discourse, within anti-vaccination discourse. Those who advocate education as a policy response to vaccine anxieties are often quite vague[13] and studies suggest that education about the facts concerning vaccines (such as the risks of vaccinations) may backfire by entrenching vaccine hesitancy.[14] Ideology contains both discursive (relating to discourse) and affective (related to moods, feelings, and emotions) components.[15] I contend that educational interventions should focus on the psychological reasons why people may invest in anti-vaccination discourse (the affective dimension of ideology). My distinctive argument is that making people aware of the psychological tricks used within anti-vaccination discourse may render them resilient to such discourse. My argument will be of interest to policymakers and academics in both medicine and law.

I adopt a novel approach, within this article, by employing a psycho-social dialectic methodology, derived from the Frankfurt School philosopher Theodor Adorno's research into anti-Semitism, to examine the broad social and

psychological factors which have influenced contemporary anxieties about vaccines. I contend that some of these factors, such as neo-liberal ideology and aspects of postmodern philosophy, ought to be resisted and challenged, as they have influenced an over emphasis on individual autonomy, resulting in the relational principles of biomedical ethics being neglected, thereby undermining the solidarity which underpins vaccination systems.

Vaccination Confidence and Uptake

As mentioned in the introduction, an increasing proportion of the population in high-income countries are sceptical of vaccines,[16] and vaccination uptake was stagnating or declining in many states, such as the US and UK, prior to the COVID-19 pandemic. Public Health England (an executive agency of the UK Department of Health and Social Care) warn that speculation that anti-vaccination ideologists have influenced the decline in vaccination uptake in England[17] could become a self-fulfilling prophecy.[18] Public Health England and NHS England (a non-departmental public body) contend that other factors may be responsible, such as inaccurate records, commissioning issues, lack of standardization of reminders and access issues.[19] Studies in both the US[20] and the UK[21] have determined that access and delivery issues have affected vaccination uptake. Nonetheless, both Public Health England and NHS England note that anti-vaccination views have impacted vaccination rates in other countries.[22] The increased spread of anti-vaccination sentiment during the COVID-19 pandemic may heighten anxieties about vaccines and hamper efforts to tackle reduced uptake.

The Danish existentialist philosopher, Søren Kierkegaard, described anxiety as the “dizziness of freedom.”[23] This means that the freedom to choose can be disconcerting. As vaccinations for children in some states (such as Austria, Denmark, Ireland, Finland, New Zealand, Spain, and the United Kingdom) are not compulsory, parents have the freedom to vaccinate their children, or not. Anxiety is often portrayed negatively, but it may mean a striving for something.[24] Some parents are anxious to vaccinate their children, and for other children to be vaccinated, to protect them from diseases. Consequently, vaccination is not simply imposed on the public, rather it is also demanded of the government and of fellow citizens.[25] By contrast, other parents are hesitant to vaccinate their children, as they are worried about the safety of vaccines. In complex modern societies, it is increasingly difficult for non-experts to know whether ideas are nonsense or not.[26] In addition, Adorno noted that ambivalent individuals may be receptive to emotional reorientation and irrational ideologies.[27] Vaccination decisions are influenced by local and national circumstances and culture.[28] It has been argued that vaccine hesitancy is on a continuum as it may relate to one or all vaccines.[29] By contrast, Patrick Paretti-Watel et al. contend that positing that vaccine views are on a continuum between pro-vaccination and anti-vaccination views is inappropriate and may lead to misunderstandings.[30] The vaccination decisions of parents are complex and multidimensional.[31] Although some people may be amenable to reconsidering their views about vaccines, others, as Adorno noted of some ideologists, are unlikely to “let anything get through to them.”[32] Isabel Rossen et al.’s research indicates that individuals categorized as fence sitters are more likely to be persuaded than individuals categorized as vaccine rejecters and that adversarial approaches may undermine trust (in the authorities that provide vaccinations) among the latter.[33]

Policy Responses

There are several potential policy responses that governments could utilize in an effort to address vaccine hesitancy and dwindling vaccination rates. One option is making some vaccinations compulsory. The penalties for non-compliance could be fines (which is the penalty for non-compliance in Slovenia) or imprisonment, or unvaccinated children could be precluded from enrolling at school (which is the penalty in states such as Australia, France, Italy and the US, although exemptions may be applicable). In the UK, Matt Hancock (Secretary of State for Health and Social Care from 2018 onwards) stated that the government was seriously considering compulsory vaccination in September 2019,[34] but this was swiftly contradicted by the Prime Minister’s Office (Number 10).[35] Nicola Glover-Thomas argues that the UK’s voluntary vaccination programme may no longer be enough to protect against the risk of infection[36] and Emma Cave argues that security (for example, if there is a vaccine preventable pandemic) and public health arguments may justify restrictions to vaccination choices.[37] Some medical professionals contend that

the UK government should make some vaccinations compulsory.[38] There have also been debates about making vaccinations compulsory in other states where they are not currently mandatory, such as Ireland[39] and Austria.[40] The policy of compulsory vaccination has been justified using jurisprudential and ethical theories. For example, the natural law scholar, John Finnis, contends that coerciveness alone is not a sufficient objection to compulsory vaccination programs as the subsistence of a community depends on upholding aspects of public good.[41] Drawing on John Rawls' theory of justice as fairness,[42] Alberto Giubilini contends that fairness is an important ethical value "when it comes to sharing burdens required by the preservation of public goods" and justifies unqualified compulsory vaccination.[43] Elsewhere, Giubilini et al. argue that ethical theories, such as utilitarianism and contractualism, and a collective duty of easy rescue, support a moral obligation to be vaccinated.[44] Glover-Thomas and Soren Holm argue that where some people choose to vaccinate their children in order to reduce community risk, this creates a reciprocal duty among others.[45] Glover-Thomas has also countered arguments against compulsion, based on individual rights and the violation of personal autonomy, on the grounds that public health justifies limits to both.[46] The problem with compulsion is not its coercive nature per se, but the potential consequences of its adoption. Nonetheless, as Benedict de Spinoza contended (in contrast to Thomas Hobbes' coercive command theory of law[47]):

in any form of state the laws should be so drawn up that people are restrained less by fear than hope of something good which they very much desire; for in this way everybody will do his duty willingly.[48]

Thus, in Spinozian terms, it would be better for people to want to vaccinate their children due to a hope for the common good that this would achieve than from a fear of the legal consequences of not doing so.

The potential deleterious consequences of making some vaccinations compulsory are evident from the historical experience, in the UK, of the series of statutes, in the nineteenth century,[49] which made smallpox vaccination compulsory for infants.[50] Such legislation galvanised the anti-vaccination movement in the UK[51] and made subsequent governments reluctant to make vaccinations compulsory.[52] The resentment caused by compulsory smallpox vaccination contrasts with the success of voluntary diphtheria vaccination, which was introduced in the UK during the Second World War.[53] The lesson that many drew from the experience of compulsory vaccination in the UK, in the nineteenth century, was that there are limits to what legislation can achieve.[54] By contrast, both France[55] and Italy[56] have made some vaccinations compulsory in recent years, which has led to a rise in vaccination uptake in both states. By contrast, coverage rates have fallen in Croatia despite mandatory vaccinations.[57] Daniel Salmon argues that mandates are a quick fix and that addressing the underlying causes of faltering uptake is needed to achieve stable uptake rates.[58] Andrea Kitta's research found that some Canadians who support vaccinations may question that support if they encounter proposals of making it mandatory.[59] In addition, the penalties associated with compulsion may disproportionately impact disadvantaged groups and exacerbate inequalities in child health.[60] My contention is that education is preferable to compulsion, but I acknowledge that the latter may be appropriate in certain circumstances (for example, during a pandemic, as Cave suggests[61]).

Some scholars argue that tort law could have a role to play where people have suffered harm as a result of parents decisions not to vaccinate their children,[62] but it may be difficult to establish causation in such cases.[63] Providing parents with incentives, such as tax rebates or direct payments, is another proposed policy.[64] However, a UK study found that parents and carers of young children and professionals viewed financial incentives to vaccinate as inappropriate.[65] In addition, an Australian study found financial penalties to be an ineffective strategy in changing the behaviour of vaccine-refusing parents.[66] In the US, many physicians dismiss families which refuse child vaccinations, which as Douglas Diekema notes, may have negative health impacts.[67] Ross Silverman and Lindsay Wiley have determined that tactics which leverage shame and social exclusion to promote vaccination may degrade public trust.[68] A more stringent approach to media regulation, in relation to information about vaccines, could be beneficial, but banning content, for example on the internet, may be problematic.[69] I contend that improved education is a preferable means of addressing vaccine hesitancy. In the following sections, I draw on the psycho-social dialectic methodology, developed by Adorno, to contend that such education should include consideration of the psychological reasons that people may invest in anti-vaccination ideology.

Psycho-Social Dialectic

The philosophers within the Institute for Social Research at Goethe University, Frankfurt (known as the Frankfurt School), whose work was influenced by Marxist philosophy, Weberian sociology and Freudian psychology, rose to prominence during the European interwar period (1918-1939). In addition to Adorno, famous members of the Frankfurt School include Max Horkheimer, Erich Fromm, Herbert Marcuse, and Jurgen Habermas. The members of the Frankfurt School produced several studies concerning anti-Semitism. There are similarities between the members of the Frankfurt School's work on anti-Semitism and other influential studies of the subject by Hannah Arendt[70] and Jean-Paul Sartre.[71] However, the reception of the Frankfurt School's theoretical output on this topic has been marginal.[72] George Cavelleto argues that the psycho-social tradition, of which the Frankfurt School were part, fell into disarray in the 1950s.[73] Nonetheless, there are similarities between the Freudo-Marxism of the Frankfurt School and the Lacanian left (scholars such as Slavoj Zizek and Yannis Stavrakakis), [74] who utilise the psychoanalytic theory of Jacques Lacan to examine modern society. In addition, Shannon Mariotti argues that Adorno's work anticipated the increased focus on emotions in subsequent social and cultural theory, which she describes as the "affective turn."[75] The renewed "politics of unreason" within contemporary societies demonstrates the continued relevance of the Frankfurt School's research concerning anti-Semitism.[76]

The Frankfurt School's members were forced into exile, in the US, during the Nazi regime's reign in Germany (1933-1945). They received funding to undertake research into anti-Semitism in the 1940s. Adorno adopted the methodology of a psycho-social dialectic[77] in his first analysis of anti-Semitic psychology,[78] his book *The Psychological Technique of Martin Luther Thomas' Radio Addresses*.[79] The book remained unpublished until 1975, six years following Adorno's death in 1969.[80] Nonetheless, it influenced his colleagues, Leo Lowenthal and Norbert Guterman, who wrote a book about fascist agitators,[81] which in turn influenced studies into conspiracy theories.[82] A content analysis of the speeches of anti-Semitic and fascist agitators was the first part of the Frankfurt School's research project into anti-Semitism.[83] The second part was to involve the production of an anti-agitational handbook, which never came to fruition.[84] In addition, Adorno and Horkheimer actively sought to make a Hollywood film, to educate people about anti-Semitism, but ultimately abandoned such efforts.[85]

The Thomas book differs from Adorno's more famous work on anti-Semitism, *The Authoritarian Personality*, which he co-wrote with some US scholars. In the authoritarian personality study, the F scale was developed "to measure the potentially antidemocratic personality."[86] Cornelia Betsch et al. have developed a similar scale to assess the psychological antecedents of views about vaccinations.[87] In unpublished remarks, Adorno noted that the focus of the authoritarian personality study is on subjective reactions rather than objective stimuli.[88] In Adorno's view, the study thereby reversed the manner of causation.[89] By contrast, in the Thomas book, Adorno uncovered the objective social conditions of late modernity in the ostensibly subjective phenomena of propagandistic manipulation.[90] Adorno contended that "the success of any attempt to fight anti-Semitism depends largely on knowledge of the social and psychological genesis of its various species."[91] I utilize Adorno's innovative psycho-social dialectic methodology to analyse several factors, in subsequent paragraphs, which have been important in the genesis of vaccine hesitancy and to explain how anti-vaccination ideologists have exploited such factors.

One factor is the economic and ideological changes wrought by neo-liberalism. Adorno diagnosed an increase in reification (the "misrecognition of reality due to social causes"[92]) within late (monopoly) capitalism. Reification causes estrangement, whereby people become strangers or enemies to one another.[93] Estrangement is the opposite of solidarity, which "signifies shared practices reflecting a collective commitment to carry 'costs' (financial, social, emotional, or otherwise) to assist others."[94] Vaccination systems are underpinned by such solidarity, as they require parents to ensure that their children are vaccinated to prevent disease, and may be undermined by reification, which causes individuals to erroneously view themselves as self-sufficient and autonomous.[95] Adorno identified several modes of reification including instrumental rationality (social reification), whereby means become ends in themselves.[96] Adorno believed that instrumental rationality had a negative impact on the psyche of subjects. According to Sigmund Freud, the psyche comprises the id (instinctual desires), the superego (self-critical consciousness) and the ego (which mediates between the former two).[97] Adorno criticised Freud for conceptualizing

the ego as fixed rather than contingent.[98] In Adorno's view, the autonomous personality structures (characterised by strong egos) which were predominant in the early stages of capitalism (entrepreneurial capitalism) had been replaced with the submissive authoritarian personality structures (characterised by weak egos) of late capitalism.[99] Adorno believed that instrumental rationality produced a collapse of ego rationalism and an upsurge of irrational and self-destructive id impulses.[100] According to Adorno, the rationalization of society, evident in the shift from entrepreneurial to monopoly capitalism, had engendered the de-rationalization of the psyche,[101] rendering people more susceptible to irrational ideologies, such as anti-vaccination ideology. Adorno contended that people perceived themselves as "at the mercy of society" and no longer the masters of their economic fates, but rather the "object of huge blind economic forces."[102] Such feelings, which have been exacerbated by changes within the neo-liberal era (such as deregulation, financialization and privatization), make people ripe for emotional manipulation.[103] For example, studies have demonstrated an association between feelings of disaffection and alienation and belief in conspiracy theories.[104] Arendt, like Adorno, noted that social atomization and extreme individualization influenced mass movements,[105] which both believed people participated in as a substitute gratification for unfulfilled social needs.[106] If someone feels as though they are not in control, the belief that someone else (the enemy identified by the movement) is acts as a compensatory control mechanism.[107]

Anti-vaccination ideologists have exploited both the economic and ideological changes in high-income countries in the neo-liberal era. In terms of the former, changes to the production of vaccines have included an increase in patents, the privatisation of vaccine institutes and the development of vaccines unrelated to infectious diseases.[108] Anti-vaccination ideologists cite such developments to contend that pro-vaccinators views are tainted by monetary considerations.[109] However, many anti-vaccination ideologists champion quack remedies, such as chelation therapy (a procedure to remove heavy metals from the body), for autism, which they contend is caused by vaccines. Such ideologists may have financial interests in such quack remedies.[110] In terms of the ideological changes wrought by neo-liberalism, the neo-liberal view of the individual as sovereign[111] has led to increased emphasis on medicine being personalized and individualized[112] and an increased emphasis on patient choice within government discourse. Such discourse reifies individuals, by treating them as autonomous, and has undermined appeals to a collective commitment to sustain herd immunity (the notion that if a sufficient number of people are vaccinated, this will disrupt the transmission of an infectious disease).[113]

The influence of post-modernism is another factor. Research has shown a link between post-material views and anti-vaccination sentiment.[114] In postmodern thought, science and philosophy are conceived as "just another set of narratives."[115] The postmodern emphasis on competing discourses has been exploited by anti-vaxxers.[116] Anti-vaccination ideologists often denigrate scientific studies (and the scientific method in general), while simultaneously craving scientific legitimacy for their theories that vaccines are harmful.[117] Thus anti-vaccination ideology evinces both a postmodern scepticism of science and an effort to mimic science.[118] For example, the Slovenian anti-vaccination ideologist, Mateja Cernic, contends that science is just one discourse among others,[119] but also emphasises the importance of verifiability (which is a key concept in the philosophy and practice of science).[120] Adorno would reject the postmodernist notion of science and philosophy as merely being narratives, as it is predicated on a view of language which fails to recognize the indissociable unity between concept and thing.[121] In contrast to some postmodernist philosophers, Adorno did not question well warranted science, although he thought that employing abstraction and objectification, which are essential to science, outside of the scientific realm could exacerbate social alienation.[122]

Another aspect of postmodern thought, which has influenced anti-vaccination ideologists and vaccine hesitant parents, is its emphasis on particularity, specifically in respect of children.[123] As children are viewed as unique,[124] there is a scepticism of vaccination schedules, which are general and treat children alike. As Bernice Hausman notes, vaccine hesitant parents "take the distinctive and differentiated self seriously as the focus of a personal (or familial) biopolitical project."[125] Adorno would view the sole focus of postmodern scholars on the particular as misguided as "neither one [the particular and the universal] can exist without the other."[126] Another link between postmodern theory and anti-vaccination ideology has been identified by Anna Kata. Kata contends that the

postmodern era is characterized by a preoccupation with risks over benefits.[127] Although some argue that the focus on risk in understanding vaccine hesitancy is misplaced,[128] it is a relevant consideration as many parents think they are best placed to analyse risk.[129] The problem is that some view educating the public towards a "correct" understanding of "real" risks as key.[130] Studies suggest that such messages are ineffective in promoting vaccination intent[131] and may backfire.[132] In addition, a US study determined that appealing to the general social benefits of vaccination, such as herd immunity, is ineffective in enhancing the intent of parents to vaccinate.[133] Nevertheless, another US study indicates that messages concentrating on the dangers of not vaccinating, rather than vaccine safety, may be effective.[134] A further US study suggests that messages concerning affective gains (for example, less anxiety) may also be beneficial.[135] Consequently, scholars, such as Andrea Grignolio, contend that confrontations with anti-vaxxers should focus on emotions.[136] I draw on Adornian theory to devise a comprehensive strategy, to educate people about the affective reasons why they may invest in anti-vaccination discourse, to immunize them from such discourse.

Hausman has utilized postmodern theory to contend that vaccine hesitant parents are not irrational, scientifically illiterate or irresponsible citizens.[137] Rather, in hesitating to medicalize their children, and seeking independent information about vaccines and their ingredients, Hausman contends that they are practicing good biological citizenship in the twenty-first century.[138] Hausman's argument draws on Nikolas Rose's concept of ethopolitics.[139] This is concerned with "the self-techniques by which human beings should judge and act upon themselves to make themselves better than they are."[140] Hausman's argument suffers from several problems. Firstly, she ignores Rose's argument about governments attempting "to shape the conduct of human beings by acting upon their sentiments, beliefs and values- in short by acting on ethics."[141] Governments want citizens to vaccinate their children, hence, in ethopolitical terms, vaccine hesitancy is a failure of governance. Secondly, the influence of postmodern philosophy has meant that some scholars regard communicating in a realist mode about scientific concepts as illusory.[142] Hausmann draws on Roberto Esposito's metaphor, that the distinction between antigens (foreign substances which induce an immune response in the body) and antibodies (blood proteins which counteract antigens) is meaningless, to contend that the distinctions between different biological entities is illusory.[143] However, Hausman communicates in a realist mode about the more abstract alleged biopolitical and ethopolitical epochs that she identifies. Thirdly, Hausman ignores the fact that the allegedly dominant ethopolitical norms may be resisted and challenged by other norms, such as residual norms.[144] The high public confidence in vaccines in many states, such as European Union (EU) member states,[145] indicates that what Rose characterizes as the collectivism of biopolitics,[146] which can be characterized as a residual norm, is still important in relation to vaccines.

The other objective social factors that have been cited as influencing vaccine hesitancy, within existing literature, include the rise in populism,[147] conspiratorial thinking,[148] and social movements (such as environmentalism, which have challenged governmental authority).[149] The Dunning-Kruger effect (whereby people overestimate their own cognitive ability)[150] and omission bias (the tendency to favor an act of omission over one of commission)[151] are psychological explanations for vaccination attitudes, within existing literature. Relevant laws, such as whether vaccines are mandatory and compensation schemes for vaccine damage, may also generate and feed into public anxieties. For example, anti-vaccination ideologists denigrate the US National Childhood Vaccine Injury Act 1986, which set up the Vaccine Injury Compensation Programme (VICP), for indemnifying vaccine producers.[152] Anti-vaxxers have cited cases where claimants have succeeded, such as the US Hannah Poling case,[153] as evidence that vaccines are unsafe.[154] The UK Vaccine Damage Payment Scheme (VDPS), established by the Vaccine Damage Payments (VDP) Act 1979, provides a payment of £120,000,[155] to eligible claimants who are, on the balance of probabilities,[156] severely disabled (the requirement is 60% disability[157]) by vaccinations. The VDP Act 1979 has been criticized as a "piecemeal, reactive and … incoherent" measure.[158] There are concerns that the VDPS' stringent eligibility criteria may be undermining confidence in vaccines.[159] I recommend that the VDPS be reviewed. In states without compensation schemes for vaccine damage, such as Australia, Canada (with the exception of Quebec) and Ireland, there are concerns about the potential costs of such schemes and fears that they could undermine confidence in vaccines.[160]

The traditional media (television and newspapers) have influenced vaccine anxieties by providing a platform for anti-vaccination ideologists.[161] For example, Paul Offit argues that the US media has been willing to provide a platform for any celebrity (such as Jenny McCarthy and Jim Carey) who wants to scare parents about vaccines.[162] In the UK, the Science Media Centre was established, in 2002, to renew public trust in science and has assisted journalists in navigating stories pertaining to vaccines.[163] The internet and social media have enabled anti-vaccination ideologists to disseminate their ideas more widely and facilitate the formation of on-line communities "where conspiracies and similar theories can flourish without constraints."[164] Social media is associated with a negative impact on public views regarding vaccinations, but is also a potential means of addressing vaccine hesitancy.[165] Anti-vaccination networks on the social media website Facebook have become highly entangled with networks of undecided people, whereas pro-vaccination networks are more peripheral.[166] Social media companies benefit from the revenue generated from the followers of on-line anti-vaxxers.[167] Research reveals that viewing typical vaccine critical websites for only five to ten minutes increases the perception of risk regarding vaccinations and decreases the perception of risk regarding the omission of vaccinations as compared to visiting a control site.[168] A Royal Society for Public Health (RSPH) study indicates that younger people are more likely to see, and believe, anti-vaccination sentiment online.[169] The UK government has proposed establishing the world's first independent regulator of internet companies,[170] but as mentioned above regulating online content may be difficult.[171]

Adorno argued that the best way to counter anti-Semitism was not by reference to the facts (the discursive dimension of ideology), but by making anti-Semites aware of the mechanisms which cause racial prejudice within them (the affective dimension of ideology). Similarly, Arendt noted that people may not necessarily be "convinced by facts."

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Psychological Tricks

Adorno argued that the best way to counter anti-Semitism was not by reference to the facts (the discursive dimension of ideology), but by making anti-Semites aware of the mechanisms which cause racial prejudice within them (the affective dimension of ideology).[172] Similarly, Arendt noted that people may not necessarily be "convinced by facts."[173] Adorno identified thirty-four psychological tricks (see Appendix 1) utilized within the anti-Semitic discourse of a US radio personality, Martin Luther Thomas.[174] The tricks describe various forms of manipulation that Thomas employed.[175] Adorno argued that there should be an "attempt to immunize the masses against these tricks."[176] Similarly, my novel argument is that education about the tricks used within anti-vaccination discourse may immunize people against such ideology and is a preferable policy response to compulsory vaccination, which historical experience indicates could exacerbate such ideology. The upsurge of anti-vaccination ideology during the COVID-19 pandemic, demonstrates the importance of developing strategies to counter it. I do not believe that every psychological trick that Adorno identified is relevant for anti-vaccination ideology, as some are specific to anti-Semitism. I have analyzed books authored by the following anti-vaccination ideologists: Mateja Cernic,[177] J.B. Handley,[178] Susan Humphries, and Roman Bystrianyk,[179] Jenny McCarthy,[180] Tetyana Obukhanych,[181] Andrew Wakefield,[182] and Brett Wilcox.[183] I have identified fourteen of the psychological tricks, that Adorno described, within their discourse, which are outlined within the following paragraphs.

The psychological tricks are as follows:

- 1. "Lone Wolf Trick": The first psychological trick which Adorno identified, within anti-Semitic discourse, which is also relevant for anti-vaccination discourse, is the lone wolf trick.[184] Andrew Wakefield, whose retracted paper on a possible link between the measles-mumps-rubella (MMR) vaccine and autism[185] is regarded as the catalyst for the contemporary anti-vaccination movement, portrays himself as a lone wolf, fighting against mainstream medicine, which he describes as "the system."[186] This trick draws on sympathy for the underdog[187] and the Galileo myth (that established opinion is frequently disrupted by maverick thinkers).[188] As Jonathan Howard and Dorit Rubinstein Reiss state, the idea here is that science has been wrong in the past, therefore science cannot be trusted now.[189]

•2. “Spontaneity and non-manipulated individuality” [190]: Anti-vaxxers often fake spontaneity and non-manipulated individuality by emphasising their emotions, such as distress and indignation, within their discourse. For example, McCarthy asks, in her book: “Why would vaccine companies believe that vaccines could be safe for all children? It’s crazy to me.”[191] This enables anti-vaxxers to distance themselves from the perceived coldness of objective science. Adorno stated that people may be receptive to this as they desire to escape feelings of loneliness, which objectivity intensifies, when engaging with public discourse.[192]

•3. “Persecuted innocence”[193]: Anti-vaccination ideologists stress the personal integrity, honesty and credentials of themselves and of other anti-vaxxers within their discourse. This is also indicative of the classic propaganda tactic (which Adorno labels the sheep and bucks trick) of painting oneself as noble and one’s enemy (those who are pro-vaccine) as evil.[194] For example, anti-vaccinators describe pro-vaccine scientists as shills of corporations and “biostitutes.”[195] Projection, which describes how within the discourse of propagandists, attributes are ascribed to others (opponents), which actually characterize the propagandists themselves, was central to Adorno and Horkheimer’s analysis of anti-Semitism in the *Dialectic of Enlightenment*.[196] The following are some examples of projection within anti-vaccination discourse: anti-vaxxers contend that pro-vaccinators are not interested in safety, [197] yet they are unconcerned with the morbidity/mortality caused by vaccine preventable illnesses; anti-vaxxers claim that pro-vaccination sentiment is based on emotion rather than logic, or is like a religion,[198] but anti-vaxxers make emotional appeals in their discourse, and cling to their views with a religious fervor; and, as mentioned above, anti-vaccine ideologists accuse pro-vaccinators of being influenced by monetary considerations, but often promote quack remedies themselves. Anti-vaxxers also portray parents, who do not vaccinate their children, as innocent. They do this by attacking herd immunity, which they misunderstand and misrepresent. For example, Wilcox erroneously states that “vaccines protect vaccine recipients but only if everyone else vaccinates.”[199]

•4. “Indefatigability”[200]: Anti-vaccination ideologists emphasise their ceaseless efforts and sacrifices within their discourse. For example, Wakefield claims that being erased from the UK medical register was a small price to pay for the privilege of working with families affected by autism.[201] However, in focusing on the discredited link between vaccines and autism, the efforts of anti-vaccination ideologists are detrimental to families affected by autism. Peter Hotez (an American scientist whose adult daughter has autism) contends that the US anti-vaccination movement is responsible for the lack of resources for people with autism.[202]

•5. Short Memories: In discussing the “great little man trick,” used within anti-Semitic discourse, Adorno stated that anti-Semites reckon that their audience have short memories,[203] which is the fifth relevant trick that I have identified within anti-vaccination discourse. Anti-vaxxers reckon on short memories when they contend that the incidence of infectious diseases would have declined without vaccination. The World Health Assembly declared that the disease of smallpox had been eradicated in 1980 following intensive global eradication efforts.[204] Humphries and Bystrianyk contend that “there is no evidence that vaccination had anything at all to do with” the decline and ultimate eradication of smallpox.[205] This ignores the effort and resources (approximately $300 million) that went into vaccinating people as part of the “Intensified Smallpox Eradication Program” between 1967 and 1979.[206]

•6. “Human interest stories”[207]: Anti-vaccination ideologists rely on human interest stories within their discourse. This contrasts with the seeming coldness of objective scientific arguments. Such stories include anecdotes from parents who claim that their children are vaccine injured. Anecdotes can be useful for science. For example, Edward Jenner’s discovery of vaccination, in the 1790s, was based on anecdotes from milkmaids, who noted that exposure

to the mild disease of cowpox seemed to protect against the more serious disease of smallpox.[208] Nonetheless, scientific study is necessary to determine whether anecdotes are valid and reliable. Several studies into the purported link between the MMR vaccine and autism have found no causal association.[209] In addition, the recipient's libido is satisfied when they are treated as an insider.[210] For example, Wilcox distinguishes between "vaccine believers" (those who, in his view, uncritically accept that vaccinations are good), "vaccine sociopaths" (those scientists who he alleges secretly know that vaccinations are harmful) and the "vaccine informed" (those who, he contends, have learned that vaccines are harmful).[211] The ascription of "vaccine informed" status to recipients of anti-vaccine discourse may make them feel part of a superior community which eschews received wisdom. Some recipients may feel as though they have been "let in" and "taken into confidence."[212] As Adorno noted of fascist propaganda, "the follower, simply through belonging to the in-group is better, higher and purer than those who are excluded."[213]

- 7. "The flight of ideas"[214]: This describes how, within their discourse, anti-vaccination ideologists pretend that they are engaging in argument, but they have already arrived at their conclusions, namely, that, in their view, vaccinations are harmful. For example, Wakefield and Cernic both claim, early on in their respective books, that there is a possible link between the MMR vaccine and autism.[215] However, by the end of their respective books, their arguments have changed, as they are both unequivocal that vaccines cause autism.[216] There is no explanation offered as to why a possibility has become a certainty. The authors are presumably hoping that enough arguments intended to inculcate uncertainty among their audiences will suffice.

- 8. "Good old time"[217]: This refers to the emphasis on the old fashioned within both anti-Semitic discourse and anti-vaccination discourse. As Kata notes, this designates something "natural" as being inherently good or right, while what is "unnatural" is bad or wrong.[218] According to this logic, which is set out in Obukhanych's book,[219] vaccines are unnatural and therefore bad,[220] whereas acquiring immunity from diseases is natural and therefore the better approach.[221] Such flawed logic overlooks the higher risks from natural infection while fixating on comparably minute risks from vaccination.[222]

- 9. "Fait accompli"[223]: This refers to statements which are made by propagandists, as though a matter has already been decided, for example by stating that a large group of people cannot be wrong. This is evident in McCarthy's foreword to Wakefield's book, in which she states that:

- 10. You hear this story [about children purportedly developing autism after vaccinations] once, it's disturbing, a dozen times it starts to feel like a pattern, a thousand times and you begin to wonder why this is still a debate.[224]

- 11. However, as noted above, studies into a potential link have found no causal association.

- 12. "Last hour device"[225]: Similarly to anti-Semites, and conspiracy theorists more generally,[226] anti-vaccination ideologists employ apocalyptic terms[227] in an attempt to convince their audience that it is the eleventh hour and that they must act immediately to prevent impending evil. They contend that rates of autism have increased and will continue to do so unless action is taken against vaccines. For example, Wilcox contends that: "the holocaust is here. It's now. It's real."[228] This purported rise in autism is designed to play on the fears of their audience. Although statistics suggest that autism has increased, this statistical variation is attributed to more accurate and expansive diagnoses of autism.[229] In response, anti-vaccination ideologists claim that, if this is true, there is an absence of older people living with autism.[230] However, surveys indicate similar rates of autism in children and adults.[231]

- 13. “The black hand (feme) device”[232]: Although anti-vaccination ideologists portray themselves as tirelessly seeking to uncover the truth and wanting to engage in a debate about vaccinations, they themselves brook no dissent. For example, in anti-vaccination groups on social media, pro-vaccination sentiment is deleted and people with pro-vaccination sentiments are banned.[233] However, the variety of claims and stances on vaccination is multifarious and often contradictory and internal debates and disagreements are conspicuously absent from anti-vaccination ideology. For example, when Wakefield posited a link between the MMR vaccine and autism, in 1998, he recommended that the triple vaccine be replaced by single vaccines for measles, mumps and rubella. It later emerged that Wakefield had patented a single measles vaccine.[234] He would therefore have benefited financially if the triple vaccine had been replaced by single vaccines. In contrast, other anti-vaccination ideologists, such as Wilcox, would not recommend any vaccines, but still praise Wakefield.[235]

- 14. “Anti-institution trick”[236]: Anti-vaccination ideologists seek to exploit the potential dislike of institutions among their audience. Their discourse may appeal to people with differing political views. For example, in criticizing the state (government) and state institutions (such as those involved in the regulation of medical technology) anti-vaccination ideologists appeal to those with libertarian and conservative views (who favor a small state). In criticizing the pharmaceutical companies, which develop and supply vaccines, anti-vaccination ideologists appeal to anti-capitalist sentiment.

- 15. “If you only knew”[237]: Similarly to anti-Semitic discourse, there is much innuendo of hidden evil within anti-vaccination discourse. Anti-vaccination ideologists endeavor to exploit the negative associations that people may relate with certain vaccine ingredients. The ingredients that anti-vaccination ideologists have focussed on include thimerosal (a mercury-based preservative), aluminium (which is used, in some vaccines, as an adjuvant to boost the body’s response to vaccine) and formaldehyde (which is used to prevent contamination by bacteria) in an effort to increase anxieties about vaccines. Many of these ingredients have been used in vaccines since the 1930s. Anti-vaccination ideologists claim that the increased number of vaccines given to children explains a purported causal link between such vaccines and illness (such as autism).[238] Many of these ingredients are already present in the body (for example, there is more formaldehyde in the body than in vaccines) and material ingested into the body, such as food (for example, infants will ingest more aluminium from breast milk than they will receive from vaccines in the first six months of their life[239]). There is no evidence that the small amounts of these ingredients that are contained in some vaccines are harmful.

- 16. “Democratic cloak”[240]: Adorno noted that the authoritarianism of Thomas was different to the authoritarianism of the Nazis in Germany.[241] Whereas German Nazis were openly critical of democracy,[242] the American attack on democracy was done in the name of democracy.[243] Anti-vaccination ideology is akin in that a tactic of anti-vaxxers is to try to shift the debate into an ethical/legal discussion about freedom and rights.[244] Anti-vaccination ideologists contend that parents have the right not to vaccinate their children. They thus conceive human rights negatively (as freedom from interference). In contrast, in international law, human rights are conceptualized positively. For example, health is defined in the WHO constitution as “a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.”[245] Every country in the world has ratified at least one treaty containing health related human rights.[246] The Committee on Economic, Social and Cultural Rights, stated, within its General Comment No.14, that the human right to health, contained in Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR),[247] requires states to “provide immunization against the major infectious diseases occurring in the community.”[248]

I contend that a theory and evidence-based[249] resource (see Appendix 2), outlining these psychological tricks, in lay terms, may render people resilient to anti-vaccination ideology. However, I acknowledge that some resources can backfire. For example, Adorno helped to create cartoons to combat anti-Semitism, but they were counterproductive as respondents interpreted them as supportive of prejudice.[250] Rob Brotherton argues that some conspiracy theorists may consider explorations of the psychological reasons that people believe such theories as an attempt to portray them as mentally unbalanced and thus worse than challenging them on the facts.[251] Nonetheless, as mentioned above, some people with vaccine anxieties may be amenable to a reconsideration of their views. I recommend that education concerning the psychological tricks should be incorporated into school curriculums, as previous studies indicate that prevention is preferable.[252] Whether informing people of the psychological tricks can reduce vaccine anxieties requires further study. While the specific focus of this article has primarily been on vaccine anxieties, it highlights the broader "need to increase self-awareness and self-determination that makes any kind of manipulation impossible."[253] In addition, as Adorno argued, "by making connections between ideology and socio-psychological structures" a naivety in the social climate can be eliminated and a certain detoxification can take place.[254] In this respect, my paper highlighted the objective social factors, such as neo-liberal ideology and aspects of postmodern philosophy, which should be resisted and challenged as they have influenced the overemphasis on individual autonomy in medico-legal discourse (thereby undermining the solidarity underpinning vaccination systems) and are exploited by anti-vaccination ideologists.

Conclusion

There has been an increase in vaccine scepticism in many high-income countries and anti-vaccination sentiment has proliferated during the COVID-19 pandemic. I considered several potential policy responses. I argued that legal coercion is generally inappropriate to address some complex social and psychological issues and may risk galvanising the anti-vaccination movement. I averred that improved education is a preferable policy response, but noted that education about the facts pertaining to vaccinations may backfire. I utilized an innovative psycho-social dialectic methodology, derived from Adorno's research into anti-Semitism, to identify the objective social processes which have influenced vaccine anxieties. I identified many of the psychological tricks that Adorno found in anti-Semitic discourse within anti-vaccination discourse. I proposed that increasing public comprehension of such devices may render people resilient to anti-vaccination discourse, thereby potentially addressing dwindling vaccination rates. The original approach that I have recommended to address vaccine anxieties, within this paper, will be of interest to policymakers and academics in both medicine and law.

Note

The author has no conflicts to disclose.

Acknowledgements

I would like to thank Professor Tsachi Keren-Paz, Dr. Angela Sorsby, Professor Richard Percival, and Dr. Arushi Garg for their comments on an earlier draft of this paper. I would also like to thank Professor Graham Gee and Dr. Russell Buchan for their comments on subsequent drafts.

Appendix 1

The thirty-four psychological tricks that Theodor Adorno identified in *The Psychological Technique of Martin Luther Thomas' Radio Addresses* are as follows:

•1. Lone wolf (p4)

•2. Emotional release (p6)

•3. Persecuted innocence (p10)

•4. Indefatigability (p13)

•5. Messenger (p15)

•6. A great little man (p18)

•7. Human interest (p24)

•8. Good old time (p25)

•9. Movement trick (p31)

•10. Flight of ideas (p32)

•11. Listen to your leader (p37)

•12. Fait accompli (p42)

•13. Unity trick (p47)

•14. Democratic cloak (p50)

•15. If you only knew (p53)

•16. Dirty linen device (p58)

•17. Tingling backbone device (p61)

•18. Last hour device (p64)

•19. Black hand (feme) device (p68)

•20. Let us be practical (p70)

•21. Speaking with tongues (p78)

•22. Decomposition (p81)

•23. Sheep and bucks (p85)

•24. Personal experience (p87)

•25. Anti-institution trick (p91)

•26. Anti-pharisees device (p95)

•27. Religious trickery in operation (p98)

•28. Faith of our fathers device (p100)

•29. Imagery of communism (p105)

•30. Communists and bankers device (p108)

•31. Administration and president baiting (p113)

•32. Pick up thy bed and walk device (p117)

•33. The Jews are coming (p120)

•34. Problem device (p123)

Appendix 2

Anti-vaxxers aim to cause anxieties about vaccinations through the following tricks:

•1. Anti-vaxxers present themselves as lone wolves fighting against the medical establishment. They seek to draw on both sympathy for the underdog and the Galileo myth (that established opinion is frequently disrupted by maverick thinkers).

•2. Anti-vaxxers emphasize distress in their discourse to fake spontaneity and distinguish themselves from the seeming coldness of objective science.

•3. Anti-vaxxers stress the personal integrity, honesty and credentials of themselves and others involved in the anti-vaxx movement. The fact that they feel the need to emphasise such attributes should give people cause for concern.

•4. Anti-vaxxers stress their own personal sacrifices and efforts. However, their efforts would be better spent campaigning for resources for people with autism.

•5. Anti-vaxxers rely on short memories. For example, they argue that the disease of smallpox would have died out without vaccines. This ignores the effort and resources (approximately £300 million) of the intensified smallpox eradication campaign between 1967 and 1979.

•6. Anti-vaxxers rely on human interest stories (anecdotes) within their propaganda, again to distinguish themselves from scientific discourse.

•7. Anti-vaxxers pretend that they are engaging in logical analysis, but their conclusions have already been reached.

•8. Anti-vaxxers value the natural over the unnatural within their propaganda, seeking to exploit modern prejudices for the natural.

•9. Anti-vaxxers use manipulative arguments, for example, X number of people cannot be wrong.

•10. Anti-vaxxers claim that vaccines are causing rising rates of autism. However, statistical increases in autism rates are due to more accurate and expansive diagnoses. Scientific studies have found no link between vaccines and autism.

•11. Anti-vaxxers claim that they want to debate, but accept no dissent to their anti-vaxx dogma.

- 12. Anti-vaxxers seek to exploit political and religious prejudices. For example, in criticising the corporations that develop vaccines they appeal to those with left wing views and by criticising state institutions they appeal to those with right-wing views.

- 13. Anti-vaxx propaganda contains innuendo regarding some vaccine ingredients in an effort to scare their audience. There is no evidence that the ingredients contained in some vaccines are harmful.

- 14. Anti-vaxxers often try to shift the debate away from science onto a legal discussion about rights. Every country has ratified a treaty including the human right to health. Such rights impose duties on states to ensure that their citizens are vaccinated against diseases.

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DETAIL

Subjek:	Anxiety; Ethics; Immunization; Public health; Disease control; Antisemitism
Lokasi:	England; United States--US; Austria; United Kingdom--UK
Orang:	Adorno, Theodor Wiesengrund (1903-1969)
Perusahaan / organisasi:	Nama: Public Health England; NAICS: 923120
Pengidentifikasi/kata kunci:	Vaccinations; Vaccine hesitancy; Vaccine; Vaccination; Vaccine Hesitancy; Anti-Vaccination Ideology; Psycho-Social Dialectic; Theodor Adorno
Judul:	The Dizziness of Freedom: Understanding and Responding to Vaccine Anxieties
Pengarang:	Benbow, David I
Judul publikasi:	The Journal of Law, Medicine &Ethics; Boston
Volume:	49
Edisi:	4
Detail sumber:	First Amendment Values in Health Care
Halaman:	580-595
Tahun publikasi:	2021
Tanggal publikasi:	Winter 2021
Bagian:	Independent Articles
Penerbit:	Cambridge University Press

Tempat publikasi:	Boston
Negara publikasi:	United Kingdom, Boston
Subjek publikasi:	Law, Medical Sciences
ISSN:	10731105
e-ISSN:	1748720X
Jenis sumber:	Jurnal Akademik
Bahasa publikasi:	English
Jenis dokumen:	Journal Article
DOI:	https://doi.org/10.1017/jme.2021.81
ID dokumen ProQuest:	2730847775
URL Dokumen:	https://www.proquest.com/scholarly-journals/dizziness-freedom-understanding-responding/docview/2730847775/se-2?accountid=211160
Hak cipta:	© 2021 The Author(s)
Terakhir diperbarui:	2023-11-27
Basis data:	Public Health Database

Assuming Access to Professional Advice

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ABSTRAK (ENGLISH)

Access to reliable health advice can make the difference between life and death. But good advice is hard to come by. Within the confines of the professional-client or doctor-patient relationship, the First Amendment operates in a way that protects good and sanctions bad advice. Outside of this relationship, however, the traditional protections of the First Amendment prohibit content- and viewpoint discrimination. Good and bad advice are treated as equal. A core assumption of First Amendment theory is the autonomy of speakers and listeners. Another assumption, as this Article demonstrates in the health context, is the availability of access to professional advice. This assumption, however, is erroneous because access to health advice in fact is unevenly distributed.

This Article argues that assuming access to professional advice creates indefensible inequality. Lack of access to expert advice puts some listeners at much higher risk than others. Current First Amendment doctrine is largely unproblematic for those who can afford expert advice, and makes expert advice much costlier where health provider

access is needed to obtain good advice. Those who lack access must place a higher degree of trust in widely-available information because they have no more reliable alternative. In other words, First Amendment doctrine places a higher burden on those who can least afford expert advice and who are most dependent on experts in public discourse.

TEKS LENGKAP

Introduction

Access to reliable health advice can make the difference between life and death. But good advice is hard to come by. While this is true in ordinary times, the COVID-19 pandemic has made the need for widely available, scientifically accurate health advice particularly pressing. Within the confines of the doctor-patient relationship, the First Amendment operates in a way that protects good and sanctions bad advice.[1] For example, there is no First Amendment defense to malpractice liability if a doctor dispenses bad advice to a patient that results in harm. [2] Outside of the doctor-patient relationship, however, the traditional protections of the First Amendment generally prohibit content and viewpoint discrimination.[3] As a result, good and bad advice are treated as equal.

A core assumption of First Amendment theory is the autonomy of speakers and listeners. But when expertise is involved, non-expert listeners cannot be assumed to have the knowledge necessary to make truly autonomous decisions. This is why we distinguish between the professional-client relationship, designed to provide necessary expertise as the basis for important life decisions, and public discourse, where ideas are freely debated among speakers, in the first place. Another assumption, as this Article demonstrates in the health context, is the availability of access to expert advice. This assumption, however, is erroneous because access to health advice in fact is unevenly distributed. What if access to the doctor-patient relationship, and thus access to expert medical knowledge, is unattainable?

The stark theoretical and doctrinal contrast between regulated speech within the doctor-patient relationship and largely unregulated speech in public discourse is only justifiable if listeners have equal access to expert advice. Lack of access puts some listeners at much higher risk than others.

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This Article argues that assuming access to professional advice creates indefensible inequality. The stark theoretical and doctrinal contrast between regulated speech within the doctor-patient relationship and largely unregulated speech in public discourse is only justifiable if listeners have equal access to expert advice. Lack of access puts some listeners at much higher risk than others. Current First Amendment doctrine is fairly unproblematic for those who can afford expert advice, but it makes expert advice much costlier where health provider access is needed to obtain good advice.[4] Those who lack access must place higher trust in widely-available information, which is unregulated as to its accuracy in public discourse, because they have no more reliable alternative. In other words, First Amendment doctrine places a higher burden on those who can least afford expert advice and who are most reliant on experts in public discourse. Differential access falls largely, though not exclusively, along racial lines;[5] vulnerable populations are less likely to receive reliable health advice routinely. [6]

Scholars have recently begun to highlight the distributive effects of First Amendment jurisprudence. As Nelson Tebbe observed, “[j]udges and other constitutional actors have been interpreting freedoms of speech and religion in a manner that unwinds government programs designed to ameliorate disparities of wealth, income, and other primary goods.”[7] This Article is situated in conversation with that emergent line of First Amendment scholarship. As in other areas, “constitutional actors might respond by improving their understanding of how First Amendment rights interact with economic justice.” [8] Excavating the mistaken premise of access to professional advice contributes to this larger project. The access problem has many facets that are widely discussed in the health law literature, but the First Amendment issue foregrounded here remains largely implicit. Although an obvious doctrinal distinction exists between the doctor-patient relationship and public discourse, the underlying assumption usually stays unacknowledged. Widely available access to healthcare, to be clear, is an important policy goal independent of First

Amendment arguments, and I do not suggest that there is a First Amendment claim to access. Rather, the argument I make here is that without equal access, the assumptions underlying First Amendment doctrine are erroneous, and therefore, the resulting differential treatment of listeners within the doctor-patient relationship and those outside of it is unjustified.

The distinctive treatment of expertise in the doctor-patient relationship is only justifiable if listener autonomy is ensured. Either reliable expert advice must be widely available, as I will argue here, or the balance between speech protection and liability outside of the doctor-patient relationship ought to be recalibrated, with potential implications beyond this context. Focusing on the narrower issue of access to professional advice, this Article offers one way of mitigating the imbalance.

This Article proceeds in three Parts. Part I sketches the current First Amendment framework governing the distinctive doctrinal treatment of professional speech, that is, speech within the professional-client or doctor-patient relationship for the purpose of giving professional advice. Part II exposes the inequalities this First Amendment framework creates and highlights its consequences, putting free speech theory into conversation with the health law literature concerned with access disparities. Part III offers improving access to advice as one approach to mitigate the disconnect between the underlying theoretical assumption of access and the reality of limited access to the doctor-patient relationship.

Expanding access to expert advice suggests an admittedly highly speech-protective approach which sustains current First Amendment doctrine. It does not alter the balance between speech protection and liability for bad advice in public discourse, outside of the doctor-patient relationship. It also does not address continuing inequity within the doctor-patient relationship that concerns the quality of available advice.[9] Short of rearranging the existing balance between speech protection and liability for bad advice in public discourse, the importance of improving access to reliable advice by broadening access to healthcare services becomes particularly salient in a pandemic where the potential health harms from following bad advice are especially high.

I. The Framework of Unequal Advice

First Amendment doctrine bifurcates the quality of information in public discourse and the doctor-patient relationship.[10] Whereas speech within the doctor-patient relationship is regulated in numerous ways to ensure its accuracy, these constraints are generally absent outside of this relationship. “The distinction between public speech and non-public speech is embedded deeply within the fabric of First Amendment doctrine …,”[11] as is evident in the issues surrounding professional advice. (For purposes of this Article, I will limit the discussion to the doctor-patient relationship, but the claims I make throughout to a large extent also apply to other professional relationships.) As the Ninth Circuit put it, “outside the doctor-patient relationship, doctors are constitutionally equivalent to soapbox orators and pamphleteers, and their speech receives robust protection under the First Amendment.”[12] This Part sketches the doctrinal distinction between professional speech and speech in public discourse and their respective normative underpinnings, focusing in particular on autonomy interests of the speaker and listener in addition to other free speech justifications such as the marketplace of ideas and democratic self-government interests.[13]

Importantly, although the Supreme Court declared in its 2018 decision in *NIFLA v. Becerra* that it has never recognized a category of professional speech, it does afford the speech within the doctor-patient relationship special doctrinal treatment.[14] Justice Thomas, writing for the *NIFLA* majority, discussed “[l]ongstanding torts for professional malpractice” and emphasized that informed consent is “firmly entrenched in American tort law.”[15] Subsequently, it is still true that “identifying professional speech as distinct merely acknowledges a specific set of doctrinal features that we have traditionally assumed apply to speech between professionals and clients.”[16] The bifurcation between speech in the doctor-patient relationship (irrespective of its “professional speech” label which, despite its descriptive accuracy, the Court disfavors) on the one hand, and in public discourse on the other thus still holds after *NIFLA*.[17]

A. Professional Speech

The law constrains what professionals may communicate to their patients within the confines of the doctor-patient relationship for the purpose of giving professional advice. These constraints are designed to ensure that patients receive comprehensive, accurate, and reliable advice. Whereas restrictions based on content and viewpoint are

generally considered suspect, these limits — including professional licensing, fiduciary duties, informed consent, and malpractice liability — all place permissible limits on the content of advice.[18] I will map each of these features in turn. They all hinge on the nature of professional advice as different from other forms of speech.

The speech within the doctor-patient relationship is of a specific quality. Unlike other types of speech, its content is tied to professional knowledge, that is, expertise specific to the profession.[19] We might think of the professions as "knowledge communities" which exist to generate and disseminate knowledge.[20] The individual professional functions as a conduit between the knowledge community and the client or patient.[21] This connection to a knowledge community distinguishes the quality of advice communicated within the doctor-patient relationship from speech, including for example health advice, that occurs outside of it for example in traditional media such as television or on social media platforms such as Facebook, YouTube, Twitter, and the like. Conceptualizing the professions as knowledge communities for speech purposes also parallels the mechanics of malpractice liability where "the knowledge community's standard of care determines the benchmark against which the individual professional's liability is assessed."[22]

Importantly, professional knowledge is neither monolithic nor static. There is a range of opinions that count for good professional advice (as also recognized in tort law through the "two schools of thought" or "respectable minority" doctrine),[23] and professional knowledge can change over time.[24] Indeed, "[w]hat once was accepted in the field may soon be outdated."[25] However, the shared notions of validity to which knowledge communities subscribe limit the range of what counts as acceptable expertise.[26] Change within the knowledge community's discourse occurs by reference to these shared notions of validity.[27] Thus, "[d]ifferent assessments of shared knowledge, if valid under the agreed upon methodology, may produce good professional advice, even if it departs from the mainstream."[28] Emergent knowledge can work its way into the mainstream, as illustrated for example by the case of medical marijuana.[29]

During the COVID-19 pandemic, this process of updating advice according to new scientific insights was in unusually plain view, at times confusing the public.[30] This confusion in significant part is due to the fact that the process of expanding and updating knowledge ordinarily occurs internally. By the time professional advice reaches the public in ordinary times, it likely will have gone through deliberations within the knowledge community. The academic literature, conferences, and personal interactions can serve as sites of professional knowledge formation.[31] Though mostly through internal mechanics, knowledge communities update their advice, and they typically do so on the basis of a shared professional standard, reflected in common ways of knowing and reasoning and, in the case of scientific insights, the scientific method.[32] This also means that certain opinions can be excluded from the body of professional knowledge — or at least made extremely costly by imposing potential liability if harm results from expressing those opinions as advice — something that is impermissible in public discourse. In this respect, as Robert Post put it, "[e]xpert knowledge requires exactly what normal First Amendment doctrine prohibits."[33]

The doctor-patient relationship is characterized by an asymmetry of knowledge, where the patient seeks the doctor's advice to obtain knowledge the patient otherwise lacks.[34] At the same time, patient autonomy demands that the ultimate decision to act on professional advice rests with the patient.[35] This most fundamentally means the patient is able to make important life decisions for herself. Being able to do so, however, first requires "accessing the knowledge community's knowledge through the individual professional."[36] Of course, access is just a necessary, but not necessarily sufficient, first step; the patient also must understand the advice. The professional, in turn, must "communicate all information necessary to make an informed decision to the client."[37] In the classic formulation of *Canterbury v. Spence*, the patient needs professional advice to gain "enlightenment with which to reach an intelligent decision."[38] The interest thus protected is the patient's decisional autonomy, the ability to "chart his own course."[39]

Among the guardrails securing reliable advice within the doctor-patient relationship are features that would otherwise run afoul of the First Amendment. Before giving advice, professionals must be licensed. As far back as 1889, the Supreme Court has linked licensing and professional qualification. In upholding a licensing requirement to practice medicine, in *Dent v. West Virginia*, the Court noted: "No one has a right to practice medicine without having the

necessary qualifications of learning and skill; and the statute only requires that whoever assumes, by offering to the community his services as a physician, that he possesses such learning and skill, shall present evidence of it by a certificate or license from a body designated by the State as competent to judge of his qualifications."[40] Professional licensing, though often criticized as an economic obstacle to limit entry to the profession, also serves to ensure health and safety of the patient by establishing minimum standards to practice.[41]

As I have explained in more detail elsewhere,

"[t]he most salient justification for professional licensing is ensuring the professional's competence; thus, the object of licensing is the professional's knowledge. Licensing so understood ties the individual professional to the knowledge community by requiring a link between the ability to speak as a professional and the communication of knowledge as defined by the profession."[42]

In an ordinary First Amendment context, by contrast, licensing requirements might be understood as prior restraints on speech.[43] But whereas government permission to speak speech is troublesome in public discourse, and serves as a justification to prohibit prior restraints, and licensing functions as an ex-ante requirement to dispense advice, "suppression of incompetent advice is normatively desirable in the professional context."[44] The goal is "preserving the reliability of expert knowledge by guarding professionals' competence, and protecting the dissemination of reliable professional advice to the client."[45] Moreover, licensed professionals are subject to professional discipline where members of the profession "evaluate whether their peers meet the community's professional standard."[46]

Professional licensing has long been debated for several reasons, mostly concerned with improper tailoring of licensing regimes.[47] And "[t]he mere fact that someone is licensed to practice medicine does not guarantee that they are scientifically competent."[48] As currently implemented, professional licensing frequently is only a rough indicator of knowledge, and professional discipline is often focused on factors outside of professional knowledge and practice. For example, Nadia Sawicki noted that medical boards "often focus on character-related misconduct, including criminal misconduct, that bears only a tangential relation to clinical quality and patient care."[49] The current regimes of licensing and discipline should be improved to better serve their goal of ensuring competent advice from licensed professionals. But as a theoretical and doctrinal matter, properly calibrated licensing and discipline serve an important function in the dissemination of expert advice to listeners, and their purpose aligns with the interest of protecting the integrity of professional advice.[50] This is also why novel First Amendment challenges to professional licensing ought to fail.[51]

In addition, fiduciary duties attach within the doctor-patient relationship that create duties of loyalty and care to mitigate the knowledge asymmetry.[52] When the patient entrusts their doctor with providing guidance on important health decisions, the doctor must act in the patient's best interest. This also means the doctor has to act according to the insights of the profession.[53] A fiduciary relationship between speakers and listeners, however, is incompatible with the idea of speaker and listener autonomy in public discourse.[54] In analyzing fiduciary obligations, one could focus primarily on the type of relationship, as some scholars do, or the content of information conveyed within the relationship. The professional's obligation is to convey the insights of the knowledge community in an accurate and comprehensive manner.[55] But whereas fiduciary duties provide normative support for a patient's trust in their doctor, it is also important to note that disparities exist in the level of trust between patient and provider. The trust between provider and patient may be influenced by a range of factors, including for example cultural, religious, political, or socio-economic differences. In short, access to the doctor-patient relationship by itself does not necessarily provide equal access to relationships of trust. I will return to this point later in Part III.

Likewise, informed consent requirements, which enforce the interest in full disclosure of relevant information in the medical context, address the knowledge asymmetry and aim to ensure patient autonomy.[56] Of course, on the eve of *Canterbury*'s fiftieth anniversary, critiques of the way consent is obtained in practice abound, but the goal of meaningful consent and understanding of risks, benefits, and alternatives remains at the core of ensuring patient autonomy.[57]

Finally, malpractice liability can be understood to protect the integrity of advice a patient receives from their doctor. Although the fiduciary duty of care includes the duty to act as a competent professional, it is not necessarily

duplicative of the malpractice regime. The category of harm is betrayal of trust in the former and professional incompetence in the latter regime.[58] The two regimes are complementary in that the patient's interests include both the accuracy of advice and the ability to rely on that advice.[59] Professional knowledge in both instances provides the benchmark against which individual professionals are assessed; thus, the knowledge community sets the standard of care and the individual professional is compared to that standard.[60] Put into a free speech perspective, "only good professional advice, as measured by the standards of the relevant knowledge community is protected."[61] Thus, "[b]ad professional advice is subject to tort liability, and the First Amendment provides no defense."[62]

Shifting to the perspective of underlying speech interests, we can see that the constraints imposed on the doctor-patient relationship are designed to govern speech in the listener's interest. Consequently, the professional's interest as a speaker within the doctor-patient relationship is unlike the speaker interest outside of it. Whereas the speaker's autonomy interest in public discourse typically is understood as the speaker's interest to speak their own mind, "the autonomy interest to freely express one's personal opinions," the speaker interest at stake within the doctor-patient relationship is the professional autonomy interest "to express one's professional opinion as a member of the knowledge community."[63] This speaker interest interacts with the listener's decisional autonomy interest in that it provides the knowledge necessary for the listener's decision.[64] Post notes that "[b]ecause the practices that produce expert knowledge regulate the autonomy of individual speakers to communicate, because they transpire in venues quite distant from the sites where democratic public opinion is forged, they seem estranged from most contemporary theories of the First Amendment."[65] I will next turn to the First Amendment landscape outside of the doctor-patient relationship to highlight the differences, focusing on the role of expertise and professional advice.

B. Speech Outside of the Professional Relationship

The constraints imposed on speech in the doctor-patient relationship to ensure its accuracy, as measured by the standards of the knowledge community, are typically absent outside of the relationship. In public discourse, there is no distinction between expertise and quackery.[66] Advice that departs from the insights of the knowledge community can be sanctioned in the professional-client relationship, but "false ideas" do not exist in public discourse.[67] Whereas malpractice liability may be imposed for bad advice in the doctor-patient realtionship that results in harm, First Amendment doctrine outside of that relationship protects lies just as much as disciplinary expertise.[68] Content-and viewpoint-based regulations, uniformly accepted for professional speech in the form of informed consent and malpractice as just discussed,[69] are presumptively unconstitutional outside of the professional-client or doctor-patient relationship.[70] Just as informed consent requirements have no place in the public discourse, so too are fiduciary duties incompatible with speech in that context.[71] Where there is no "personal nexus between professional and client …, and a speaker does not purport to be exercising judgment on behalf of any particular individual with whose circumstances he is directly acquainted,"[72] the duties owed within the professional relationship do not exist. In public discourse, in short, each speaker and listener is on their own.

Importantly, the identity of the speaker in public discourse is irrelevant for First Amendment purposes. Thus, a professional's private speech in public discourse receives the same protection as anyone else's.[73] Of course, it is possible that a professional's private speech will be perceived as more likely to convey accurate information.[74] Based on their training and licensing, doctors in public discourse, for example, might be considered trustworthy, and their statements on medical matters might be deemed more reliable than those of laypeople. But unlike in the doctor-patient relationship, there are no legal guardrails — such as malpractice liability for bad advice — to ensure that this is actually the case: "When a physician speaks to the public, his opinions cannot be censored and suppressed, even if they are at odds with preponderant opinion within the medical establishment."[75] Outside of the professional relationship, individual professionals are not bound by the knowledge community's insights.[76]

Moreover, professionals may challenge the professional knowledge community's most fundamental insights in public discourse, something they are not free to do while dispensing professional advice within the professional relationship.[77] Imagine, for example, that a trained and licensed physician hosts a television program in which he gives advice. No matter how inaccurate the advice may be, such a professional "cannot under the First Amendment be held to the standard of medical malpractice that would censor him within the professional-client relationship. In

short, a professional may give bad advice to millions of viewers — but not to one client."[78]

The reason for this difference is that under existing doctrine as currently understood, "[w]ithin public discourse, traditional First Amendment doctrine systematically transmutes claims of expert knowledge into assertions of opinion."[79] Moreover, the speaker's perspective tends to be the central concern in public discourse.[80] Normatively, the constraints that limit speech in the professional-client relationship are absent in public discourse, because speakers are considered to be equals.[81] As I have explained, a "traditionally strong notion of equality continues to pervade our understanding of the First Amendment. The justification is based in democratic theory: a fundamental belief in equality of speakers and opinions in public discourse is necessary for equal participation, which in turn forms the basis of democracy."[82]

By contrast, in the professional setting, one could consider the lack of equality among speakers — and, characteristically for that relationship, the lack of equality between speakers and listeners — with respect to expert knowledge "undemocratic." Professional knowledge, and expertise more generally, breaks the assumption of equality among speakers and opinions. But it still serves an important function, because "it informs public discourse in a manner that can lead to more informed decisions of citizens without expert knowledge by providing expertise that would not otherwise exist. Thus, precisely by virtue of its undemocratic nature, professional knowledge has the potential to advance democratic public discourse. On this view, the presence of expert knowledge is better for public discourse than its absence."[83]

In addition to the justification for speaker equality based in democracy and autonomy among speakers in public discourse generally, the marketplace of ideas rationale may supply good reasons to let professionals challenge their knowledge community's consensus outside of the professional relationship. Whereas an "epistemic marketplace" exists within the profession where new insights are generated through arguments based on agreed-upon methods, it might further innovation to challenge the orthodoxy from the outside. Airing unorthodox ideas outside of the doctor-patient relationship could provide an avenue to push knowledge in unexpected directions. In addition, it helps to educate the public about cutting-edge research that might advance professional knowledge. On this reasoning, the "professional ahead of the curve" is a potentially valuable voice that should not be silenced because they depart from the current state of professional knowledge. Airing unorthodox ideas outside of the doctor-patient relationship could provide an avenue to push knowledge in unexpected directions. In addition, it helps to educate the public about cutting-edge research that might advance professional knowledge. But this trade-off to favor innovation also can result in serious harm. In the context of health advice, emergent and untested ideas might have adverse effects that have not yet been discovered or sufficiently studied. While this potential for harm is to be avoided within the doctor-patient relationship, it is generally accepted in public discourse.

The COVID-19 pandemic provides a cautionary tale. Whereas updating knowledge within the discourse of the profession is based on shared ways of knowing and reasoning, challenges in public discourse are not necessarily based on a shared methodology. Thus, in the spirit of equality among speakers, any challenge is permissible. During the pandemic, we have seen such challenges from both experts and non-experts. While challenges to expertise from government speakers, such as for example former White House advisor Dr. Scott Atlas,[84] may be particularly problematic especially if they are couched in the form of advice or commands, and the normative basis might be challenged for considering them equals in public discourse, other speakers, including other professionals, are free to challenge even the most fundamental professional insights.[85] This has led to harmful outcomes such as the widely-reported death of a man and hospitalization of his wife after ingesting chloroquine to prevent coronavirus, reportedly relying on President Trump's erroneous assertions about its benefits.[86] As currently understood, however, the balance between speech protection and liability for harm in public discourse cuts decisively in favor of protecting speech.

II. Unequal Access to Advice and Its Consequences

In discussing the racial inequities in the context of the public health response to COVID-19 in the United States, Aziza Ahmed and Jason Jackson point out that "[t]he legal system has … contributed to the production of the background conditions that lead to extreme health disparities and lay the foundation for poor health outcomes

among vulnerable populations, particularly racial minorities."[87] The legal system also both governs who has access to healthcare and sets the legal parameters for speech protection. The interaction of First Amendment doctrine with its underlying assumption of access and the reality of limited access come together to exacerbate such disparity. The immediate consequence of unequal access to health advice is that some individuals must rely on information publicly available to make health decisions.

Access to medical care in the United States is limited, and vulnerable populations — including racial minorities — suffer from the resulting inequities.[88] To be sure, the First Amendment perspective highlights a narrow conception of access, that is, it focuses only on the individual's ability to enter into a doctor-patient relationship. But it is important to note that the access to healthcare problem is much larger, encompassing both "(1) dearth of actual services and (2) racism in healthcare settings that impedes access."[89] During the COVID-19 pandemic, the problem of unequal access intensified, but the pandemic has only exacerbated a problem that has existed all along.[90]

To reiterate, the lack of access to health advice results in inequality in many ways, including with respect to the First Amendment. Improving access to healthcare is an essential policy goal independent of First Amendment concerns. But from a First Amendment perspective, it is meaningful to acknowledge that without equal access, the assumptions underlying current doctrine are erroneous, and the resulting differential treatment of listeners is unjustified. A necessary prerequisite for listener autonomy in public discourse is equal access to relevant information. Information may come from any number of sources, including traditional media outlets, social media and the like. But information in public discourse is not the same as expert knowledge. Even in public discourse, it makes a difference for an individual's autonomy interest whether information is supported by scientific standards or based on junk science. In the health context, however, equal access to information means equal access to a specific kind of information, namely expert knowledge. As I have explained, "[t]he listener's perspective reveals the qualitative difference between them. A client or patient today may have access to virtually unlimited amounts of information through multiple channels. Yet, none of this information amounts to expert knowledge. To be flip, Dr. Google is not *really* your doctor."[91] This significantly limits decisional autonomy, which requires comprehensive, accurate (as measured by the standards of the relevant knowledge community), and reliable information personally tailored to the patient.[92]

Again, the COVID-19 example usefully illustrates the pitfalls of relying soley on public discourse. Perhaps most prominently, celebrity "TV doctors" have been dispensing advice to large audiences that is inconsistent with professional expertise.[93] On the one hand, there are known personalities with large pre-pandemic followings, maybe best exemplified by Dr. Oz, whose penchant for unorthodox views may have already been known by many viewers.[94] On the other hand, less prominent professionals emerged who may "sincerely and authentically hold false scientific beliefs."[95] Take the example of Dr. Stella Immanuel who appeared in a video widely shared on social media.[96] As Post recounts, she promoted — apparently based on her sincere conviction — hydroxychloroquine as a cure for COVID-19. However, had she advised a patient in the same way and subsequently been sued for malpractice, Post argues that a First Amendment defense would likely be unsuccessful in this scenario, because doctors cannot demand that their patients gamble with their health to follow doctors' unorthodox views.[97]

This is not to suggest that there is no reliable health advice available outside of the doctor-patient relationship. Throughout the pandemic, for example, good medical advice was also dispensed by "the doctor-journalists who usually play a supporting role in network and cable newscasts and have now become the leading performers."[98] But while the American Medical Association provides guidelines for physicians' media interactions,[99] the quality of advice is not secured by the same legal guardrails as advice within the doctor-patient relationship.

III. One Approach: Improving Access

The bottleneck for First Amendment purposes between generally available but unchecked health information and reliable expert knowledge is access to the doctor-patient relationship. Improving access to advice is the least doctrinally disruptive and thus most speech-protective solution to the First Amendment problem. It may not ultimately be the one that is normatively most desirable, but in terms of immediate payoff, it seems worth examining. From a First Amendment perspective, a wide range of approaches could lead to the desired result. Whether Medicare for all,

a robust ACA expansion, or more targeted programs to improve access for vulnerable populations is the most suitable approach from a health policy perspective would not meaningfully change the First Amendment calculus. As long as equality among listeners as recipients of health advice is ensured, First Amendment theory is largely agnostic as to the specifics of expanding advice. Another, less speech-protective alternative might realign the balance between speech protection and liability for advice that results in harm.[100] But, as Tebbe convincingly argues, "it must be accepted that a turnabout in First Amendment interpretation is not likely anytime soon."[101] Though unquestionably a massive policy challenge, improving access would not require a change in First Amendment interpretation. And, as already indicated, improving the availability of access is only a first step which must be followed by ensuring the high quality of personally tailored advice within professional relationships of trust for all patients.

An even narrower proposal not centered on access to the doctor-patient relationship itself might be a "public option" for supplying expertise in public discourse, particularly in times of public health crises. One possibility could be an aggressive public rollout of expertise, for example by the CDC. But such a strategy may be only of limited success. First, it depends on political willingness to take on the role of providing expertise, something that was notably absent in the early days of the pandemic during the Trump administration. And even assuming that a competent agency was able to disseminate advice, it may be unsatisfactory. One central problem to such an approach is the position of government experts in the marketplace of ideas more broadly. In an age of viral memes, and widespread mis-and disinformation, which I will return to, the government's message may be lost in the cacophony of messages. Indeed, to combat this challenge, the administration is now seeking to enlist influencers on social media to amplify its public health message.[102]

Another issue is related to the individualized nature of public health measures. To illustrate, Ahmed and Jackson explain that the CDC's COVID-19 response displayed features of the "neoliberal" turn in public health that "emphasizes individual actions over structural responses."[103] Thus, in the early stages of the pandemic, individual actions such as washing hands — "what might have seemed like an easy individual behavior change exercise"[104] — were stressed, largely disregarding the social determinants of health.[105] They further note that this is not a new approach, but rather continues a trend "that has transformed virtually all arenas of public policy since the 1970s. It haunts the response to public health crises in the United States including epidemics that preceded COVID-19."[106] In this approach, racial inequities are perpetuated.[107] Although "race was formally absent in the policies that promoted individual responsibility, it was fundamental to the underlying political logic that fueled the rise of the neoliberal approach."[108] Thus, there are structural inequities that may be packaged into a public rollout of medical information that are based in the government's overall contemporary approach to public health.

In short, attempting to replace the doctor-patient relationship with such a "public option" for obtaining expertise, perhaps even limited to a particular public health crisis, is a fraught alternative. Ultimately, short of shifting the balance between speech protection and liability, expanding access to the doctor-patient relationship is the most speech-protective way to justify the bifurcation between advice within the doctor-patient relationship and public discourse.

Finally, two caveats to the partial solution of expanding access. First, expertise has been eroded even when there is access. This is part of the larger story of the "democratization" of expertise.[109] Even equalized access to healthcare still does not solve the problem of educational disparities and a fragmented information landscape. Not everyone will get information from reliable sources, and access does not guard against dis-or misinformation. To illustrate, there is evidence of large-scale mis- and disinformation about a wide range of aspects related to the COVID-19 pandemic,[110] including an intensified problem of vaccine misinformation.[111] Distinct from the role of experts in public discourse, non-experts also have rendered advice. In the current pandemic, influencers have had a large role in disseminating bad advice.[112] It helps to have access to the doctor-patient relationship, but it's not the solution to the plague of health mis-and disinformation.[113] Individuals can still fall prey to bad advice from these sources and suffer significant harm, even if they have access to premium care. And, as we have seen in connection with mask mandates and COVID-19 vaccine efforts, there can be political resistance of individuals that has nothing to do with lack of access

to expertise.[114]

Second, the argument here solves a First Amendment theory problem with a policy problem, that is, improving access to healthcare. A critic might suggest that rather than thinking about how to best fix First Amendment doctrine, we ought to focus on policy strategies to end the distributive inequities. The social determinants of health suggest a sprawling problem that goes well beyond access to the doctor-patient relationship. Vulnerable "populations disproportionately suffer from health conditions, including higher rates of asthma, diabetes, cancer, and heart disease."[115] This is due to a variety of "structural and environmental issues, such as poor housing conditions; living in food deserts and food swamps; contaminated water; air pollution; and persistent stress due to employment and financial insecurity, poverty, and racial discrimination."[116] The underlying problem is the unequal distribution of resources and opportunities in addition to access to healthcare, not First Amendment doctrine or access to information. As Ahmed and Jackson argue, "the literature on the social determinants of health focuses on structural constraints to good health, including the mechanisms through which the upstream legal regime produces poor health outcomes. This approach emphasizes the point that the idea of risk is not about a rational individual making a calculated choice, nor is it about access to information. Instead, people's poor health outcomes are often the result of structural factors well outside of their control."[117] And, relatedly, even access to healthcare or (equal) health information would not necessarily and without more lead to equitable health outcomes.[118] Merely creating better access thus is not by itself sufficient for the larger problem of health disparities. Nonetheless, it is worth exposing the assumption of access as a central flaw in First Amendment doctrine. And one way to remedy this mistaken assumption is through improved access.

IV. Conclusion

Angela Harris and Aysha Pamukcu note that "[w]e live in a time of increasingly steep inequalities, not only in income and wealth, but also in access to basic public goods like healthy food, clean water, and adequate housing."[119] Current First Amendment doctrine exacerbates these inequalities. As Tebbe diagnoses with respect to current interpretations of freedom of speech (and religion), "the regressive impact of actions grounded in these constitutional freedoms is particularly noticeable against the backdrop of historic levels of economic inequality. Paradoxically, these constitutional rights, which are commonly associated with democracy, are working to undermine the material conditions for a cooperative society."[120] The lack of access to expert advice and the idea of a largely unregulated free trade in ideas in public discourse places an indefensible burden on some listeners that undermines the equality justification for speech protection and content-and viewpoint neutrality. This Article exposed a central flaw in First Amendment doctrine, the assumption of access to advice, and suggests as one plausible remedy the expansion of access to the doctor-patient relationship.

Acknowledgements

Many thanks to Caroline Corbin, Hiba Hafiz, Jonathan Kahn, Chip Lupu, Kristin Madison, Wendy Parmet, Catherine Ross, Blaine Saito, and Sonia Suter as well as participants in the GW Law Symposium "First Amendment Values in Health Care," the Northeastern University School of Law Faculty Colloquium, and the Boston Area Junior Faculty Roundtable for helpful comments and conversations. Thanks also to Kemelly Fortunati and Erin Gannon for excellent research assistance.

Note

The author has no conflicts to disclose.

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DETAIL

Subjek:	Accuracy; Discrimination; Knowledge; Pandemics; Social networks; Liability; Medical malpractice; Health; First Amendment-US; Access; Federal court decisions; Professions; Professional relationships
Ketentuan indeks bisnis:	Subjek: Social networks Professional relationships
Pengidentifikasi/kata kunci:	First Amendment; Public sphere; Trust; Advice; Professional; Professional Speech; Torts; Malpractice; Fiduciary Duties; Professional Licensing
Judul:	Assuming Access to Professional Advice
Pengarang:	Haupt, Claudia E
Judul publikasi:	The Journal of Law, Medicine &Ethics; Boston
Volume:	49
Edisi:	4
Detail sumber:	First Amendment Values in Health Care
Halaman:	531-541
Tahun publikasi:	2021
Tanggal publikasi:	Winter 2021
Bagian:	Symposium Articles
Penerbit:	Cambridge University Press
Tempat publikasi:	Boston
Negara publikasi:	United Kingdom, Boston
Subjek publikasi:	Law, Medical Sciences
ISSN:	10731105
e-ISSN:	1748720X
Jenis sumber:	Jurnal Akademik
Bahasa publikasi:	English
Jenis dokumen:	Journal Article
DOI:	https://doi.org/10.1017/jme.2021.77
ID dokumen ProQuest:	2730847773

Letter to the Editor

Rattani, Abbas; Hyder, Adnan A

TEKS LENGKAP

Health Policy and Systems Research Ethics Review Requires Global Participation, Iteration, and Adaptation

To the Editor:

We were elated to see our article, “Operationalizing the Ethical Review of Global Health Policy and Systems Research: A Proposed Checklist,”[1] inspire much needed discussion on the topic of health policy and system research (HPSR) ethics. We are grateful that the *Journal of Law, Medicine &Ethics* has created an avenue for dialog, and we thank the editor for the opportunity to respond to Govind Persad’s recent commentary on our paper entitled “Improving the Ethical Review of Health Policy and Systems Research: Some Suggestions.”[2] When we first began thinking about the ethical uniqueness of HPSR and its distinction from clinical and related human-subjects public health research nearly a decade ago,[3] our goal was to foster a dynamic, fair, and communal international dialogue toward a valid and sound process of addressing and responding to the ethical issues unique to HPSR —especially in low and middle-income countries (LMICs). To that end —and as we have stated in our paper —our proposed checklist should be seen as a summary of those efforts and is meant to be iterative and adaptive.

In reading Persad’s commentary, we were pleased to receive his suggestions on the nature of the checklist itself. We agree that identifying *who* the most relevant parties are in reviewing HPSR need to be decided at all levels. As we have previously shown, most research ethics review committees (RECs) are not adequately equipped to review, appraise, or identify the salient ethical challenges for LMIC HPSR.[4] However, given that there are current ethical review mechanisms in place —albeit for clinical/human-subjects research —we suggest that perhaps these mechanisms may be an appropriate starting point and could be modified in the short-term to accommodate the ethical review of HPSR. We agree, and repeatedly state throughout our paper, that each component/section of our checklist should not be taken as definitive, but subject to deliberation. While we have proposed these checklist sections as basic considerations in the ethical review of HPSR, we do appreciate the mandated versus encouraged (or required versus recommended) suggestion and hope this leads to more conversation on what falls under which category. We also agree that HPSR studies are unique, and some studies may not exactly fit under the global justice or ethical considerations we have outlined. However, it is important for researchers and RECs alike to participate in a joint deliberative process to decide what aspects of any proposed HPSR study require additional ethical considerations.

However, we question the conclusion Persad draws about the construction of the ethical framework that informs the

checklist. As we have made clear in our methods section, the ethics frameworks that inform the current iteration of our proposed HPSR checklist is in fact grounded in research ethics, public health ethics, implementation research, and global justice frameworks. These frameworks are also in part informed by some of the higher-order ethics philosophy outlined in the "principlist" framework. For our purposes, we did not find it useful to view the principlist paradigm as a distinct framework, but rather as a starting point for considering our ethical duties in the larger context of what is owed to those impacted by HPSR. We hope others recognize this alternate reading of the principlist paradigm and are able to review the cited literature we provide throughout our methods section.

Persad also raises many specific points within the checklist itself. We agree with Persad's discussion on the challenges of identifying legitimate representatives in the setting of institutional-level consent when individual consent is infeasible. The HPSR example of conditional cash transfers within our paper should not distract from identifying how best to obtain consent at the institutional-level. We invite other colleagues who work within this space to share some of their examples as well with the aim of creating a repository of HPSR didactic case studies.

We also share Persad's concerns that current RECs may place an inappropriate amount of focus on incentives and hyper-scrutinize its effect on autonomy. However, we also cannot help but to consider the very real ways in which poverty affects decision-making among the super vulnerable —which should not be underestimated or overlooked when considering the use of incentives. Ultimately, RECs may require additional training to appropriately apply the checklist. Furthermore, Persad's analogy of incentives for performing less-desirable work requires further clarity because participating in health research versus performing labor have arguably different ontologies and teleologies that do not render the comparison entirely appropriate. Regardless, it is clear that role of incentives in HPSR merits further discussion. Additionally, we agree that further clarification of the research-community relationship that Persad raises later in his commentary warrants more exploration too.

A major point of disagreement with Persad —and point of caution —is the implication that ethical scrutiny of HPSR interventions can promote exceptionalism and be counterproductive. Forgoing ethical review undermines our commitments to protecting those worst-off from harm, abuse, and exploitation. As we have articulated before, what differentiates our call for a more robust ethical review of HPSR is our commitments to global justice.[5]

It is true that governments, corporations, or philanthropists could (and often do) implement interventions in LMICs without a review process. However, as we have seen and continue to see —these interventions are often implemented with little knowledge of effectiveness, efficiency, or longitudinal impact. Without such investigations or evaluations —the worst-off, especially in LMICs, will continue to be negatively impacted. HPSR has a distinct function of *understanding* the best strategy, issue, or intervention for a particular system. The most successful policies are those that are well-informed, but in the process of obtaining that information, we must also ensure that the knowledge-generating/gathering process is not exploitative or abusive to systems, institutions, or individuals who are worst-off.

The suggestion that "valuable research" may be obstructed if quality ethical review is expected is disconcerting; it is this very excuse that has led to more stringent human-subjects protections in clinical research globally. We generously read Persad's discussion of research exceptionalism as identifying a gap where HSPR interventions *could* and *have* circumvented ethical review (in similar ways to the discussions on comparative effectiveness research or patient-centered outcomes research). Our ultimate concern is for the LMIC entities that have much to lose at the hands of poorly thought-out interventions that have avoided ethical review. As we are seeing in other fields, there is much at stake when interventions are not appropriately designed, studied, and reviewed.

Our checklist is a step toward a more robust HPSR ethics review process. It is designed to advance efforts in the appropriate training of RECs (in the US and globally) and the systematization of HPSR ethics review. A more deliberative process is needed from the global HPSR community to develop the training tools and processes necessary for appropriate HPSR ethics review. We hope others are inspired to engage in a global deliberative process required to strengthen the ethical review of HPSR.

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DETAIL

Subjek:	Research ethics; Public health; Medicine; Health research; Exceptionalism; Justice; Medical research; Health care policy; Bioethics; Law; Consent
Judul:	Letter to the Editor
Pengarang:	Rattani, Abbas; Hyder, Adnan A
Judul publikasi:	The Journal of Law, Medicine &Ethics; Boston
Volume:	49
Edisi:	4
Detail sumber:	First Amendment Values in Health Care
Halaman:	692-693
Tahun publikasi:	2021
Tanggal publikasi:	Winter 2021
Bagian:	Letter to the Editor
Penerbit:	Cambridge University Press
Tempat publikasi:	Boston
Negara publikasi:	United Kingdom, Boston
Subjek publikasi:	Law, Medical Sciences
ISSN:	10731105

e-ISSN:	1748720X
Jenis sumber:	Jurnal Akademik
Bahasa publikasi:	English
Jenis dokumen:	Letter To The Editor
DOI:	https://doi.org/10.1017/jme.2021.95
ID dokumen ProQuest:	2730847737
URL Dokumen:	https://www.proquest.com/scholarly-journals/letter-editor/docview/2730847737/se-2?accountid=211160
Hak cipta:	© 2021 The Author(s)
Terakhir diperbarui:	2022-11-29
Basis data:	Public Health Database

Big Data, Surveillance Capitalism, and Precision Medicine: Challenges for Privacy

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ABSTRAK (ENGLISH)

Surveillance capitalism companies, such as Google and Facebook, have substantially increased the amount of information collected, analyzed, and monetized, including health information increasingly used in precision medicine research, thereby presenting great challenges for health privacy.

TEKS LENGKAP

Introduction: Big Data and Modern Medicine

We live in the information age. Technological developments in recent decades have enabled the compilation, aggregation, and curation of vast amounts of data of every conceivable kind. The term “Big Data” is used to describe an important subset of this information, “a large collection of disparate data sets that, taken together, can be analyzed to find unusual trends.”[1] Four key concepts are embodied in this brief definition. First, Big Data involves the acquisition of unprecedented amounts of information that have become available through digitization of already compiled data and the systematic collection of staggering amounts of new information. Second, Big Data often involves linking types of information that previously were rarely, if ever, considered together. Third, analysis of the data is facilitated by artificial intelligence, including various applications of machine learning. Fourth, continually updated algorithms are intended to produce unanticipated associations or trends. Because it is not known what

diverse data may be valuable, Big Data requires extensive data collection, and therefore it proceeds on the assumption that more data are always good to collect.

Big Data's entry into medical practice has been accelerated by the widespread adoption of electronic health records (EHRs). Spurred on by $35 billion in federal financial assistance from the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009,[2] by 2015, 96 percent of hospitals[3] and 80 percent of physicians [4] had an EHR system certified by the Department of Health and Human Services. The next wave of development is the adoption of federal interoperability standards, which will facilitate data transfer and analytics that can span multiple health care systems.[5]

The compilation and analysis of personal data have been dominated by huge, highly profitable technology companies, such as Google and Facebook. Substantial revenue for these types of companies comes from the commercial value derived from detailed facts about individuals that document prior actions, predict future actions and risks, and can be used to nudge or encourage certain behaviors. Surveillance capitalism describes the various ways in which technology companies generate personal data through intrusive surveillance methods, use proprietary algorithms to analyze personal data, and monetize the data by selling it to a wide range of customers.

Some experts believe that Big Data will transform the practice of medicine,[6] although insights from Big Data are now used mostly in health research.[7] The federally sponsored and administered Precision Medicine Initiative is the most ambitious Big Data undertaking in health care. Its research protocol, the All of Us research program, is collecting vast amounts of data from diverse individuals for long-term research use. However, the acquisition, storage, analysis, use, and dissemination of prodigious amounts of health and other sensitive information raise significant privacy concerns, brought into stark relief by inadequate current laws.[8]

This article explores how Big Data technology and novel, aggressive business practices have led to the prominent role of surveillance capitalism. Furthermore, surveillance capitalism can be expected to play a substantial role in precision medicine in generating data for and expropriating the findings of precision medicine. The article concludes with a discussion of some essential elements that should be included in new health privacy legislation to provide stringent but reasonable protections.

Surveillance Capitalism

In her highly acclaimed and deeply disturbing book, *The Age of Surveillance Capitalism: The Fight for a Human Future at the Frontier of Power*, Shoshana Zuboff defines surveillance capitalism as "the unilateral claiming of private human experience as free raw material for translation into behavioral data."[9] She describes how the business models of technology companies such as Google are based on exploiting vast amounts of personal data. Zuboff quotes Larry Page, co-founder of Google: "People will generate enormous amounts of data … Everything you've ever heard or seen or experienced will become searchable. Your whole life will be searchable."[10] Eric Schmidt, former Chief Executive Officer of Google, similarly stated:

You give us more information about you, about your friends, and we can improve the quality of our searches. We don't need you to type at all. We know where you are. We know where you've been. We can more or less know what you're thinking about.[11]

Why would billions of people[12] allow technology companies to appropriate their private information for data mining and sale to an undisclosed, vast array of interested parties? Zuboff suggests an answer. "Surveillance capitalism offers solutions to individuals in the form of social connection, access to information, time-saving convenience, and, too often, the illusion of support."[13] And all of these services are seemingly "free."

This article explores how Big Data technology and novel, aggressive business practices have led to the prominent role of surveillance capitalism. Furthermore, surveillance capitalism can be expected to play a substantial role in precision medicine in generating data for and expropriating the findings of precision medicine. The article concludes with a discussion of some essential elements that should be included in new health privacy legislation to provide stringent but reasonable protections.

Proprietary Algorithms

An initial concern about surveillance capitalism is that businesses using the internet have unfettered access to everyone's personal information for an unlimited time[14] and for good or nefarious purposes. But disparate data snippets, associations, and preferences are merely the raw materials for the black box algorithms of Google, Facebook, and other technology companies.[15] The technology companies do not merely compile data and sell personal information to commercial entities for targeted advertising and marketing. The value added and huge profits of surveillance capitalism are based on developing and using proprietary algorithms to continually update the digital profiles of billions of people — their characteristics, lifestyles, experiences, environments, interests, associations, wants, and beliefs. This allows the companies to *predict* individuals' likely behaviors, such as their interest in various products and services and the most effective way for commercial entities to exploit consumer profiles for financial gain.

Influencing Behavior

Even more troubling, comprehensive data collection and analytics can *influence* behavior through the ostensibly innocuous algorithms that order online search results and select the content for personalized news feeds.[16] Personal data about interests and attitudes also can be used to motivate actions, such as organizing and coordinating the activities of groups comprised of like-minded individuals regarding social, racial, political, religious, or other sensitive matters. Joining with others who share interests can be personally and socially beneficial, such as enabling individuals with certain health conditions to communicate with others with similar afflictions. Yet, manipulation of data and people raises increasingly troubling societal issues of privacy, autonomy, liberty, social cohesion, and democracy.

National Security, Politics, and Disinformation

There is an irony in invasive surveillance technology being used to undermine or even destabilize government. After the terrorist attacks of September 11, 2001, federal agencies responsible for intelligence gathering and national security solicited Google and other technology companies to accumulate vast troves of data on potentially violent individuals and groups. The connection between the technology companies and government security agencies was revealed by Edward Snowden in 2013,[17] but the simultaneous, ubiquitous, private surveillance by these companies makes the national security uses of surveillance capitalism less surprising and perhaps more inevitable than previously assumed.

Meanwhile, beginning with Barack Obama's 2008 presidential campaign, data analytics became an integral part of mainstream American politics. Targeted fundraising and voter appeals gave the Obama campaign an edge, thereby initiating an "arms race" in cyber campaigning. By 2012, Obama's reelection campaign, working with Eric Schmidt of Google, "knew every wavering voter in the country that it needed to persuade to vote for Obama, by name, address, race, sex, and income,"[18] to permit "micro-targeting" of campaign efforts. By 2016, these same techniques were utilized by both political parties at the federal and state levels, and by numerous political campaigns around the world, including the Brexit vote.[19] Also in 2016, Cambridge Analytica, a political data analytics firm, improperly obtained personal data from 87 million Facebook users to develop predictive voter profiles later used by the Trump campaign.[20]

Since then, the largely unregulated universe of data acquisition, aggregation, analytics, and application has been exploited by malevolent domestic and foreign operatives to launch disinformation campaigns.[21] It also facilitated diverse and dispersed individuals to coordinate and carry out violent acts, as epitomized by the insurrection at the U.S. Capitol on January 6, 2021.[22] Additionally, misinformation about COVID-19 distributed on social media has led to significant resistance to vaccination, masking, social distancing, and other public health measures, resulting in many thousands of preventable deaths and the prolongation of the worst pandemic in a century.[23]

New Sources of Data

To maintain their competitive advantage and to continue generating vast profits the largest technology companies have updated their predictive capabilities by exploiting new sources of data. The best example is Google. Through aggressive deployment of internally developed surveillance methods (e.g., Street View, Google Maps) and corporate

acquisitions (e.g., YouTube, Fitbit), Google extended its data sources beyond internet searches to e-mails, texts, photos, songs, videos, locations, interests, faces, emotions, social networks, consumer activity, smart home devices, wearables, and health information.[24] The goal is ubiquitous data capture, intervention, action, and control of economic behavior.

Other technology giants followed Google's financially successful strategy of diversifying and expanding their sources of unique, personal data. For example, Facebook acquired Instagram, developed the Novi digital wallet, and harvested data from its Like button to get a more robust view of individuals' preferences and associations. Microsoft acquired LinkedIn to provide additional data that could be analyzed and marketed.[25] Internet service providers, including Verizon, AT&T, and Comcast, also began monetizing data derived from subscribers' internet activity. To launch these new ventures quickly, some companies with large customer bases acquired established technology companies, as exemplified by Verizon's purchase of Yahoo! and AOL.[26]

Internet of Things

Novel methods of surveillance capitalism generate new sources of data and new privacy concerns. This is especially the case with the "Internet of Things," which involves billions of networked sensors that record and transmit data over the internet,[27] producing additional raw materials for artificial intelligence. These data sources include medical devices; environmental sensors; surveillance in public spaces, including facial recognition; "smart" televisions and other entertainment systems; "smart" cars, buildings, homes, and clothing; and digital assistants that record and relay users' commands and other conversations.[28] Many consumers infatuated with the latest "smart" technology do not realize that detailed data may be continuously recorded and transmitted for analysis.[29]

An example of these privacy issues involves smart toys, which can recognize the voices of individual children and interact in a personal way for appropriate educational and entertainment purposes. These toys usually have external Bluetooth and Wi-Fi connections, which can disclose a child's location information and make the child vulnerable to harm.[30] In theory, parents who give these toys to their child implicitly or explicitly consent to data collection and transmission about their child, but they cannot consent to disclosures made by their child's playmates that may occur at the same time.[31] Lawsuits and regulatory actions dealing with smart toys include data breaches involving hundreds of thousands of passwords, user names, email addresses, and actual conversations children had with their dolls.[32]

The most notorious incident of a smart toy creating risks to young children and their families is Hello Barbie, which was introduced in 2015. The interactive Barbie doll was Wi-Fi enabled and could be hacked into a surveillance device for spying on children. It was also possible to hack the doll's system information and gain access to a family's Wi-Fi network, thereby enabling control of all internet-connected devices at the owner's home. Mattel, manufacturer of Hello Barbie, pulled the doll from the market.[33]

Medical Records

In 2019, the disclosure of Google's Project Nightingale, in partnership with Ascension, raised serious concerns about access to millions of medical records by Google. Ascension is a St. Louis-based, Catholic chain of 150 hospitals and 6,700 physicians, covering 50 million patients in 20 states and the District of Columbia. Without any notice to patients, consent, or even an opportunity to opt out, Ascension gave Google access to all of Ascension's complete, individually identifiable, EHRs.[34] The stated purpose was to use artificial intelligence to identify ways of improving patient outcomes.

After Project Nightingale was disclosed in the media, the first question many patients asked was whether this arrangement was legal under the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, and the short answer is yes. As described below, covered entities under HIPAA, including health care providers, are permitted to use and disclose "protected health information" (individually identifiable information) without notice or consent for treatment, payment, or health care operations.[35] Quality improvement, the avowed purpose of Project Nightingale, is included in the definition of health care operations.[36] Since Ascension was permitted to do this analysis under HIPAA, Google, a "business associate" of Ascension, also could undertake the analysis on Ascension's behalf because the parties executed a business associate agreement.[37]

Unsurprisingly, Project Nightingale is not a “one off” arrangement of Google and Ascension. Other large technology companies, including Amazon, Apple, and Microsoft, have actively pursued research arrangements with some of the largest and most respected medical institutions in the country.[38] Even assuming there will be insights leading to improved health care, questions remain about whether health privacy and security will be maintained and whether it is acceptable to use millions of individually identifiable patient records for analysis and commercialization without notice to or consent from patients.

Using Surveillance Data to Predict and Control Risks

Predictive data are increasingly being used in common consumer activities. For example, most auto accidents are caused by careless acts, such as speeding, tailgating, running red lights, unsafe lane changing, and driving in bad weather.[39] Drivers involved in these accidents are more likely to be distracted, intoxicated, or teenaged.[40] Sensors installed in cars can measure how someone is driving, and some insurance companies believe that predictive information of driver behavior generated by sensors can reduce auto accidents and insurers’ liability. A few years ago, my insurance agent offered me a discount on my auto insurance if I would allow placement of a sensor on my car to monitor how I drive.[41] I declined the discount and said I would pay what amounts to a “privacy tax” not to be monitored. However, drivers might not have this option much longer, as auto insurance is highly competitive, and companies requiring the use of sensors might be able to offer less costly auto insurance.[42]

Closely related, rental car companies could begin using sensors to monitor how their cars are being driven and then prevent their cars from being started if the driver has been careless or reckless.[43] Car rental companies could even base their driving predictions on sensor data of destinations, identity of occupants, and even the private conversations of passengers. Such surveillance measures probably would be legal under the weak version of consent in the United States in which consent is valid if individuals merely click “I agree” at the end of a multi-page document that virtually nobody reads.

Predictive analytics are also used to “encourage” individuals to make positive behavioral changes. For example, several years ago, my university-employer, like most large employers, began offering all employees a discount on their employee contributions for health insurance if we enrolled in an employer-sponsored and third-party administered wellness program involving self-reports on various health measures, such as weight, exercise, smoking, and alcohol consumption. I declined and chose to pay the “privacy tax.” Lower paid employees at my university, such as housekeeping and cafeteria workers, could not afford to forego an increase in their take home pay and therefore enrolled in the wellness program and have been monitored and urged to achieve certain health goals.

Few would object to encouraging individuals to adopt healthier lifestyles, but the evidence is mixed, at best, that employer-sponsored wellness programs are effective in improving employee health, reducing health costs, or producing a positive return on investment.[44] Moreover, it is questionable whether any modest gains in wellness are worth the price of permitting employers to control health care costs by contracting with third-party companies to surveil employees’ lifestyles and “encourage” health-promoting behavioral changes.

The examples of auto and health insurance only begin to scratch the surface of predictive analytics based on personal data harvesting. Other insurance products (e.g., life, disability, long-term care, and property and casualty) are among the next likely targets. Financial applications include consumer credit and home mortgages in which predictive analytics could consider consumers’ purchasing history, credit card usage, and credit scores. Employment, education, and government uses are other likely applications. In these and other areas the two main issues are whether the algorithmic predictions are accurate and, if so, whether the insights they provide are worth the privacy incursions and other social costs.

Precision Medicine

At least since the Human Genome Project (1990-2003), the National Institutes of Health (NIH) has embraced large-scale research projects, such as the current Cancer Moonshot[45] and Brain Initiative.[46] NIH’s large-scale precision medicine research project is called All of Us.[47] Precision medicine has been defined as an approach for protecting health and treating disease that takes into account a person’s genes, behaviors, and environment.[48] Precision

medicine has proven to be valuable in clinical settings for treating various cancers and rare disorders, as well as for identifying the safest and most efficacious drugs for specific individuals.[49]

More widespread introduction of precision medicine into clinical settings depends on research developments, and this is where NIH is playing a leading role. The All of Us Research Program was begun in 2015, and in 2018 it began enrolling at least one million diverse individuals in the United States.[50] In addition to genome sequencing, All of Us participants are asked to share data from (1) health surveys (demographic, lifestyle, and substance use); (2) physical measurements (blood pressure, heart rate, weight, height, and body-mass index); (3) biospecimens (blood and urine); (4) EHRs (including medications, laboratory results, vital signs, and billing codes); (5) digital health (from Fitbit and other wearables); and (6) geospatial and environmental data (including weather, air pollution, and sensor readings).[51] The last two categories of data are especially relevant to surveillance capitalism.

Even though the All of Us Research Program is collecting an unprecedented volume of health data, it is not collecting all the data that could affect an individual's health. Additional precision medicine research and clinical applications also could include the following data fields: (1) health histories and vital statistics of family members, including birth and death certificates; (2) military service records, including health records and data on hazardous exposures; (3) employment records, including exposure and biological monitoring data: (4) financial information, including consumer data generated by credit cards and consumer loyalty programs; (5) educational records, including behavioral health information and student health service records; (6) travel information and geo-location data, including exposures; (7) social media postings, including behavioral and mental health self-reports; and (8) government records, including Social Security data, Veterans Administration health records, criminal justice information, professional licensure applications, drivers' license information, and passport information. What could emerge from virtually unlimited data collection would be health-based dossiers of incredible detail for algorithms to probe for associations, interpretations, and predictions.[52]

Precision medicine faces significant challenges. In addition to the scientific obstacles of demonstrating clinical utility in various settings, precision medicine has generated vigorous ethical and policy criticisms.[53] These include the argument that precision medicine, by developing individually tailored and therefore more expensive diagnostics and therapeutics, will exacerbate health inequities; that numerous predictions of slightly increased risks will create a population of "worried well" people; and that health system budgets for costly medical interventions providing only slightly improved outcomes could be better spent elsewhere.[54] Perhaps the greatest legal and ethical challenge would be protecting privacy if health records contained increasingly voluminous quantities of sensitive information that go beyond traditional medical information to include social, behavioral, financial, and other data.[55]

Challenges to Privacy

The All of Us Research Program has pledged to protect the privacy and security of participants' information through deidentification, storage of information on protected computers, certificates of confidentiality, and other measures.[56] Even assuming that there are no breaches of security, it is easy to envision sensitive health information being widely disclosed to third parties. Under the All of Us guidelines, research participants have access to their own health information, including the predictive health assessments produced by algorithms developed by researchers.[57] If a participant is to benefit from this personalized information, the data must be uploaded or somehow incorporated into the participant's clinical EHR, where it can be used by the participant's health care providers. Many people in the United States do not realize that once health information becomes part of their clinical record it does not gain privacy protection; in fact, it becomes more vulnerable to disclosure.[58]

HIPAA Privacy Rule

Much of this misunderstanding is related to the erroneous assumption that the HIPAA Privacy Rule[59] is comprehensive and stringent. It is neither. First, the Privacy Rule only applies to health care providers, health plans, health clearinghouses, and their business associates.[60] It does not apply to, among other entities, insurance companies (other than health insurers), employers, schools, financial institutions, or technology companies. Second, the Privacy Rule is weakened by numerous, broadly worded exceptions. As mentioned earlier, a covered entity, such as a hospital, is free to use and disclose individually-identifiable health information without a patient's

knowledge or consent for treatment, payment, and health care operations.[61] In addition, there are twelve public purpose exceptions that permit covered entities to disclose individually-identifiable health information without notice or consent: (1) where required by law; (2) for public health activities; (3) about victims of abuse, neglect, or domestic violence; (4) for health oversight activities; (5) for judicial and administrative proceedings; (6) for law enforcement; (7) about decedents; (8) for cadaveric organ, eye, or tissue donations; (9) for some types of research; (10) when there is a serious threat to health or safety; (11) for special government functions, including national security; and (12) for workers' compensation.[62]

In the context of precision medicine, the most important exception to the HIPAA Privacy Rule is consent (or authorization). Individuals have a right to access their own health records and to direct a covered entity to disclose some or all of the contents of their health records to any other person or entity.[63] This gives rise to "compelled authorizations," whereby individuals subject to economic leverage or legal compulsion can be required to provide their health records for a governmental or commercial purpose, such as applying for employment, insurance (life, disability, and long-term care), Social Security disability, workers' compensation, veterans' benefits, and professional licensure. The best estimate is that there are at least 25 million compelled authorizations each year in the United States.[64]

In many cases, third parties can require the disclosure of complete health records, and even where the authorization is for more limited records, covered entities often find it easier to send complete records than engaging in the time-consuming and costly process of reviewing and redacting certain information. In the era of precision medicine, health records could contain sensitive information about matters ancillary to health status, such as relational, lifestyle, or financial data. Furthermore, once health records are received by an entity not subject to the HIPAA Privacy Rule (e.g., prospective employer), HIPAA does not limit redisclosure of the information to other individuals and entities.

Procedural and Substantive Privacy

Challenges to privacy can be divided into procedural and substantive issues. The United States, having failed to enact a broad privacy law in the 1970s when it was first considered,[65] has adopted the default position that data access practices by public and private entities are lawful unless they violate a specific statute or regulation.[66] In operation, notice and consent for access, use, and disclosure of private information, epitomized by online "click through" consent, is seriously deficient because the notice is rarely read or understood, and the consent is rarely informed or knowing. Even where notice is more informative and consent is more intentional, the process of compelled authorization, discussed above, is inherently coercive.

Compelled authorizations, permissible under the HIPAA Privacy Rule and other laws in the United States, are prohibited under the European Union's General Data Protection Regulation (GDPR).[67] Recital 32 defines consent in a much more stringent way than in the United States.

Consent should be given by a clear affirmative act establishing a freely given, specific, informed and unambiguous indication of a data subject's agreement to the processing of personal data relating to him or her, such as by a written statement, including by electronic means or an oral statement.[68]

Legislation protecting privacy should address a range of procedural issues, such as transparency, limiting disclosures to the minimum necessary information, limiting identifiability to the minimum necessary, limiting time for use and disclosure of data, and prohibiting the reidentification of individuals and the redisclosure of information. Many of these limitations already are part of the GDPR. In the United States, these types of reforms are necessary but insufficient to protect informational privacy.

Substantive privacy protections require an analysis of the lawful uses of information. For example, under the Americans with Disabilities Act (ADA),[69] after an employer extends a conditional offer of employment, the employer may condition employment on the satisfactory completion of a medical examination and a review of the individual's health records.[70] This is a reasonable requirement because many jobs involve strenuous physical exertion or exposure to hazardous environments. Nevertheless, neither the medical examination nor the health record review must be limited to matters directly related to the prospective employee's job duties, even though an employer may

not rescind a conditional offer for medical reasons that are not job-related.[71] The substantive issue is what information an employer may lawfully use in deciding employability, such as whether it is permissible to refuse to employ an individual who is at greater risk of a future health problem.[72] Other substantive health privacy issues include what personal health information insurers may consider in deciding insurability[73] and what health information government agencies may consider in ruling on eligibility for benefits.[74]

Toward Reasonable, Effective Regulation

Legislative, regulatory, and other legal measures to curtail excessive disclosure or use of health information have been adopted at an extraordinarily slow pace and existing enactments are ineffective. Three reasons for this unacceptable situation come to mind: (1) technology changes more quickly than law; (2) surveillance capitalists include some of the largest and most powerful companies with well-financed cadres of lobbyists and lawyers; and (3) regulation of information implicates fundamental aspects of American society, such as First Amendment freedom of speech and freedom of contract. The following elements should be a part of any enactment to protect health privacy in the age of Big Data, surveillance capitalism, and precision medicine.

Comprehensive Health Privacy Legislation

Unlike the great majority of industrialized democracies, the United States lacks comprehensive health privacy legislation.[75] The HIPAA Privacy Rule was only intended to protect privacy in the payment chain of health care. It does not apply broadly and does not prohibit the redisclosure of health information received by non-covered entities. The Privacy Rule also lacks effective remedies and does not include a private right of action for aggrieved individuals to redress harms caused by unlawful privacy breaches.[76]

A few states have recently enacted privacy legislation of a general nature, beginning with the California Consumer Privacy Act,[77] which has been followed, so far, by Virginia[78] and Colorado.[79] Illinois enacted the nation's first biometric information privacy law,[80] followed by Texas,[81] Washington,[82] and California.[83] Although state legislatures have been termed the "laboratories of democracy,"[84] it simply takes too long to enact legislation on emerging technologies in a substantial number of states, and some states are unlikely ever to enact such legislation. For the foreseeable future, the small number of idiosyncratic state laws are likely to remain inconsistent and often indecipherable.

In contrast to the limited protections of federal and state laws, the GDPR categorically treats health data as sensitive and strictly protected. Article 9, section 1 prohibits the processing of "data concerning health,"[85] which could be construed as covering not only traditional clinical information, but the broad classes of data collected by precision medicine.[86] Following the GDPR model would mean comprehensive, consistent privacy legislation rather than categorical legislation separately dealing with educational, financial, health, and other types of information.[87]

Big Data, surveillance capitalism, and precision medicine are all complicated and still evolving. When combined and applied in the context of health privacy, the three concepts become even more difficult to analyze or regulate. This article has argued that vital privacy interests are at stake at the intersection of Big Data, surveillance capitalism, and precision medicine. Furthermore, the speed at which vast amounts of personal data are being accumulated means that the negative consequences of the current, largely *laissez faire* approach are becoming more pronounced. Comprehensive, federal health privacy legislation should be enacted to, among other things, limit the use of compelled authorization consent, prohibit "click through" consent, and place substantive controls on the use of health information.

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Stringent Consent Requirements

The viability of consent has been destroyed by technology companies. Many millions — if not billions — of people now regard consent as a "click through" burden that is a worthless, time consuming, formalistic requirement before they can download an app or software update. The actual consent language is often part of a long, legalistic document in small type, which further ensures that virtually nobody reads it.[88] Some consent documents even grant app developers and technology companies an extraordinary license to invade privacy.[89] In addition, compelled

authorization is a form of coercion, but it is not prohibited by the HIPAA Privacy Rule or any state law in the United States.

Limiting the Use of Data

There are two main ways of protecting health privacy: limiting access to data and limiting use of data. Limiting access to data may be considered a procedural strategy to keep certain entities from obtaining data. For example, under the Genetic Information Nondiscrimination Act (GINA),[90] it is unlawful for an employer to "request, require, or purchase genetic information with respect to an employee or a family member of an employee …"[91] In theory, if an employer or other entity does not have access to certain data, it cannot use the data to the detriment of the individual, and the individual's privacy is also protected. In the case of GINA, this approach is undermined by compelled authorization practices, because even though employers may not request genetic information, healthcare providers and other entities in possession of genetic information often fail to take the extraordinary steps to delete or redact genetic information when complying with an authorization.

By contrast, limiting the use of data does not explicitly prohibit access to data, although GINA prohibits both access to and discrimination based on genetic information.[92] Where only use is prohibited, no reasonable individual or entity would want access to data that cannot legally be used because it might expose them to legal liability.[93] Thus, even without explicit access restrictions, use limitations may be effective in protecting privacy indirectly. However, legislation prohibiting the use of data is more difficult to enact because it must address the substantive issues of how decisions about inclusion and exclusion (e.g., employability, insurability) are made by employers, insurers, and other data users.[94]

Conclusion

Big Data, surveillance capitalism, and precision medicine are all complicated and still evolving. When combined and applied in the context of health privacy, the three concepts become even more difficult to analyze or regulate.[95] This article has argued that vital privacy interests are at stake at the intersection of Big Data, surveillance capitalism, and precision medicine. Furthermore, the speed at which vast amounts of personal data are being accumulated means that the negative consequences of the current, largely *laissez faire* approach are becoming more pronounced. Comprehensive, federal health privacy legislation should be enacted to, among other things, limit the use of compelled authorization consent, prohibit "click through" consent, and place substantive controls on the use of health information.

This article is an expanded and annotated version of a presentation for the Institute for Biomedical Ethics at the University of Basel, Switzerland, on August 24, 2021.

Acknowledgements

The author greatly appreciates the valuable input from Kyle Brothers, Laura Rothstein, and John Wilbanks. Mary E. Dyche, J.D. 2022, Louis D. Brandeis School of Law, University of Louisville, provided excellent research assistance.

Note

The author has no conflicts of interest to disclose.

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35. 45 C.F.R. § 164.502(a)(1)(ii).

36. 45 C.F.R. § 164.501 (the term health care operations, includes “conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines…”).
37. 45 C.F.R. § 164.504(e).
38. Copeland, Mattioli, and Evans, supra note 34. See Dinerstein v. Google, LLC, 484 F. Supp.3d 561 (N.D. Ill. 2020) (dismissing class action for invasion of privacy and other causes of action arising from the University of Chicago Medical Center’s providing Google with access to all patient health records for analysis).
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54. See M.A. Rothstein, “ Structural Challenges of Precision Medicine,” Journal of Law, Medicine &Ethics 45, no. 1

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55. See J.H. Jain et al., “ The Digital Phenotype,” Nature Biotechnology 33, no. 5 (2015): 462–463 (discussing composite picture of digital data).
56. See All of Us Research Program, National Institutes of Health, Protecting Data and Privacy, available at <https://allofus.nih.gov/protecting-data-and-privacy >(last visited July 18, 2021).
57. See All of Us Research Program, National Institutes of Health, Core Values, available at <https://allofus.nih.gov/about/core-values >(last visited July 18, 2021) (“participants have access to their information”).
58. Reportedly, prospective and current participants in All of Us are not informed about the risk of privacy caused by compelled disclosure of their “enhanced” health records. The same process threatens the privacy of individuals who use direct-to-consumer genetic testing and then have the results added to their health records.
59. 45 C.F.R. pts. 160, 162, 164.
60. 45 C.F.R. § 160.102.
61. A covered entity is merely required to mention the disclosures in its Notice of Privacy Practices. 45 C.F.R. § 164.520.
62. 45 C.F.R. § 1964.512.
63. 45 C.F.R. § 1964.524.
64. M.A. Rothstein and M.K. Talbott, “ Compelled Disclosures of Health Records: Updated Estimates,” Journal of Law, Medicine &Ethics 45, no. 1 (2017): 149–155.
65. For a discussion of early congressional proposals, see A.R. Miller, The Assault on Privacy: Computers, Data Banks, and Dossiers (Ann Arbor: University of Michigan Press, 1971): at 220–238. The Privacy Act of 1974, 5 U.S.C. § 552a, was enacted in response to the Watergate scandal, but it was limited to protections for information maintained by the federal government.
66. By contrast, under the European Union’s General Data Protection Regulation (GDPR), access or use of personal data is illegal unless there is an express provision permitting it. European General Data Protection Regulation, available at <https://gdpr.eu/ >(last visited July 22, 2021).
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77. Cal. Civ. Code §§ 1798.100-1798.198 (2018). The law applies to for-profit entities that do business in California, that collect consumers’ personal information, and that meet certain financial thresholds. The law does not apply to, among other exempt entities, covered entities and business associates regulated by the HIPAA Privacy Rule. The law provides for civil damages, civil penalties, injunctive or declaratory relief, and other relief that a court may deem appropriate. See M.A. Rothstein and S.A. Tovino, “ California Takes the Lead on Data Privacy Law,” Hastings

Center Report 49, no. 5 (2019): 4–5.
78. Virginia Consumer Data Protection Act, H.B. 2307 (2021), applies to entities that conduct business in Virginia or produce products or services targeted to Virginia residents and that either control or process personal data of at least 100,000 consumers in a calendar year or control or process personal data of at least 25,000 consumers and derive at least 50% of gross revenues from the sale of personal data. Among the exemptions from the statute are entities subject to HIPAA.
79. Colorado Privacy Act, S.B. 21-190 (2021), applies coverage standards identical to Virginia. Although the law exempts certain controllers of health data, it does not exempt them completely, as in California and Virginia.
80. 740 Ill. Comp. Stat. Ann. 14/1 et seq. (2008). The law prohibits private entities from obtaining, using, or selling a person's biometric identifier or information without first obtaining the individual's written, informed consent. A "biometric identifier" means "a retina or iris scan, fingerprint, voiceprint, or scan of hand or face geometry." Any person aggrieved by a violation of the act may recover from an entity that negligently violates any provision of the law, liquidated damages of $1,000 or actual damages, whichever is greater. If the violation is intentional or reckless, the liquidated damages are $5,000. Reasonable attorney fees and costs, and injunctive relief also are recoverable. See Patel v. Facebook, Inc., 932 F.3d 1264 (9th Cir. 2019), cert. denied, 140 S. Ct. 937 (2020) (holding that class action status was proper in action challenging Facebook's "tag suggestions" photo feature); Vance v. Microsoft Corp., 2021 WL 963485 (W.D. Wash. 2021) (action brought by Illinois residents alleging Microsoft downloaded and conducted facial scans of plaintiffs' photos without consent to improve its facial recognition technology).
81. Vernon's Tex. Bus. &Com. Code Ann. § 503.001 (violators subject to $25,000 civil penalty in action brought by state attorney general).
82. West's Wash. Rev. Code Ann. §§ 19.375.010 et seq. (act does not provide for a private right of action).
83. California's Consumer Privacy Act, supra note 77, includes "biometric information" within the definition of "personal information" protected by the statute, but damages are limited to $100 to $750 per violation if there is unauthorized access, theft, or disclosure because of a business' violation.
84. See New State Ice Co. v. Liebmann, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting) ("It is one of the happy accidents of the federal system that a single, courageous state, may, if its citizens choose, serve as a laboratory, and try novel social and economic experiments without risk to the rest of the country.").
85. "Processing of personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation shall be prohibited." GDPR art. 9, § 1 (emphasis added).
86. See text accompanying notes 51-52 supra.
87. See N.P. Terry, " Big Data Proxies and Health Privacy Exceptionalism," Health Matrix 24, no. 1 (2014): 65–108.
88. See K. Litman-Navarro, " We Read 150 Privacy Policies. They Were an Incomprehensible Disaster," New York Times, June 12, 2019, available at <https://www.nytimes.com/interactive/2019/06/12/opinion/facebook-google-privacy-policies.html >(last visited August 1, 2021); See also A. Bruvere and V. Lovic, "Rethinking Informed Consent in the Context of Big Data," Cambridge Journal of Science and Policy 2, no. 2 (2021), doi.org/10.17863/CAM.68396.
89. In an assessment of the 36 top-ranked apps for depression and smoking cessation, 29 transmitted data for advertising and marketing purposes to Google and Facebook, but only 12 of 28 transmitting data to Google and 6 of 12 transmitting to Facebook disclosed this fact. K. Huckvale, J. Torous, and M.E. Larsen, " Assessment of Data Sharing and Privacy Practices of Smartphone Apps for Depression and Smoking Cessation," JAMA Network Open 2, no. 4 (2019): e192542. Also, in a study of 211 Android diabetes apps, permissions required to download the app authorized collection of tracking information (17.5%), activating the camera (11.4%), activating the microphone (3.8%), and modifying or deleting information (64.0%). S.R. Blenner et al., "Privacy Policies of Android Diabetes Apps and Sharing of Health Information," Journal of the American Medical Association 315, no. 10 (2016): 1051-1052.
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91. 42 U.S.C. § 2000ff-1(b).
92. 42 U.S.C. § 2000ff-1(a)
93. For example, Title VII of the Civil Rights Act of 1964, 42 U.S.C. §§ 2000e-2000e-17, does not prohibit employers from asking about the race of applicants and employees, but virtually no employers do so because inquiries about race might be offered as evidence of discrimination if a lawsuit were brought. See U.S. Equal Employment Opportunity Commission, Prohibited Employment Policies/Practices, available at <eeoc.gov/prohibited-employment-policiespractices >(last visited August 29, 2021).
94. See note 73 supra.
95. The possible regulation of surveillance technology companies by application of antitrust, consumer protection, or other laws is beyond the scope of this article.
About This Column
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DETAIL

Subjek:	Behavior; Personal information; Surveillance; Trends; Politics; Social networks; Intelligence gathering; Data analysis; Privacy; Capitalism; Big Data; Electronic health records; Medicine; Artificial intelligence; National security; Proprietary; Access to information; Data collection; False information; Rebellions; Algorithms; Precision medicine
Ketentuan indeks bisnis:	Subjek: Social networks Capitalism Big Data Artificial intelligence
Pengidentifikasi/kata kunci:	HIPAA; Health informatics; Surveillance capitalism; Information privacy; Privacy; Precision medicine; Big data; Precision Medicine; Privacy; Social Media; Surveillance Capitalism
Judul:	Big Data, Surveillance Capitalism, and Precision Medicine: Challenges for Privacy
Pengarang:	Rothstein, Mark A
Judul publikasi:	The Journal of Law, Medicine &Ethics; Boston
Volume:	49
Edisi:	4
Detail sumber:	First Amendment Values in Health Care
Halaman:	666-676
Tahun publikasi:	2021
Tanggal publikasi:	Winter 2021
Bagian:	Columns: Currents in Contemporary Bioethics

Penerbit:	Cambridge University Press
Tempat publikasi:	Boston
Negara publikasi:	United Kingdom, Boston
Subjek publikasi:	Law, Medical Sciences
ISSN:	10731105
e-ISSN:	1748720X
Jenis sumber:	Jurnal Akademik
Bahasa publikasi:	English
Jenis dokumen:	Journal Article
DOI:	https://doi.org/10.1017/jme.2021.91
ID dokumen ProQuest:	2730847736
URL Dokumen:	https://www.proquest.com/scholarly-journals/big-data-surveillance-capitalism-precision/docview/2730847736/se-2?accountid=211160
Hak cipta:	© 2021 The Author(s)
Terakhir diperbarui:	2023-11-27
Basis data:	Public Health Database

Say No to This: Unilateral Do-Not-Resuscitate Orders for Patients with COVID-19

Leiter, Richard E; Tulsky, James A

ABSTRAK (ENGLISH)

In this article, we comment on Ciaffa's article 'The Ethics of Unilateral Do-Not-Resuscitate Orders for COVID-19 Patients.' We summarize his argument criticizing futility and utilitarianism as the key ethical justifications for unilateral do-not-resuscitate orders for patients with COVID-19.

TEKS LENGKAP

Despite a generation's work on the ethics of end-of-life decision-making, we still struggle to know who gets to make critical decisions, and when. In this issue, Ciaffa[1] explores the ethics of unilateral do not resuscitate (DNR) orders for patients with COVID-19. He reviews several widely discussed guidelines recommending unilateral DNR orders during the pandemic and argues that the key ethical principles on which they rely, futility and utilitarianism, fail to provide adequate justification. The first, futility, suggests that clinicians are not obligated to provide interventions that have no demonstrable chance of success. As Ciaffa correctly points out, universal unilateral DNR orders for patients with COVID-19 unreasonably expand futility beyond the accepted notion of physiologic futility, in which a procedure has no chance of achieving the intended physiologic effect. The second principle, utilitarianism, suggests that in a pandemic clinicians should not be exposed to unnecessary risk that may reduce their ability to help the greatest number of patients. Ciaffa maintains that such a justification overestimates risk in all but situations that invoke crisis standards of care. He concludes by calling for more proactive communication with patients, families, and the public about the potential benefits and burdens of CPR.

Ciaffa puts forth a valid and important critique of the well-intentioned efforts to limit potentially non-beneficial interventions during the pandemic. In discussing unilateral DNRs, though, we must also consider the human factors that complicate end-of-life decision-making for patients, surrogates, and clinicians, particularly in an unprecedented global crisis.

Paradigms for shared decision-making around CPR and intubation draw heavily on the science of serious illness communication.[2] In the face of a life-threatening illness, patients and their surrogates confront powerful emotions — sadness, grief, anger, guilt, and fear, among others. These emotions overwhelm them and limit their cognitive abilities to make decisions. For instance, when faced with an open-ended question about code status, a family member serving as a health care proxy agent may opt for CPR and intubation, as she fears "giving up" prematurely and feeling responsible for her loved one's death. Evidence-based approaches to these conversations thus involve clinicians eliciting patient and family goals and values and then making medical recommendations considering these values and the clinical situation.[3] Amid these challenging decisions, patients and their surrogates look for guidance from their clinicians. In turn, this guidance exists on a spectrum, ranging from a soft-pedaled suggestion to a strong, definitive recommendation. The University of Washington protocol for informed assent during COVID[4] exists at the far end of this continuum, whereby the clinician asserts the plan to withhold CPR, and then, importantly, checks in with the patient or surrogate to assess their agreement or disagreement. Some families may never be able to decide to withhold treatments aimed at prolonging life; they may, however, be able to assent to a compassionate, yet strong recommendation from a clinician.

When faced with new, uncertain situations, overworked and fearful clinicians need guardrails that reinforce established ethical principles and standards of care. Unilateral DNRs, too often serve as shortcuts to skilled goals of care and code status conversations. If anything, individual patient and family goals and values assume more importance when there is considerable prognostic uncertainty. At the same time, frontline health care workers who, in this pandemic, have been willing to put themselves at great risk physically and emotionally to meet their obligations to patients need to know that hospital policymakers place intrinsic value on their health and safety.

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Ciaffa's critique also underemphasizes the risk to the clinician of performing CPR on a patient with COVID-19. Early in the pandemic, when most of the referenced protocols were written, hospitals lacked sufficient personal protective equipment (PPE) and knowledge of COVID-19's transmissibility continued to evolve. As a result, clinicians and staff on the front lines justifiably feared for their safety. Indeed, 3,607 American health care workers died in the first year of the pandemic.[5] Ciaffa maintains that health care workers should be protected based on a utilitarian conception of their value to society. It follows, then, that such arguments function only when the health care system views all its components through a utilitarian lens, i.e., in crisis standards of care. However, the utilitarian view fails to consider health care workers' intrinsic moral weight as individuals, not just as vehicles to achieve the greater good. Along with transparency and justice, reciprocity for clinicians forms a critical piece of pandemic ethical frameworks. Reciprocity

suggests that health care workers deserve to be fairly compensated for their work, and adequately protected while doing it.[6] We must then balance the principle of reciprocity against patient autonomy. Whereas the balance will generally tilt in favor of the patient, there are situations in which CPR could be exposing health care workers to unnecessary risk as the procedure's chance of success is not zero, but extremely low. Even outside of crisis standards, it behooves health systems to consider how to best protect their staff in these cases. And, the same systems should be obligated to rethink their approach as the data and frontline situation (i.e. availability of PPE) change.

Proactive efforts at patient education, as Ciaffa points out, may allow us to avoid unilateral DNRs completely. We agree that education is critical, but believe that the time, effort, and money spent on education would be better spent on teaching clinicians how to have an effective goal of care or code status conversations.[7] Clinicians, patients, and surrogates often share similar goals — to see the patient improve and, if that proves to be impossible, to see them comfortable at the end-of-life. For the reasons stated earlier, a clinician trained in high quality serious illness communication may have the requisite skill to elicit these goals, align with them, and make a goal-concordant recommendation to withhold CPR.

When faced with new, uncertain situations, overworked and fearful clinicians need guardrails that reinforce established ethical principles and standards of care. Unilateral DNRs, too often serve as shortcuts to skilled goals of care and code status conversations. If anything, individual patient and family goals and values assume more importance when there is considerable prognostic uncertainty. At the same time, frontline health care workers who, in this pandemic, have been willing to put themselves at great risk physically and emotionally to meet their obligations to patients need to know that hospital policymakers place intrinsic value on their health and safety.

Note

The authors have no conflicts of interest to disclose.

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DETAIL

Subjek:	COVID-19; Utilitarianism; Patients; Ethics; Unilateralism; Coronaviruses; Decision making

Pengidentifikasi/kata kunci:	COVID-19; Utilitarianism; Resuscitation; Coronavirus; Futility; COVID-19; Cardiopulmonary Resuscitation; Decision-Making; Medical Communication; Futility
Judul:	Say No to This: Unilateral Do-Not-Resuscitate Orders for Patients with COVID-19
Pengarang:	Leiter, Richard E; Tulsky, James A
Judul publikasi:	The Journal of Law, Medicine &Ethics; Boston
Volume:	49
Edisi:	4
Detail sumber:	First Amendment Values in Health Care
Halaman:	641-643
Tahun publikasi:	2021
Tanggal publikasi:	Winter 2021
Bagian:	Independent Articles: Commentary
Penerbit:	Cambridge University Press
Tempat publikasi:	Boston
Negara publikasi:	United Kingdom, Boston
Subjek publikasi:	Law, Medical Sciences
ISSN:	10731105
e-ISSN:	1748720X
Jenis sumber:	Jurnal Akademik
Bahasa publikasi:	English
Jenis dokumen:	Commentary
DOI:	https://doi.org/10.1017/jme.2021.88
ID dokumen ProQuest:	2730847735
URL Dokumen:	https://www.proquest.com/scholarly-journals/say-no-this-unilateral-do-not-resuscitate-orders/docview/2730847735/se-2?accountid=211160
Hak cipta:	
Terakhir diperbarui:	2023-11-27

A Global Pandemic Treaty Must Address Antimicrobial Resistance

Wilson, Lindsay A; Rogers Van Katwyk, Susan; Weldon, Isaac; Hoffman, Steven J

ABSTRAK (ENGLISH)

Antimicrobial resistance (AMR) is one of the defining global health threats of our time, but no international legal instrument currently offers the framework and mechanisms needed to address it. Fortunately, the actions needed to address AMR have considerable overlap with the actions needed to confront other pandemic threats.

TEKS LENGKAP

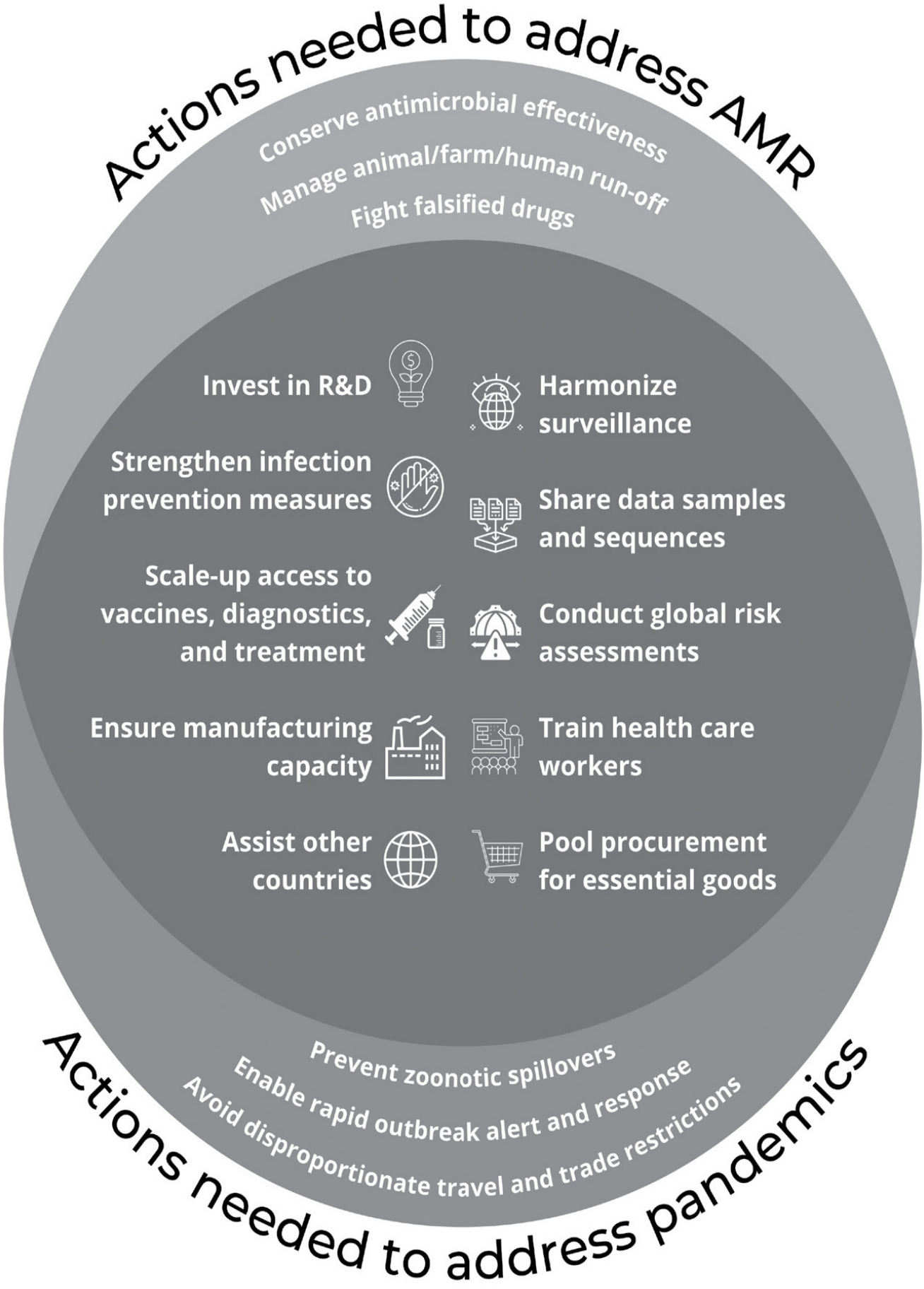
The COVID-19 pandemic has demonstrated that no single country can address global health threats alone.[1] As attention shifts to ensuring better preparedness for future disease outbreaks, a coordinated global strategy will be needed to address future pandemics and mitigate their human, economic, and social toll. International law represents an important tool in this preparedness effort, but existing legal mechanisms lack the coordination and enforcement measures necessary to ensure a coherent and unified pandemic response.[2] In response to these limitations, members of the World Health Organization agreed in May 2021 to begin discussions about the possibility of a new international pandemic treaty to catalyze collective action against future pandemics.[3] However, early discussions of the treaty have taken an overly narrow approach to defining pandemics, with the majority of attention focusing on the need for better surveillance and monitoring of emerging zoonotic infections.[4]

While zoonoses may indeed play a role in the next pandemic, comprehensive pandemic preparedness must involve planning for all potential pandemic sources: zoonoses, antimicrobial resistance (AMR), accidental release, and deliberate release.[5] While deliberate release is already addressed through the *Biological Weapons Convention*,[6] an inclusive global pandemic treaty must include provisions to tackle the other three main pandemic sources. Unfortunately, current discussions of a proposed treaty have focused on zoonoses and, to a lesser extent, accidental release, while completely ignoring AMR —a global health threat that is expected to result in USD $120 billion in excess hospital costs and potentially tens of millions of deaths by 2050.[7] AMR is a natural process wherein pathogens evolve to become resistant to the antimicrobial medicines that are intended to treat them. Unlike acute disease threats, AMR is an ongoing evolutionary process that requires continuous management. This trait means AMR may appear to be a slower moving challenge than many zoonotic infections, but resistant pathogens already kill 700,000 people annually —and are getting worse each year.[8] Managing the crisis of AMR will require global cooperation that can best be achieved through the robust coordination and accountability mechanisms offered under global health law.[9] The potential negotiation of a pandemic treaty is the right time and appropriate context to ensure that effective global governance arrangements are in place to meaningfully address AMR in any emerging global health security instrument.

While the global governance of AMR requires unique legal considerations that may not all apply to zoonoses and accidental release, there are many important actions that overlap across pandemic sources (Figure 1).[10] This overlap highlights the opportunity to develop regulatory strategies that proactively address all pandemic sources simultaneously rather than responding reactively to each type of threat in isolation. To address the threat of AMR

alongside other pandemic threats, three major areas for action will be needed: 1) global intersectoral cooperation; 2) equitable resource allocation; and 3) strengthened accountability mechanisms.

To address the threat of AMR alongside other pandemic threats, three major areas for action will be needed: 1) global intersectoral cooperation; 2) equitable resource allocation; and 3) strengthened accountability mechanisms.



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Global Intersectoral Cooperation

Preparing for AMR and zoonotic pandemics will require significant coordination across human, animal, and

environmental health sectors, as well as within and among countries. Given the ease with which pathogens can cross national borders, countries are incentivized to ensure that each individual country can address outbreaks before they spread.[11] While interconnections between countries and sectors may facilitate the spread of disease, they can also facilitate the sharing of knowledge and innovation; a new strategy, technology, or antimicrobial can benefit all parties, provided these innovations are shared globally. A well-designed treaty that addresses AMR and other pandemics should incentivize the sharing of these innovations through global health governance to ensure that shared vulnerabilities are minimized while simultaneously strengthening preparedness across countries. Despite the emphasis currently being placed on averting future zoonoses, our lack of preparedness for the COVID-19 pandemic is a reminder that we cannot be sure what the source of the next pandemic will be or which sectors it will impact. A proactive plan that is enshrined in international law and comprehensively accounts for *all* potential pandemic sources will help to bolster global efforts to respond quickly and effectively.

Equitable Resource Allocation

Many of the countries most impacted by global health threats are also among the poorest, making it particularly challenging, if not unrealistic, for them to bear the full financial burden of a pandemic alone. Furthermore, in our globalized world, action on the part of low-income countries inherently benefits high-income countries, which may raise concerns about equity when the burdens and benefits accrued from action against health threats are unfairly distributed.[12] These realities disincentivize cooperation and may generate nationalist actions, undermining the global solidarity necessary in a global response. The core capacities for mounting an effective response to AMR and other global health threats are extremely similar across pandemic sources —e.g., sanitation and hygiene for infection prevention; procurement of personal protective equipment; access to vaccines, diagnostics, and treatment[13] —but current international legal mechanisms do not enable the global pooling of resources that would be required for all countries to meet their needs. Thus, in addition to offering an efficient means of simultaneously mitigating the harms associated with AMR and other global health threats, a comprehensive pandemic treaty that supports resource pooling can strengthen overall global pandemic preparedness while also promoting global health equity.

Strengthened Accountability Mechanisms

The current system of global governance presents many challenges and incentive structures that hinder cooperation in global health. The COVID-19 pandemic has revealed that existing international legal frameworks do not incentivize cooperation with clear regulations, lack accountability mechanisms for those who do not comply, and provide inadequate support for those who are unable to fully implement them.[14] Like the COVID-19 pandemic response, previous efforts to manage the global antimicrobial commons have also suffered from a lack of effective surveillance and enforcement that would enable the early identification of new threats and opportunities.[15] Harmonized monitoring and accountability mechanisms that are simple, robust, transparent, and responsive are needed for all global health threats. A comprehensive and well-designed pandemic treaty should provide these mechanisms so that they can be applied to any of the main pandemic sources, regardless of the perceived speed at which they move.

Conclusion

Many of the challenges hindering the global governance of AMR are the same challenges that must be overcome to address future zoonotic pandemics. COVID-19 has offered an unprecedented opportunity to evaluate the ways in which we approach global health threats under global health law, but early discussions of a global pandemic treaty remain narrowly focused on zoonotic diseases, with insufficient attention to other pandemic sources. In order for this treaty to be robust and comprehensive, AMR must be addressed in it as well. If AMR has to remain outside the scope of the treaty's core content for political or logistical reasons, the treaty should have a mechanism for negotiating legally binding protocols on different issues that can be applied to a broader range of global health threats that are not addressed in the treaty's main text. If that happens, an AMR-specific protocol should be among the first protocols to be developed in order to build quickly the necessary global governance arrangements needed to redress this growing crisis. A policy window is currently open to meaningfully address both AMR and other global pandemics, and the world should seize the opportunity to enact real change.

Note

Steven J. Hoffman is funded by the Canadian Institutes of Health Research and the Ontario Ministry of Research, Innovation &Science.

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DETAIL

Subjek:	Innovations; Threats; Coronaviruses; Pandemics; Resistance; Zoonoses; COVID-19; Antimicrobial agents
Perusahaan / organisasi:	Nama: World Health Organization; NAICS: 923120
Pengidentifikasi/kata kunci:	Antimicrobial Resistance; Pandemic; Global Health; Antimicrobial; Antimicrobial resistance; Treaty; International Health Regulations; Pandemic Andemic Treaty; World Health Organization; Gl obal Health Law
Judul:	A Global Pandemic Treaty Must Address Antimicrobial Resistance
Pengarang:	Wilson, Lindsay A; Rogers Van Katwyk, Susan; Weldon, Isaac; Hoffman, Steven J
Judul publikasi:	The Journal of Law, Medicine &Ethics; Boston
Volume:	49
Edisi:	4
Detail sumber:	First Amendment Values in Health Care
Halaman:	688-691
Tahun publikasi:	2021
Tanggal publikasi:	Winter 2021
Bagian:	Columns: Global Health Law
Penerbit:	Cambridge University Press
Tempat publikasi:	Boston

Negara publikasi:	United Kingdom, Boston
Subjek publikasi:	Law, Medical Sciences
ISSN:	10731105
e-ISSN:	1748720X
Jenis sumber:	Jurnal Akademik
Bahasa publikasi:	English
Jenis dokumen:	Journal Article
DOI:	https://doi.org/10.1017/jme.2021.94
ID dokumen ProQuest:	2730847733
URL Dokumen:	https://www.proquest.com/scholarly-journals/global-pandemic-treaty-must-address-antimicrobial/docview/2730847733/se-2?accountid=211160
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Terakhir diperbarui:	2023-11-28
Basis data:	Public Health Database

Reproductive Technologies and Free Speech

Suter, Sonia M

ABSTRAK (ENGLISH)

The Supreme Court and lower courts have not articulated a clear or consistent framework for First Amendment analysis of speech restrictions in health care and with respect to abortion. After offering a coherent doctrine for analysis of speech restrictions in the doctor-patient relationship, this piece demonstrates how potential legislation restricting patient access to information from reproductive testing intended to limit “undesirable” reproductive choices would violate the First Amendment.

TEKS LENGKAP

The nature of First Amendment protection for speech in the context of the doctor-patient relationship has been the subject of inquiry for several decades. The Supreme Court has only addressed this issue three times — and each

instance involved the regulation of speech regarding reproductive care. Unfortunately, the Court been less than clear about the role of the First Amendment in this context. In *Planned Parenthood of Southeastern Penn. v. Casey,* it held that mandated speech with respect to doctors performing abortions is consistent with the First Amendment.[1] Twenty-six years later, it held in *Nat'l Inst. of Family Life &Life Advocates (NIFLA) v. Becerra* that mandated speech for crisis pregnancy centers that try to discourage women from seeking abortions is not.[2] To achieve these divergent outcomes, the Court has had to thread the needle by making fine distinctions between speech in very similar contexts.

While some argue that the Court has carved a path that will make it difficult to uphold further state regulations of speech concerning abortion,[3] others suggest these holdings reflect a form of "constitutional gerrymandering against abortion rights" by twisting First Amendment jurisprudence to achieve a desired outcome.[4] This piece examines what these Supreme Court cases mean for regulations of speech in reproductive care. Specifically, it explores whether states can prohibit doctors from providing certain information obtained through prenatal testing or preimplantation testing of embryos created through in vitro fertilization (IVF).

While that scenario is currently hypothetical, it does not seem far-fetched. For decades, legislatures have been whittling away at reproductive rights through abortion regulations[5] and limits on access to contraception.[6] Often the measures are wrapped in the guise of uncontroversial goals, such as protecting maternal health or improving informed consent. But the ulterior motive is clear: to restrict reproductive rights.

One area of growing focus is reason-based abortion (RBA) bans — prohibitions of abortions based on particular reasons — first sex,[7] then race,[8] and more recently, Down syndrome and other genetic anomalies.[9] As of July, 2021, nearly every state has proposed, and 17 states have enacted, such bans.[10] Like other laws intended to chip away at reproductive rights, these laws draw on values that transcend the anti-choice movement, in this case, concerns about equality, disability rights, and preventing "eugenics." Indeed, when the Court denied certiorari after the Seventh Circuit invalidated an Indiana law banning reason-based abortions, Justice Thomas wrote an impassioned concurrence describing such laws as remedies to the scourge of eugenics.[11] Because Justice Thomas has long adamantly opposed constitutional protections of abortion, it is easy to dismiss his diatribe as simply rooted in animosity toward abortion rights.

While some argue that the Court has carved a path that will make it difficult to uphold further state regulations of speech with respect to abortion, others suggest these holdings reflect a form of "constitutional gerrymandering against abortion rights" by twisting First Amendment jurisprudence to achieve a desired outcome. This piece examines what these Supreme Court cases mean for regulations of speech in reproductive care. Specifically, it explores whether states can prohibit doctors from providing certain information obtained through prenatal testing or preimplantation testing of embryos created through in vitro fertilization.

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But concerns about equality, disability rights, and eugenics exist on both sides of the political spectrum, not just among the antichoice camps. They are frequently cited in discussions about the societal and ethical implications of the expansion of reproductive testing. It therefore seems plausible, as some scholars have suggested, that reason-based abortion (RBA) bans could be just the first step down a path toward prohibiting the disclosure of some or all information from prenatal testing during pregnancy[12] and preimplantation testing of embryos. Such laws would clearly raise First Amendment issues. Whether they would survive First Amendment challenges is the subject of this piece.

Part I describes current and future forms of reproductive testing. It then briefly delineates the concerns these technologies raise and how legislatures might use them to justify prohibiting disclosures of certain types of information from prenatal testing and preimplantation testing. Part II turns to the confusing Supreme Court jurisprudence on speech in health care as well as the lower courts' struggles to develop coherent First Amendment principles in this area. Part III attempts to make sense of the contradictory case law to describe the level of scrutiny that should apply to regulations of speech in health care. Finally, Part IV analyzes how potential future laws

prohibiting disclosure of reproductive testing results would fare under those approaches. It concludes that they would not survive First Amendment attacks.

I. Reproductive Testing

To set the stage for a discussion of the concerns that might prompt legislative action in this arena, I begin with a brief overview of prenatal and preimplantation genetic testing today and the direction it might go in the future.

A. Reproductive Technologies and Testing

Many forms of prenatal testing, including ultrasound, amniocentesis, chorionic villus sampling (CVS), and the increasingly routine non-invasive prenatal testing (NIPT), are available to pregnant people today. Amniocentesis and CVS involve obtaining fetal or placental cells for genetic analysis to determine whether the fetus has a genetic condition, like cystic fibrosis, or a chromosome anomaly, like Down syndrome (trisomy 21).[13] While some individuals seek prenatal testing to avoid having a child with a particular genetic or chromosomal disorder, to prepare for their future child, or to help physicians plan for possible complications during delivery, others are unsure how they might use the information.[14]

The newest prenatal test is NIPT, which analyzes fragments of cell-free fetal DNA circulating in maternal blood. It can identify chromosomal abnormalities like trisomy 21, 13, and 18, as well as fetal sex.[15] NIPT is not yet truly diagnostic. If, as some anticipate, this noninvasive test ultimately provides the same information as amniocentesis and CVS, but without their risks, it could significantly increase the interest in prenatal testing.[16]

Reproductive testing can also occur through preimplantation genetic testing (PGT), which involves genetic analysis of an embryo created through in vitro fertilization (IVF). Like amniocentesis and CVS, PGT provides information about chromosomal anomalies and single-gene disorders.[17] The results can be used to select embryos to avoid having a child with a genetic disease. While abortion would not be involved, it might result in embryo destruction.

The scope of information available through prenatal testing and PGT will likely expand as our understanding of genetics grows. Scientists are identifying ever more genetic variants associated with several complex diseases and even nonmedical traits. While many such variants may have limited predictive value because they have only a small effect on disease or traits, analysis of the aggregate effect of several variants can be calculated to determine polygenic risk scores for particular diseases or traits.[18] Polygenic risk scores are not yet part of prenatal testing. So far, only one company, Genomic Predictions, offers analysis of several hundred thousand genetic variants to help parents “prioritize embryos for transfer” based on risks for several polygenic diseases, including diabetes, coronary artery disease, some cancers, and schizophrenia.[19] Some, however, question whether the science is good enough at this point to offer meaningful polygenic scores.[20]

Polygenic risk scores could also potentially be used in reproductive testing for nonmedical traits, like skin, eye, and hair color; height; or maybe even intelligence.[21] Fertility Institutes in California, for example, advertises itself as “the first and only genetics-based fertility program … anywhere worldwide” that can “offer high level genetic screening of parents seeking to have a voice in determining the eye color of planned children.”[22] In addition, two of the founders of Genomic Prediction are searching for genetic variants associated with intelligence and height. One of them recently suggested that “[a]ccurate IQ predictors will be possible” within five to ten years to help couples select the “smartest” embryo for implantation.[23] One study, however, showed PRS has limited predictive value for complex traits like height and intelligence.[24]

It is crucial to emphasize that most diseases and traits are the result of a complex combination of genes and environmental factors; that is, genes are often not fully determinative. Even so, some traits, like height, have a strong genetic component, even though environment (diet, health, activity, etc.) can impact their expression.[25] Whether PRS will ever meaningfully predict complex traits is uncertain. But as we better understand the relationship between genes and traits, it may well become a part of PGT, even if the results are only probabilistic.

Finally, genome sequencing (identifying all of the base pairs of the genome) might be used with reproductive testing in the future.[26] Although not yet a routine part of clinical care, its decreasing costs might change that.[27] Interpreting the sequence is the real challenge, however, because our understanding of the entire genome is still incomplete. Nevertheless, with more time and research, our knowledge will undoubtedly grow.

For all these reasons, future reproductive testing will provide more information about the fetus and embryo, potentially even information about minor medical traits, like myopia, and nonmedical traits beyond sex, like height, athleticism, intelligence, etc.

B. Concerns about Selecting Offspring

For some, the concerns about prenatal testing and PGT are rooted in anti-choice views that oppose pregnancy termination or embryo destruction regardless of the reason. But various other concerns have been raised about this technology. One is its potential harm to people with disabilities. Some fear it can lead to fewer births of people with disabilities as well as reduced social support for, negative societal attitudes towards, and heightened discrimination against them.[28]

Testing for nonmedical traits raises additional concerns. Sex selection, which is currently possible through prenatal testing and PGT, has altered the normal male to female birth ratio in some countries, although not in the United States.[29] Scholars and professional societies worry it reflects "prejudice against female children" or might take us down "a 'slippery slope' toward selection of many other traits" that some find "ethically problematic."[30]

Several arguments against nonmedical sex selection apply to other forms of nonmedical trait selection. Some fear it denies children a "right to an open future" by imposing expectations associated with a particular trait, which might cause psychological harm or disrupt the parent-child relationship.[31] A related fear is that reproductive selection commodifies reproduction, challenging parents' ability to "appreciate children as gifts" and "not as objects of our design or products of our will."[32] Finally, some worry that such reproductive selection will exacerbate societal inequities because insurance is unlikely to cover testing for nonmedical traits. They fear the wealthy will be most likely to select for traits, such as height or intelligence, that will increase the societal advantages of their children.[33]

C. Legislation that Goes Beyond Reason-Based Abortion (RBA) Legislation

While counter-arguments can be made in response to the concerns described above, including their speculative nature,[34] legislatures might draw upon those concerns to justify limiting patient access to information from prenatal testing and PGT. With the growing focus on RBA bans, anti-choice efforts might commandeer these concerns, as they have done with respect to other values, to limit reproductive rights.[35] Legislatures could prohibit the disclosure of information accessible through prenatal testing entirely or before the point of viability to discourage reason-based abortions, particularly because it is difficult to establish a person's reasons for an abortion.[36] Laws might also proscribe disclosure of information from PGT to discourage destruction of embryos.

Another possibility might be to ban disclosure of certain information, like information about nonmedical traits or minor medical conditions. States might adopt approaches used by countries like Germany, Austria, France, and Italy, which only allow PGT to prevent serious diseases, or the UK, which bans nonmedical sex selection.[37] Such laws would align with public attitudes. While polls find majority support for using PGT to select against lethal, early childhood diseases (72.9%) or diseases that cause life-long disability (66.7%), only a minority support using it to select for sex (21.1%); traits like intelligence (18.9%); characteristics like height, eye color, or athleticism (14.5%); traits like intelligence (18.9%); and sexual orientation (13.3%).[38]

Legislatures could not be faulted for viewing the Supreme Court's First Amendment jurisprudence in the reproductive realm as condoning such laws. After all, it has shown deference to speech restrictions disfavoring abortion, while applying strict scrutiny to those that don't. As Part IV argues, however, such restrictions would violate the First Amendment. But before we turn to that analysis, we must first review the judicial landscape in this area.

II. Judicial Treatment of Speech in the Health-Care Context

Courts have tried to decipher the appropriate degree of First Amendment protection for speech in health care given the tension between the states' power to regulate health care and the First Amendment interests of providers. The Supreme Court has done little to unravel these conceptual knots. In fact, it has spawned continued confusion for the lower courts regarding the extent to which the state may restrict speech in this context.

A. The Supreme Court

The Supreme Court has only examined First Amendment issues related to the speech of health-care professionals in three instances.[39] The first was *Rust v. Sullivan*,[40] which addressed federal regulations restricting recipients of

Title X family planning funds from offering abortion counseling, referrals, or advocacy of abortion as a method of family planning. The Court rejected the Title X recipients' First Amendment challenge of the regulations. It first observed that the government may make "'a value judgment favoring childbirth over abortion, and … implement that judgment by the allocation of public funds.'"[41] Because the speech restriction was tied to Title X's goals to "encourage family planning," this was not government suppression of "'a dangerous idea.'" Instead, the government was simply prohibiting grantees from "engaging in activities outside of the project's scope."[42] Because the regulation did not prohibit health care providers from engaging in abortion counseling or referrals through other programs "separate and independent" from Title-X funded programs, it found no First Amendment issue.[43]

Despite hinting that speech regulations in the doctor-patient relationship may be unique,[44] the Court refused to address the argument that speech within those relationships "should enjoy projection under the First Amendment," even when the government subsidizes those relationships. Instead, it unpersuasively asserted that "the regulations did not "significantly impinge upon the doctor-patient relationship"[45] because physicians were not required to represent views they did not hold. Moreover, the Title X doctor-patient relationship was limited to preconception care, so patients would not expect "comprehensive medical advice." Because the provider could explain that advice about abortion "is simply beyond the scope of the program," clients could not interpret "silence" as an indication the physician "does not consider abortion an appropriate option."[46] This was the Court's first hint that speech restrictions intended to promote childbirth and discourage abortion could survive First Amendment challenges.

Just a year later, in *Planned Parenthood v. Casey*, the Court addressed several abortion regulations, including an informed consent requirement that physicians performing abortions describe the risks of the procedure, the risks of childbirth, and the probable age of the fetus, and inform patients of the availability of state-provided information about adoption and child support.[47] In upholding the informed consent mandate, the *Casey* plurality focused primarily on whether the regulation violated the Due Process Clause. Relying on its newly crafted undue-burden test, it found the law did not impose a substantial obstacle because the mandated language was "truthful and not misleading."[48]

While acknowledging that the statute raised First Amendment issues, the plurality devoted only a paragraph to conclude that the mandated disclosures presented "no constitutional infirmity." The heart of its argument can be found in one sentence and two citations:[49]

To be sure, the physician's First Amendment rights not to speak are implicated, see *Wooley v. Maynard*, 430 U.S. 705 (1977), but only as part of the practice of medicine, subject to reasonable licensing and regulation by the State, cf. *Whalen v. Roe*, 429 U.S. 589, 603 (1977).[50]

In failing to explain the applicable standard of review, this brief and opaque discussion functions like a Rorschach test.[51] Some read it as using a rational basis test, and certainly not strict scrutiny.[52] Others see it as employing some kind of intermediate or heightened scrutiny.[53]

Many hoped the Court would clarify its position on speech in health care in *NIFLA v. Becerra*.[54] In that 2018 case, the Court considered the constitutionality of a California statute requiring licensed clinics that offer services to pregnant people to provide specific notices about the availability of "free or low-cost access to comprehensive family planning services … prenatal care, and abortion."[55] The National Institute of Family and Life Advocates (NIFLA), an organization of crisis pregnancy centers, challenged the notice requirements as violating their First Amendment rights to free speech (and free exercise of religion). The Ninth Circuit affirmed the denial of a motion for a preliminary injunction,[56] concluding that the notice was a form of professional speech subject to, and likely to survive, intermediate scrutiny.[57]

Describing the law as intended to regulate crisis pregnancy centers, which "'aim to discourage and prevent women from seeking abortions'" and are commonly associated with groups that oppose abortion,[58] the Supreme Court disagreed. It first noted that content-based regulations of speech are generally "presumptively unconstitutional" and subject to strict scrutiny.[59] And it insisted that the mere fact that speech "is uttered by 'professionals'" does not mean it is not protected.[60] In fact, it emphasized that the Court's precedents have not recognized "a category for 'professional speech.'"[61]

Writing for the majority, Justice Thomas had to acknowledge that the Court had, in fact, "afforded less protection for professional speech" before. One exception he pointed to involved the mandated disclosure upheld in *Casey*.[62] Despite the strong parallels between the speech regulations in *Casey* and *NIFLA*, both of which compelled statements about reproductive options, Justice Thomas made a tortured attempt to treat them as distinct. *Casey*, he stated, involved State regulation of "professional *conduct*" that "incidentally involves speech" and was consistent with "firmly entrenched" informed consent requirements for operations.[63] Allegedly in contrast, *NIFLA*'s notice requirement applied "whether a medical procedure [was] ever sought, offered, or performed."[64] Thus, it did not "facilitate informed consent to a medical *procedure*."[65]

As Justice Breyer noted in his dissent, this distinction "lacks moral, practical, and legal force."[66] While abortion is "a medical procedure that involves certain health risks," he emphasized, "carrying a child to term and giving birth" also poses risks. Thus, health "considerations do not favor disclosure of alternatives and risks associated with the latter but not those associated with the former."[67] Further, even if the majority believes that "speech about abortion is special" because it involves "views based on deeply held religious and moral beliefs about the nature of the practice," Justice Breyer argued, the Court should treat "like cases alike," especially given the "strong, and differing, views" American hold regarding abortion.[68]

Justice Thomas did not disguise the Court's view that speech concerning abortion is special when he distinguished *NIFLA* from *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio,*[69] the other instance where he noted the Court applied lesser scrutiny to a law regulating the speech of professionals.[70] Thomas observed that *Zauderer* upheld the state's discipline of an attorney for failing to disclose the terms of contingent fees in his advertising[71] because it involved "'purely factual and *uncontroversial* information" about payment for services, and it was not "'unjustified or unduly burdensome.'"[72] Even though the *NIFLA* notice was also purely factual, the Court remarkably found the compelled disclosures distinct because it mentioned abortion, which the Court described as "anything but …'uncontroversial.'"[73]

The Court implied that requiring mention of the "controversial" word abortion raised the "the danger of content-based regulations 'in the fields of medicine and public health, where information can save lives.'"[74] It devoted a full 41.8% of the opinion's words to describe the threats of regulating speech in health care "to increase state power and suppress minorities,"[75] to suppress "'unpopular ideas or information,'"[76] and to "'maniuplate[] the content of doctor-patient discourse' to advance … iniquitous interests.'"[77] But the Court never explained why compelled disclosures of reproductive options, including prenatal care, contraception, and abortion, impose such a threat, while compelled disclosures of nonmedical options, such as adoption and child support, do not. The implication is that compelled speech that treats abortion as acceptable is dangerous, whereas compelled speech that discourages it is not.

Finally, in an unusual series of decisions that were vacated and replaced by new ones, the Eleventh Circuit addressed a Florida law prohibiting physicians from asking patients whether anyone in their family owned firearms or ammunition. After three decisions upheld the law under different approaches, the Eleventh Circuit en banc invalidated it. Despite the state's "substantial interest in regulating professions like medicine," it found the state does not have "carte blanche to restrict the speech of doctors and medical professionals."

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Despite the Court's strong rhetoric that professional speech should be treated like all other speech for First Amendment purposes, it did not "foreclose the possibility" that there may be a "persuasive reason for treating professional speech as a unique category, exempt from ordinary First Amendment principles."[78] What constitutes a "persuasive reason" is the million-dollar question, making *NIFLA* the Court's latest Rorschach test in this area.

B. Lower Courts

The Supreme Court's opaqueness has left the lower courts struggling to discern the proper standard of review for speech regulations in the doctor-patient relationship. Not surprisingly, "nothing even approaching judicial consensus" exists among the circuit courts.[79] Further confusing matters, most of lower court decisions arose before *NIFLA*, creating uncertainty about the reach of their holdings.[80] We turn first to decisions concerning prohibitions of speech,

and then to compelled speech.

1. prohibitions of speech

The Ninth Circuit was the first to address prohibitions of speech in health care, which it handled differently in two cases by drawing on a speech/conduct distinction. In *Conant v. Walters*, it found unconstitutional the government's threat to revoke controlled substance registrations from physicians who recommended marijuana use for medical purposes.[81] A decade later, in *Pickup v. Brown*, however, it upheld a law banning mental health care providers from using sexual orientation change efforts (SOCE) to try to alter minors' sexual orientations.[82] The rationale for more "deferential review" in the latter case was that, unlike the regulations in *Conant*, which targeted "doctor-patient communications *about* medical treatment,"[83] the restriction in *Pickup* was a "regulation of the practice of medicine" because it applied to a form of therapy that was not, itself, "an act of communication."[84]

The Third Circuit rejected this speech/conduct distinction when it upheld a ban on SOCE in *King v. Governor of New Jersey*.[85] Although it considered SOCE "'speech' for purposes of the First Amendment,"[86] it reasoned that "speech that occurs as part of the practice of a licensed profession" is not "fully protected by the First Amendment."[87] The court also emphasized that patients "have no choice but to place their trust in" these highly trained and educated professionals.[88] To strike a balance between allowing legislatures to prohibit "harmful or ineffective professional services" and preventing legislatures from "too easily suppress[ing] disfavored ideas under the guise of professional regulation,"[89] it applied intermediate scrutiny. Because SOCE could harm patients, the ban survived such scrutiny.[90]

Finally, in an unusual series of decisions that were vacated and replaced by new ones, the Eleventh Circuit addressed a Florida law prohibiting physicians from asking patients whether anyone in their family owned firearms or ammunition.[91] After three decisions upheld the law under different approaches,[92] the Eleventh Circuit en banc invalidated it.[93] Despite the state's "substantial interest in regulating professions like medicine," it found the state does not have "carte blanche to restrict the speech of doctors and medical professionals."[94]

Most recently, in a post-*NIFLA* decision, *Otto v. City of Boca Raton*, the Eleventh Circuit found unconstitutional an ordinance prohibiting therapists from practicing SOCE on minors.[95] Unlike the Ninth and Third Circuits, it applied strict scrutiny. Pointing to the speech/conduct used in *NIFLA*,[96] it concluded that the banned therapy is not conduct or a procedure because it is based entirely on speech.[97] Further the regulation was a content-based restriction of speech, prohibiting therapists "from communicating a particular message."[98] Quoting *NIFLA*, it spoke of the "'inherent risk that the Government seeks not to advance a legitimate regulatory goal, but to suppress unpopular ideas or information.'"[99] Finally, it emphasized *NIFLA*'s and its own refusal "to recognize professional speech as a new speech category deserving less protection."[100]

The court found that the law didn't survive strict scrutiny. First, the state's compelling interest in protecting minors did not allow it to "'restrict the ideas to which children may be exposed.'"[101] Second, unpersuaded by the government's assertions of the risks of SOCE, it found the law was not narrowly tailored. Demonstrating a remarkable lack of deference to voluminous research, it concluded that relying on "professional societies' opposition to speech," would simply allow "majority preference" to justify speech restrictions.[102] Finally, it argued, if the SOCE ban could stand, so could laws prohibiting therapists from validating clients' same-sex attraction or gender identity,[103] completely ignoring that such laws would deviate wildly from professional standards.

The dissent argued for intermediate scrutiny, but believed the law would survive strict scrutiny. Not only did it find compelling the state interests in "protecting minors from harmful professional practices" and regulating the practice of medicine, but it also found the law was narrowly tailored to that goal based on the "mountain of rigorous evidence" that SOCE was harmful and inefficacious in changing sexual orientation.[104] Notable for our purposes is the test it advocated for the standard of review. Rejecting the speech/conduct distinction, it proposed that lesser scrutiny should apply when a speech restriction is "auxiliary to" the practice of medicine.[105]

2. compelled speech

The inconsistency courts have shown regarding speech restrictions applies equally to compelled speech, including laws requiring ultrasounds to be performed on and displayed to people seeking abortions. The Fifth Circuit, in *Tex. Med. Providers Performing Abortion Servs. v. Lakey*, found such compelled expression "more graphic" than that in

Casey, but not "different in kind" because both provide truthful and not misleading information.[106] Describing *Casey* 's standard of review as the "antithesis of strict scrutiny," the court seemed to apply rational basis in easily finding the law constitutional.

The Fourth Circuit applied decidedly more stringent scrutiny in *Stuart v. Camnitz.*[107] While finding the ultrasound information to be "the epitome of truthful [and] nonmisleading,"[108] it found the regulation "ideological."[109] By requiring the disclosure of "facts that all fall on one side of the abortion debate," it essentially compelled a "pro-life message." [110] Moreover, the law deviated from informed consent by forcing the display and description of the ultrasound to a pregnant person when she was "most vulnerable."[111] The patient could only avoid it by covering her eyes and ears, thus threatening her psychological wellbeing and undermining her trust in her doctor by making the physician "the mouthpiece of the state."[112]

In a post-*NIFLA* decision, the Sixth Circuit, in *EMW Women's Surgical Center, P.S.C. v. Beshear*, upheld a Kentucky mandatory speech-and-display ultrasound law.[113] Reasoning much like the Eleventh Circuit, it found no material difference between the mandates in *Casey* and the Kentucky law. Drawing heavily from *NIFLA,* the Sixth Circuit concluded that heightened scrutiny should not apply because the ultrasound law regulated "professional conduct that only incidentally burdens professional speech."[114] Moreover, it rejected a "'sliding scale' test" for professional speech, which, it noted, *NIFLA* expressly refused to adopt.[115] It also rejected the Fourth Circuit's pre-*NIFLA* argument that heightened scrutiny was appropriate because the compelled message was ideological.[116]

Like the Eleventh Circuit, the Sixth Circuit ignored professional norms in evaluating the speech restrictions. It reasoned that informed consent "may be created by law, as opposed to merely medical custom,"[117] and it observed that both *Casey* and *Gonzales v. Carhart*[118] upheld medical requirements "directly contrary to alleged medical-professional custom."[119] Thus, the key inquiry was whether the law provided "truthful, non-misleading, and relevant information aimed at informing a patient about her decision to abort unborn life,"[120] not "necessarily whether the law is consistent with medical-profession custom or views of certain medical groups."[121] It found that in offering more specific information about the pregnancy than the *Casey* disclosures, the Kentucky law was "the epitome of ensuring informed consent."[122]

The dissent countered that the guiding First Amendment principle in *Casey* was that the "'physician's First Amendment rights not to speak are implicated, but *only as part of the practice of medicine,* subject to reasonable licensing and regulation by the State.'"[123] Thus, together, *Casey* and *NIFLA* established "that reasonable regulations that facilitate informed consent to a medical procedure are excepted from heightened scrutiny."[124]

In the spirit of the Otto dissent, the EMW dissent pointed to overwhelming evidence that the mandate requires "physicians to violate their professional and ethical obligations" by imposing a "one-size-fits all approach" for informed consent,[125] potentially harming patients by forcing them to see images that could cause distress.[126] The dissent feared that upholding the mandate would "open floodgates … to manipulate doctor-patient discourse solely for ideological reasons,[127] which, it reasoned, violates NIFLA's admonition that "the state 'cannot co-opt [physicians] to deliver its message for it.'"[128]

As we have seen, the courts have offered contradictory and inconsistent approaches to First Amendment doctrine in the context of health care both with respect to prohibited and compelled speech regulations. We turn now to scholarly interpretations of the doctrine.

III. Making Sense of the Cases

A. Scholarly Views of Speech in Health Care

Given the confusion created by the Supreme Court and lower courts regarding the level of scrutiny for regulations of doctor-patient communications, it is not surprising that scholars interpret this body of law in various ways. Some suggest strict scrutiny should apply,[129] which seems consistent with *NIFLA*'s reluctance to afford less First Amendment protection to professional speech. Indeed, the Court cited one of these scholars to argue that strict scrutiny applies to virtually all content-based restrictions, even in healthcare.[130] But that standard cannot be the uniform rule given *NIFLA's* recognition of the *Casey* exception.

Many scholars carve out areas of speech in health care that deserve more or less First Amendment protection.

Claudia Haupt, for example, argues for "robust First Amendment protection" for speech that would be "acceptable as good professional advice," whereas speech that falls outside that" acceptable range" should have no First Amendment protection."[131] Others argue that compelled "ideological" messages should be subject to "rigorous and almost certainly fatal First Amendment scrutiny"[132] or that laws regulating professional-client communications about constitutional rights, like abortion rights or the right to bear arms, should be subject to strict scrutiny because they "are, and ought generally to be treated as, regulations of political expression based on content."[133] I have argued that heightened scrutiny should apply to laws regulating informed consent because such speech is central to helping patients exercise their autonomy in making informed medical decisions.[134]

It is difficult, however, to square these positions with *NIFLA*'s interpretation of *Casey* as deferential to an informed consent mandate that 1) dealt with abortion rights; 2) was ideological in discouraging abortion, as the Casey Court itself acknowledged; and 3) required disclosure of nonmedical information, which deviates from typical informed consent doctrine.

Writing after *NIFLA*, Carl Coleman suggests the level of scrutiny depends on the governmental purpose of the law. If the restriction is "substantially related to … professional quality,"[135] it should survive intermediate scrutiny. But if the justification is based on "*other* governmental interests," strict scrutiny applies.[136] He emphasizes that "the primary justification for regulating professional speech is to counterbalance the inherent knowledge disparity between professional and clients, which makes individuals vulnerable to exploitation by incompetent or unscrupulous practitioners."[137] He does not find *Casey* inconsistent because it dealt with "factual information that a reasonable patient would arguably want to know."[138] Moreover, although regulations must be "informed by those who have specialized knowledge and experience that laypersons lack,"[139] "nontechnical dimensions, including materiality of information to patients," are also relevant in assessing professional quality.[140]

Coleman's view raises questions about what to do when states justify speech regulations in the *guise* of protecting professional quality. Even more challenging, it does not help courts decide how much laws can deviate from professional norms in regulating professional quality and how much deference should be accorded such norms. It risks inviting the kind of blithe dismissal of professional standards that the Sixth and the Eleventh Circuits demonstrated in dismissing comprehensive research and established medical customs.

Miller and Berkman, also writing after *NIFLA*, argue that physician speech is "*instrumentally* high value" speech because of its role in achieving "good medicine,"[141] therefore "rational basis is wholly inappropriate."[142] They criticize *NIFLA* for trying to distinguish physician speech based on whether or not it is tied to a medical procedure. Instead, they suggest, physician speech, should be treated as high value speech or "professional speech — not medical conduct — when it promotes patient safety, occurs within the confines of a doctor-patient relationship, and is supported by evidence-based medicine."[143] While entirely sensible, this doesn't accord with *NIFLA*'s implication that the speech in *Casey* should be accorded less First Amendment protection. Informed consent, after all, falls within their category of high value speech[144] — it "promotes patient-safety, occurs within the confines of a doctor-patient relationship," and is largely supported by evidence-based medicine (to determine material risks).

In fact, the gerrymandering in *NIFLA* and the two post-*NIFLA* cases goes beyond reproductive rights and is intertwined with concerns about religious liberties. Thus, strict scrutiny applies to restrictions of speech that conflict with a group's religious beliefs (such as mandating statements with the word "abortion" or prohibiting SOCE), even if they are informed by and consistent with professional standards. Yet laws that promote a particular perspective, such as an anti-abortion stance, are subject to less scrutiny, potentially even rational basis, no matter how much they deviate from medical customs and professional norms. The Court, it seems, is using the First Amendment to protect and promote certain perspectives, which as Chermerinsky and Goodwin argue, is unconstitutional.

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Another view is that *NIFLA* did not concern professional speech in the context of a doctor-patient relationship. As Haupt points out, someone could enter a clinic, receive the mandated notice, and leave before any relationship was created between a patient and health care provider.[145] The Court, however, never made such a distinction; in fact, it

took great pains to emphasize why the speech of professionals generally should not be less protected than other speech. It also spent a great deal of time discussing the dangers of the state controlling communications between doctor and patient,[146] suggesting that *any* regulation of physician speech in the doctor-patient relationship should be subject to strict scrutiny, as long as it is not incidental to regulation of conduct. The Eleventh Circuit certainly adopted that view in applying strict scrutiny to and overturning the SOCE ban.[147]

Finally, Professors Chemerinsky and Goodwin simply avoid seeking doctrinal consistency between *Casey* and *NIFLA.* Instead, they attribute the Court's different treatment of speech in the context of abortion and speech within a licensed pregnancy clinic to a form of "constitutional gerrymandering against abortion rights" that twists First Amendment jurisprudence to achieve a desired outcome.[148] Under this view, speech regulations aimed at discouraging abortion are subject to deferential review, whereas most other speech regulations are subject to strict scrutiny. Thus, a statute that goes against informed consent norms in mandating the disclosure of nonmedical information to discourage abortion can stand. But mandated disclosures about access to reproductive options (including abortion) that are consistent with medical norms cannot.

As Chemerinsky and Goodwin point out, this inconsistency reflects "not simply a content-based restriction on speech," but a viewpoint restriction, which is "never allowed."[149] In fact, the gerrymandering in *NIFLA* and the two post-*NIFLA* cases goes beyond reproductive rights and is intertwined with concerns about religious liberties. Thus, strict scrutiny applies to restrictions of speech that conflict with a group's religious beliefs (such as mandating statements with the word "abortion" or prohibiting SOCE), even if they are informed by and consistent with professional standards. Yet laws that promote a particular perspective, such as an anti-abortion stance, are subject to less scrutiny, potentially even rational basis, no matter how much they deviate from medical customs and professional norms. The Court, it seems, is using the First Amendment to protect and promote certain perspectives, which as Chermerinsky and Goodwin argue, is unconstitutional.

B. Attempting to Reconcile the Various Views

In many ways, I am most sympathetic to Chermerinsky and Goodwin. Yet I fear that succumbing to their position allows for continued gerrymandering that could undermine reproductive and other rights and run roughshod over professional custom and medical expertise, as occurred in *EMW* and *Otto*. Instead, we must try to find a coherent doctrinal position that balances the First Amendment interests of physicians and patients with the state interest in regulating health care, without allowing the state to use regulations to promote ideologies contrary to medical practice. Trying to thread that needle, given *NIFLA*, is challenging.

On the one hand, speech within the doctor-patient relationship is of great importance. It is "*instrumentally* high value" speech because it promotes health,[150] and its "[u]ndue regulation" could undermine the "well-being of patients."[151] But the State also has authority to regulate the "practice of medicine," as Coleman suggests, to protect patients who are "vulnerable to exploitation by incompetent or unscrupulous practitioners" given the knowledge disparity.[152] Thus, some form of intermediate scrutiny should apply.

The line *NIFLA* draws between speech and conduct, however, challenges this view as do the two post-*NIFLA* appellate decisions — one, applying strict scrutiny to speech qua speech,[153] and the other, applying something like rational basis to speech incidental to a procedure.[154] The *NIFLA* Court, however, never offered a persuasive rationale to explain why the level of scrutiny depends on whether the regulated speech is tied to a medical procedure.[155] It pointed to precedents that "have long drawn" a "line between speech and conduct," even though none of them distinguished speech incidental to conduct and speech as speech in health care. It also noted the state's authority to regulate professional conduct, as exemplified by malpractice torts.[156] But of course, the state's interest in regulating speech in the doctor-patient relationship exists whether or not a procedure is involved.[157]

The dissenting opinions in *Otto* and *EMW* offer a potential framework for deciding when a less stringent standard of review applies to speech restrictions like that in *Casey.* The *EMW* dissent identified the "'practice of medicine'" as "the driving term" in *Casey.*[158] Building on this idea, the *Otto* dissent looks to whether the "affected speech is 'auxiliary to' or 'inconsistent with' the practice of medicine."[159] When a law regulates speech "auxiliary to a medical practice," it should receive more deferential review, but when it is "inconsistent with the practice of medicine,"

heightened scrutiny should apply.[160]

While the speech mandate in *Casey* is not consistent with informed consent norms in requiring disclosure of nonmedical information intended to discourage abortion, it only required the doctor to mention the *availability* of a state-created document with nonmedical information about adoption and child support. It did not require physicians to actually make statements inconsistent with informed consent or to conduct procedures that were not medically indicated. Thus, under the law, physicians could speak in a manner consistent with the professional and ethical norms of informed consent. Reading the law as mandating mention of the *availability* of such information, but not as mandating actual disclosure of non-medical information, offers a way to find it consistent with informed consent norms.

I readily concede that this distinction is somewhat forced, but it offers a way to understand the doctrine that does not allow states to profoundly distort medical practice "solely for ideological reasons."[161] Wholesale acceptance of legislative disregard for the standard of care when regulating speech is problematic, particularly when driven by ideological concerns. Under the approach I advocate, speech restrictions wholly inconsistent with medical practice should be subject to heightened scrutiny. This approach thus avoids the troubling lack of deference to professional expertise demonstrated in *Otto* and *EMW.*

With respect to regulations of speech auxiliary to the practice of medicine, intermediate scrutiny is appropriate. As discussed above, it accommodates the tension between important First Amendment values and the States' interest in regulating medicine. Some have even suggested that *NIFLA* implied that intermediate scrutiny applies to regulations like those challenged in *Casey* when it emphasized that the notice requirement did not even survive such scrutiny.[162] While one might argue that the Court's terse support of the informed consent statute in *Casey* hinted at a rational basis test, it is also possible the plurality thought the law easily satisfied intermediate scrutiny, believing (as it seemed to) that the mandated disclosure was consistent with informed consent practices.[163] Thus, intermediate scrutiny in this context can be reconciled with *Casey* and *NIFLA.*

Although the speech/conduct distinction articulated in *NIFLA* and two circuit courts is problematic, it may nevertheless become binding. Thus, I also consider how that distinction might play out with respect to laws banning disclosure of information from reproductive testing. But even if that line holds, one question remains. Are there only two relevant categories of speech in health care — speech incidental to conduct and speech qua speech — or is the second category really two categories — speech qua speech within the doctor-patient relationship and speech qua speech outside the doctor-patient relationship? If three categories exist, intermediate scrutiny would apply to speech incidental to conduct because the state has wider authority to regulate medical conduct than speech,[164] heightened intermediate scrutiny would apply to speech as speech in the doctor-patient relationship, while strict scrutiny would apply to the last category. Under these different theories, therefore, speech regulations within the doctor-patient relationship should receive at least intermediate scrutiny.

IV. Evaluating Prohibitions of Disclosures of Prenatal and PGT Information

A. Standard of Review

As noted in Part I, legislatures might commandeer concerns about disability rights, equality, commodification, and eugenics to prohibit the disclosure of certain information that could be obtained through prenatal testing or PGT. To assess whether such laws would survive First Amendment challenges, the first question is the level of scrutiny.

If the *NIFLA* Court's distinction between speech incidental to procedures and speech as speech is binding, the outcome is not immediately clear. Are laws that prohibit the disclosure of or analysis of certain types of genetic information restrictions on speech qua speech or speech incidental to a medical procedure? These potential speech regulations are clearly distinct from laws prohibiting SOCE therapy or restricting health care providers from making inquiries about gun ownership, neither of which centers around a particular medical procedure.

One might argue they are very much "tied to a procedure" because medical procedures — amniocentesis, CVS, drawing blood for NIPT, or retrieving eggs for IVF/PGT — are necessary to obtain the information. Viewed that way, intermediate scrutiny would apply. However, the information is not *incidental* to the procedure; it is *derived* from a procedure. Obtaining that information is the *very purpose* of the procedure. Thus, information gleaned from prenatal

testing and PGT is speech qua speech, not speech incidental to a procedure. Under a theory that does not distinguish between speech within the doctor patient relationship and other speech, strict scrutiny should apply because these laws are content-based regulations. Even if *NIFLA* does allow some lesser protection of professional speech, as opposed to other speech, heightened scrutiny should apply because this is speech qua speech.

If a court were instead to determine the level of scrutiny by asking whether the regulation is auxiliary to the practice of medicine, à la the *Otto* and *EMW* dissents, the analysis would be different. Under this test, laws prohibiting access to information about genetic risks from prenatal testing or PGT would violate clearly established standards of care. The very purpose of these procedures is to provide information so individuals can make reproductive decisions — e.g., whether to terminate or continue the pregnancy or to select embryos to prevent disease in a future child. Prohibiting disclosure of this information would render the procedures worthless. Indeed, the standard of care is so clearly established here that most jurisdictions allow wrongful birth claims when providers negligently fail to deliver correct information from reproductive testing.[165] Laws banning disclosure of this information would therefore be highly inconsistent with medical practice and should fail under First Amendment scrutiny.

But what about information that is not directly related to medical risks, such as sex or nonmedical traits?[166] While information about fetal sex from prenatal testing is routinely disclosed, the purpose is not to facilitate decisions regarding prenatal care, whether to continue a pregnancy, or decisions regarding delivery.[167] Instead, the information is provided because of its personal and social value to some parents. Failing to provide such information would likely not be the basis for a wrongful birth claim. After all, what would the damages be?[168]

In the context of PGT, only a slight majority of clinics offer nonmedical sex selection,[169] and very few offer other kinds of nonmedical trait selection.[170] Even though information about sex (and potentially other nonmedical traits) is far more likely to influence embryo selection than decisions about pregnancy termination, at least in the United States, no clear standard of care exists regarding nonmedical trait selection through PGT. Indeed, professional organizations seem ambivalent about the ethics of nonmedical sex selection.[171] Thus bans on disclosure of nonmedical information about fetuses and embryos are not "inconsistent with the practice of medicine," suggesting they should be subject only to intermediate scrutiny.[172]

B. Applying the Standards

As we saw above, the level of scrutiny for these laws ranges from intermediate to strict. We begin by analyzing them under intermediate scrutiny, which requires a showing that a "statute directly advances a governmental interest and that the measure is drawn to achieve that interest."[173] The regulations need not be perfectly tailored to the important state interests, but if the restrictions do not sufficiently advance those interests, they cannot survive.[174]

To evaluate the laws, we must first articulate the state interests. The state would likely assert three, the first being the promotion of fetal and embryonic life.[175] The Supreme Court has described the interest in fetal life as "legitimate and substantial."[176] While it focused on the state's interest in life from the outset of *pregnancy*,[177] courts would likely also find a legitimate and maybe even substantial interest in *ex vivo* embryos given their potentiality for life.

Second, the state might assert interests in promoting social values and preventing "morally repugnant" acts,[178] in this case, what Thomas calls "eugenic-like" practices.[179] It might also assert an interest in preventing negative social effects, including discrimination based on sex, disability, or disfavored traits. A related goal might be preventing a reduction in the number of children born with disabilities or less desirable traits[180] and the exacerbation of inequalities if those with more resources are better able to select for traits that confer social advantages.[181] Finally, the State might want to discourage parents from treating their children as products whose quality must be controlled.[182]

Courts would likely view the state's interests in addressing troubling social values and societal effects such as alleged eugenic uses, discrimination, prejudice, and commodification of reproduction as legitimate, and perhaps substantial, interests, particularly when considered in the aggregate. Even if those state interests are substantial, however, preventing physicians from disclosing information they would otherwise disclose to patients under the medical standard of care is not sufficiently related to these interests to satisfy a heightened or even intermediate standard of scrutiny for several reasons.

First, such legislation would be overly broad, at least with respect to prenatal testing. Not all people seeking such testing would terminate based on prenatal information. Patients may want information to prepare for having a child with certain traits (including gender) or a disability.[183] In addition, some prenatal information is central to prenatal care and birthing.[184] Thus, these laws would restrict access to information that can be of great personal and medical value to patients, without protecting fetal life when the patient wasn't considering termination. In addition, sometimes such laws might result in fetal loss. A couple at risk for a serious genetic condition, for example, might terminate the pregnancy, rather than risk passing on a serious disease gene. Thus, they could potentially end a pregnancy with an unaffected fetus they would not have terminated if they had had access to the prenatal information.

While information from PGT almost always influences which embryo is implanted (that is, after all, why people seek PGT), a ban on disclosure of information may not actually spare many embryos. Because IVF often results in more embryos than can be implanted, information from PGT usually affects *which* embryos are implanted, but not how many; it is not likely to influence decisions about whether to destroy embryos or donate them to infertile couples. Bans on disclosure of this reproductive information would also be too broad to address the state interest in social values and effects, particularly in the context of prenatal testing. Even if the information were used to decide whether to terminate a pregnancy, not all (and perhaps not most) choices to terminate pregnancies based on prenatal information are rooted in prejudice or commodification of children. A pregnant person may decide, for example, to terminate a pregnancy based on a condition like Tay Sachs, not because of prejudice or because she views her child as a product. Instead, she may want to prevent suffering or have concerns about her emotional and/or financial capacity to care for a child with a disability.

One might defend the laws by pointing to the dramatic decline of children born with Down syndrome in Scandinavian countries.[185] Although not nearly so stark, the numbers in the United States are not insignificant.[186] Even so, prohibiting disclosure of prenatal information normally disclosed as part of the standard of care is not a useful way to address these behaviors. First, under the approach I advocate, the law would be subject to strict scrutiny because it would deviate from the standard of care. Second, far less intrusive and more effective measures exist. States could educate the public about Down syndrome (or other disabilities) or provide relevant information about the condition when prenatal testing identifies it.[187] Most important, they could offer adequate educational and other support for children with disabilities so that having such children would feel like a viable option to parents.

Nor do worries about the aggregate effect of embryo selection based on disease, sex, or other nonmedical traits support such bans. Given IVF's high cost, PGT is not likely to become widespread. And although wealthier people could more easily access PGT, potentially exacerbating social inequities, the physical burdens of egg retrieval would likely discourage many of them from using PGT, especially for minor diseases or mere traits. Indeed, polls suggest only a minority support embryo selection for purposes other than avoiding serious disease. Moreover, societal inequities due to wealth disparities may be more profound than those based on genetics. Studies have shown that household income is far more predictive of future success than genetics.[188] Thus, addressing income inequality through something like child tax credits would do far more to prevent exacerbation of inequities than banning information from PGT.[189]

For all these reasons, even if the state interests motivating such bans are deemed substantial, these potential laws would not advance those interests in a meaningful way. Because the laws would struggle under intermediate scrutiny, they would surely fail under strict scrutiny. As a starting point, the state interests are not compelling. Preserving fetal life only becomes compelling at viability,[190] but prenatal testing usually occurs before viability and PGT before a pregnancy is even established. Further, the Supreme Court has not expressly described a state interest in the social values and effects legislatures might point to, suggesting they too are not compelling. Finally, because the laws are not closely enough drawn to the state interests for intermediate scrutiny, they clearly are not narrowly tailored to those interests.

V. Conclusion

Given the increase in reason-based abortion bans, it seems entirely possible that some legislatures may restrict physicians from disclosing information obtained through prenatal testing and PGT based on concerns about

eugenics, disability rights, commodification, and equality. While cognizant of the First Amendment doctrinal morass regarding speech in health care, I nevertheless attempt to offer a consistent and coherent interpretation of *NIFLA* and *Casey.* Under that approach, such laws would violate the First Amendment.

I end by noting a few key issues left unexplored in this piece, given space constraints. First, should the law treat compelled speech differently from restricted speech? Courts rarely raise this issue and the "Supreme Court has been deliberately noncommittal"[191] about it, despite suggesting the distinction is not constitutionally significant.[192] Second, how should legislatures and courts grapple with the challenges and normative elements of drawing lines between medical and nonmedical conditions — a line that informs the analysis? Nor do I fully grapple with the political elements that may shape understandings of the standard of care or what constitutes a medical condition. Finally, I do not address the variations of intermediate scrutiny that courts have deployed. I hope to address these issues in a future project that will propose a theory of First Amendment analysis for speech regulations in health care generally and that avoids potential constitutional gerrymandering of the First Amendment.

Acknowledgements

Many thanks to Catherine Ross, Radhika Rao, Rachel Rebouché, Barbara Billauer, Doron Dorfman, as well as participants in the GW Law Symposium "First Amendment Values in Health Care" and the Virtual Health Law Workshop. I am also grateful to Alexandra Marshall and Heather Skrabak for their excellent research assistance.

Note

The author has no conflicts to disclose.

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17. Mehlman et al., supra note 15, at 170.
18. S.W. Choi, T.S.H. Mak, and P.F. O'Reilly, " Tutorial: A Guide to Performing Polygenic Risk Score Analyses," Nature Protocols 15, no. 9 (2020): 2759–2772.
19. " FAQ," Genomic Prediction, available at <https://www.lifeview.com/faq >(last visited July 28, 2021). Another company, Orchid, offers similar analysis before conception "to predict how a couple's combined genetics can influence their future child's genetic predisposition to common conditions" and to prepare them for. Orchid Guides, available at <https://guides.orchidhealth.com/post/what-genetic-risk-means-and-what-genetic-testing-can-tell-you >(last visited July 30, 2021).
20. A. Regalado, "The World's First Gattaca Baby Tests Are Finally Here," MIT Technology Review, November 8, 2019, available at <https://www.technologyreview.com/s/614690/polygenic-score-ivf-embryo-dna-tests-genomic-prediction-gattaca/ >(last visited July 29, 2021).
21. P. Sulem et al., " Genetic Determinants of Hair, Eye and Skin Pigmentation in Europeans," Nature Genetics 39 no. 12 (2007): 1443–1452.
22. " Choose Your Baby's Eye Color," The Fertility Institutes, available at <https://www.fertility-docs.com/programs-and-services/pgd-screening/choose-your-babys-eye-color.php >(last visited July 30, 2021). So far, the clinic only allows this testing in conjunction with screening for chromosomal aneuploidy and/or sex selection.
23. See H. Devlin, "IVF Couples Could Be Able to Choose the 'Smartest' Embryo," Guardian, May 24, 2019, available at <https://www.theguardian.com/society/2019/may/24/ivf-couples-could-be-able-to-choose-the-smartest-embryo >(last visited July 29, 2021).
24. See E. Karavani et al., " Screening Human Embryos for Polygenic Traits Has Limited Utility," Cell 179, no. 6 (2019): 1424–1435 at 1426-1428.
25. While some variants contribute as little as a millimeter of difference in height, others contribute as much as inch. See R. Harris, "Which Genes Make You Taller? A Whole Bunch of Them, It Turns Out," NPR, February 1, 2017, available at <https://www.npr.org/sections/health-shots/2017/02/01/512859830/which-genes-make-you-taller-a-whole-lot-it-turns-out >(last visited July 29, 2021).
26. Exome sequencing is related and involves sequencing of the parts of the genome that codes for proteins (the exons). Mehlman et al., supra note 15.
27. S.M. Suter, " Genomic Medicine — New Norms Regarding Genetic Information," Houston Journal of Health Law &Policy 15 (2015): 83–130.
28. See M. Saxton, " Disability Rights and Selective Abortion," in The Disability Studies Reader (Psychology Press 2006); S. Baruch et al., "Preimplantation Genetic Diagnosis: A Discussion of Challenges, Concerns, and Preliminary Policy Options Related to the Genetic Testing of Human Embryos," Genetics &Public Policy Center, January 2004, available at <https://jscholarship.library.jhu.edu/bitstream/handle/1774.2/978/PGDDiscussionChallengesConcerns.pdf?sequence=1&isAllowed=y >(last visited July 29, 2021); see also M. Leach, "People with Down Syndrome Are Not Costs to be Avoided Through Prenatal Testing," Down Syndrome Prenatal Testing, April 3, 2014, available at <http://www.downsyndromeprenataltesting.com/people-with-down-syndrome-are-not-costs-to-be-avoided-through-prenatal-testing/ >(last visited July 29, 2021); N.J. Williams, "Harms to 'Others' and the Selection Against Disability View," The Journal of Medicine and Philosophy: A Forum for Bioethics and Philosophy of Medicine 42 no. 2 (2017):

154-183; E. Parens and A. Asch, eds., “The Disability Rights Critique of Prenatal Genetic Testing: Reflections and Recommendations,” in Prenatal Testing and Disability Rights (Washington, DC: Georgetown University Press 2000); F.K. Boardman and R. Hale, “How Do Genetically Disabled Adults View Selective Reproduction? Impairment, Identity, and Genetic Screening,” Molecular Genetics &Genomic Medicine 6, no. 6 (2018): 941 - 956.
29. See F. Chao et al., “ Systematic Assessment of Sex Ratio at Birth for All Countries and Estimation of National Imbalances and Regional Reference Levels,” PNAS 116, no. 19 (2019): 9303–9311.
30. Ethics Committee of the American Society for Reproductive Medicine, “Use of Reproductive Technology for Sex Selection for Nonmedical Reasons,” Fertility and Sterility 103 no. 6 (2015): 1418–1422. See also R. Rebouché, “Testing Sex,” University of Richmond Law Review 519, no. 2 (2015): 519-577.
31. Id.
32. M. Sandel, “The Case Against Perfection,” Atlantic Monthly, April 1, 2004, available at <https://www.theatlantic.com/magazine/archive/2004/04/the-case-against-perfection/302927/ >(last visited July 31, 2021). See also J.L. Scully, S. Banks, and T.W. Shakespeare, “Chance, Choice and Control: Lay Debate on Prenatal Social Sex Selection,” Social Science &Medicine 63, no. 1 (2006): 21-31.
33. M. J. Mehlman, “ The Law of Above Averages: Leveling the New Genetic Enhancement Playing Field,” Iowa Law Review 85, no. 2 (2000): 517–593.
34. S.M. Suter, “ A Brave New World of Designer Babies? ” Berkeley Technology Law Journal 22, no. 2 (2007): 897–969.
35. See, e.g., R. Colker, “ Uninformed Consent,” Boston University Law Review 10, no. 2 (2021) 431–487.
36. See Miller and Berkman, supra note 12. A few states have enacted a related form of legislation that allows genetic counselors involved in prenatal testing “to omit discussion of abortion in options counseling.” R. Rebouché, “ Non-Invasive Testing, Non-Invasive Counseling,” Journal of Law, Medicine &Ethics 43, no. 2 (2015): 228–240, at 233.
37. Mehlman et al., supra note 15 at 209.
38. W.D. Winkelman et al., “ Public Perspectives on the Use of Preimplantation Genetic Diagnosis,” Journal of Assisted Reproduction and Genetics 32, no. 5 (2015): 665–675, at 667-68.
39. It has examined the regulation of the speech of other professionals to some extent, however. See Lowe v. SEC, 477 U.S. 181 (1985) (examining whether the SEC could bar an unregistered investment adviser from publishing general investment advice and commentary in a newsletter); see also Gentile v. State Bar of Nevada, 501 U.S. 1030 (1991) (examining judicially imposed limits on attorney speech in Nevada).
40. 500 U.S. 173 (1991).
41. Id. at 192-93 (quoting Maher v. Roe, 432 Us 464, 474 (1977)).
42. Id. at 194.
43. Id. at 196 (distinguishing cases, like Federal Communications Commission v. League of Women Voters of California, 468 U.S. 364 (1984), where “a recipient of federal funds was ‘barred absolutely from all editorializing’ because it ‘is not able to segregate its activities according to the source of its fund’”).
44. Id. at 200.
45. Id.
46. Id.
47. 505 U.S. 833 (1992) (plurality opinion).
48. Id. at 882.
49. Id. at 884.
50. Id.
51. S.M. Suter, “ The First Amendment and Physician Speech in Reproductive Decision Making,” Journal of Law Medicine &Ethics 43, no. 1 (2015): 22–34 at 24.
52. See C.H. Coleman, “ Regulating Physician Speech,” North Carolina Law Review 97, no. 4 (2019): 843–898, at 852 (“The most that can be said about Casey is that the plurality was clearly not applying strict scrutiny in its First

Amendment analysis as it made no effort to determine whether the statute was 'narrowly tailored' or based on a 'compelling state interest.'"); B. Jessie Hill, "Sex, Lies, and Ultrasound," University of Colorado Law Review 89 (2018): 421-452; S.W. Gaylord, "A Matter of Context: Casey and the Constitutionality of Compelled Physicians Speech," Journal of Law Medicine &Ethics 43, no. 1 (2015): 35-50 at 36; Tex. Med. Providers Performing Abortion Servs. v. Lakey, 667 F.3d 570 (5th Cir. 2012).
53. Suter, supra note 51; Stuart v. Camnitz, 774 F. 3d 238, 248-49 (4th Cir. 2014); M. Dunlap, " Challenging Abortion Informed Consent Regulations through the First Amendment: The Case for Protecting Physicians' Speech," University of Chicago Legal Forum, 2019 (2019): 443–471.
54. 138 S. Ct. 2361 (2018).
55. Cal. Health &Safety Code Ann. § 123472(a)(1). It also required unlicensed clinics to provide notices stating they are "not licensed as a medical facility." Id. at § 123472(b)(1).
56. Nat'l Inst. of Family Life &Life Advocates v. Harr is, 839 F.3d 823, 845 (9th Cir. 2016).
57. Id. at 833-842. It also found that the unlicensed notice would survive any level of scrutiny. Id. at 843-844.
58. 138 S. Ct. at 2368.
59. Id. at 2371.
60. Id. at 2371-2372.
61. Id. at 2372.
62. Id.
63. Id. (emphasis added).
64. Id. at 2373.
65. Id. at 2373.
66. Id. at 2385 (Breyer, J., dissenting).
67. Id. at 2386.
68. Id. at 2388.
69. 471 U.S. 626, 651 (1985).
70. 138 S. Ct at 2372. Some scholars question the characterization of speech in Zauderer as professional speech, arguing that " Zauderer … involved speech directed to prospective clients as opposed to speech occurring within an established professional relationship." L. Noah, "Censorship Is So Last Century: Therapeutic Products, Propaganda, and Compelled Speech," St. Louis University Law Journal 66 (forthcoming 2021), at 7 n.32.
71. Id. at 638.
72. 138 S. Ct at 2372 (citing to Zauderer, 471 U.S. at 651) (emphasis added).
73. Id. at 2372. In addition, it found that the notice requirements concerned information that "in no way related to the services that licensed clinics provide" because it concerned services sponsored by the state. Id.
74. Id. at 2374 (quoting Sorrell, supra at 566).
75. Id.
76. Id. (internal citations omitted).
77. EMW Women's Surgical Ctr., P.S.C. v. Beshear, 920 F.3d 421, 453 (6th Cir. 2019) (Donald, J., dissenting) (quoting NIFLA, 138 S. Ct at 2374) (citations omitted)).
78. 138 S. Ct at 2375.
79. Miller and Berkman, supra note 12, at 645.
80. See Harris, 839 F.3d at 838-39 (2016); see also King v. Governors of N.J., 767 F.3d 216, 232 (3d Cir. 2014); Pickup v. Brown, 740 F.3d 1208, 1227-29 (9th Cir. 2014); Moore-King v. County of Chesterfield, 708 F.3d 560, 568-570 (4th Cir. 2014); see also D. Halberstam, " Commercial Speech, Professional Speech, and the Constitutional Status of Social Institutions, " University of Pennsylvania Law Review 147, no. 4 (1999): 771–874 at 843; R. Post, "Informed Consent to Abortion: A First Amendment Analysis of Compelled Physician Speech," University of Illinois Law Review 2007, no. 3 (2007): 939-990 at 947; M. Swartz, "Physician-Patient Communication and the First Amendment After Sorrell," Michigan State University Journal of Medicine and Law 17, no. 2 (2012): 101–140 at 110;

C.E. Haupt, “Professional Speech,” Yale Law Journal 125, no. 5 (2016): 1238-1303.
81. 309 F.3d 629 (9th Cir. 2002).
82. 740 F. 3d 1208 (9th Cir. 2014).
83. Id. at 1227.
84. Id. at 1230-31.
85. 767 F. 3d 216 (3d Cir. 2014).
86. Id. at 225-26.
87. Id. at 229.
88. Id. at 232-234.
89. Id. at 236.
90. Id. at 238.
91. Fla. Stat. Ann. §§ 381.026, 456.072, 790.338.
92. Wollschlaeger v. Governor of Fla., 760 F.3d 1195 (11th Cir. 2014), vacated on reh’g. 797 F.3d 859 (11th Cir. 2015) (reversing the lower court’s use of heightened scrutiny to enjoin the statute on the grounds that the law regulated conduct and therefore did not implicate the First Amendment); Wollschlaeger v. Governor of Fla., 797 F.3d 859 (11th Cir.), vacated on reh’g, 814 F.3d 1159 (11th Cir. 2015) (finding that the law did in fact regulate speech and therefore was subject to First Amendment analysis, but because the law regulated speech within a fiduciary relationship, intermediate scrutiny applied); Wollschlaeger v. Governor of Fla., 814 F.3d 1159, 1186 (11th Cir. 2015), aff’d in part and rev’d in part en banc, 848 F.3d 1293 (11th Cir. 2017) (hinting that strict scrutiny might apply to all content-based restrictions on speech, but avoiding the “difficult question” as to whether strict scrutiny was appropriate, because the law survived strict scrutiny, and therefore would survive “any less demanding level of scrutiny”).
93. Wollschlaeger v. Governor of Fla., 848 F.3d 1293 (11th Cir. 2017) (en banc).
94. Id. at 1316. It didn’t decide whether strict scrutiny applied finding the law failed intermediate scrutiny. Id. at 1311.
95. 981 F. 3d 854 (11th Cir. 2020).
96. Id. at 865 (“‘States may regulate professional conduct, even though that conduct incidentally involves speech.’”).
97. Id.
98. Id. at 863.
99. Id. at 861 (quoting NIFLA v. Becerra, 138 S. Ct. 2361, 2374 (2014)).
100. Id. at 867 (quoting NIFLA v. Becerra, 138 S. Ct. 2361. 2374 (2018)); id. at 866 (Wollschlaeger “already rejected the suggestion that government’s ability to regulate entry into a profession entitles it to regulate the speech of professionals”).
101. Id. at 868.
102. Id. at 869 (concluding that an American Psychological Association report found “’no clear indication of the prevalence of harmful outcomes among people who have undergone’” SOCE).
103. Id. at 871.
104. Id. at 878.
105. Id. at 880, n.1 (Martin, J, dissenting).
106. 667 F.3d 570, 578-79 (5th Cir. 2012) (describing the mandated message as the “epitome of truthful”).
107. 774 F.3d 238 (4th Cir. 2014).
108. Id. at 246.
109. Id. at 242.
110. Id. at 246.
111. Id. See also id. at 255 (describing the patient’s vulnerable posture in finding herself “half-naked or disrobed on her back on an examination table, with an ultrasound probe either on her belly or inserted into her vagina”).
112. Id. at 251-253.
113. 920 F.3d 421 (6th Cir. 2019).

114. Id. at 429.
115. Id. at 436.
116. Id. at 435.
117. Id. at 436-37.
118. 550 U.S. 124 (2007).
119. Beshear, 920 F.3d at 438 (The Court upheld the statute in Casey despite the lower court's finding that the informed consent requirements "'represent a substantial departure from the ordinary medical requirements of informed consent'" and Gonzales upheld a ban on a late-term abortion procedure despite the lower court's finding that "the law was contrary to certain medical-profession views").
120. Id. at 432.
121. Id. at 439.
122. Id. at 444.
123. Id. at 450 (quoting Planned Parenthood of Southeastern Penn. v. Casey, 505 U.S. 833, 884 (1992)) (emphasis added).
124. Id. at 453.
125. Id. at 456.
126. It noted the lack of evidence that the mandate accords with "the medically-accepted standard of care," id. at 459, or benefits the informed consent process, id. at 458.
127. Id. at 460.
128. Id. at 453 (citing NIFLA v. Becerra, 138 S. Ct. 2361, 2376 (2018)).
129. P. Berg, " Toward a First Amendment Theory of Doctor-Patient Discourse and the Right to Receive Unbiased Medical Advice," Boston University Law Review 74, no. 2 (1994): 201–266, at 201, 235; M. Swartz, "Physician-Patient Communication and the First Amendment After Sorrell," Michigan State University Journal of Medicine &Law 17, no. 1 (2012): 101-126, at 101, 107; P. Sherman, Commentary, "Occupational Speech and the First Amendment," Harvard Law Review Forum 128 (2015): 183-205, at 183, 199, available at <http://harvardlawreview.org/wp-content/uploads/2015/03/vol128_Sherman.pdf >(last visited July 28, 2021).
130. NIFLA, 138 S. Ct. at 2374 (citing Berg, supra note 129, at 201-02).
131. C.E. Haupt, " Unprofessional Advice," University of Pennsylvania Journal of Constitutional Law 19, no. 3 (2017): 671–729, at 671, 675 (2017). She also argues that because the professional community should decide "what is good professional advice," the "further state regulation diverges from professional consensus … the more skeptical courts ought to be." C.E. Haupt, "Professional Speech and the Content-Neutrality Trap," Yale Law Journal Forum 127 (2017): 150-172, at 150, 167, available at <https://www.yalelawjournal.org/pdf/Haupt_xv7cdx9m.pdf >(last visited July 28. 2021).
132. Post, supra note 80, at 957. See also D. Orentlicher, " Abortion and Compelled Physician Speech," Journal of Law, Medicine &Ethics 43, no. 1 (2015): 9–21, at 9, 13; J.L. Dolgin, "Physician Speech and State Control: Furthering Partisan Interests at the Expense of Good Health," New England Law Review 48, no. 2 (2014): 293-342, at 293, 342; Suter, supra note 51.
133. T. Zick, " Professional Rights Speech," Arizona State Law Journal 47, no. 4 (2015): 1290–1360, at 1289, 1294, 1327-29, 1359.
134. Suter, supra note 51, at 22; See also Post, supra note 80, at 978.
135 Coleman, supra note 53, at 88.
136. Id. at 884.
137. Id. at 872.
138. Id. at 892.
139. Id. at 887.
140. Id. at 889-890.
141. Miller and Berkman, supra note 12, at 652.

142. Id. at 654.
143. Id. at 654.
144. I have argued similarly. Suter, supra note 51.
145. C.E. Haupt, “The Limits of Professional Speech,” Yale Law Journal Forum, September 5, 2018, available at <https://www.yalelawjournal.org/pdf/Haupt_e652yj62.pdf >(last visited August 1, 2021). See also Noah, supra note 70, at 6-7.
146. See supra text accompanying notes 77-80.
147. Otto, 981 F.3d at 861.
148. E. Chemerinsky and M. Goodwin, “ Constitutional Gerrymandering Against Abortion Rights: NIFLA v. Becerra,” New York University Law Review 94, no. 1 (2019): 61–124.
149. Id. at 111.
150. Miller and Berkman, supra note 12, at 652.
151. Suter, supra note 51, at 26.
152. Coleman, supra note 52, at 887.
153. See supra text accompanying notes 96-103.
154. See supra text accompanying notes 113-119.
155. Miller and Berkman, supra note 12.
156. 138 S. Ct at 2373.
157. Id. at 2386 (Breyer, J., dissenting).
158. Beshear, 920 F.3d at, 447 (Donald, J., dissenting) (quoting NIFLA, 138 S. Ct. at 2373)).
159. Otto, 981 F.3d at 880, n.1 (Martin, J., dissenting) (quoting Beshear, 920 F.3d at 447 (Donald, J., dissenting) (citing NIFLA, 138 S. Ct. at 2372)).
160. Beshear, 920 F.3d at 447 (Donald, J., dissenting).
161. Id. at 460.
162. Otto, 981 F.3d at 874 (Martin, J., dissenting).
163. Casey, 505 U.S. at 882-83 (comparing the requirement that women seeking abortion be informed of “the availability of materials relating to the consequences to the fetus, even when those consequences have no direct relation to her health,” with requiring the recipient of a kidney transplant operation to “be supplied with information about risks to the donor as well as risks to himself or herself”).
164. Coleman, supra note 52.
165. See Mehlman et al., supra note 15, at 172-82.
166. I concede that the between medical and nonmedical information is decidedly blurry, an issue I save for future work.
167. The exception would be in cases where there is a family history of sex-linked diseases.
168. While termination of pregnancies in many countries are not uncommon because of sex, usually female sex, most people in the United States have preferences for family balancing, not because one sex is deemed superior to another. See Guttmacher, supra note 10.
169. One survey found that 59% of ART clinics offer sex selection through PGT for any non-specific elective reason to infertile couples (81.2% of the 72.7% that offer sex selection) and 54% to couples without infertility (74.6% of 72.7%). See S.M. Capelouto et al., “ Sex Selection for Non-Medical Indications: A Survey of Current Pre-Implantation Genetic Screening Practices Among U.S. ART Clinics,” Journal of Assisted Reproduction and Genetics 35, no. 3 (2018): 409–416.
170. See supra text accompanying notes 22-23.
171. The Ethics Committee of the American Society for Reproductive Medicine “does not have a consensus on the Permissibility” of nonmedical sex selection selection. See Ethics Committee, supra note 30. In contrast, the American College of Obstetricians and Gynecologists Committee on Ethics “opposes all forms of sex selection not related to the diagnosis of sex-linked conditions.” American College of Obstetricians and Gynecologists, “ACOG

Committee Opinion No. 410: Ethical Issues in Genetic Testing," Obstetrics &Gynecology 111, no. 6 (2008): 1495-1502.
172. See R.L. Weaver and D.E. Lively, Understanding the First Amendment (2d ed. LexisNexis, 2003): at 14 (describing potentially different calibrations of intermediate levels of scrutiny with a balancing of "the competing constitutional and regulatory interests").
173. Sorrell v. IMS Health Inc., 564 U.S. 552, 572 (2011).
174. See McCutcheon v. Federal Election Comm'n, 572 U.S. 185, 218 (2014).
175. Gonzales v. Carhart, 550 U.S. 124, 145 (2007).
176. Id. at 145 (noting it is a "legitimate and substantial interest").
177. Casey, 505 U.S. at 834.
178. S.M. Suter, " The 'Repugnance' Lens of Gonzales v. Carhart and Other Theories of Reproductive Rights: Evaluating Advanced Reproductive Technologies," George Washington Law Review 76, no. 6 (2008): 1514–1598, at 1580-1583; D. Fox, "Interest Creep," George Washington Law Review 82, no. 2 (2014): 273-357, at 303-312, (describing such concerns as a state interest in social values).
179. Supra text accompanying note 11.
180. Supra text accompanying note 27.
181. Supra text accompanying note 33.
182. Supra text accompanying note 32.
183. Suter, supra note 14.
184. Id.
185. W. Christian, "Down Syndrome Heading for Extinction in Denmark," CPH Postonline, Oct. 20, 2015, available at <http://cphpost.dk/?p=30968#:~:text=The%20number%20of%20children%20born,the%20past%20in%2030%20years >(finding that, in Denmark, 98% of pregnant women found to be carrying an unborn child with Down syndrome terminated their pregnancy); D. McLean, "Iceland Close to Becoming First Country Where No Down's Syndrome Children Are Born," Independent, Aug. 16, 2017, available at <https://www.independent.co.uk/life-style/health-and-families/iceland-downs-syndrome-no-children-born-first-country-world-screening-a7895996.html >(reporting that "just one or two children with Down's syndrome are born in Iceland each year," sometimes because of inaccurate test results, and stating that 85% of pregnant women in Iceland were undergoing prenatal testing or screening and most terminated pregnancies positive for Down syndrome).
186. G. de Graaf et al., " Estimation of Live Birth and Population Prevalence of Down Syndrome in Nine U.S. States," American Journal of Medical Genetics 173, no. 10 (2017): 2710–2719 (finding that selective termination reduced the number of children born with Down syndrome by 39% overall in nine states, but that because people with Down syndrome now live longer than ever. There is currently a plateau in population levels of individuals with trisomy 21).
187. There has been some legislation at the state and federal level "to ensure that prospective parents receive balanced information about … conditions identified in the fetus." Mehlman et al., supra note 15, at 168.
188. A.V. Dam, "It is Better to Be Born Rich than Gifted," Washington Post, Oct. 9, 2018, available at <https://www.washingtonpost.com/business/2018/10/09/its-better-be-born-rich-than-talented/ >(last visited July 31, 2021).
189. C. Pulliam and R.V. Reeves, "New Child Tax Credit Could Slash Poverty Now and Boost Social Mobility Later," Brookings, March 11, 2011, available at <https://www.brookings.edu/blog/up-front/2021/03/11/new-child-tax-credit-could-slash-poverty-now-and-boost-social-mobility-later/ >(last viewed July 31, 2021).
190. Dobbs v. Jackson Women's Health Organization, 141 S. Ct. 2619 (2021). The Supreme Court granted Mississippi's petition for certiorari, after its 15-week ban of abortions was deemed unconstitutional by the lower courts for violating well-established precedent. The Supreme Court's willingness to address the question as to whether a 15-week abortion ban may sometimes be constitutional suggests this line is on shaky ground.
191. Post, supra note 80, at 980.

192. * Riley v. Nat'l Fed'n of the Blind of N. Carolina, Inc., 487 U.S. 781, 796 (1988) ("There is certainly some difference between compelled speech and compelled silence, but in the context of protected speech, the difference is without constitutional significance."). Some courts have found that regulations that compel commercial speech "'tend[] to [be] less objectionable under the First Amendment'" than regulations that prohibit such speech. Post, supra note 80, at 980 (quoting Walker v. Bd of Prof'l Responsibility of the Supreme Court of Tenn., 38 S.W.3d 540, 545 (Tenn. 2001)). "[O]thers believe the reverse." Id. at 980-981.

DETAIL

Subjek:	Reproductive rights; Supreme courts; In vitro fertilization; Speech; Jurisprudence; Genomes; Reproductive technologies; First Amendment-US; State laws; Legislation; Fetuses; Genetic testing; Embryos; Bans; Redistricting; Genetic engineering; Cardiovascular disease; Fertility; Down syndrome; Patients; Abortion; Federal court decisions; Amniocentesis; Equal rights
Pengidentifikasi/kata kunci:	First Amendment; Abortion; Speech; Reproduction; Health care; Reproductive technology; Free; Freedom of speech; Prenatal Testing; Preimplantation Genetic Testing; Abortion; Reproductive Rights
Judul:	Reproductive Technologies and Free Speech
Pengarang:	Suter, Sonia M
Judul publikasi:	The Journal of Law, Medicine &Ethics; Boston
Volume:	49
Edisi:	4
Detail sumber:	First Amendment Values in Health Care
Halaman:	514-530
Tahun publikasi:	2021
Tanggal publikasi:	Winter 2021
Bagian:	Symposium Articles
Penerbit:	Cambridge University Press
Tempat publikasi:	Boston
Negara publikasi:	United Kingdom, Boston
Subjek publikasi:	Law, Medical Sciences
ISSN:	10731105

e-ISSN:	1748720X
Jenis sumber:	Jurnal Akademik
Bahasa publikasi:	Eng lish
Jenis dokumen:	Journal Article
DOI:	https://doi.org/10.1017/jme.2021.76
ID dokumen ProQuest:	2730847553
URL Dokumen:	https://www.proquest.com/scholarly-journals/reproductive-technologies-free-speech/docview/2730847553/se-2?accountid=211160

Terakhir diperbarui:	2023-11-27
Basis data:	Public Health Database

Mandates for Shared Decisions: Means to which Ends?

Kramer, Daniel B

ABSTRAK (ENGLISH)

Carefully aligning invasive cardiovascular therapies to patients' health care goals appeals to every stakeholder involved in treatment decisions.1 Patients should only pursue procedures intended to promote outcomes they value balanced against risks they consider acceptable. Physicians performing procedures and payers providing reimbursement similarly ought to favor matching expensive devices with patients most likely to benefit according to patient-centered preferences for extended survival, improved quality of life, or both. Cardiac electrophysiology therapies including implantable cardioverter-defibrillator (ICD) insertion highlight these shared goals in stark terms: Treatment is designed only to extend survival, without improving quality of life; includes small but important risks for implantation and long-term therapy; and only provides clinically significant benefits to a subset of device recipients.2 ICD implantation would thus seem an ideal environment for formally implementing shared decision-making (SDM) to ensure that patients are well-informed not just on acute procedural considerations, but the overall place of ICD implantation within their health care.3

In this issue of *JLME*, Rao and colleagues explore implications of the controversial 2018 Centers for Medicare and Medicaid Services (CMS) final memo updating national coverage determination conditions for ICD implantation.4 CMS issued its first national coverage determination for ICDs in 1986 and has updated it periodically as new evidence and technology emerged, most recently in 2005 with expansion of primary prevention implantation to include most patients with systolic heart failure. The 2018 updated memo (which CMS curiously called "relatively minimal") included a controversial requirement for a SDM encounter using an "evidence-based decision aid" prior to

primary prevention ICD implantation for heart failure patients.5 As Rao et al observe, formally mandating SDM in a legally-binding, nationwide requirement adding logistical and practical complexity to a common, costly procedure demands a clear understanding of what CMS hoped to accomplish in doing so. It is critical to note that CMS coverage determinations have real teeth: In 2015, nearly 500 hospitals paid >$250 million over False Claims Act allegations brought by the Department of Justice related to ICD implantation outside of coverage requirements.6

TEKS LENGKAP

Carefully aligning invasive cardiovascular therapies to patients' health care goals appeals to every stakeholder involved in treatment decisions.[1] Patients should only pursue procedures intended to promote outcomes they value balanced against risks they consider acceptable. Physicians performing procedures and payers providing reimbursement similarly ought to favor matching expensive devices with patients most likely to benefit according to patient-centered preferences for extended survival, improved quality of life, or both. Cardiac electrophysiology therapies including implantable cardioverter-defibrillator (ICD) insertion highlight these shared goals in stark terms: Treatment is designed only to extend survival, without improving quality of life; includes small but important risks for implantation and long-term therapy; and only provides clinically significant benefits to a subset of device recipients.[2] ICD implantation would thus seem an ideal environment for formally implementing shared decision-making (SDM) to ensure that patients are well-informed not just on acute procedural considerations, but the overall place of ICD implantation within their health care.[3]

In this issue of *JLME*, Rao and colleagues explore implications of the controversial 2018 Centers for Medicare and Medicaid Services (CMS) final memo updating national coverage determination conditions for ICD implantation.[4] CMS issued its first national coverage determination for ICDs in 1986 and has updated it periodically as new evidence and technology emerged, most recently in 2005 with expansion of primary prevention implantation to include most patients with systolic heart failure. The 2018 updated memo (which CMS curiously called "relatively minimal") included a controversial requirement for a SDM encounter using an "evidence-based decision aid" prior to primary prevention ICD implantation for heart failure patients.[5] As Rao et al observe, formally mandating SDM in a legally-binding, nationwide requirement adding logistical and practical complexity to a common, costly procedure demands a clear understanding of what CMS hoped to accomplish in doing so. It is critical to note that CMS coverage determinations have real teeth: In 2015, nearly 500 hospitals paid >$250 million over False Claims Act allegations brought by the Department of Justice related to ICD implantation outside of coverage requirements.[6]

Rao et al suggest 3 potential overlapping goals of SDM requirements, briefly summarized here as improving knowledge and engagement; improving alignment of values with actual treatment choices; and improved utilization, understood either as reduced variability in care, reduced overall use, or improved clinical outcomes in the eligible population. Disambiguating these goals is essential, they correctly argue, because the metrics for assessing the impact of SDM on each varies widely and potentially conflict with each other. For example, if selected groups of older ICD-eligible patients decline ICD implantation based on their values, this may improve value-choice concordance while potentially worsening overall survival for that same group of patients. Their case study in SDM use and careful dissection of potential CMS objectives also illustrates that apparently simple changes in implementation may impact selected outcomes (such as knowledge) differentially, whereas other potential goals seem poorly advanced by any known approach to SDM for ICDs. Their summary question — is this mandate worthwhile? — thus lingers uncomfortably.

What *did* CMS intend with this requirement, and does the SDM mandate actually meet its own goals in a measurable way? Defending the SDM requirement explicitly in response to submitted public comments, CMS observes: "We believe that an SDM encounter … is a critical step in empowering patient choice in their treatment plan. While ICDs have remained a common treatment option for many years, the strength of evidence for an ICD benefit is different for different patient populations … We want to ensure that the patient receives more information than the risks and benefits of the procedure."[7] Rao et al suggest, though, that the SDM requirement at best only addresses the last observation — improving patients' understanding — while leaving the treatment heterogeneity

and overall survival benefits among eligible patients completely unexplored.

In this issue of *JLME*, Rao and colleagues explore implications of the controversial 2018 Centers for Medicare and Medicaid Services (CMS) final memo updating national coverage determination conditions for ICD implantation.

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The CMS memo summarizes primary data calling into question the clinical benefits of ICDs under conditions that are currently within covered circumstances. For example, the added benefits of ICD back-up to cardiac resynchronization therapy,[8] or in patients with non-infarct cardiomyopathy,[9] appears increasingly narrow based on accumulated observational studies and randomized trials. Routine ICD replacement at the end of expected battery life also provides uncertain benefits to many patients, particularly those whose left ventricular systolic function has recovered and those who have not previously received an ICD shock.[10] Secondary prevention ICD implantation — device insertion following a cardiac arrest for non-reversible causes — also has not been evaluated in a randomized trial for 25 years despite advances in diagnostics, medical therapy, and resuscitation. As the memo notes, even within the boundaries of the Class IA recommendations for primary prevention ICDs, substantial treatment heterogeneity exists that might improve device utilization and patient selection with better prospective data to guide decisions.[11]

Yet CMS ultimately dodges responsibility for developing these data: “While we encourage such research on risk stratification to continue, we acknowledge that other agencies are better equipped and have clearer authority to take the lead in vetting and supporting such a large and varied research portfolio, some of which is in earlier discovery and testing phases.”[12]

In taking this stance, CMS undersells its potential influence with an overly narrow reading of its regulatory mandate. CMS retains substantial discretion in characterizing services as reasonable and necessary for its beneficiaries, particularly in regards to extrapolating data from randomized trials to real-world cohorts that tend to be older and sicker than those in pivotal studies.[13] Every *month*, it is likely that more CMS beneficiaries receive ICDs than in all of the randomized trials evaluating their effectiveness combined. (The 2 pivotal trials on which most primary prevention ICD implantations are based randomized only 3753 patients combined, only 1571 of whom received an ICD.[14]) CMS has ample authority and discretion to require the exact evidence generation it deems currently lacking to clearly demonstrate meaningful benefits to its own beneficiaries. For example, the coverage with evidence development pathway allows CMS to require all device recipients to participate in a study approved by CMS as a condition of reimbursement.[15] A previously required study focused more narrowly on procedural complications and straightforward descriptive outcomes was included in the 2005 coverage memo; the ICD registry enrolled over 1 million patients over its nearly 15 year history.[16] In other contexts, including selected cardiac devices, CMS has engaged with manufacturers as well as the Food and Drug Administration to ensure that clinical trials performed for marketing authority also meet evidentiary standards for CMS coverage.[17]

As the largest payer for ICDs in the United States, CMS could take the stance — entirely defensible based on accrued evidence — that a new randomized trial was required for even a subset of its beneficiaries prior to ICD implantation either for initial primary prevention placement, routine replacement, or even secondary prevention. Indeed, European regulators are supporting design and implementation of 2 prospective clinical trials of ICD explicitly targeting treatment heterogeneity among patients to identify those at greatest likelihood of benefit.[18] CMS might have declared restrictions on coverage, with or without a specific requirement to enroll in a prospective study, around patients with plausible equipoise around the benefits of ICDs, prompting immediate scientific engagement from researchers, industry, and potential payers (including CMS itself). If CMS’ goal is to “empower patients” and provide data beyond simple procedural risks, requiring SDM even with the best available tools will necessarily fall short without better evidence on which to base shared decisions.

Note

Dr. Kramer is supported by NIH grants R01HL136403 and R01AG068141.

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DETAIL

Subjek:	Reimbursement; Medicaid fraud; Heart failure; Hospitals; Medicare; Patients; Quality of life; Prevention; Decision making; Empowerment; Clinical trials; Medicaid; Health services; Medical treatment; Patient-centered care
Ketentuan indeks bisnis:	Subjek: Medicaid fraud Medicare
Lokasi:	United States--US
Perusahaan / organisasi:	Nama: Centers for Medicare &Medicaid Services; NAICS: 923120; Nama: Department of Justice; NAICS: 922130
Pengidentifikasi/kata kunci:	Implantable Cardioverter-Defibrillators; Shared Decision-Making; Informed Consent; Cardiology; Health Policy
Judul:	Mandates for Shared Decisions: Means to which Ends?
Pengarang:	Kramer, Daniel B
Judul publikasi:	The Journal of Law, Medicine &Ethics; Boston
Volume:	49
Edisi:	4
Detail sumber:	First Amendment Values in Health Care

Halaman:	630-632
Tahun publikasi:	2021
Tanggal publikasi:	Winter 2021
Bagian:	Independent Articles: Commentary
Penerbit:	Cambridge University Press
Tempat publikasi:	Boston
Negara publikasi:	United Kingdom, Boston
Subjek publikasi:	Law, Medical Sciences
ISSN:	10731105
e-ISSN:	1748720X
Jenis sumber:	Jurnal Akademik
Bahasa publikasi:	English
Jenis dokumen:	Commentar y
DOI:	https://doi.org/10.1017/jme.2021.86
ID dokumen ProQuest:	2730847528
URL Dokumen:	https://www.proquest.com/scholarly-journals/mandates-shared-decisions-means-which-ends/docview/2730847528/se-2?accountid=211160
Hak cipta:	© 2021 The Author(s)
Terakhir diperbarui:	2023-03-20
Basis data:	Public Health Database

Promoting Competition in Drug Pricing: A Review of Recent Congressional Legislation

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ABSTRAK (ENGLISH)

Brand-name prescription drug manufacturers use various strategies to extend their market exclusivity periods by delaying generic or biosimilar competition. Recent Congressional legislation has targeted four such tactics. We analyze these proposals and assess their likely effect on competition in the U.S. drug market.

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Drug prices for brand-name medications in the U.S. are substantially higher than in comparable industrialized nations.[1] Spending on brand-name drugs also accounts for a majority of total American drug spending.[2] High prices are facilitated by market exclusivity periods that begin after FDA approval, during which time patents and other statutory protections shield the approved drug from direct competition.[3] Prices only predictably fall after the end of the market exclusivity period and the entry of competitor generic or biosimilar drugs.[4]

Delays to generic or biosimilar entry have therefore been very profitable to drug manufacturers. Examples of strategies brand-name manufacturers have used or tried to use in recent years to block generic entry include obtaining dozens of patents protecting their drug product and transferring the patent rights to a Native American tribe to undermine patent challenges.[5] In October 2021, the U.S. House of Representatives evaluated some new pieces of legislation seeking to address four competition-delaying tactics: reverse payment settlements, product hopping, sham petitions, and the patent dance. In this article, we explain how these tactics work, review the design of the legislative proposals seeking to address these practices, and assess the likelihood that these proposals, if enacted, would effectively promote timely competition in the US drug market.

Product Hopping

Product hopping refers to the practice in which brand-name drug manufacturers switch from selling an established version of their drug to a new formulation that has existing patents or other market exclusivities.[6] Product hopping is often timed strategically to occur in the year or two before generics are about to enter so that the brand-name manufacturer can retain a revenue stream from a subset of patients. It is most problematic when the new formulation offers no effectiveness or safety advantages over the original version.

A classic example of product hopping was the introduction of proton-pump inhibitor esomeprazole (Nexium) by AstraZeneca as the market exclusivity for its original blockbuster “purple pill” proton-pump inhibitor omeprazole (Prilosec) was ending.[7] Esomeprazole was the single-enantiomer formulation of the racemic omeprazole, and it had no clinical benefits at equivalent doses. A more recent example involved the opioid use disorder (OUD) drug buprenorphine/naloxone (Suboxone), in which the drug’s manufacturer, Reckitt Benckiser, introduced a sublingual film as the exclusivity on the original tablet formulation of the drug was expiring.[8] Reckitt Benckiser then began publicizing the possibility of safety concerns about the original tablet formulation to promote sales of the follow-on product.[9]

Product-hopping can involve a “hard switch” in which a manufacturer discontinues the original drug in favor of the follow-on product or a “soft switch” in which both drugs remain on the market, but only the follow-on drug is marketed.[10] An example of an attempted hard switch occurred with the Alzheimer’s drug memantine (Namenda), a twice-daily formulation, in which the drug’s manufacturer, Forest Laboratories, attempted to discontinue the sale of memantine at the end of its market exclusivity period in favor of memantine XR, a once-daily formulation.[11] Memantine XR had no clinical benefits (other than convenience) over memantine, but the follow-on product had about a decade of additional market exclusivity left after the original memantine’s exclusivity expired.[12] The case of esomeprazole and omeprazole is an example of a soft switch, as, unlike memantine, omeprazole remained on the market even after it lost market exclusivity, but AstraZeneca stopped advertising the original prescription formulation of omeprazole and instead promoted the follow-on esomeprazole as “the new purple pill.”[13]

H.R. 2873, the Affordable Prescriptions for Patients Through Promoting Competition Act of 2021, was introduced by Rep. David Cicilline (D-RI) to address product hopping. The bill classifies both hard switch and soft switch product hopping as potentially illegal anticompetitive behavior and permits the Federal Trade Commission (FTC) to initiate litigation or impose administrative penalties on manufacturers engaging in illegal product-hopping. The bill specifies

that switches for certain clearly legitimate reasons like safety or supply are exempted from being classified as product hopping.[14]

Sham Citizen Petitions

The FDA permits American consumers to file so-called citizen petitions to request changes to health care regulations.[15] Brand-name drug manufacturers, however, have been found to frequently use this pathway to petition for delayed entry of generic medications, claiming that the generic is non-substitutable or even dangerous.[16] While some of these petitions express legitimate concerns, so-called sham petitions allege without reasonable scientific basis that generic medications are unsafe and require further testing.[17] From 2011-2015, 124 citizen petitions relating to generic applications were filed, with 87% arising from brand-name manufacturers (92% were ultimately denied).[18] Their adjudication can cause substantial delays to generic approval (of up to 150 days per petition, according to one report), and thus petitions extend market exclusivity for high-priced brand-name drugs.[19]

The FDA permits American consumers to file so-called citizen petitions to request changes to health care regulations. Brand-name drug manufacturers, however, have been found to frequently use this pathway to petition for delayed entry of generic medications, claiming that the generic is non-substitutable or even dangerous. While some of these petitions express legitimate concerns, so-called sham petitions allege without reasonable scientific basis that generic medications are unsafe and require further testing.

One prominent example of a questionable citizen petition involves the brand-name opioid use disorder (OUD) drug buprenorphine (Subutex).[20] When buprenorphine's market exclusivity was close to expiring, the drug's manufacturer, Reckitt Benckiser, filed citizen petitions requesting the FDA take action and block the sale of generic buprenorphine.[21] The petition was filed on the grounds that the generic drug's packaging was not as child-safe as the packing of the reference product.[22] The FDA denied the petition, but the adjudication process delayed the market entry of generic buprenorphine. Other examples of potentially problematic petitions include one filed by Mutual Pharmaceuticals to delay the entry of generic competitors to their blood pressure medication felodipine (Plendil), in which Mutual alleged that the generic competitor drug negatively impacted a patient's ability to digest a certain variety of orange juice.[23] This petition was also denied by the FDA, but only after delaying generic market entry.

In Congress, Rep. Hakeem Jeffries (D-NY) introduced H.R. 2883, the Stop Stalling Access to Affordable Medications Act, to help prevent frivolous petitions. The bill classifies "sham" petitions as a violation of antitrust law and permits the Secretary of Health and Human Services to label citizen petitions as such if evidence suggests that a brand-name drug manufacturer filed the petition to delay generic entry, such as if petitions coincided temporally with the filing of a generic drug's approval application. The Federal Trade Commission (FTC) can then sue the drug manufacturer that filed the petition to seek civil relief.[24]

Reverse Payment Settlements

The 1984 Hatch-Waxman Act, which defined the process for regulatory approval of generic drugs, created a mechanism to adjudicate brand-name manufacturers' drug patents leading up to generic entry. In brief, generic manufacturer must certify that they are entering a market not protected by patents, or that their products do not infringe brand-name manufacturers' patents or that those patents are invalid. If the brand-name manufacturer disagrees as to existing patents, it can file a claim, leading to a lawsuit.[25] These lawsuits are critical for public health, because they can clear out weak or improperly granted patents that block entry of lower-cost generic drugs (or, alternatively, allow manufacturers to enforce their valid intellectual property against competitors).[26] However, many of these lawsuits end with settlements, some of which include direct financial payments from the brand-name to the generic challenger.[27] When such settlements prop up patents that would have been invalidated, they extend a brand-name drug's market exclusivity and allow prices to remain high. A classic example of a so-called "reverse payment settlement" (called such because the patent holder is paying the patent challenger as part of the settlement, rather than the more normal opposite situation) is the case of narcolepsy drug modafinil (Provigil), in which the drug's manufacturer, Cephalon, resolved a patent infringement case in part by paying generic

manufacturers $300 million in exchange for which the generic agreed to delay market entry for six years.[28]
The Hatch-Waxman Act litigation patent settlement landscape changed about a decade ago with a Supreme Court case involving patents related to testosterone gel (Androgel). In 2003, the period of market exclusivity for Solvay Pharmaceuticals' topical testosterone gel neared expiry, prompting Actavis to file for approval of a competitor generic. To maintain market exclusivity, Solvay filed a patent infringement claim against Actavis as part of the Hatch-Waxman process. When the resulting challenge was settled, Actavis agreed to delay the market entry of its generic in exchange for an annual payment of up to $30 million dollars from Solvay for nine years. The Federal Trade Commission (FTC) alleged this agreement was anticompetitive and sued Actavis.[29] In *FTC v. Actavis,* the Supreme Court held that reverse payment settlements could be challenged on antitrust grounds if they unreasonably restricted market competition.[30] *FTC v. Actavis* thus opened the door to legal scrutiny of reverse payment settlements, resulting in a substantial decline in the prevalence of reverse payment settlements.[31] While settlements have continued, they have tended to avoid direct payments and instead brand-name and generic manufacturers have developed alternative arrangements.[32] For example, in no-authorized generic agreements, generic companies agree to delay market entry of their product in exchange for brand-name manufacturers agreeing not to authorize or make their own generic drugs in the future.[33] The generic manufacturer is functionally "paid" to delay generic market entry with a legal guarantee that their generic product will face less possible competition in the future.[34]
H.R. 2891, the Preserve Access to Affordable Generics and Biosimilars Act, was introduced by Rep. Jerrold Nadler (D-NY) to combat reverse payment settlements. H.R. 2891 bans legal settlements that delay the market entry of generic competitor medications in exchange for any form of compensation, whether a direct payment, royalty, or in any other item. It allows the FTC to initiate civil proceedings against manufacturers that sign such settlements. The only settlements permitted under H.R. 2891 are agreements unrelated to generic entry or with pro-competitive effects.[35]

Biosimilar Competition

The 2009 Biologics Price Competition and Innovation Act (BPCIA) created an expedited entry process for competition in the biologic drug market via biosimilar drugs, versions of biologics made by other manufacturers. In place of the patent listing and litigation procedure in the Hatch-Waxman Act, the BPCIA created a "patent dance" in which prospective biosimilar manufacturers must submit a copy of their regulatory approval application to the originator biologic manufacturer.[36] The originator manufacturer then provides a list of patents on which it claims the biosimilar infringes within 60 days, which eventually leads to litigation. This "dance" of information exchanges occurs fully outside of the public eye and may last for hundreds of days and still end in drawn-out litigation.[37] For example, in 2019, Hospira attempted to introduce a biosimilar to Amgen's anemia drug epoetin (Epogen).[38] Amgen reportedly dragged out the dance, leading to a delay in the approval of the biosimilar.[39]
Because the patent dance can lead to delays and because biosimilar manufacturers may not be comfortable revealing business information contained in their regulatory application to their competitors, some biosimilar manufacturers have skipped the patent dance. Sandoz introduced a biosimilar to Amgen's cancer drug filgrastim (Neupogen), but refused to follow through with the dance.[40] After Amgen sued Sandoz, the Supreme Court ruled in 2017 that the patent dance was not mandatory.[41]
H.R. 2884, the Affordable Prescriptions for Patients Through Improvements to Patent Litigation Act, was introduced by Rep. Henry Johnson (D-GA) to improve the patent dance. The bill redefines "patent infringement" to refer to solely those patents that infringe on claims on a biological product or the products or methods used in its manufacturing. The bill sets a limit of 20 patents that biologic manufacturers can reference in patent infringement claims during the patent dance and requires that these patents fit certain criteria for recency and importance. However, H.R. 2884 also permits manufacturers to supersede these limitations if courts deem the consideration of certain excluded patents to be important.[42]

Discussion

Of the four bills, H.R. 2884 is likely to have the smallest impact on drug prices. While the biosimilar entry process as designed in the BPCIA can significantly delay the entry of competitor biosimilars, H.R. 2884 only limits the number of

patents included in the dance, rather than limiting the amount of time allocated for each step in the so-called patent dance.[43] Hence, even with a limited number of patent infringement claims, brand-name drug manufacturers may still attempt to delay their responses and slow the process to delay biosimilar entry. The degree to which courts may grant exemptions to H.R. 2884's patent limitations further creates uncertainty about the bill's ability to hasten biosimilar market entry and lower drug prices.

H.R. 2883 on citizen petitions is more tangentially related to drug prices. In the past, the FTC has lost cases in which it alleged citizen petition abuse, such as in the 2019 case *FTC v. ShireViroPharma* in the Third Circuit Court of Appeals, because it has previously been unclear whether frivolous citizen petitions constitute violations of antitrust law.[44] H.R. 2883 resolves this problem by classifying frivolous petitions as illegal and anticompetitive behavior. However, H.R. 2883 relies on HHS to designate instances of frivolous petitions against which the FTC may litigate, and therefore requires HHS to be aggressive in making these designations. In 2007, Congress gave HHS and the FDA the ability to identify and summarily deny frivolous petitions without lengthy adjudication periods, but for the next seven years, the FDA did not summarily deny a single petition, despite hundreds of petitions being filed, many of limited merit.[45] If FDA and HHS continue to be reticent to aggressively identify and act against frivolous petitions, it may limit the effectiveness of H.R. 2883.

H.R. 2891, on reverse payment settlements, is likely to have a more substantial impact on hastening generic entry and lowering prices. H.R. 2891 bans settlements in which brand-name manufacturers pay or compensate generic manufacturers in some form to delay competitor generic drug market entry.[46] Therefore, H.R. 2891 blocks both traditional reverse-payment settlements and may extend to other alternative settlements such as no-authorized generic agreements. As a result, H.R. 2891 would broadly curb the use of settlements as a tactic to delay generic entry. However, whether that result would translate directly into lower drug prices remains to be seen, as in the post-*Actavis* era, the number of settlements involving direct payments has declined as many manufacturers have already switched to using more FTC-friendly settlements to avoid legal scrutiny.[47]

H.R. 2873 on product hopping may also have an important effect on drug prices. Currently, legal efforts to block product hopping have been stymied by inconsistent definitions of product hopping and uncertainty over whether it can constitute anticompetitive behavior.[48] H.R. 2873 provides standard definitions of both hard-switch and soft-switch product hopping and classifying both actions as potentially anticompetitive.[49] The clear definitions and legal grounds give the FTC more support in initiating litigation against parties engaged in problematic product hopping. Since the FTC has historically been aggressive in countering tactics that delay generic entry, it is likely the agency would vigorously enforce H.R. 2873. In turn, this enforcement would prevent brand-name manufacturers from extending market exclusivity and lead to lower drug prices.

Conclusion

The four bills introduced into Congress may have varying levels of effectiveness in hastening generic drug entry and lowering drug prices. To supplement these efforts to lower drug prices, Congress should adopt other measures, such as permitting Medicare and other insurers to negotiate brand-name drug prices or implement value-based pricing (VBP) and health technology assessment (HTA) standards to help ensure a drug's price is more closely related to its therapeutic benefits. These reforms would help lower the price of existing brand-name drugs, and combined with efforts to promote generic competition included in these four bills, would promote pharmaceutical competition and innovation for the benefit of patients.

Note

The authors declare funding from Arnold Ventures.

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About This Column

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DETAIL

Subjek:	Antitrust; Markets; Generic drugs; Brand names; FDA approval; Pharmaceuticals; Competition; Regulatory approval; Drug prices; Biological products; Infringement; Market entry; Substance use disorder; Litigation; Legislation; Narcotics
Ketentuan indeks bisnis:	Subjek: Antitrust Brand names FDA approval Regulatory approval Infringement Market entry

Lokasi:	United States--US
Perusahaan / organisasi:	Nama: AstraZeneca; NAICS: 325412; Nama: Food &Drug Administration--FDA; NAICS: 922190; Nama: Reckitt Benckiser PLC; NAICS: 325412, 325611; Nama: Federal Trade Commission--FTC; NAICS: 926150
Pengidentifikasi/kata kunci:	Drug Prices; Legislation; Competition; Generic drug; Medication costs; Patents; Product; Hopping; Generic Drug
Judul:	Promoting Competition in Drug Pricing: A Review of Recent Congressional Legislation
Pengarang:	Nagar, Sarosh; Kesselheim, Aaron S
Judul publikasi:	The Journal of Law, Medicine &Ethics; Boston
Volume:	49
Edisi:	4
Detail sumber:	First Amendment Values in Health Care
Halaman:	683-687
Tahun publikasi:	2021
Tanggal publikasi:	Winter 2021
Bagian:	Columns: Health Policy Portal
Penerbit:	Cambridge University Press
Tempat publikasi:	Boston
Negara publikasi:	United Kingdom, Boston
Subjek publikasi:	Law, Medical Sciences
ISSN:	10731105
e-ISSN:	1748720X
Jenis sumber:	Jurnal Akademik
Bahasa publikasi:	English
Jenis dokumen:	Journal Article
DOI:	https://doi.org/10.1017/jme.2021.93
ID dokumen ProQuest:	2730847526

Disestablishing Hospitals

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ABSTRAK (ENGLISH)

We argue that concentration of power in religious hospitals threatens disestablishment values. When hospitals deny care for religious reasons, they dominate patients' bodies and convictions. Health law should — and to some extent already does — constrain such religious domination.

TEKS LENGKAP

Even as the rest of the hospital market has contracted, Catholic health systems have grown rapidly since the 1990s through acquisitions, affiliations, and joint ventures.[1] The 688 officially designated Catholic hospitals now vastly outnumber all other religious hospitals combined.[2] In the past year, more than 1 in 7 patients received care and half a million babies were delivered in a Catholic hospital.[3]

With size comes economic — and religious — power. Like other major players in the healthcare market, Catholic systems enjoy significant market clout. They experience the concomitant advantages in administration, contract negotiations, physician recruitment, and patient services.

But, unlike other players, they combine their economic power with religious stringency. They require healthcare providers and partner entities to deliver care consistent with rules based on religious doctrine. As a consequence, patients — and entire communities — are denied access to an array of health services, from abortion to IVF to end-of-life care to gender-affirming treatment. They find themselves subjected to religious convictions that they do not share.

To date, the problem of religious hospital concentration has been analyzed through the lens of healthcare access, antitrust law, and informed consent.[4] In this Essay, we instead argue that the increasing size, scope, and power of religious hospitals threatens disestablishment values. We show that market power combined with control over critical resources can translate into the imposition of religion on patients, contrary to the disestablishment value of non-domination. Under such circumstances, we argue, the non-domination principle should — and to some extent already does — constrain institutions from deploying their authority outside its legitimate scope. Hospitals may deny care and exercise power legitimately where they act with the goal of delivering medically indicated care and serving the community. But when they deploy authority in a manner unconnected to this goal in order to serve institutional religion, they dominate patients' bodies and beliefs and threaten the normative core of religious disestablishment.

To be clear, ours is not a claim that the Establishment Clause applies directly to privately owned hospitals. But Establishment Clause values have some application where religious actors hold economic power and play a vital

social role. Indeed, although health law may not have been designed with disestablishment in mind, we show that it nevertheless reflects concerns about religious domination and contains some tools to deter it.

With market concentration comes organizational power. Catholic hospitals are increasingly organized into mega-systems. Four of the ten largest systems in the United States are Catholic, garnering billions of dollars in revenue. System-wide consolidation provides advantages ranging from economies of scale to network effects. It also delivers the well-known efficiency benefits of centralized management.

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Our focus on disestablishment values also illuminates the constitutional significance of critical markets dominated by religion. Framing the problem in terms of disestablishment values, in turn, may help reorient reform efforts toward structural solutions to a concentrated religious healthcare market that go beyond individual patient access.

Concentration of Religious Hospitals

Many Americans live in areas where a religious hospital predominates. For most of them, that hospital will be Catholic. In the last two decades, the number of Catholic acute-care hospitals has grown a substantial 28%.[5] At the same time, the rest of the market has shrunk almost 14%.[6] Hospitals with Catholic affiliation now occupy 15.8% of the national market but hold considerably larger market shares in the range of 30% and 40% in many states.[7]

With market concentration comes organizational power. Catholic hospitals are increasingly organized into mega-systems. Four of the ten largest systems in the United States are Catholic, garnering billions of dollars in revenue.[8] System-wide consolidation provides advantages ranging from economies of scale to network effects. It also delivers the well-known efficiency benefits of centralized management.

Catholic systems leverage their control over assets to dictate what services doctors provide to patients. Providers must commit by contract to comply with the Ethical and Religious Directives for Catholic Health Care Services (the "ERDs") in their care of patients.[9] These directives prohibit a wide range of common reproductive health services, including contraception, sterilization, abortion, some miscarriage management techniques, the least invasive treatments for ectopic pregnancies, and assisted reproductive technologies. Treatments derived from fetal tissue or embryonic stem cells are not permitted. Under the ERDs, patients may only be informed of "morally legitimate alternatives."[10] And patients' wishes about the use or withdrawal of artificial life support will not be honored if they run counter to Catholic teaching.[11] Some hospitals also refuse to provide gender-affirming care for transgender patients, although the ERDs do not contain any explicit prohibition.

Through the legal institutions of private law — primarily property and contract — Catholic hospitals have expanded the scope and scale of their religious restrictions. As one of us has explained, Catholic healthcare systems have used leases and contracts to require other institutions to comply with Catholic doctrine.[12] As a result, hospitals that are nonsectarian, affiliated with other faiths, or even public follow the ERDs as part of joint ventures, management agreements, mergers, or even loose collaborations with Catholic healthcare. This trend likely will intensify, because the latest version of the ERDs now requires that all entities "be operated in full accord with the moral teaching of the Catholic Church" regardless of whether the collaboration takes the form of "acquisition, governance, or management."[13]

Commentators have observed the obstacles that religious hospitals pose for patient access to reproductive and end-of-life care. We aim to widen the lens and explore the denial of care as a form of religious domination, which both raises distinct concerns and suggests the constitutional valence of critical markets governed by religion.[14]

The Constitutional Value of Religious Non-Domination

Religious domination is a familiar concern from foundational discussions of Establishment Clause doctrine and theory.[15] In the *Memorial and Remonstrance Against Religious Assessments*, James Madison put the problem in sharp relief. Madison was particularly worried about the state's arbitrary use of power: "the same authority which can force a citizen to contribute three pence only of his property for the support of any one establishment, may force him to conform to any other establishment in all cases whatsoever[.]"[16] Madison continued, "Who does not see that the same authority which can establish Christianity, in exclusion of all other Religions, may establish with the same ease

any particular sect of Christians, in exclusion of all other Sects?"[17] The tendency of unchecked authority to creep beyond its bounds, as Madison explained, risked domination. The value of non-domination would guard against such illegitimate uses of power.

In other writing, Madison expressed similar concerns about private power. In an essay entitled *Monopolies, Perpetuities, Corporations, Ecclesiastical Endowments*, he presaged, "[b]esides the danger of a direct mixture of Religion and civil government, there is an evil which ought to be guarded against in the indefinite accumulation of property from the capacity of holding it in perpetuity by ecclesiastical corporations."[18] Control over property could risk disestablishment values. And yet, Madison said, "[t]he danger of silent accumulations and encroachments by Ecclesiastical Bodies ha[s] not sufficiently engaged attention in the U.S."[19]

Madison's warnings about religious domination proved influential in the modern development of Establishment Clause doctrine. In *Engel v. Vitale*, an early school prayer case, the Supreme Court quoted the *Memorial* at length in support of a non-domination principle.[20] So too in *Abington School District v. Schempp*, a case challenging Bible reading in public school, Justice Clark echoed Madison's concern with unchecked religious power, noting that "today a trickling stream may all too soon become a raging torrent."[21]

The non-domination principle, to be sure, does not hold that power is always problematic or abusive. Indeed, it grants ample scope to the exercise of legitimate authority. But when that same authority extends beyond its legitimate scope — no longer controlled by the principle that justified its use in the first place — that use of power becomes arbitrary and works to dominate and subordinate those subject to its imposition.[22] Public schooling, for example, falls well within the state's legitimate authority to educate and form citizens. When state power is employed to impose religion on students, however, it falls outside its legitimate scope, and religious domination ensues.[23]

The Establishment Clause, of course, directly applies only to governmental actors. Nonetheless, it affects how the state may structure markets and subsidies to purportedly private actors. And it informs regulatory responses to those entities that otherwise might have power to subvert religious freedoms of weaker individuals and institutions. Moreover, relationships between private parties may be regulated in ways that reflect the values enshrined in the Establishment Clause. For example, as one of us has argued, Title VII of the Civil Rights Act of 1964 safeguards employee religion and practice by applying disestablishment values to employers.[24] Analogous to the state, employers must respect employee conscience, show mutual respect toward workers, and refrain from using economic power to engage in religious domination of employees.[25]

So how does the non-domination value in particular apply to employment? To start, employment law recognizes a broad realm of legitimate uses of employer power over employees. Employers can set rules for employees and hire and fire them based on business reasons that underlie why we structure production through firms. They can fire an inefficient employee, require workers to greet customers with the company motto, and sell goods that may offend particular employees' religious convictions.

Employment law, however, bars employers from engaging in acts of religious domination, which necessarily exceed the economic rationales for organizing production through firms in the first place.[26] Given employer authority over the corporate workplace, Title VII both mandates reasonable accommodation of employees' religious exercise and forbids companies from imposing religion on them. So, for example, while an employer may require employees to wear nametags — "a practice with a clear and close nexus to business objectives" — it may not demand that employees display religious messages on their nametags.[27] In this vein, courts have "rejected the notion that an employer is entitled to religious subservience in return for paying an employee's salary."[28]

The exercise of corporate authority thus requires an economic justification, consistent with the social purpose of firms. Companies may deploy their power to control employees in innumerable ways to bolster efficient production.[29] But use of corporate power beyond these ample parameters — for example, to dominate employees' deepest projects and commitments — lies beyond the pale.[30]

Does the same principle hold for hospitals as service providers? Are these institutions similarly constrained in using their economic power to impose religion on patients? The next Part argues that a similar logic should apply.

Power and the Principle of Non-Domination

Hospitals bear two central hallmarks of actors likely to dominate the vulnerable. Their markets manifest significant failings from concentration and information asymmetries. And they meet critical and time-sensitive needs.

First, ninety-five percent of hospital markets in America are highly consolidated — and becoming more consolidated.[31] In urban and rural areas, the overall supply of hospital care has declined.[32] As a result, in most areas, the prices that hospitals charge are not in any significant way determined by competitive forces.[33] This control over assets and other critical resources — as the law and economics literature teaches — can lead to control over people.[34] As in other concentrated markets, the consumers of healthcare services — that is, the patients — suffer disadvantages from lack of options.[35]

Second, not only are hospitals economically powerful, but they also provide critically important services. As Nicholas Bagley has argued, hospitals both serve important human needs and operate in a market that risks oppression of people.[36] Healthcare markets, Bagley explains, "suffer from well-understood failings associated with market concentration, informational asymmetries, and moral hazard"[37] — to the detriment of patients. People depend on hospitals for succor in urgent and emergent situations and for access to technological innovation. Patients typically must rely on providers for knowledge and expertise in health and medicine. And in exigent circumstances, they must place their bodies under the control of the nearest hospital and its staff. Though ostensibly in a contractual relationship, patients have no effective means by which to bargain with hospitals for better terms or otherwise to check hospital power.[38] These markets are necessarily local — patients typically seek care in a nearby hospital, rather than travel far from family and home. They also tend to be locked into a hospital based on where their physician practices or which doctors are part of their insurance network of providers.[39]

The urgency of care delivered in hospitals further undermines patients' ability to exert countervailing power. Unlike other healthcare institutions, hospitals deal with emergencies, which pair the acute interests of patients with the difficulty — if not impossibility — of seeking care elsewhere. Many patients would suffer severe hardships if hospitals denied them urgent care. And even where transfer to a different institution is possible, transfer in emergencies delays treatment and increases risks for patients.

When concentrated power combines with control over access to critical services, the need to impose limits on the use of such power becomes acute. Non-domination, in our view, is one such limit. Hospitals should not employ economic power to dominate their patients by imposing moral and religious restrictions on healthcare.

One might accept this argument as applied to nonsectarian hospitals, but object on legal grounds to wider applications. While disestablishment values may have a place in public or nonsectarian institutions, it might be thought counterintuitive — even a bit shocking — to suggest that disestablishment values ought to apply to religious hospitals. After all, these institutions generally are organized as religious corporations and dedicated to the mission and ministry of healing. Consistent with free exercise values, Title VII of the Civil Rights Act authorizes them to choose employees based on shared faith.[40] These hospitals often bear religious names — like St. James — and display religious symbols — like crucifixes. And while these names and symbols might make some uncomfortable, one would be hard-pressed to identify how they run afoul of legal norms.[41]

Nevertheless, we think that the non-domination principle should — and at least to some limited extent already does — apply to religious hospitals.[42] To begin with, religious hospitals have the same power and control over critical resources as their secular and public counterparts. Indeed, in many circumstances, religious hospitals hold monopolies. Due to geographic constraints and market concentration, Catholic hospitals are the only available provider for many populations.[43] Twenty-six percent of Catholic hospitals are rural.[44] Fifty-two Catholic hospitals are "sole community hospitals" — a federal designation that applies where the nearest alternative is at least 35 miles away or the hospital is rural and meets other qualifications.[45]

Like their secular and public peers, Catholic hospitals operate in markets driven by revenue, with healthcare providers and patients of many beliefs drawn from the local community. These modern hospitals compete on services, technology, and patient experience. They choose staff for their expertise, not their faith. The vast majority of patients who seek treatment in Catholic hospitals are not Catholic and/or do not subscribe to the doctrinal interpretations of the U.S. bishops.

Consistent with this functional similarity between secular and religious institutions, the public views religious hospitals as healthcare providers, not ministries to co-religionists. Indeed, in *Bradfield v. Roberts* — a case now over a century old — the Supreme Court upheld government financing for construction on a Catholic hospital on the theory that the institution was engaged in secular activities and provided its hospital services to the general public without sectarian discrimination.[46]

Catholic hospitals have long cultivated this public understanding. By the mid-1800s, Catholic hospitals already advertised themselves as being open to all, providing admission and treatment without discrimination, and ensuring all patients' "ability to avail themselves of their own spiritual advisers."[47] Along the same lines, The Metropolitan Catholic Almanac of 1859 explained that, within hospitals, "[t]he rights of conscience must be held paramount to all others."[48] And administrators made clear that institutional religion would not oppress patients. Today, this public understanding is entrenched. Patients consider Catholic hospitals a resource for services and treatments identical to other sophisticated healthcare providers.

Given this cultural understanding, patients are not well-positioned to guard against religious hospitals' exercise of religious domination. Just as patients lack the expertise in medicine to evaluate their own needs and treatment with precision, considerable empirical evidence now shows that most patients are not aware of religious restrictions that apply to their care.[49] Nor are they typically in a position to do extensive research on where such limitations are in place. Access can vary between and even within Catholic institutions, moreover, because the stringency of the directives depends on ad hoc decision-making by ethics committees, workarounds of providers, and interpretations of local bishops. Indeed, with the rapid spread of Catholic restrictions to institutions that are not identifiably Catholic — including hospitals affiliated with other religious traditions or associated with governmental bodies — it can be very difficult to determine where one will encounter religious limitations on care.[50]

One might object that competitive markets will prevent religious hospitals from wielding this sort of power over patients. But that is not the world in which we live. Hospital markets are far from competitive. And in emergencies, the power of choice that consumers enjoy in well-functioning markets is noticeably absent.

None of this analysis is meant to deny the scope and scale of necessary care delivered in Catholic and other religious hospitals. Decision makers in these hospitals can — and often do — use their institutional power for benevolent ends. But as Louis Brandeis once observed, organizations may "develop a benevolent absolutism, but it is an absolutism all the same."[51] It is that absolutism — that power *over* others to arbitrarily interfere with their life prospects — that motivates the principle of non-domination. The next Part considers where the line between domination and non-domination lies in hospital settings.

Locating the Line between Legitimate and Arbitrary Uses of Hospital Power

The idea of domination requires separating arbitrary from legitimate uses of hospital power. As with employment, we first need to identify the role that hospitals play in the basic structure of our social institutions. Once we've done that, we can distinguish between uses of power inside and outside the bounds of legitimacy. Our claim here is that while some denials of care prove legitimate, religious refusals contravene the social role of hospitals.

So, what role do hospitals play in our system of social cooperation among people who differ on fundamental questions? In short, the hospital's primary role today is to channel professional medical care to patients and to serve community health needs. Although it originated as a place to tend to the deserving, dying poor, the modern hospital is defined by the complexity and sophistication of its services and procedures.[52] It operates within a complex network of rules set by federal, state, and private regulators to ensure patient safety.[53] In many states, to enter a market or expand services or facilities, hospitals must secure a certificate of need from the state through a process that aims to expand access to healthcare and minimize unnecessary spending.[54] The very term "community hospital" reflects the ways hospitals straddle a fine line between private entity and public function — financed, regulated, and supported by the state and local community.[55]

The hospital's obligation to serve the community is also reflected in a variety of laws. Hospitals must periodically engage in community needs assessments to design their services for the public. Their boards must include members of the community, drawn from outside the institution. They may not discriminate against patients and must

safeguard their privacy. These laws reflect widespread recognition that healthcare is a “critical good or service.”[56]
Consistent with its social role of delivering professional medical care that meets community needs, Catholic hospitals — like their peers — exercise economic and healthcare power in many legitimate ways. Most often, they use control over facilities, equipment, and staff to deliver medically indicated care to patients. They leverage the scope and scale of their operations to deliver services more efficiently or at lower cost. In these respects, no issue of domination arises.
Many denials of care that patients desire also qualify as legitimate uses of hospital power. In order to serve their social role, hospitals must allocate treatments and resources efficiently and responsibly. Most obviously, hospitals may deny care that is futile or medically unnecessary. Staff availability and expertise may also structure the services provided. Health law recognizes the legitimacy of such decisions by, for example, allowing hospitals to transfer patients with emergency medical conditions to another facility when the medical benefits of transfer outweigh the risks to patients.[57]
Revenue generation may also provide the basis for legitimate hospital decisions. Economic concerns, for example, drive closures of particular departments (labor and delivery, for example) and credentialing of medical staff (requiring, for example, a minimum number of annual patient admissions). These denials of care may be inconvenient, frustrating, or even harmful, but they do not result in domination.
But hospitals also deny medically indicated services for religious reasons to patients who depend upon them for care. Women have found Catholic hospitals unwilling to authorize their ob-gyns to perform tubal ligations following labor and delivery — requiring them to undergo two surgeries or to travel to another hospital. Others have suffered injuries when hospitals denied them abortions and ectopic pregnancy treatment in urgent situations.[58]
Are these uses of power within the legitimating reasons for hospital authority? To see why they are not, let’s consider a few examples removed from the context of Catholic healthcare. Imagine a hospital affiliated with Christian Science — a faith community that rejects most medical care. It seems quite clear that such an institution cannot plausibly fulfil the social role of a hospital while offering only care consistent with Christian Science. Or to move the hypothetical closer to reality, we might think of a Jehovah’s Witness hospital that generally would offer care consistent with medical practice but might withhold blood transfusions. There is little doubt that no state or federal regulator would license or fund such an institution as a hospital. So why are these hypotheticals so clearly beyond the pale?
Our claim is that these religious restrictions on hospital care prove socially illegitimate because they cannot be justified by the reasons that support use of hospital authority in the first place. They fail to advance the goal of providing medically appropriate care to the public and, in doing so, they depart significantly from social expectations of the hospital’s role. While hospitals vary in the specialized services they offer, patients and the public anticipate that they have equipment, expertise, and staff to deliver general medical services and meet acceptable standards of practice. In urgent and emergent situations, they expect to receive comprehensive care consistent with the emergency department function. In denying care for religious reasons, hospitals instead extend their institutional authority over patients’ healthcare to require religious adherence. And their denial of necessary and expected care serves to dominate patients’ bodies and convictions.
A reader might be persuaded by the normative argument against domination in Catholic hospitals, but nonetheless query whether the value of non-domination has any practical foothold in these settings. Scholars have explored nondomination in areas from employment law[59] to financial regulation,[60] but it has received less attention in health law. In this short Essay, we don’t aim for a comprehensive review of health law’s protections against domination, but we can nevertheless identify a few obvious examples that provide proof of concept.
For starters, laws related to pastoral care in hospitals draw lines that reflect concerns about domination. Under federal and state law, all hospitals must respect patients’ rights to spiritual and pastoral care consistent with their own needs.[61] These requirements apply regardless of whether a hospital is secular or sectarian. Hospital chaplains must work not as proponents of their specific faith but as providers of non-directive pastoral care reflective of the needs and values of each patient.[62] Moreover, as Stacey Tovino explains, one of the functions of hospital chaplains

is “protecting patients from unwelcome forms of spiritual intrusion.”[63] Consistent with that goal, hospital admissions documents often ask for a patient’s religious preferences, including whether they welcome a chaplain visit. The regulatory framework thus distinguishes between the legitimate — an offer of pastoral care — and the arbitrary — an imposition of pastoral care, in a way consistent with non-domination.

In a similar vein, Medicare’s Conditions of Participation establish that it is for patients to determine their own family structures and select their visitors consistent with their own commitments. Promulgated in response to incidents of hospitals denying access to same-sex partners and spouses of patients,[64] the regulation distinguishes arbitrary denials of visitation from “clinically necessary” or otherwise reasonable limitations that the hospital “may need to place on such rights.”[65] In effect, the regulation prohibits institutional religious teachings about marriage and family to dominate patients. A hospital thus may not deny visitation because its affiliated church disapproves of divorce or same-sex marriage, but it may set conditions for reasons of efficiency and healthcare provision consistent with its social role.[66]

Duties of informed consent — contained in administrative regulations, state statutes, and common law precedent — also specifically seek to avoid domination of patient values.[67] Although these laws sometimes take the form of transparency and notice requirements, they nevertheless work to safeguard patients from the imposition of views about medical care that they do not share. The Patient Self Determination Act, for example, aims “to assure that individuals receiving services will be given an opportunity to participate in and direct health care decisions affecting themselves.”[68] State statutes commonly require institutions to inform patients in advance of any religion-based objections to compliance with advance directives and then to “immediately make all reasonable efforts to assist in the transfer of the patient” to a willing provider or institution and to comply with the treatment request during the search.[69] Religious objections do not excuse institutions from duties to respect patients’ rights to informed consent and decision making.

Ultimately, going forward, we need to consider how law and politics structure and shape the role of religion in healthcare. In doing so, we ought to be mindful of the growing power of religious hospitals in the healthcare system and the corresponding threat they pose to our deeply rooted disestablishment values.

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Finally, the priority of emergency care duties over religious objection, reflected in Emergency Medical Treatment and Labor Act (EMTALA), further reflects a nondomination principle. Under normal circumstances, as we have noted, hospitals need not provide a particular specialized service or admit a patient who cannot pay. Conscientious refusal laws, moreover, explicitly grant them the authority to deny contested services, commonly abortion, often sterilization, and sometimes other procedures for reasons of religious objection. Where, however, a patient arrives at the hospital with an emergency medical condition — a narrow category of severe conditions, including labor — a hospital must provide care to stabilize the patient, regardless of whether she requires treatment that it otherwise might refuse on religious grounds. Conscientious refusal laws cede to the federal EMTALA.[70] At least in emergencies, the institution’s interest in adherence to religious doctrine is outweighed by the patient’s bodily and decisional integrity.

Once again, we make no claim to have provided an exhaustive catalogue of non-domination in health law. And, to be sure, some laws allow hospitals to thwart patient access and self-determination in various ways. Yet these examples should suffice to make our basic point that traces of the non-domination principle are already part of health law.

Conclusion

The chief aim of this Essay has been to re-frame religious refusals of hospital care in terms of domination and religious establishment. This frame offers a number of advantages. To begin with, it trains our sights on pervasive power relations between religious hospitals and their patients. Patients depend on local hospitals for the necessities of life and are therefore vulnerable to their arbitrary use of power.

The lens of non-domination can also help us see state action in what we thought were narrower conflicts between private parties. Recognizing that the state not only regulates, but also constitutes the healthcare markets may in turn

illuminate a range of First Amendment values in healthcare.[71] We may even start to see the outlines of a healthcare constitution, akin to the “workplace constitution” that has gained momentum in employment law.[72]

By the same token, thinking in terms of disestablishment values might illuminate what’s really wrong with religious restrictions on care and point toward a more appropriate vocabulary for the harms that patients suffer. To be sure, one problem with such restrictions on care is that they are often inadequately disclosed — and, for this problem, more transparency would be a welcome development.[73] But the problems with religious restrictions run deeper than insufficient transparency.

Faced with hospitals that provide urgently needed care and operate in concentrated markets, we have two pathways before us. First, we might attempt to foster competition. If we want to respect institutional freedom while at the same time mitigating religious domination, then we may need to think in terms of dispersing market power and preserving patient options. We might adopt more robust antitrust enforcement as generative of religious non-dominance as well as vibrant markets.[74] Given the control that religious institutions have over critical hospital resources, the public has a significant interest in curtailing their institutional power. The revival of a public option in the form of public hospitals may need to be considered.

Second, we might regulate so as to ensure non-domination. The proliferation of religious doctrine across distinctly Catholic hospitals, partner secular hospitals, and public hospitals speaks to weaknesses of the regulatory environment. We might consider limiting the spread of religious restrictions, consistent with goals of having religious and secular options in the marketplace. California law, for example, has moved in this direction, preventing hospitals from maintaining restrictions on treatments after a hospital is sold.[75] And in Oregon, the Equal Access to Care Act — passed in July 2021 — protects against the loss of reproductive and gender-affirming services when ownership is transferred to a religious institution.[76] More ambitiously, commentators for decades have suggested treating hospitals as public utilities. The basic argument is that “[b]ecause service, cost, utilization, and quality decisions affect not only providers and users but also the wider social environment, it is necessary to make society privy to those decisions” through public utility regulation.[77]

Ultimately, going forward, we need to consider how law and politics structure and shape the role of religion in healthcare. In doing so, we ought to be mindful of the growing power of religious hospitals in the healthcare system and the corresponding threat they pose to our deeply rooted disestablishment values.

Acknowledgements

Thank you to Sonia Suter and Chip Lupu for their commentary and excellent suggestions and to Malia Hamilton for her research assistance.

Note

The authors have no conflicts to disclose.

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1. See Community Catalyst, “Bigger and Bigger: The Growth of Catholic Health Systems” 3-7, available at <https://www.communitycatalyst.org/resources/publications/document/2020-Cath-Hosp-Report-2020-31.pdf >(last visited July 30, 2021).

2. Catholic Health Association, U.S. Catholic Health Care (2020): at 1. There are 4233 non-governmental community hospitals in the US. American Hospital Association, Fast Facts on US Hospitals (2020).

3. Catholic Health Association, supra note 2, at 2.

4. See, e.g., L.C. Ikemoto, “ When a Hospital Becomes Catholic,” Mercer Law Review 47, no. 4 (1996): 1087–1134; B.R. Clark, “When Free Exercise Exemptions Undermine Religious Liberty and the Liberty of Conscience: A Case Study of the Catholic Hospital Conflict,” Oregon Law Review 82, no. 3 (2003): 625-694; N.N. Sawicki, “Mandating Disclosure of Conscience-Based Limitations on Medical Practice,” American Journal of Law &Medicine 42, no. 1 (2016): 85-128; C.M. Durand, “Who Blesses This Merger? Antitrust’s Role in Maintaining Access to Reproductive Health Care in the Wake of Catholic Hospital Mergers,” Boston College Law Review 61, no. 7 (2020): 2595-2642.

5. See Community Catalyst, supra note 1, at 4.

6. Id.

7. Id. See also C. Drake et al., “Market Share of US Catholic Hospitals and Associated Geographic Network Access to Reproductive Health Services,” JAMA Network Open (Jan. 29, 2020) (reporting that 35.3% of US counties, where 38.7% of US women of reproductive age live, have a high or dominant Catholic hospital market share).
8. See Community Catalyst, supra note 1, at 9. As the second largest healthcare system in the US, CommonSpirit Health brought in over $20 billion in 2019.
9. United States Conference of Catholic Bishops, Ethical and Religious Directives for Catholic Health Care Services (6th ed. 2018), available at <https://www.usccb.org/about/doctrine/ethical-and-religious-directives/upload/ethical-religious-directives-catholic-health-service-sixth-edition-2016-06.pdf >(last visited July 30, 2021) [hereinafter ERDs].
10. ERD 27, supra note 9, at 14.
11. ERD 59, supra note 9, at 21.
12. See E. Sepper, “ Zombie Religious Institutions,” Northwestern University Law Review 112, no. 5 (2018): 929–988, at 974.
13. ERD 74, supra note 9, at 26.
14. For explorations of the effect of the ERDs on physician conscience, see L. Eisenstadt, “ Separation of Church and Hospital: Strategies to Protect Pro-Choice Physicians in Religiously Affiliated Hospitals,” Yale Journal of Law &Feminism 15, no. 2 (2003): 135–173; M.R. Wicclair, Conscientious Objection in Health Care: An Ethical Analysis (New York: Cambridge University Press, 2011); E. Sepper, “Taking Conscience Seriously,” Virginia Law Review 98, no. 7 (2012): 1501-1575.
15. Avoiding state impositions of religion is often thought to be the central Establishment Clause value. See A. Schwarz, “ No Imposition of Religion: The Establishment Clause Value,” Yale Law Journal 77, no. 4 (1968): 692–737; see also J.D. Nelson, “Corporate Disestablishment,” Virginia Law Review 105, no. 3 (2019): 595-654, at 626-634.
16. J. Madison, “ Memorial and Remonstrance Against Religious Assessments,” in J.N. Rakove ed., James Madison: Writings (New York: Library of America, 1999): 29–36.
17. Id.
18. See E. Fleet, “ Madison’s ‘Detached Memoranda’,” William &Mary Law Review 3, no. 4 (1946): 534–568, at 556 (abbreviations removed).
19. Id. at 554.
20. Engel v. Vitale, 370 U.S. 421, 436 (1962).
21. School Dist. of Abington Tp., Pa. v. Schempp, 374 U.S. 203, 225 (1963).
22. For sophisticated philosophical work on non-domination, see P. Pettit, On the People’s Terms: A Republican Theory and Model of Democracy (New York: Cambridge University Press, 2012); P. Pettit, Republicanism: A Theory of Freedom and Government (New York: Oxford University Press, 1997); P. Pettit, “Freedom as Antipower,” Ethics 106, no. 3 (1996). 576-604.
23. See Nelson, supra note 15, at 631-32.
24. Nelson, supra note 15. In a similar vein, Leora Eisenstadt has argued that federal law barring employer discrimination against healthcare providers based on their performance or refusal of abortions and sterilizations also functions to implement disestablishment in hospital workplaces. Eisenstadt, supra note 14, at 147-55.
25. See Nelson, supra note 15, at 606-26.
26. See id. at 615-20.
27. See id. at 617.
28. See id. at 619.
29. See A.A. Berle, Power without Property: A New Development in American Political Economy (New York: Harcourt, 1959): at 98–110 (discussing the concept of “legitimacy”).
30. See id.
31. J.S. King et al., Preventing Anticompetitive Healthcare Consolidation: Lessons from Five States 6 (June 2020), available at <https://2zele1bn0sl2i91io41niae1-wpengine.netdna-ssl.com/wp-

content/uploads/2020/06/PreventingAnticompetitiveHealthcareConsolidation.pdf >(last visited July 30, 2021).
32. See Community Catalyst, supra note 1, at 4.
33. N. Bagley, " Medicine as a Public Calling," Michigan Law Review 114, no. 1 (2015): 57–106, at 65.
34. See, e.g., O. Hart and J. Moore, " Property Rights and the Nature of the Firm," Journal of Political Economy 98, no. 6 (1990): 1119–1158; R.G. Rajan and L. Zingales, "Power in a Theory of the Firm," Quarterly Journal of Economics 113, no. 2 (1998): 387-432; Nelson, supra note 15, at 635-41.
35. See Bagley, supra note 33, at 84-87. On the harms of economic concentration more generally, see T. Wu, The Curse of Bigness: Antitrust in the New Gilded Age (New York: Columbia Global Reports, 2018); L. Khan, " The End of Antitrust History Revisited," Harvard Law Review 133, no. 5 (2020): 1655–1683 (reviewing Wu).
36. See Bagley, supra note 33, at 59.
37. Id. at 62.
38. See, e.g., Tunkl v. Regents of the University of California, 383 P.2d 441 (Ca. 1963) (establishing a highly influential test to determine when a waiver of liability relates to the "public interest" and concluding that hospital care meets each of the factors given the importance of the service that is a practical necessity, the hospital's decisive advantage in bargaining strength, and the state's extensive regulation).
39. See Sepper, supra note 12, at 977.
40. 42 U.S.C. § 2000e-1(a).
41. E.g., I.C. Lupu, " The Increasingly Anachronistic Case Against School Vouchers," Notre Dame Journal of Law, Ethics &Public Policy 13, no. 2 (1999): 375–396 (describing a Catholic hospital with religious symbols and name caring for his Jewish father at the end of his life and observing that "[n]o Religion Clause scholar or advocate of whom I am aware would argue that government payment to St. Peter's Hospital for the cost of medical service for my father's benefit violated the Establishment Clause.").
42. See infra Part IV.
43. See A. Littlefield, "Barrett's Confirmation Would Empower Catholic Hospitals to Deny Crucial Care: Catholic Hospitals Have Increasingly Become the Only Option for Many Communities," Truthout, October 15, 2020, available at <https://truthout.org/articles/barretts-confirmation-would-empower-catholic-hospitals-to-deny-crucial-care/ >.
44. Catholic Health Association, supra note 2, at 1.
45. This number has increased from thirty in 2013.
46. Bradfield v. Roberts, 175 U.S. 291 (1899).
47. C.J. Kauffman, Ministry and Meaning: A Religious History of Catholic Health Care in the United States (New York: Crossroad, 1995): at 71 (noting such an advertisement in the 1850s); see id. at 104, 149, 151 (noting other nineteenth century examples of Catholic hospitals asserting nonsectarian character and management and nondiscrimination in admission and treatment of patients).
48. Id. at 76 (quoting the almanac).
49. D.B. Stulberg et al., " Women's Expectation of Receiving Reproductive Health Care at Catholic and Non-Catholic Hospitals," Perspectives on Sexual &Reproductive Health 51, no. 3 (2019): 135–142; L.R. Freedman et al., "Religious Hospital Policies on Reproductive Care: What Do Patients Want to Know?" American Journal of Obstetrics &Gynecology 21, no. 2 (2018): 251.e1-251.e9; M. Guiahi et al., "What Are Women Told When Requesting Family Planning Services at Clinics Associated with Catholic Hospitals? A Mystery Caller Study," Perspectives on Sexual &Reproductive Health 49, no. 4 (2017): 207-212.
50. E.L. Hill, D.J.G. Slusky, and D.K. Ginther, " Reproductive Health Care in Catholic-Owned Hospitals," Journal of Health Economics 65 (2019): 48–62 (finding that hospital affiliation with a Catholic health care system reduced tubal ligation rates by over 30%).
51. L. Brandeis, Industrial Relations: Final Report and Testimony (Washington, DC: Government Printing Office, 1916): 7657–7681, at 7659.
52. Kauffman, supra note 47, at 73 (observing that all voluntary hospitals at mid nineteenth century admitted only the "worthy poor"); D.B. Smith, Health Care Divided: Race and Healing a Nation (Ann Arbor: University of Michigan

Press, 1999): at 13 (observing that whereas private hospitals limited care to the “deserving” poor, public hospitals served the remainder of the indigent); K.M. Bridges, “The Deserving Poor, the Undeserving Poor, and Class-Based Affirmative Action,” Emory Law Journal 66, no. 5 (2017): 1049-1114 (discussing the ways social welfare programs in the United States, including Medicaid, were constructed around categories of morally deserving poor).
53. Governments have long engaged in such regulation. Kauffman, supra note 47, at 138 (observing that in the 1880s “provincial statutes codified the proper procedures from admitting to releasing patients” for secular and sectarian hospitals alike).
54. P.C. Smith and D.A. Forgione, “ The Development of Certificate of Need Legislation,” Journal of Health Care Finance 36, no. 2 (2009): 35–44, at 37.
55. Catholic hospitals alone took in $47.8 billion in federal funding in 2020. See Littlefield, supra note 43, at 6.
56. K.S. Rahman, “ The New Utilities: Private Power, Social Infrastructure, and the Revival of the Public Utility Concept,” Cardozo Law Review 39, no. 5 (2017): 1621–1692 (discussing control over critical services and its relation to public utility regulation).
57. Emergency Medical Treatment and Labor Act, 42 U.S.C. 1395dd(c)(1)(A)(ii).
58. National Health Law Program, “Health Care Refusals: Undermining Quality Care for Women” (2010): 1-84, at 15, 40, 57, available at <https://9kqpw4dcaw91s37kozm5jx17-wpengine.netdna-ssl.com/wp-content/uploads/2018/09/Health_Care_Refusals_Undermining_Quality_Care_for_Women.pdf >(last visited August 3, 2021); A.M. Foster et al., “Do Religious Restrictions Influence Ectopic Pregnancy Management? A National Qualitative Study,” Women’s Health Issues 21, no. 2 (2011): 104-109, at 106.
59. See, e.g., S. Bagenstos, “ Employment Law and Social Equality,” Michigan Law Review 112, no. 2 (2013): 225–274.
60. See, e.g., Rahman, supra note 56.
61. The Joint Commission on Accreditation of Healthcare Organizations, the primary independent accreditor for hospital Medicare participation, sets standards that require hospitals to “accommodate the right to pastoral and other spiritual services for patients” and to end-of-life care that “addresses the patient’s and his or her family’s psychosocial and spiritual needs.” Joint Commission on Accreditation of Healthcare Organizations, Hospital Accreditation Standards RI.2.10(2) &(4) (2021). State laws also often contain similar duties. S.A. Tovino, “ Hospital Chaplaincy Under the HIPAA Privacy Rule: Health Care or ‘Just Visiting the Sick?’ ” Indiana Health Law Review 2, no. 1 (2005): 51–92, at 83 (citing Texas law).
62. Tovino, supra note 61, at 81. See “Hospice Chaplain Reflects on Life, Death and the ‘Strength of the Human Soul,’” National Public Radio, October 31, 2016, available at <https://www.npr.org/sections/health-shots/2016/10/31/499762656/hospice-chaplain-reflects-on-life-death-and-the-strength-of-the-human-soul >(last visited August 2, 2021) (discussing role and experiences of chaplaincy).
63. Tovino, supra note 61, at 69.
64. See, e.g., T. Parker-Pope, “Kept from a Dying Partner’s Bedside,” New York Times, May 19, 2009; M.D. Shear, “Obama Extends Hospital Visitation Rights to Same-Sex Partners of Gays,” Washington Post, April 16, 2010.
65. 42 C.F.R. § 482.13(h).
66. Under the Conditions of Participation, reasons must be given in written form to patients.
67. See, e.g., Medicare Conditions of Participation, Patient’s Bill of Rights, 42 C.F.R. § 482.13 (“The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care. The patient’s rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate.”).
68. Patient Self Determination Act of 1990, Pub. Law No. 101-508, Sec. 4206, Nov. 5, 1990.
69. B.R. Furrow, T.L. Greaney, S.H. Johnson, T.S. Jost, R.L. Schwartz, B.R. Clark, E.C. Fuse Brown, R. Gatter, J.S. King, and E. Pendo, Health Law: Cases, Materials and Problems (West Academic Publishing, 8th ed. 2018): at 1337. Under the Uniform Health Care Decisions Act for example, which has been adopted in some form in a number

of states, an institution that declines to comply with a healthcare decision must promptly inform the patient, provide continuing care until a transfer can be effected, and “immediately make all reasonable efforts to assist in the transfer of the patient.” Uniform Health Care Decisions Act Sec. 7 (g).
70. Some state laws make explicit that state refusal laws do not justify refusal of emergency medical care. See, e.g., Cal. Health &Safety Code § 123420(d) (West 2016) (containing an exception for emergency for abortion); Tex. Occ. Code Ann. § 103.004 (West 2016) (“A private hospital or private health care facility is not required to make its facilities available for the performance of an abortion unless a physician determines that the life of the mother is immediately endangered.”).
71. Some scholars have begun to think about the ways in which delegation of power and discretion to private entities both conceals and implicates the state in denial of healthcare. Jessie Hill, for example, argues that looking to abortion restrictions as spatial regulation renders visible the action of the state in creating and reinforcing what otherwise appear to be private decisions. See B.J. Hill, “ The Geography of Abortion Rights,” Georgetown Law Journal 109, no. 5, (2021): 1081–1138.
72. For discussion of the “workplace constitution,” see S.Z. Lee, The Workplace Constitution from the New Deal to the New Right (Cambridge: Cambridge University Press, 2014): at 1; see also C. Estlund, “Rethinking Autocracy at Work,” Harvard Law Review 131, no. 3 (2018): 795-826 (discussing the “constitution of the workplace”).
73. J. Takahashi et al., “ Disclosure of Religious Identity and Health Care Practices on Catholic Hospital Websites,” Journal of the American Medical Association 321, no. 11 (2019): 1103 –04.
74. Some authors have proposed a role for antitrust law in preserving reproductive healthcare. Durand, supra note 4; J.C. Appelbaum and J.C. Morrison, “ Hospital Mergers and the Threat to Women’s Reproductive Health Services: Applying the Antitrust Laws,” New York University Review of Law &Social Change 26, no. 1 (2001): 1–36. Because antitrust often falls short as an effective tool against extensive concentration in many healthcare markets, scholars have begun to develop other tools to confront institutional power. See T.L. Greaney, “Coping with Concentration,” Health Affairs 36, no. 9 (2017): 1564–1571.
75. Cal. Corp. Code § 5917.5.
76. H.B. 2362, 81st Leg. Assemb., Reg. Sess. (Or. 2021). For analysis, see A. Littlefield, “Oregon Will Protect Reproductive Health Care When Hospitals Merge,” The Nation, July 19, 2021.
77. W.E. Corley, “ Hospitals as a Public Utility: or ‘Work with Us Now or Work for Us Later,’ ” Journal of Health Politics, Policy &Law 2, no. 3 (1977): 304–309, at 304 (noting arguments from 1950s).

DETAIL

Subjek:	Patients; Dominance; Joint ventures; Values; Christianity; Employees; Labor law; Palliative care; Religion; Employers; Abortion; Stem cells; Contract negotiations; Health services; Hospitals
Ketentuan indeks bisnis:	Subjek: Joint ventures Employees Labor law Employers Contract negotiations
Lokasi:	United States--US
Pengidentifikasi/kata kunci:	Hospitals; Religion; Health law; Hospital; Separation of church and state; Religion; First Amendment; Concentration
Judul:	Disestablishing Hospitals
Pengarang:	Sepper, Elizabeth; Nelson, James D

Judul publikasi:	The Journal of Law, Medicine &Ethics; Boston
Volume:	49
Edisi:	4
Detail sumber:	First Amendment Values in Health Care
Halaman:	542-551
Tahun publikasi:	2021
Tanggal publikasi:	Winter 2021
Bagian:	Symposium Articles
Penerbit:	Cambridge University Press
Tempat publikasi:	Boston
Negara publikasi:	United Kingdom, Boston
Subjek publikasi:	Law, Medical Sciences
ISSN:	10731105
e-ISSN:	1748720X
Jenis sumber:	Jurnal Akademik
Bahasa publikasi:	English
Jenis dokumen:	Journal Article
DOI:	https://doi.org/10.1017/jme.2021.78
ID dokumen ProQuest:	2730847502
URL Dokumen:	https://www.proquest.com/scholarly-journals/disestablishing-hospitals/docview/2730847502/se-2?accountid=211160
Hak cipta:	
Terakhir diperbarui:	2023-11-27
Basis data:	Public Health Database

“Damned If You Do, Doomed If You Don’t”: A Socio-Medical Commentary on “Of Athletes, Bodies and Rules: Making Sense of Caster Semenya ”

Holtzman, Bryan; Ackerman, Kathryn E

ABSTRAK (ENGLISH)

As medical professionals, we outline the science underlying disorders or differences of sexual development (DSD), discuss the nuances of sex and gender and how terminology can differ based on medical vs. non-medical context, briefly review the evidence of the ergogenic effects of hyperandrogenism, and discuss the medical complications with the hormonal contraceptive use currently dictated by World Athletics to allow DSD athletes to compete in the female category.

TEKS LENGKAP

DETAIL

Subjek:	Patients; Testes; Hair; Disorders; Clitoris; Penis; Hyperplasia; Puberty; Congenital diseases; Classification; Sports; Athletes; Chromosomes; Neurosciences; Terminology; Testosterone; Androgens; Enzymes; Sexes; Gender identity
Orang:	Semenya, Caster
Pengidentifikasi/kata kunci:	Disorders of Sexual Development; Puberty; Contraception; Athlete; Caster Semenya; Hyperandrogenism; Gender; Sex Testing; Track and Field
Judul:	“Damned If You Do, Doomed If You Don’t”: A Socio-Medical Commentary on “Of Athletes, Bodies and Rules: Making Sense of Caster Semenya ”
Pengarang:	Holtzman, Bryan; Ackerman, Kathryn E
Judul publikasi:	The Journal of Law, Medicine &Ethics; Boston
Volume:	49
Edisi:	4
Detail sumber:	First Amendment Values in Health Care
Halaman:	661-665
Tahun publikasi:	2021
Tanggal publikasi:	Winter 2021

Bagian:	Independent Articles: Commentary
Penerbit:	Cambridge University Press
Tempat publikasi:	Boston
Negara publikasi:	United Kingdom, Boston
Subjek publikasi:	Law, Medical Sciences
ISSN:	10731105
e-ISSN:	1748720X
Jenis sumber:	Jurnal Akademik
Bahasa publikasi:	English
Jenis dokumen:	Commentary
DOI:	https://doi.org/10.1017/jme.2021.90
ID dokumen ProQuest:	2730847499
URL Dokumen:	https://www.proquest.com/scholarly-journals/damned-if-you-do-doomed-don-t-socio-medical/docview/2730847499/se-2?accountid=211160
Hak cipta:	© 2021 The Author(s)
Terakhir diperbarui:	2023-11-28
Basis data:	Public Health Database

Curbside Consults in Clinical Medicine: Empirical and Liability Challenges

Zacharias, Rachel L; Feldman, Eric A; Joffe, Steven; Holly Fernandez Lynch

ABSTRAK (ENGLISH)

In most U.S. jurisdictions, clinicians providing informal “curbside” consults are protected from medical malpractice liability due to the absence of a doctor-patient relationship. A recent Minnesota Supreme Court case, *Warren v. Dinter*, offers the opportunity to reassess whether the majority rule is truly serving the best interests of patients.

TEKS LENGKAP

DETAIL

Subjek:	Medical diagnosis; Hospitalists; Medical records; Patients; Supreme courts; Majority rule; Physicians; Consultants; Nurse practitioners; Liability; Medical malpractice; State court decisions; Professional malpractice; Clinical medicine
Lokasi:	United States--US
Pengidentifikasi/kata kunci:	Medical Malpractice; Medical malpractice; Malpractice; Medicine; Curbside Consultation; Informal Consultation; Doctor-Patient Relationship; Warren v. Dinter
Judul:	Curbside Consults in Clinical Medicine: Empirical and Liability Challenges
Pengarang:	Zacharias, Rachel L; Feldman, Eric A; Joffe, Steven; Holly Fernandez Lynch
Judul publikasi:	The Journal of Law, Medicine &Ethics; Boston
Volume:	49
Edisi:	4
Detail sumber:	First Amendment Values in Health Care
Halaman:	599-610
Tahun publikasi:	2021
Tanggal publikasi:	Winter 2021
Bagian:	Independent Articles
Penerbit:	Cambridge University Press
Tempat publikasi:	Boston
Negara publikasi:	United Kingdom, Boston
Subjek publikasi:	Law, Medical Sciences
ISSN:	10731105
e-ISSN:	1748720X
Jenis sumber:	Jurnal Akademik
Bahasa publikasi:	English
Jenis dokumen:	Journal Article

Letter From The Editor

Hutchinson, Ted

TEKS LENGKAP

In this issue of the *Journal of Law, Medicine &Ethics*, our friend Sonia M. Suter of George Washington University Law School corrals a great team of authors to collectively examine “First Amendment Values in Health Care,” a topic of great depth, complexity, and variety that impacts nearly ever facet of law and health care in the United States today. In her opening article on reproductive technologies and free speech, Sonia writes that “The Court, it seems, is using the First Amendment to protect and promote certain perspectives, which …is unconstitutional.” Readers of this symposium will see this scenario play out again and again, as the First Amendment is used as a blunt tool, sometimes more credibly and effectively than others, to silence some voices while amplifying others. And the variety of situations touched upon by First Amendment issues is breathtaking. In this symposium alone we see articles focused on physician’s professional advice, the disestablishment of hospitals with religious affiliations, vaccine hesitancy and religion, and the implications of the Supreme Court’s COVID-free exercise cases. Taken together this is a fascinating collection of important papers, with topics that are at once both timely and timeless.

Of course, just as with the symposium above, our independent articles and columns remain full of material related to the continuing COVID-19 pandemic. This issue contains articles on vaccine anxieties, justice for marginalized populations during the pandemic, do-not-resuscitate orders for COVID-19 patients, and legal interventions to counter COVID-19 denialism. Our peer review queue remains full of thoughtful and probing articles investigating many different aspects of the pandemic, so look for more of this content in future issues of *JLME*.

Finally, we are proud to note that beginning with next issue we will be celebrating the 50th anniversary of the *Journal of Law, Medicine &Ethics*. While we will be publishing special content in the pages of our physical journal, look as well for commemorative collections of *JLME* articles through the years at our online home hosted by Cambridge University Press. Most of these collections will be open-access and free to everyone, so we invite you to look back on some of our old classics collected next to our most current work. I think you will find that the last 50 years have been quite a journey for *JLME*, and we remain ever-grateful that you have chosen to take that journey with us.

DETAIL

Subjek:	COVID-19 vaccines; First Amendment-US; Coronaviruses; Pandemics
Judul:	Letter From The Editor
Pengarang:	Hutchinson, Ted
Judul publikasi:	The Journal of Law, Medicine &Ethics; Boston
Volume:	49
Edisi:	4
Detail sumber:	First Amendment Values in Health Care
Halaman:	509-509
Tahun publikasi:	2021
Tanggal publikasi:	Winter 2021
Bagian:	Letter from the Editor
Penerbit:	Cambridge University Press
Tempat publikasi:	Boston
Negara publikasi:	United Kingdom, Boston
Subjek publikasi:	Law, Medical Sciences
ISSN:	10731105
e-ISSN:	1748720X
Jenis sumber:	Jurnal Akademik
Bahasa publikasi:	English
Jenis dokumen:	Letter To The Editor
DOI:	https://doi.org/10.1017/jme.2021.75
ID dokumen ProQuest:	2730847324
URL Dokumen:	https://www.proquest.com/scholarly-journals/letter-editor/docview/2730847324/se-2?accountid=211160
Hak cipta:	© 2021 The Author(s)

Rethinking the Principle of Justice for Marginalized Populations During COVID-19

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ABSTRAK (ENGLISH)

In the face of limited resources during the COVID-19 pandemic response, public health experts and ethicists have sought to apply guiding principles in determining how those resources, including vaccines, should be allocated.

TEKS LENGKAP

"This white man who is saying 'it takes time.' For three hundred and more years they have had 'time,' and now it is time for them to listen."

— Fannie Lou Hamer

I. Introduction

As COVID-19 continues to spread and vaccines are being distributed, policy makers and providers are faced with consequential decisions on how to allocate scarce medical resources. In addition to ventilators and hospital beds, health systems around the world are constructing plans to distribute vaccines, forcing life and death decisions. To guide this allocation process, public health experts and ethicists ordinarily apply the following four principles: maximize benefits, promote instrumental value, treat people equally, and give priority to the worst off.[1] Each of these subjective principles requires individual considerations that can create competing allocation priorities, leading to debates among healthcare providers and communities on what principles ultimately should govern in a crisis situation.[2] While these four principles may not on their face set up discriminatory allocation of healthcare resources, published data indicate that marginalized racial and socio-economic groups are disproportionately affected by disasters, including COVID-19.[3] These unjust outcomes have not been adequately considered in developing healthcare allocation frameworks. As the inequities in COVID-19 outcomes continue to be uncovered and marginalized communities disproportionately suffer from the pandemic, healthcare providers must consider their role in perpetuating or, alternatively, alleviating these sorts of injustices.[4]

Current data demonstrate that due to structural inequities Black, Latinx, Indigenous, and populations living in poverty suffer higher rates of morbidity and mortality from COVID-19, demonstrating a significant health inequity.[5] Additionally, as vaccines are being distributed based upon age, marginalized populations with lower life expectancies will not receive them at the same rate as White populations. For the purposes of this paper, two phrases require elaboration: A "health disparity" is defined as any differences between population cohorts in terms of incidence of disease, morbidity, mortality, or other adverse health events. A "health inequity" is a health disparity caused by avoidable systemic structures rooted in racial, social and economic injustice, and connected to environmental conditions in which people live, work and play.[6] Equity exists when all persons can attain their full health potential without interference from structures and factors that generate health gaps, including socioeconomic status, race, gender, ethnicity, religion, sexual orientation, or geographic factors.[7]

The inequity across health outcomes for Black, Indigenous and People of Color (BIPOC) diagnosed with COVID-19 has led to calls for states to amend their COVID-19 resource allocation guidelines.[8] In a recent effort to consider health inequities, the Massachusetts Department of Public Health revised its COVID-19 guidelines to advise allocation of resources to patients with the best chance of short term survival.[9] However, critics contest that this change addresses neither preexisting structural inequities nor provider bias, thereby perpetuating worse outcomes in already marginalized groups who enter the care system with compromised health status from unjust exposure to risk.[10]

This paper begins with a discussion around justice and the various ways philosophers have defined it. It then addresses historical and current medical injustices to build the evidence and reason for the argument made in the final section. To better prioritize resource allocation, this paper finally advocates for three applicative justice-based recommendations: (1) when giving priority to the worst off, address historical and ongoing discrimination; (2) place a premium on equitable treatment rather than equal treatment; and (3) maximize healthcare outcomes between and among communities. Doing so will combat structural inequities in prioritizing those who have been historically disadvantaged and continue to be structurally excluded.

Members of the medical community have an important role in shaping policy for the allocation of scarce resources as well as mobilizing additional resources. In considering a historical perspective and medicine's role in society's structural inequities, healthcare providers have an ethical obligation to act in deliberation and collaboration with marginalized populations. They should change the current guiding ethical principles and consider persistent inequities between and among different populations, employing applicative justice (which frames injustice as a curable ill) to reform allocation of scarce resources in the healthcare system and achieve greater justice for all.[11]

This paper begins with a discussion around justice and the various ways philosophers have defined it. It then addresses historical and current medical injustices to build the evidence and reason for the argument made in the final section. To better prioritize resource allocation, this paper finally advocates for three applicative justice-based recommendations: (1) when giving priority to the worst off, address historical and ongoing discrimination; (2) place a premium on equitable treatment rather than equal treatment; and (3) maximize healthcare outcomes between and among communities. Doing so will combat structural inequities in prioritizing those who have been historically disadvantaged and continue to be structurally excluded. Furthermore, by exploring applicative justice frameworks, this paper establishes an ethical framework for reparations to address the historical atrocities and the health inequities experienced by marginalized BIPOC communities.

II. Background: Defining Justice

In the medical sphere, multiple philosophical theories have sought to explain how justice should be implemented. Modern bioethical frameworks for conceiving justice include models from utilitarian, libertarian, egalitarian, feminist, deontological, and religious ethics. Two of the most used theories are (A) egalitarianism and (B) utilitarianism. This paper argues why these leading theories are inadequate and that (C) applicative justice provides a framework for appropriately increasing resource allocation to marginalized communities. Each of these theories has its merits and limitations in guiding decision-making, particularly regarding the issue of resource allocation.

A. Egalitarianism

An egalitarian approach to justice is that all individuals are equal and, therefore, should have identical resources.[12] In the allocation of resources, an egalitarian approach would support a strict distribution of equal value regardless of one's attributes or characteristics. Putting this theory into practice would place a premium on guidelines based upon first-come, first-serve or random selection. Current guidelines put forward by ethicists for treating people during COVID19 recommend using random chance as a way to distribute resources between patients of similar prognoses.[13] The benefit of an egalitarian approach to distributing resources is that implementation is simple; a patient's complex individual characteristics are not considered.[14] Proponents argue that this approach embodies justice by allowing equal access to all regardless of income.[15]

In practice, however, the egalitarian approach continues to worsen health inequities, as research in the United Kingdom specifically demonstrated that a lack of institutional policies and leadership focusing on equitable access across ethnicities further perpetuated inequities.[16] Data reveal that while an egalitarian approach may provide equal access, due to historical and ongoing institutional and structural racism it does not achieve equal outcomes. Beyond this fundamental flaw, the UK's National Health Service has seen a breakdown in its egalitarian approach during the current COVID-19 pandemic, resulting in the institution of a utilitarian approach (discussed below).[17] This paradigm shift provides evidence that an egalitarian approach may work efficiently when resources are plentiful, but it fails when they are scarce.

B. Utilitarianism

A utilitarian approach to justice emphasizes maximizing overall benefits. The founders of classic utilitarianism, including John Stuart Mill and Jeremy Bentham, defined utilitarianism as the greatest good for the greatest number of people.[18] In times of disaster and limited resources, the utilitarian principle has been a historical foundation for guiding decision making.[19] Strict utilitarianism is perceived as impartial because it does not consider inequities if the overall outcome is maximized. In contrast to the egalitarian focus on equal distribution, utilitarianism focuses on managing distributions to maximize outcomes. The benefit of a utilitarian approach is that by focusing on outcomes, resources can be used most effectively. Epitomized by phrases such as "saving the most lives possible," ethical guidelines for allocating resources in the COVID-19 response are primarily built upon utilitarianism.[20] The use of triage (i.e., individuals are categorized into groups based upon their likelihood of survival so that resources can be allocated to ensure survival for the highest number of people) is another manifestation of an utilitarian approach.[21] Research has shown that in settings of pressure and time constraints, triage misdiagnosis is commonplace, particularly in crisis implementation.[22] Further, utilitarian principles often have been misused to justify withdrawing care from a patient for the sake of conserving resources for future cases. Examples of this phenomenon are the alleged euthanasia of patients at New Orleans' Memorial Medical Center in the wake of Hurricane Katrina or the case of a Black quadriplegic man who did not receive advanced care in a Texas hospital, defended by some as justified to maximize the outcome for all patients.[23] These patients, however, were not sick or dying, but instead had chronic medical conditions that made their care difficult, their prognosis poor, and possible evacuation challenging; withdrawing care from these patients violated the ethical principles of patient autonomy, non-maleficence, and justice. Patients from whom care was withdrawn were more likely to be Black or Latinx and of lower socioeconomic status.[24] In situations where resources are limited and the utilitarian paradigm is applied to maximize outcomes, marginalized populations risk being harmed disproportionately because they are already excluded from accessing the healthcare system, have been subjected to historical harms, and are unfairly exposed to risk leading to higher rates of chronic disease.

C. Applicative Justice

Distributive justice is a twentieth century counterpoint to both egalitarianism and utilitarianism. Proposed by John Rawls in *A Theory of Justice,* distributive justice is composed of the concepts of "equal liberty" and the "difference principle."[25] Together, these concepts mandate that resources should be allocated to those with the greatest need in a manner that does not infringe upon individual liberties.[26] This approach requires sensitivity to societal inequality — a factor absent from consideration in egalitarianism and utilitarianism. However, Rawls neglected to address health in his theory since he did not see it as a resource.

Naomi Zack directly critiques this flaw and distributive justice in general, developing her own theory known as applicative justice, which reorients injustice as a curable illness that society can remediate.[27] Applicative justice extends beyond distributive justice to directly addresses social inequities and how one's access to resources, including healthcare, education, and employment, affects one's health and is therefore an issue that justice should address. This is vital for realizing a true theory of justice in the allocation of healthcare resources. This kind of approach in ethics is supported by the human development approach used in research which acknowledges that, "health status of individuals is affected by the matrix of political, social, [and] economic factors."[28]

Advocates of applicative justice believe that for justice to be achieved, systemic changes are needed in society's

institutions to improve the lives of the most marginalized individuals. In many ways, applicative justice comes closest to providing a resource allocation framework that satisfies the Aristotelian definition of justice, namely, to distribute resources to account for differences in order to equalize outcomes.[29] While applicative justice seeks to balance inequities, effective implementation can be fraught in systems where White supremacy is normalized.[30]

The most common criticism of applicative justice is that its implementation can be intricate, complex, and potentially lead to errors. Applicative justice opponents assert that since there is no clear path to its implementation, none should be taken.[31] This argument for intransigent inaction perpetuates structural racism, heterosexual biases, and socioeconomic inequities.[32] White supremacy is pervasive in our current system, a system with inherent and overt biases in favor of economic elite White cis-gendered heterosexual norms and against all non-conforming groups.[33] In other words, White supremacy creates a culture in which discrimination against non-conforming groups (e.g., BIPOC) is purposely perpetuated. Our current medical system and its resource allocation approaches, overtly and covertly ensure that resources and opportunities are kept from BIPOC communities, gender minorities, and marginalized socioeconomic groups.[34] As we have seen for decades, any policy that looks to distribute resources equally rather than equitably will further perpetuate poor outcomes for BIPOC communities.[35] While it may be challenging to implement a system that considers intersectionality, applicative justice demands it.

In light of this philosophical framework, the next section details why our current medical system violates the core tenet of justice in medical ethics and reinforces White supremacy.

III. Ethical Grounding: Medical Injustices

Medical injustices have been perpetuated by social and medical institutions and White supremacy. Subsection A discusses this sordid medical history, and subsection B describes the current structures that fuel these inequities. These sections collectively build the evidence for the final argument in Section IV.

A. A Brief History of Injustice in Medicine

Past harms caused by the flawed delivery of medical care and medical research systems are ethical catalysts to act.[36] Below is a brief historical review of medical injustices, highlighting the need and obligation for reform.

Reports of medical discrimination against various communities are numerous in both practice and research. Medical discrimination based upon (1) race,[37] (2) biological sex,[38] (3) sexual orientation,[39] (4) gender identity,[40] and (5) socioeconomics[41] is well documented.

- 1. *Race*: Examples of discrimination based on racial grounds are plentiful. In her book *Medical Apartheid*, historian Harriet Washington has chronologically covered the horrific experimentation to which Black communities were subjugated from colonial times to the present day.[42] Her work describes the racial pseudoscience of eugenics, the Tuskegee syphilis study, and less well-known atrocities perpetuated by the government and private institutions. These events contributed to inequities in medical care, fostered mistrust, and resulted in unnecessary death (it is estimated that between 1970 and 2004 racism in multiple forms resulted in more than 2.7 million Black deaths).[43] These examples are often cited and barely begin to represent the violence experienced by Black communities.

  In the Latinx community, there is deep-seated, historical discrimination associated with the view that immigrants are less deserving of access to care.[44] Additionally, as a result of a series of legislative initiatives, Latinx people have been accorded fewer benefits and support in seeking and receiving culturally-appropriate medical care, and obtaining it in a manner that addresses language barriers.[45]

Finally, at the hands of the United States government, Indigenous populations have experienced centuries of systematic genocide and ethnocide with scant public acknowledgement.[46] Examples specific to the medical community include the violation of research ethics to use blood samples from the Havasupai tribe and the involuntary sterilization of over 3,000 women by the Indian Health Service (IHS), a numerical figure likely to be higher since only four out of twelve IHS areas were studied.[47] The women sterilized by the IHS were coerced, threatened, and fed misinformation to ensure cooperation.

Collectively, these examples just scratch the surface of the racist atrocities in medicine driven by normative White supremacy. They also show why many BIPOC communities have vaccine hesitancy and why many institutions are not trustworthy.[48]

- 2. *Gender and Sexual Orientation*: The lesbian, gay, bisexual, transgender, queer, intersex, asexual, (LGBTQIA+) communities in the United States have a history of stigma and abuse by the medical establishment with their personhood being classified as a pathologic diagnosis.[49] These communities have suffered healthcare marked by insensitivity, prejudice, and ignorance, leading to higher rates of chronic health disease and mental health disorders. Up until the 1970s, not being of heterosexual orientation was considered a pathological mental disorder classified in the Diagnostic and Statistical Manual of Mental Disorders (DSM).[50] Further, efforts to eradicate homosexuality in individuals have been considered reasonable and treatment by conversion therapy previously garnished medical support. Systematic reviews of conversion therapy have shown it not only violates human rights, but it also leads to physiological and psychological harm.[51] Transgender and gender non-conforming individuals have faced systemic abuse, as gender identity disorder was considered a pathologic diagnosis up until the latest DSM.[52] This population has continually experienced abuse and refusal of services from the healthcare system and has been blocked from accessing gender conversion services.

- 3. *Economic Status*: The medical community has harmed impoverished groups, which are disproportionately BIPOC, by a) withholding care (and distributing care based on ability to pay), b) providing lower quality care, and c) targeting members of this community for research.[53] In contrast to many other countries, healthcare in the United States is not considered a human right but rather it is thought to be a commodity requiring paid access. Because we ration health services by ability to pay, this history has kept necessary care out of reach for the economically disadvantaged, perpetuating their poor health and thereby impacting their opportunities for socioeconomic advancement. In the 1940s, as a means of increasing access to healthcare, this dynamic began to change with adoption of the Social Security Act, and further expansion was achieved by the passage in 2010 of the Affordable Care Act.[54] Despite some gains in insurance access, other barriers, including availability and location of providers and healthcare centers, still exist and prevent impoverished patients from obtaining the same quality of care received by others.[55] While the medical field may not have control over all of these factors, research has shown that physicians consciously and unconsciously discriminate against patients with public or low-cost health insurance.[56] This discrimination happens both at the interpersonal level between patients, staff, and providers, as well as structurally when it comes to how patients are treated by healthcare and insurance systems and hospitals.[57]

Collectively, this history of abuses and inequities contradicts the goals and principles of egalitarianism, utilitarianism, distributive justice, and applicative justice. This brief review of historical brutalities and discrimination committed by the medical community offers necessary context to propel action to take definitive steps towards achieving applicative justice and systemic changes that remove White normative biases.

B. Current Structural Inequities

An influential essay by Dr. Camara Jones, entitled “Levels of Racism: A Theoretic Framework and a Gardener’s Tale,” outlines the levels of racism in our society and how it perpetuates healthcare inequities.[58] The essay defines *institutional racism* as unequal access to goods, services, and opportunities through structural systems, often manifested as inaction in the face of need. This definition extends beyond race and includes other forms of discrimination based upon biological sex, socio-economic status, and other social factors, which indirectly and directly affect one’s health. These factors help explain why, even after controlling for individual risk factors, people with lower incomes and BIPOC live shorter lives.[59] As mentioned previously, any system that has the net effect of

benefitting White communities over BIPOC, is one of White supremacy. For example, it is clear that our education, housing, insurance, and employment systems uphold White supremacy by perpetuating racial inequities, leaving the medical community with the obligation to consider the contributing role it plays.

It is a fact that medical treatment is unfairly allocated based on race and the social interpretation of people's appearance.[60] Even when insurance coverage is considered, reviews have found that there is a notable racial gap across many therapeutic procedures.[61] A recent study showed that this gap may be due to the causal relationships that healthcare providers construct across racial groups.[62] For example, a meta-analysis covering the last twenty years found that Latinx and Blacks were significantly undertreated for pain compared to their White counterparts.[63] This is partly due to bias and racist beliefs that providers hold. In interviewing trainees, a study by the National Academy of Science found that half of medical students and residents harbored racist beliefs such as "Black people's nerve endings are less sensitive than White people's" or "Black people's skin is thicker than White's."[64] This evidence points to why direct and systematic action is needed counter the prejudices that people of color experience.

It is a fact that in the United States patients of different biological sexes do not receive the same quality of healthcare.[65] To this day, compared to men, women experience complex health conditions that are not always properly managed.[66] From barriers in accessing quality reproductive healthcare to how much care women receive overall, health inequities persist for women. Middle-aged and older women are more likely to have fewer hospital stays and physician visits compared to men of similar demographics and health risk profiles.[67] In the field of critical care, women are less likely to be admitted to the ICU, are less likely to receive interventions such as mechanical ventilation, and are more likely to die compared to their male ICU counterparts.[68] These inequities can be attributed to both provider bias and the traditional use of male subjects to develop treatment algorithms.[69] The data on unequal treatment in ICUs are particularly troubling as COVID-19 places thousands of women with acute respiratory needs at risk of needing ICU care.

It is a fact that in the United States, patients living in poverty do not receive the same quality of healthcare as their higher economic status counterparts.[70] Patients with lower incomes are more likely to have higher rates of infant mortality, chronic disease, and a shorter life span.[71] This is also seen by how the United States treats those who experience homelessness who have a life expectancy decades shorter than the overall population and one in three of their deaths could have been prevented by timely and effective medical care.[72] As previously mentioned, this discrimination is multifactorial and includes discrimination based on insurance plans (or lack thereof), and includes receiving lower quality care, longer wait times, poor communication, and even emotional and verbal abuse.[73] Justice in medicine has not been applied equitably across our nation, and this is particularly evident as the lives of BIPOC and impoverished communities are being lost to COVID-19 at higher rates than other populations. As described in the research studies cited above, the factors at play are complex though not immutable, and involve structural, institutional, and interpersonal elements. Taking no action to address these factors is unethical and perpetuates white supremacy.[74] Therefore, it is necessary to end these inequities.

IV. Expanding Justice for COVID-19 Response

There will never be a convenient time to consider how to respond to these inequities, but with the harm that COVID-19 has and will cause to marginalized populations, any further delay in addressing them means unjust and unnecessary mortality. This is particularly highlighted by how the average life expectancy gap widening among races with a new drop in life expectance of 2.7 years for Blacks, 1.9 for Latinx, and 1 year for Whites.[75] As vaccines are being rolled out based upon age, these factors must be considered to make sure every population is getting equitable access. The literature indicates there are both structural and individual factors that require consideration.

While states such as Massachusetts have started to contemplate these factors in formulating guidelines, they are not being fully addressed. Redefining justice is especially pertinent now as the vaccine is just beginning to be distributed. There is no simple solution to resolve these inequities, but they are overlapping and interdependent, and therefore require individual and collective attention.

We can start with expanding our current model of justice to acknowledge and account for inequities. Current models of justice such as egalitarianism and utilitarianism are insufficient; instead, we must follow the dictates of an applicative justice approach to expand health care coverage and adjust COVID-19 guidelines to provide equitable care and prevent further harm to marginalized communities. Of note, applicative justice is one of the only ways to combat historical medical injustice and structural inequities. This is because it is the only framework that prioritizes equity based on health outcomes and individuals who are disadvantaged for social or cultural reasons. Subsection A, below, describes the nature of the proposed allocation reform, Subsection B then details the implications associated with reform, and Subsection C describes how an applicative justice framework demands medical reparations.

A. Nature of Proposed Reform

In a manner consistent with applicative justice, there are a number of ways in which medical reforms could be instituted. Three specific reforms to allocation of healthcare are suggested below.

1. By giving priority to the worst off, historical and ongoing discrimination will be addressed

Current recommendations suggest that when aligned with maximizing benefits, the sickest and the youngest should receive resources.[76] As we note, prior to COVD-19, marginalized groups were worse off for a multitude of reasons, including institutional biases, structural barriers, and unfairly distributed co-morbidities. Therefore, this guideline addressing factors associated with discrimination should be added to ensure that allocation aligns with maximizing benefits for the most marginalized.

Justice in medicine has not been applied equitably across our nation, and this is particularly evident as the lives of BIPOC and impoverished communities are being lost to COVID-19 at higher rates than other populations. As described in the research studies cited above, the factors at play are complex though not immutable, and involve structural, institutional, and interpersonal elements. Taking no action to address these factors is unethical and perpetuates white supremacy. Therefore, it is necessary to end these inequities.

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2. In lieu of equal treatment, there should be equitable treatment

Under current recommendations for COVID-19 guidelines, the only principle recommended in the section on “treating people equally” is using random selection to allocate resources among patients with similar prognoses. As the research above has shown, BIPOC, those of lower socioeconomic status, LGBTQIA+, and women are less likely to receive appropriate care. These inequities have occurred in our system since its inception. Given these systemic inequities, we must pursue equitable policies to assure that these populations receive the resources they deserve — otherwise the current observed inequities will persist, and our inaction will continue to actively perpetuate harm.

3. Across communities, maximize medical benefits

We use the value of maximizing benefits to guide healthcare decisions in and out of crises and to set priorities, agendas, and budgets, including those in the COVID-19 response. It is this current principle that is directing guidelines in Massachusetts and California.[77] However, simply maximizing benefits favors privileged White individuals since they tend to be healthier and more likely to have a favorable prognosis compared to marginalized communities. A more just benefits allocation will be mindful of the need to apportion resources across communities

equitably, accounting for historical and current biases against communities at the intersection of non-normative race, gender and class, meaning BIPOC and LGBTQIA+, and impoverished communities. This principle would also consider demographics in allocation of vaccine, acknowledging that specific communities are more likely to contract and die from COVID-19. By doing so, the unjust distribution of COIVD deaths due to systemic discrimination could directly be addressed providing greater equity across the total population.

B. Implications Associated with Reform

There are several implications associated with reform, as enumerated below.

1. Suggestions for Research-Based Implementation:

For successful implementation of the proposed policy changes, two important factors need to be considered: structural biases and individual biases.

More research is needed to understand the structural inequities in society at the local, state, and national levels. Institutions at each one of these levels need to initiate research cycles that continually evaluate inequities, outcomes, effectiveness of interventions, and systems of accountability. Completely rooting out flawed assumptions and biases is difficult; nevertheless, research efforts rooted in public health critical race praxis could, over time, systematically improve our healthcare systems at all levels.[78] It is important to note that while quantification through algorithms may be useful, recent research has shown how algorithmic approaches could incorporate biases and further perpetuate inequities.[79]

Individual biases expressed through healthcare provider attitudes and decisions are common and difficult to address. A research-based, adaptive approach with built-in community engagement has the potential to provide a counterpoint to cognitive biases that providers hold.[80] Each healthcare network should use the three proposed guidelines to amend their systems by first accounting for the ways in which they contribute to inequities among each marginalized group. This step requires engaging the communities experiencing discrimination and working under their direction to find appropriate solutions.

The advantages of the suggested revised COVID-19 guidelines based on an applicative justice ethic are clear. They acknowledge past discrimination marginalized groups have faced, combat current discrimination, and still maximize resources across the public served by the United States healthcare system. Further, these guidelines will help mitigate the inequitable distribution of COVID-19 cases and negative outcomes seen in marginalized populations. Building applicative justice principles into hospital guidelines is a progressive step that should result in decreased morbidity and mortality for the most at-risk individuals. Ultimately, this approach can and should be adapted to various disciplines in medicine outside the current pandemic.

2. Critiques of the Proposed Applicative Justice Approach: There are a few alleged critiques of these proposed guidelines that cannot be ignored.

First, the recommendations may be misconstrued as “reverse discrimination,” or discrimination against a majority group that is historically advantaged.[81] In many respects, the idea of “reverse discrimination” is a fallacy for the following reasons:

- a. Discrimination requires that one group uses its power and privilege to affect the opportunities and lives of another group. As previously noted, the power and privilege in American medicine has always been, and continues to be, held by Whites.[82] That being the case, any recommendation increasing access to marginalized groups cannot marginalize or oppress Whites since they generally continue to hold the power and privilege in the medical system and social structure. Instead, these recommendations attempt to increase access and opportunity for those being oppressed.

- b. As the data presented in this paper reveal, our current system already unjustly benefits privileged groups, mainly middle and upper class Christian White cis-males and does not treat all individuals equally. Therefore any policy that does not acknowledge existing inequalities and their unjust outcomes, or that supports a colorblind approach, instead furthers White supremacy.[83] These measures aim to increase equity and enhance justice at a systematic level.

- c. Overall, these proposed policies are not advocating for the betterment of marginalized groups at the expense of the White majority. Applicative justice does not seek to disenfranchise groups that hold power in the system but transform the system so that those in power do not continue to obtain unfair benefits. Further it accounts for unjust historical oppression and current injustices to provide equitable outcomes to all.

- d. Finally, applicative justice does not intentionally target any privileged groups, but seeks to raise up those who have been marginalized. The only reason that a privileged group (i.e., the White majority) might "lose" something is because they are unjustly receiving a disproportionate number of resources at the expense of others in the current system as it exists.

Second, critics might argue that these guidelines could start a chain reaction of policy reconsideration leading to reverse discrimination in medicine and elsewhere in society. This slippery slope argument is a classic logical fallacy and not a true critique. Considering our nation's historically embedded institutional and interpersonal discrimination based on normative White supremacy, we can hardly expect an avalanche of change. Instead, these measures will likely face intense opposition from those leading current structures. And again, reversing biased public health responses is not an example of reverse discrimination so long as the focus is on equitability.

A third critique is that applicative justice-based guidelines fail to achieve the ultimate maximization of resources from a utilitarian perspective and that such guidelines unethically waste resources in a crisis. While there may be fewer overall life-years saved per available resource, it is the goal of these guidelines to maximize resources while ethically and equitably distributing them across the sick population. Using utilitarian phrasing, this is the greatest good for the greatest number of people across demographics. Therefore, these policies still fulfill the utilitarian maxim, but do so in a way that applies the maxim fairly across all people. This ethical imperative for this measure has been addressed previously in our need to account for historical and current inequities.

C. The Case for Reparations

The proposed policy changes are an attempt to provide equitable care in the context of the current pandemic. Yet, they do not address all the historical atrocities committed against marginalized communities or the systemic, institutional, interpersonal, and internalized biases that created today's expansive health inequities. Under the applicative justice framework, it is clear that justice demands not only that inequities be tackled going forward but past injustices be acknowledged and addressed.

If we had enacted reparations for Black American descendants of enslaved persons, projections demonstrate that COVID-19 transmission would have been reduced by 31-68% in Louisiana.[84] This is partially due to the complex interplay of factors that Cedric Robinson defines as racial capitalism.[85] Robinson outlines how all layers of capitalism are built upon racial stratification, which has led to exploitation of BIPOC communities and subsequent inequities. To generate equity, the underlying economic system must be rethought and transformed.

To directly right health inequities, the medical community needs to support wide spanning financial restitution to systematically address historical discrimination and resource extraction from BIPOC communities. Using the framework of William Darity and A. Kristen Mullen, reparations should be structured in a process that ensures

acknowledgement, redress, and closure that is led by the affected community.[86]

V. Conclusion

Structural inequity continues to create the conditions for poor health outcomes in BIPOC communities and the devastating impact of COVID-19 only makes that longstanding pattern more obvious. Applicative justice makes it clear that it is unethical to let these inequities continue without decisive action. New policies and actions must be implemented to help providers and institutions alleviate ongoing health inequities, especially as the vaccine is now being distributed. Supported by data-driven principles, our three proposed guidelines seek to improve current recommendations and to make an ideological shift in healthcare resource allocation. Using the guiding principles of applicative justice, additional initiatives are also needed to transition the healthcare system from White supremacy towards equity and racial justice. While critics may suggest this is reverse discrimination, the proposed theory and guidelines — which, over time, will require further refinement — do not discriminate; rather they seek to remedy existing inequities and policies that discriminate against BIPOC.

The disruption caused by COVID-19 is a unique opportunity to adopt changes that should have occurred long ago, curtailing unfair disability and death amongst marginalized populations, righting injustice, and starting to rebuild trust. While implementation of these guidelines may achieve a more just outcome, restitution is also needed to correct historical systemic biases and attempt to heal the centuries of violence and neglect committed by the medical community against BIPOC. Collective action grounded in applicative justice can bring our medical system closer to equity during the present crisis and in the future.

Note

The authors have no conflicts to disclose.

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DETAIL

Subjek:	Patients; Public health; COVID-19 vaccines; Principles; Socioeconomic factors; COVID-19; Medical prognosis; Egalitarianism; Minority &ethnic groups; Mortality; Pandemics; Utilitarianism; Health disparities; Ethics; Coronaviruses; Philosophers; Social exclusion
Lokasi:	United Kingdom--UK
Pengidentifikasi/kata kunci:	Justice; Outbreak response; Coronavirus; Social exclusion; COVID-19; Vaccine; Justice; COVID-19; Systematic Discrimination; Equity; Racism; Distributive Justice; Applicative Justice; Normative White Supremacy
Judul:	Rethinking the Principle of Justice for Marginalized Populations During COVID-19
Pengarang:	Ashworth, Henry; Soled, Derek; Morse, Michelle
Judul publikasi:	The Journal of Law, Medicine &Ethics; Boston
Volume:	49
Edisi:	4
Detail sumber:	First Amendment Values in Health Care
Halaman:	611-621
Tahun publikasi:	2021
Tanggal publikasi:	Winter 2021
Bagian:	Independent Articles
Penerbit:	Cambridge University Press
Tempat publikasi:	Boston
Negara publikasi:	United Kingdom, Boston
Subjek publikasi:	Law, Medical Sciences
ISSN:	10731105
e-ISSN:	1748720X

The Ethics of Unilateral Do-Not-Resuscitate Orders for COVID-19 Patients

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ABSTRAK (ENGLISH)

This paper examines several decision-making models that have been proposed to limit the use of CPR for COVID-19 patients. My main concern will be to assess proposals for the implementation of unilateral DNRs — i.e., orders to withhold CPR without the agreement of patients or their surrogates.

TEKS LENGKAP

Response to the COVID-19 pandemic requires a careful balancing of the ethical principles that guide medical practice, particularly when clinicians and institutions consider adjustments to standards treatment protocols. In conventional circumstances, medical decisions are guided primarily by the welfare and autonomy of individual patients. Medically indicated treatments are typically administered when they accord with the duly considered wishes of consenting patients. In crisis circumstances, however, the individualistic focus of conventional decision-making must be supplemented by a utilitarian model, which aims to promote effective stewardship of resources and, ultimately, to treat and save the greatest number of patients. Interventions that would ordinarily be offered to an individual patient might be withheld or withdrawn, despite the wishes of that patient or her/their surrogate, in order to provide care to those who are more likely to benefit. The most obvious example of a deviation from ordinary standards of care occurs when acute care facilities exceed functional capacity and triage decisions become necessary. Though triage decisions are clearly utilitarian in character, due consideration for the rights and dignity of all patients can be preserved so long as fair allocation criteria are adopted.

In the early days of the COVID-19 pandemic, crisis planners in the United States reflected on the triggers that would signal transitions from conventional to contingency to crisis operations at acute care facilities, and the adjustments to treatment protocols that might be warranted as supplies, space, and staff became more scarce. Understandably, much discussion focused on procedures that would be employed in the worst-case scenario, when demand severely outstrips capacity and crisis standards of care must be implemented. Discussions of resource allocation in the popular media were similarly focused on the specter of overwhelmed health care facilities and, in particular, on the dramatic zero-sum game that would result from allocating a potentially life-saving resource to one patient over another. Less dramatic though equally important were decisions to modify conventional treatment protocols to help conserve resources and hopefully prevent escalation to crisis operations. Examples of modifications to protocols that have been instituted to conserve resources include: reusing personal protective equipment (PPE), which has been in chronically short supply; accepting lower saturation levels before initiating use of oxygen, in order to conserve oxygen and oxygen administration supplies; and limiting the number of health care workers engaged in direct care of COVID-19 patients, in order to reduce the risk of contagion.1

Measures to conserve both material and human resources are a key component of crisis management, but they are not without controversy, particularly when they involve significant deviations from established practices. Debates about the use of cardiopulmonary resuscitation (CPR) for COVID-19 patients are an important example of such controversy. In ordinary circumstances, CPR is provided by default to all patients who might be successfully resuscitated; exceptions are made when patients or their surrogates request or agree to a do-not-attempt-resuscitation (DNR) order. Some have argued that CPR is overused, because success rates are very low for many critically ill patients and the burdens associated with the intervention, which are not always understood by patients, often outweigh any possible benefits.2 Nevertheless, CPR is almost always provided when requested by patients or their surrogates. This holds even for cases in which clinicians believe that CPR will not benefit the patient by prolonging life or serving any reasonable goal of care. Though physicians are not obligated to offer interventions that are medically ineffective, unilateral decisions by physicians to withhold CPR on grounds of futility are rare.

Measures to conserve both material and human resources are a key component of crisis management, but they are not without controversy, particularly when they involve significant deviations from established practices. Debates about the use of cardiopulmonary resuscitation (CPR) for COVID-19 patients are an important example of such controversy.

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In order to effectively manage critical resources during the pandemic, some crisis planners have called for revisions to standard procedures governing the use of CPR, specifically as applies to COVID-19 patients. CPR is a resource intensive intervention, requiring significant expenditures of PPE and other medical equipment, as well as deployment of multiple health care workers who are exposed to increased risk of contagion. Moreover, some studies have shown high mortality rates among critically ill COVID-19 patients, despite use of aggressive intensive care interventions.[3] In light of these factors, it is plausible to argue for a more judicious use of CPR for COVID-19 patients, both to safeguard human and material resources, and to avoid administering a burdensome intervention that is not likely to provide any meaningful benefit.

In what follows I will examine several models that have been proposed to limit the use of CPR for COVID-19 patients. My main concern will be to assess proposals for the implementation of unilateral DNRs — i.e., orders to withhold CPR without the agreement of patients or their surrogates. Decision-making models include both patient-centered justifications for unilateral DNRs, grounded in appeals to futility, and utilitarian justifications, grounded in concerns about resource scarcity. I will argue that patient-centered rationales for unilateral DNRs appear to extend the concept of futility beyond its usual meaning and application, while utilitarian justifications sometimes fail to delineate the circumstances under which a shift from patient-focused care to maximization of public health outcomes is warranted. This lack of clarity can sow confusion and lead to clinical judgments that don’t align with well-established principles of crisis management, such as consistency, transparency, the duty of care, and fairness.

Though unilateral DNRs can be justified as an element of pandemic response, I will argue that their use should be carefully restricted. Rationales for withholding CPR based on futility judgments must be consistent with current practice, and rationales based on scarcity of human and material resources should only be used when crisis standards of care are in effect.

1. Proposals to Limit the Use of CPR for COVID-19 Patients

The most extreme proposal to alter CPR protocols in response to the pandemic was circulated for discussion in March of 2020 at several institutions, including Northwestern Memorial Hospital in Chicago.[4] This proposal called for declaring a Universal No Code for COVID-19 patients. According to this policy, a DNR order would be written for all COVID-19 patients, irrespective of their wishes, and natural death would be allowed for any patient who went into cardiac arrest. The primary rationale for this proposal was to protect health care workers and to conserve personnel for the predicted surge of patients. Though the pandemic had yet to hit the United States with full force (only about 100 persons had died in New York state at the time the proposal was circulated), statistics from the raging pandemic in Italy were bleak, with health care workers accounting for about 1 out of 6 COVID-19 deaths, and a much larger number sidelined after contracting the virus. Obviously, loss of trained personnel severely undermines our ability to treat and save critically ill patients in a public health crisis, and the Universal No Code proposal reflected a legitimate desire to avoid the severe degradation of medical personnel witnessed in Italy. An additional rationale for this proposal centered on the fact that administering CPR to COVID-19 patients requires enhanced protective measures. The time it takes to don PPE before administering CPR to a COVID-19 patient in cardiac arrest significantly reduces the chance of a successful outcome. As one clinician noted, “By the time you get all gowned up and double gloved the patient is going to be dead … We are going to be coding dead people.”[5]

Though motivated by legitimate public health concerns, the Universal No Code proposal proved controversial, and has not yet been adopted by any acute care institution in the United States. The most significant problem with the proposal is that it lacks sufficient nuance, failing to differentiate between COVID-19 patients who are unlikely to benefit from CPR and those who may well benefit, such as younger, otherwise healthy patients. Physicians are not obligated to provide futile interventions, as would occur when attempting to “code a dead person,” and scarcity may provide a basis for withholding CPR from patients who are unlikely to benefit during crisis operations, when triage decisions are necessary; but declaring a Universal No Code as a resource conserving measure prior to the implementation of tirage procedures denies CPR to those who might benefit, and deviates too severely from the primary duty of care that must be maintained even during a pandemic. Adopting a Universal No Code policy for COVID-19 patients could also erode public trust in health care institutions and discourage patients with other illnesses from considering DNR orders that might align with their wishes and interests.6

While the Universal No Code proposal gained little traction, more nuanced proposals calling for selective use of CPR on COVID-19 patients have been widely endorsed as a component of pandemic response. These proposals call for providing CPR to COVID-19 patients who might benefit but withholding it from those for whom it is likely to be medically ineffective. A prominent example was produced by Mark Tonelli and colleagues at the University of Washington Medical Center, in a policy statement entitled “Code Status and Covid-19 Patients.”[7] This statement begins by noting increased mortality among hospitalized COVID-19 patients based on advanced age and the presence of comorbidities such as hypertension, diabetes, and coronary artery disease. Patients requiring invasive mechanical ventilation also suffer higher mortality rates, as indicated in a study of patients in two hospitals in Wuhan, China, which confirmed only one survivor out of 32 COVID-19 patients who received such ventilation. In addition, the authors note that “survival to hospital discharge for [all] critically ill patients receiving CPR is very low (<15%), with already being on mechanical ventilation, older age, and comorbidities reducing that likelihood even further.” In light of these statistics, the authors state their central policy recommendation:

CPR may be medically inappropriate in a significant portion of elderly, critically ill patients with Covid-19 and underlying comorbidities … Per [University of Washington Medical Center] and [Harborview Medical Center] policies, clinicians are not obligated to provide medically inappropriate treatment, even when requested by patients and/or designated surrogates. If treating clinicians, including more than one physician, determine that CPR is medically

inappropriate, a Do Not Attempt Resuscitation Order (DNR) may be written without explicit patient or family consent.8

The document concludes by emphasizing the need for clear and sensitive communication aimed at securing "informed assent" from patients or surrogates of patients who will not receive CPR.9 But the salient element of the proposal is unmistakable: Clinicians should be prepared to write unilateral DNRs for COVID-19 patients when they determine that CPR is not medically appropriate due to poor prognosis.

"Code Status and Covid-19 Patients" was distributed for discussion among crisis planners across Washington state, and it also influenced pandemic response discussions elsewhere. Perhaps most notably, the document was adopted by the Catholic Health Association of the United States (CHA) and incorporated almost verbatim into its own guidelines for the use of CPR on COVID-19 patients at Catholic institutions.10 As is to be expected, the CHA guidelines are expanded to include language that reflects core principles of Catholic medical ethics, such as commitment to "the inherent dignity of all who seek care" and to compassionate "accompaniment" of those who face life-threatening illness. The CHA emphasizes two additional points that are worth noting. First, it emphasizes that "the clinical indica for decision-making about any medical intervention are the same as they have always been"; in other words, the CPR guidelines for COVID-19 patients are "merely an application and implementation of best-practices applied to the current setting."11 Second, the CHA emphasizes that besides clinical benefit to individual patients, hospitals must consider the health and safety of staff and take steps to reduce their exposure to the virus when CPR is administered. By emphasizing that the "duty to care exists not only for the patient but also for the health care team," the CHA guidelines appear to suggest that danger to health care workers might also factor in to code status decisions for COVID-19 patients, though there is no explicit guidance on when or how this should occur.12

This suggestion is made explicit in "Guidance for Decisions Regarding Cardiopulmonary Resuscitation during the Covid-19 Pandemic," coauthored by Scott Halpern and Douglas White, and disseminated by the Palliative and Advanced Illness Research Center (PAIR) at Penn Medicine.13 According to the PAIR website, these guidelines aim "to promote a nationally standardized approach to these difficult decisions" and they have been "adopted by hundreds of hospitals around the world."14 The guidelines identify three key considerations that should guide CPR decisions during the pandemic: (1) the potential for benefit to patients; (2) the risk of contagion to health care workers; and (3) the importance of individualized decision making, as opposed to blanket withholding of care to certain groups of patients based on illness, age, or comorbidity. In light of these considerations, the authors make three recommendations. The first recommendation is that CPR should not be offered when it is "medically inappropriate," because it would not improve the patient's prognosis or serve any reasonable goal of care. For COVID-19 patients, this may include "those with advanced age and comorbidities, and/or with progressive respiratory failure despite maximal levels of invasive mechanical ventilation." Importantly, the authors add that "the risks to healthcare providers of performing CPR may influence the determination that CPR is not medically appropriate, if coupled with considerations of individual patients' prognoses"; the same would hold true if PPE "is already being rationed." This suggests that risks to clinicians and/or shortage of PPE can justify concluding that CPR is medically inappropriate, even if there is a small chance of benefit to a patient. If crisis operations have been declared and triage procedures are in effect, CPR might also be judged inappropriate for a patient who might be saved if "the patient would not receive high enough priority for subsequent critical care." The second and third recommendations of the Pennsylvania guidelines pertain to fair process, emphasizing the need for independent review from a consulting physician before writing a DNR, and the need to inform the patient or surrogate of the rationale for the DNR. As in the Washington and CHA guidelines, assent from the patient or surrogate should be sought but is not required.

2. Assessing the Models: Patient-centered versus Utilitarian Justifications for Unilateral DNRs

The Washington, CHA, and Pennsylvania models each provide useful recommendations for physicians that are grounded in well-established ethical principles and clinical practices. Especially helpful are recommendations for increased advance care planning to promote patient understanding and alignment of care with their wishes and

interests. At the same time, these models give rise to some significant ethical questions, particularly with respect to the conditions under which unilateral DNRs for Covid-19 patients might be justified. Two key areas that warrant critical attention are: (1) the use of futility judgments to justify unilateral DNRs and (2) the use of unilateral DNRs during conventional or contingency as opposed to crisis operations.

It should be clear from the preceding review that futility judgments provide a key rationale for the use of unilateral DNRs for Covid-19 patients. While the term “futility” is now largely avoided in favor of terms such as “medical ineffective” and “medically inappropriate,” these terms all point to scenarios in which an intervention is not expected to provide benefit to the patient. Each of the proposed guidelines note increased mortality rates among critically ill COVID-19 patients based on age, comorbidities, and the use of mechanical ventilation, and assert that CPR might therefore be medically inappropriate for these patients. In such cases, CPR may be withheld in accordance with a well-established principle of clinical ethics, which states that “Physicians are not required to offer or to provide interventions that, in their best medical judgment, cannot reasonably be expected to yield the intended clinical benefit or achieve agreed-on goals for care.”15

Though consistent with accepted ethical principles, invoking futility to justify unilateral DNRs for COVID-19 patients is potentially problematic for several reasons. First, determining what constitutes reasonable expectation of clinical benefit becomes controversial once we move beyond cases of “strict” or “physiologic futility,” i.e., cases in which an intervention has no chance whatsoever of achieving the intended physiologic effect. CPR would be futile in the strict sense for a person exhibiting signs of “irreversible death,” such as dependent lividity or rigor mortis. In a hospital setting, CPR would be strictly futile for any patient whose disease is so advanced that it would not restore spontaneous circulation, as would be the case for “a patient whose cardiac arrest is terminal and occurs despite optimal treatment for progressive septic or cardiogenic shock.”16 Of course, in most cases, CPR will have at least some chance of achieving the intended physiologic effect of restoring spontaneous circulation. But when that chance approaches zero, CPR can be properly described as “quantitatively” futile, despite a very small chance of success. CPR would be futile in this sense for an elderly COVID-19 patient with comorbidities, who has been declining despite use of the most aggressive critical care measures, including mechanical ventilation and vasopressors. While CPR might succeed in restoring spontaneous circulation, this outcome is highly unlikely, and even so would only return the patient to a condition of “active clinical deterioration.”17 In such a case, there is no reasonable expectation that the patient will benefit by achieving either the minimal physiologic standard for success or the more demanding but commonly used standard of survival to discharge. For these reasons, few would dispute the claim that it would be futile to administer CPR.

Yet, as the probability of success increases, judgments of “quantitative futility” become more problematic, and this is where critical questions may be raised about the previously described guidelines. Of particular concern is the claim made in the WA and CHA guidelines that CPR may be futile in a “significant portion” of elderly, critically ill COVID-19 patients with underlying comorbidities. This language suggests something more than the narrow range of uncontroversial cases in which patients exhibit refractory deterioration despite maximal interventions. In a similar vein, the guidelines highlight data that exaggerate negative outcomes for COVID-19 patients. Especially problematic is the statistic from the Wuhan study, featured prominently in the guidelines, which identifies only a single survivor among 32 COVID-19 patients receiving mechanical ventilation. While a survival rate of just over 3% might arguably provide grounds for a judgment of quantitative futility, this statistic is not representative of outcomes for ventilated COVID-19 patients. Subsequent cohort studies with larger samples provide evidence of significantly higher survival rates for COVID-19 patients receiving invasive mechanical ventilation. In the US, a study of 165 patients at Atlanta hospitals found a mortality rate of 35.7% for these patients — which is comparable to that of patients with acute respiratory disease syndrome and other infectious pneumonias — with 53.3% surviving to discharge.18 A second, much larger study of 4,287 patients in the UK showed a mortality rate of 58.8% for patients receiving invasive mechanical ventilation, with 41.2% surviving to discharge.19 Notably, the UK study showed a mortality rate of 73.4% for patients with “very severe comorbidities,” in comparison to 57.9% for those without.20 While there is room for disagreement about the threshold for judgments of quantitative futility, the survival rate of 26.4% for this group of

patients would not justify a futility judgment according to any accepted standard.

Although the Atlanta and UK studies both shed light on survival rates for critical ill COVID-19 patients, neither contain data on the most relevant demographic for the issue at hand — namely, COVID-19 patients who received CPR for in-hospital cardiac arrest. Studies for this group of patients are scarce, but they also do not support withholding CPR on grounds of futility. A single center study of 136 patients in Wuhan reported restoration of spontaneous circulation in 13.2% of patients, with a mere 2.9% surviving at least 30 days after the intervention. While this survival rate is very poor, the authors caution that the "results may not be generalizable to other settings and healthcare systems," because their study was limited to a single center that experienced a shortage of medical resources and "uncertain quality of the CPR."21 Studies of CPR for COVID-19 patients are currently lacking in the US, but researchers for the American Heart Association have argued that survival rates can be reasonably estimated from studies of CPR for patients with comparable disease severity, specifically, for "critically ill patients with pneumonia or sepsis who were receiving mechanical ventilation in an intensive care unit (ICU) at the time of arrest."22 Data from a cohort of 5,690 patients at US hospitals from 2014-18 show an overall survival to discharge rate 12.5% for this group of patients, with variations among patient subgroups from a low of 3.9% to a high of 26.4% based on "age, presenting rhythm, and illness severity." For patients aged 70 and above, survival rates ranged from 3.9% to 20.1% depending on cardiac arrest rhythm status and use of vasopressors.23 At best, this would justify a judgment of futility for only the most seriously ill among this cohort of patients.

These studies provide context for assessing the claim that CPR might be medically inappropriate for a "significant portion" of elderly, critically ill COVID-19 patients with underlying comorbidities. If we interpret "elderly" as aged 70 and above and focus on patients receiving mechanical ventilation, it is reasonable to infer from the previously cited data that overall survival rates for this group of patients will be no better than 10%. A corresponding mortality rate of 90% would indeed show that CPR proved medically ineffective for a significant portion of patients in this demographic. But this does not justify withholding CPR from this group of patients on grounds of futility. The most commonly cited standard of quantitative futility, put forth by Schneiderman, sets a threshold at "less than 1% chance of success."24 Schneiderman describes this as a "conservative standard," which is needed to account for prognostic uncertainty, and to acknowledge that the decision of what constitutes an acceptable risk to benefit ratio is inherently value-laden. In other words, it is not a strictly clinical decision, and thus requires due deference to the preferences of patients and surrogates. The American Heart Association echoes this judgment, asserting that "resuscitation should be offered to all patients who want it unless there is clear evidence … of quantitative futility … [i.e.,] that survival is not expected after CPR under given circumstances."25 As noted previously, in conventional circumstances patient and surrogate preferences typically prevail even in cases where life-saving interventions are reasonably judged to be futile. In their discussion of CPR protocols for COVID-19 patients, Cheruku and colleagues articulate the ethical context for this practice as follows: "The ethics supporting the general provision of CPR in cardiac arrest are based on giving each patient the opportunity to survive. Among the competing ethical principles of autonomy, utility, and justice, autonomy is prioritized in the United States. The principle of autonomy has supported the use of CPR even in patients in whom medical professionals have deemed the procedure to be futile."26 These observations appear to undermine the claim that the Washington and CHA guidelines are merely applying existing standards to "the current setting." To implement unilateral DNRs based solely on judgments of futility would in fact constitute a significant deviation from standard practice and would specifically deviate from the prevailing deference to patient autonomy.

In this review, I have emphasized several important points that are not always clear in guidelines that have been proposed for the use of CPR during the pandemic. First, the use of unilateral DNRs deviates significantly from standard practice and should be carefully restricted as a component of pandemic response. Second, unilateral DNRs based on futility judgments are justified only in a narrow range of cases in which survival is not expected due to refractory deterioration.

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A second problem with the Washington and CHA guidelines is that they do not differentiate between the use of

unilateral DNRs during crisis versus non-crisis operations. Emergency preparedness plans typically delineate a continuum of three operational stages: a conventional stage, in which resources are not yet diminished and health care services are unaltered; a contingency stage, in which standards of care remain “functionally equivalent” despite some degradation of resources; and a crisis stage, “when demand acutely exceeds supply of resources and usual medical practices cannot be maintained.”27 When crisis standards of care are in effect, unilateral DNRs for some critically ill patients, including those with COVID-19, are clearly justified as a function of triage protocols. But this does not imply that the same practice is justified in conventional or even in contingency circumstances. In fact, crisis planning documents typically emphasize that allocation of scarce resources to patients who are more likely to benefit should take place only when crisis standards of care are in effect and all reasonable alternatives have been exhausted.28 During contingency operations, adjustments to treatment protocols are justified to conserve diminishing resources, so long as these adjustments are consistent with the delivery of functionally equivalent care — i.e., care in which outcomes are substantially similar to those achieved during conventional operations. The use of unilateral DNRs in cases where CPR is judged to be quantitatively futile can be reasonably interpreted as an example of such an adjustment. While this deviates from standard practice, which defers to patient autonomy, it would not substantially alter outcomes for patients suffering from in-hospital cardiac arrest. In contrast, withholding CPR against the wishes of patients who might benefit is a more significant departure from patient-centered decision-making, and should be limited to crisis operations. In such cases, it should be emphasized that the rationale for a unilateral DNR is one of scarcity, not futility. Limiting interventions based on the need to ration should not be confused with limiting interventions on grounds of futility.29

The Pennsylvania guidelines, in contrast to those from Washington and the CHA, explicitly limit deviations from standard protocols for CPR and other life-sustaining interventions to crisis circumstances, when “the focus of medical care may shift from the individual patients to the thoughtful use of limited resources for the best possible health outcomes for the population as a whole.”30 This provides helpful clarification of the conditions under which unilateral DNRs might be justified. Unfortunately, the Pennsylvania guidelines proceed to use the term “medically inappropriate” in a way that risks blurring the distinction between withholding interventions on utilitarian versus patient-centered grounds. As previously noted, this term is typically used interchangeably with “futile” and “medically ineffective” to identify treatments that cannot be expected to provide any benefit *to the patient*. But the Pennsylvania guidelines assert that risks to providers and shortages of PPE may “influence a determination that CPR is not medically appropriate.” This strikes me as an unfortunate expansion of prevailing usage. Concerns about human and material resources may well justify withholding CPR from some patients in crisis circumstances, but it does not follow that CPR becomes medically inappropriate, ineffective, or futile for those patients. It would be more accurate to acknowledge that *a potentially beneficial intervention* was withheld due to crisis circumstances, as we would say for any routine intervention that was not provided to a patient because of a public health emergency.

In this review, I have emphasized several important points that are not always clear in guidelines that have been proposed for the use of CPR during the pandemic. First, the use of unilateral DNRs deviates significantly from standard practice and should be carefully restricted as a component of pandemic response. Second, unilateral DNRs based on futility judgments are justified only in a narrow range of cases in which survival is not expected due to refractory deterioration. Futility based DNRs should not be implemented in conventional circumstances, where prevailing deference to patient autonomy remains appropriate, but they may be justified during contingency operations to conserve diminishing resources, since they do not substantially alter outcomes for critically ill patients. Third, expanded use of unilateral DNRs on utilitarian grounds is justified only when a surge of patients severely outstrips capacity and crisis standards of care are implemented. In crisis settings, the justification for unilateral DNRs should be understood and explained in terms of scarcity and the need to ration, not futility.

Policies governing the use of CPR cannot be expected to address all variables and nuances that might arise when treating critically ill patients during a pandemic. But clarity on the points noted above is necessary to promote effective communication with patients and clinical decisions that align with ethical principles that are central to crisis management — most notably, transparency, consistency, fairness, and the duty of care. Expanding the use of

unilateral DNRs during a pandemic, particularly based on appeals to futility, is inconsistent with current practice, risks creating distrust among patients and surrogates, and can adversely impact patients who are already vulnerable to socially influenced health disparities.31 These concerns are compounded if clinicians begin to liberalize criteria for futility, expanding the pool of patients who are deemed “too sick to benefit” or if they begin to write DNRs based on resource concerns prior to crisis operations, when decisions are typically made by triage teams based on clearly stated criteria that aim to promote fair treatment for all patients. Instead of pursuing an ethically hazardous expansion of unilateral DNRs, it would be better to redouble efforts at proactive communication concerning the benefits and burdens of CPR for critically ill patients, which are not well understood by the general public. DNRs that result from the duly considered wishes of patients or their surrogates avoid the aforementioned risks and allow us to achieve the best of both worlds, insofar as they preserve patient autonomy while conserving human and material resources that are needed to effectively address the COVID-19 pandemic.

Note

The author has no conflicts of interest to disclose.

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28. Minnesota emphasizes that "proactive" triage is justified only when resources remain critically limited despite maximum efforts to conserve and adapt ("Crisis Standards": 14-15). A key assumption reiterated throughout Washington's "Scarce Resource Management" is that triage algorithms should be used only when "Healthcare systems are overwhelmed despite maximizing all surge and mitigation strategies impacting the space and/or staff and/or supplies needed to deliver usual levels of care."
29. As Schneiderman notes, arguments for limiting treatment on grounds of resource allocation "should proceed by an entirely different route" from those based on futility. "Medical Futility," supra note 24.
30. Halpern and White, "Guidance for Decisions Regarding Cardiopulmonary Resuscitation."
31. For an example of the ethical pitfalls and disparities that can arise when potentially life-sustaining interventions are withheld without sufficient clarity and transparency, see A. Waldman and J. Kaplan, "Sent Home to Die," ProPublica, September 2, 2020, available at <https://www.propublica.org/article/sent-home-to-die >(last visited October 22, 2021). In this case, numerous patients (all of whom were African American) were discharged from or denied admission to Ochsner Medical Center in New Orleans, Louisiana after being told that nothing more could be done for them. While Ochsner denies any wrongdoing or deviation from standard protocols, confusion persists about whether these decisions were based on resource scarcity, and about whether some patients could have indeed benefitted from continued care in the hospital. There was, in addition, a perception of discrimination among some

families.

DETAIL

Subjek:	Patients; COVID-19; Personal protective equipment; Intervention; Pandemics; Decision making; Physicians; Proposals; Management of crises; Public health; Cardiopulmonary resuscitation--CPR; Unilateralism; Coronaviruses; Medical ethics
Ketentuan indeks bisnis:	Subjek: Proposals Management of crises
Lokasi:	Italy; United States--US
Pengidentifikasi/kata kunci:	COVID-19 Triage; Decision-making models; Resuscitation; Coronavirus; COVID-19; Cardiopulmonary resuscitation; CPR for COVID-19 Patients; Crisis Standards of Care; Futility; Medically Inappropriate CPR
Judul:	The Ethics of Unilateral Do-Not-Resuscitate Orders for COVID-19 Patients
Pengarang:	Ciaffa, Jay
Judul publikasi:	The Journal of Law, Medicine &Ethics; Boston
Volume:	49
Edisi:	4
Detail sumber:	First Amendment Values in Health Care
Halaman:	633-640
Tahun publikasi:	2021
Tanggal publikasi:	Winter 2021
Bagian:	Independent Articles
Penerbit:	Cambridge University Press
Tempat publikasi:	Boston
Negara publikasi:	United Kingdom, Boston
Subjek publikasi:	Law, Medical Sciences
ISSN:	10731105
e-ISSN:	1748720X
Jenis sumber:	Jurnal Akademik

Legal Interventions to Counter COVID-19 Denialism

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ABSTRAK (ENGLISH)

A series of denialist state laws thwart efficacious public health emergency response efforts despite escalating impacts of the spread of the Delta variant during the COVID-19 pandemic.

TEKS LENGKAP

Persistent political undertones, extensive economic ploys, reckless re-openings, misperceived liberties, and aspirations for a return to normalcy contribute to an improbable series of legislative and executive machinations grounded in COVID-19 denialism. Facing an evolving and lingering pandemic, select state legislatures and governors have dismissed emergency declarations, banned mask requirements, prohibited vaccine mandates or passports, limited social distancing, and forbidden school or business closures. Casting aside epidemiology, they have thwarted interventions proven earlier in the pandemic to tamp down infections and save lives even as the Delta variant ravages unprotected populations. Some states have even foreclosed local governments from using their public health powers to protect communities. As San Antonio Mayor Ron Nirenberg observed on August 10, 2021, "[w]e have seen [Texas'] governor systematically tie the hands of local health officials and local authorities throughout this pandemic."[1]

Distressed public health officials on the front lines see their populations suffer under denialist emergency laws and policies. It is the public health equivalent of obstructing doctors from using efficacious medical treatments at the bedside. Neither doctors nor public health professionals should stand idle over such efforts. Nor are they. Legal counter-strategies are actively underway or in consideration among municipal and public health officials, clinicians, parents, and affected citizens seeking to delay, offset, or overturn COVID-19 denialist policies through (1) constitutional structural- and rights-based challenges; (2) conditional spending supporting national public health priorities; (3) federal preemption of contrary state-based maneuvers; (4) disability and other anti-discrimination laws;

(5) circumventions through waivers or routine uses of public health powers; and (6) civil liability claims.

Constitutional Challenges. As state legislators and governors effectuate imprudent, anti-public health emergency laws, significant constitutional issues have surfaced.[2] School mask bans in multiple jurisdictions (e.g., AR, FL, IA, OK, SC, TN, UT) have resulted in extensive litigation and early victories in select cases. In June 2021, Arizona's state legislature added a provision to a budget reconciliation bill to ban mask requirements in K-12 public schools.[3] It included a retroactivity clause to try to bypass a constitutional 90-day waiting period prior to enforcement. Litigation quickly ensued when several school districts required masks to start the Fall term.[4] Coupled with equal protection claims, counter-allegations centered on the legislature's attempt to bypass the 90-day requirement[5] and "single-subject rule"[6] (requiring state bills to focus on a dominant theme). On August 16, 2021, a Maricopa County (Phoenix) court determined the 90-day rule limited immediate enforcement of the state's mask ban.[7] In Texas, successful challenges to Governor Abbott's school mask prohibition[8] in courts in San Antonio/Bexar County[9] and Dallas[10] were subsequently backed by the Texas Supreme Court, which remanded the cases for further review.[11] Despite being diagnosed with COVID-19 on August 17,[12] Governor Abbot has vowed continued appeals.[13]

Alternatively, some courts have dismissed denialist-grounded opposition to effective public health interventions. Constitutional challenges to Indiana University's vaccine mandate (imposed against gubernatorial orders) were rebuffed first by a federal district court, then the Seventh Circuit Court of Appeals, and finally the U.S. Supreme Court on August 12, 2021.[14] After Florida's legislature prohibited COVID-19 vaccination travel documentation requirements,[15] Norwegian Cruise Lines obtained a preliminary injunction on grounds that Florida's ban inhibited First Amendment free speech protections and unconstitutionally interceded on interstate commerce.[16]

Federal Spending Conditions. Initial judicial triumphs over state-based denialist laws may still be subject to attack through appeals, executive actions, or additional legislation. Governors Hutchison (AR)[17] and Holcomb (IN)[18] have voluntarily sought to derail or put aside their states' school mask bans, despite internal political resistance, given surges of Delta variant infections among school-age children. Not so in Arizona. Facing what they described as "anarchy" regarding school board imposition of mask mandates,[19] select Arizona legislators pled with Governor Ducey to deny districts federal funds through the American Rescue Plan Act.[20] When the Governor obliged on August 17, 2021, the U.S. Department of the Treasury instantly rejected such restrictions.[21] A day later, President Biden pledged to "use all of his authority and legal action if appropriate" to counter states' masks bans in schools.[22] The President's remarks are consistent with expansive federal roles in protecting national security and public health,[23] especially through the use of conditional spending. Such requirements help assure adherence to medical countermeasures (MCMs) such as mask use in schools[24] and COVID-19 vaccinations in select settings. The U.S. Department of Education (DOE) is considering allowing school districts to seek funding directly if states like Arizona attempt to block their access to federal COVID-19 relief funds.[25] On August 19, the Centers for Medicare and Medicaid Services (CMS) announced plans to require nursing facilities to vaccinate employees (with exceptions) to continue to receive federal reimbursements.[26]

Federal Preemption. Consistent with principles of federalism[27] and federal supremacy,[28] the national government can preempt, or override, contradictory state laws impinging national public health objectives.[29] The scope of federal preemption is exemplified by the invocation of the Public Readiness and Emergency Preparedness (PREP) Act during the COVID-19 pandemic.[30] Among other authorities, PREP Act declarations by the U.S. Secretary of Health and Human Services (HHS) provide for the emergency use and implementation of MCMs.[31] The act's strong preemptive language expressly prohibits conflicting state laws in manifold ways.[32] On September 3, 2020, HHS asserted that certain state-licensed pharmacists could administer COVID-19 vaccinations via its amended PREP Act declaration[33] irrespective of contrary state licensing or other laws.[34] In October 2020, HHS preempted Nevada's attempt to legally prevent uses of certain authorized COVID-19 tests.[35] In correspondence dated July 2, 2021,[36] one senior CDC official addressed the reach of PREP Act preemption among state and local governments rescinding their emergency declarations and orders despite continuing threats of COVID-19.[37] It unequivocally concludes that the nation remained in a state of emergency and subject to PREP Act requirements, "regardless of state laws and regulations."[38] Any supposed state or local barriers to federal emergency action under the PREP Act are preempted.

Anti-discrimination Laws. Denialist public health actions are also contested under existing federal or state disability protections or other anti-discrimination laws. Litigants in Florida, South Carolina, and Texas challenged school mask mandate bans as violative of disability-based protections. On July 30, 2021, Florida Governor Ron DeSantis banned school-based mask mandates via executive order[39] and subsequently threatened to withhold state funding from schools defying it.[40] Parents of children with disabilities sued alleging violations of: (1) the Americans with Disabilities Act (ADA) by excluding children with disabilities from equal educational opportunities and failing to make programs readily accessible;[41] (2) Section 504 of the federal Rehabilitation Act of 1973[42] guaranteeing access to free appropriate public education;[43] and (3) Florida's Educational Equity Act[44] preventing disability-based discrimination in education.[45] The American Civil Liberties Union similarly challenged South Carolina's ban.[46] Plaintiffs in Texas[47] alleged that Governor Abbott's school mask prohibition[48] and accompanying Texas Education Agency (TEA) guidance[49] violate the ADA and the Rehabilitation Act.[50] TEA updated its guidance to clarify that mask bans are not being enforced pending litigation.[51] On August 17, 2021, Secretary Miguel Cardona indicated that DOE is taking necessary legal actions to investigate bans on universal masking, gain compliance with federal anti-discrimination acts,[52] and ensure school safety upon return to in-person instruction.[53]

Circumvention Via Waivers or Routine Powers. State health departments, local municipalities, school districts, and others are forging new pathways to circumvent state-based denialist laws using waiver authorities (where available) and an array of routine health powers or existing regulatory authorities. In states where executive and legislative branches are not in lockstep on specific policies, governors may have the capacity to waive or suspend conflicting state laws in declared emergencies (if not expressly foreclosed by the legislature). During the pandemic, nearly every governor has waived state laws interfering with emergency response efforts.[54] To control the spread of COVID-19, Maryland Governor Hogan reinstituted his state's emergency declaration in June 2021 to extend expiration dates for nursing licenses and permits and suspend conflicting statutes or rules.[55]

Legal interventions countering or limiting the impacts of state-based denialist laws and policies collectively reflect the promise of meaningful and constitutional public health safeguards in the throes of the pandemic. Promotion of individualism without justification over communal health is untenable. *Ultimately, public health will prevail.*

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Use of routine public health powers may also bypass state legislative prohibitions. After the Michigan Supreme Court limited Governor Whitmer's emergency authority in October 2020,[56] the state health department ordered face coverings in schools (which survived judicial challenge)[57] and restricted gatherings under its existing statutory public health authorities.[58] Similar efforts were undertaken among larger municipalities in Wisconsin seeking to continue stay-home orders after state emergency powers were abruptly restricted by its supreme court.[59] Other cities have demonstrated legal resiliency.[60] In March 2021, the Ohio Legislature passed an act over Governor DeWine's veto forbidding city boards of health from ordering face masks applicable "to a class of persons."[61] On August 18, 2021 the Athens City Council, relying on its constitutional home rule authority,[62] amended the city's mandate to require face coverings indoors regardless of vaccination status.[63] The city's attorney argued its revisions did not violate state law, which only restricted the board of health, and not the city itself.[64] Local school districts have employed similar tactics. Prior to the start of the 2021 term, one school district in Texas altered the dress code to include face coverings, arguing that the Governor's ban did not suspend its distinct authorities.[65]

Civil Liability. Placing hundreds of thousands of persons at direct risk of exposure to a deadly infectious agent through state-based laws or policies seemingly designed to assure harm under the guise of promoting liberty and self-interests is not only reckless, but also a backdrop for civil liability. State laws facilitating autonomous adults in their quest to avoid vaccines is one thing. Inhibiting public or private schools from instituting efficacious mask requirements to protect children who must attend but cannot lawfully be vaccinated is another. As DOE Secretary Cardona observed, "[w]hat we're dealing with now is negligence."[66]

Massive liability may extend from purposeful governmental legal interventions contrary to science impacting the health of children and adults. Extensive and varied civil claims[67] flowing from the Flint (MI) water crisis[68] are

illustrative. After state and local officials averted existing water supplies, extensive exposure to lead through municipal water pipes resulted, leaving “lasting developmental effects,”[69] especially among children in Flint. Class action litigation followed. In August 2020, the State settled a lawsuit for $600 million, including creation of a compensation fund for city residents.[70]

Governments or their agents may be insulated from liability under principles of sovereign immunity, but not for claims grounded in gross negligence or constitutional violations.[71] Multiple states like Ohio and Arizona have enacted laws shielding health care providers,[72] businesses, and educational institutions[73] from civil liability during the pandemic, but these protections are revocable. On April 6, 2021, New York state repealed its liability protections applicable to health care facilities.[74] A subsequent lawsuit filed in June 2021 against a nursing home in upstate New York alleged that the facility’s lack of sufficient staffing, personal protection equipment, and infectious control policies caused a husband and wife to contract and perish from COVID-19.[75] The specter of impending liability against government, its agents, or private sector entities sustains legal reconsideration and reversals of COVID-19 denialist approaches.

Legal interventions countering or limiting the impacts of state-based denialist laws and policies collectively reflect the promise of meaningful and constitutional public health safeguards in the throes of the pandemic. Promotion of individualism without justification over communal health is untenable. *Ultimately, public health will prevail.*

Acknowledgments

The authors thank Rebecca Freed and Nora Wells, J.D. Candidates and Senior Legal Researchers, Center for Public Health Law and Policy, ASU Sandra Day O’Connor College of Law, for their research, editing, and formatting contributions.

Note

The authors have no conflicts of interest to disclose.

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DETAIL

Subjek:	Public health; COVID-19 vaccines; COVID-19; Governors; Immunization; Masks
Lokasi:	South Carolina; Texas; Florida; United States--US; Arizona
Perusahaan / organisasi:	Nama: Department of Health &Human Services; NAICS: 923120
Pengidentifikasi/kata kunci:	COVID-19 Denialism; SARS-CoV-2 Delta variant; Pandemic; Denialism; COVID-19; Legal Challenges; Constitutional Principles; Preemption; Liability
Judul:	Legal Interventions to Counter COVID-19 Denialism
Pengarang:	Hodge, James G; Piatt, Jennifer L; Barraza, Leila
Judul publikasi:	The Journal of Law, Medicine &Ethics; Boston
Volume:	49
Edisi:	4
Detail sumber:	First Amendment Values in Health Care
Halaman:	677-682
Tahun publikasi:	2021
Tanggal publikasi:	Winter 2021
Bagian:	Columns: Public Health and the Law
Penerbit:	Cambridge University Press

Tempat publikasi:	Boston
Negara publikasi:	United Kingdom, Boston
Subjek publikasi:	Law, Medical Sciences
ISSN:	10731105
e-ISSN:	1748720X
Jenis sumber:	Jurnal Akademik
Bahasa publikasi:	English
Jenis dokumen:	Journal Article
DOI:	https://doi.org/10.1017/jme.2021.92
ID dokumen ProQuest:	2730847311
URL Dokumen:	https://www.proquest.com/scholarly-journals/legal-interventions-counter-covid-19-denialism/docview/2730847311/se-2?accountid=211160
Hak cipta:	© 2021 The Author(s)
Terakhir diperbarui:	2023-11-28
Basis data:	Public Health Database

Vaccines Mandates and Religion: Where are We Headed with the Current Supreme Court?

Reiss, Dorit R

ABSTRAK (ENGLISH)

This article argues that the Supreme Court should not require a religious exemption from vaccine mandates. For children, who cannot yet make autonomous religious decision, religious exemptions would allow parents to make a choice that puts the child at risk and makes the shared environment of the school unsafe — risking other people's children. For adults, there are still good reasons not to require a religious exemption, since vaccines mandates are adopted for public health reasons, not to target religion, are an area where free riding is a real risk, no religion actually prohibits vaccinating under a mandate, and policing religious exemptions is very difficult.

TEKS LENGKAP

Introduction

Vaccines are one of the greatest medical advances of the twentieth century, responsible for saving hundreds of millions of lives.[1] Although nothing is without risk, as the National Academies of Science, Engineering and Medicine point out, "[v]accines are extremely safe. They have many health benefits and few side effects."[2] In spite of that data, there has long been an anti-vaccine movement, and its impact has grown over time.[3] In the past two decades, rates of vaccine exemptions in some states have grown dramatically.[4] The increase in non-medical exemptions directly led to increases in outbreaks.[5] Most recently (and before the COVID-19 pandemic), in 2019, outbreaks of measles in the United States resulted in 1,249 cases, the highest number since 1992.[6] A substantial majority of the cases were in unvaccinated individuals and in communities with low vaccines rates.[7] Politicization of the COVID-19 pandemic is not going to help with this.[8]

In response to outbreaks, several states have acted to remove or tighten their non-medical exemptions. In 2015, California removed its non-medical exemption.[9] The repeal was challenged several times in court, but all the challenges were unsuccessful.[10] In 2019, both New York and Maine removed their non-medical exemptions, and Washington State removed the personal belief exemption to the MMR vaccine.[11] The New York repeal was also challenged in court, but so far, all challenges have failed. These challenges included claims that not having a religious exemption violates the First Amendment, but as late as March 2021, courts were unsympathetic to those claims.[12]

Courts that have rejected the claims that not having a religious exemption violates the First Amendment drew on several strands of case law. These included Supreme Court doctrine that general rules do not need to include an exemption for religious objectors.[13] Other cases suggest that mandates do not have to include a religious exemption because school vaccines mandates apply to children — who cannot yet decide on their own religion — and to a shared environment, where unvaccinated children can put other people's children at risk.[14] This jurisprudence will be addressed more in depth in Part II.

This article contends that for children and school mandates, the new jurisprudence should not change the current legal situation, and that the arguments for not requiring a religious exemption remain extremely strong. For mandates applicable to adults, the argument for a religious exemption is more robust; but there are still good reasons not to require one. Among other reasons, vaccines mandates are adopted for public health reasons, clearly not targeting religion, are an area where free riding is a real risk, and policing religious exemptions to these mandates is very difficult. Even if strict scrutiny is applied, courts should not require that a religious exemption be added to a well-crafted law mandating a vaccine that clearly prevents death and other serious harms.

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But there is another aspect to the vaccine religious exemptions issue, which is the reality that very few religions actually oppose vaccines.[15] Most religions either support vaccines or leave it to the believer. Even Christian Science, while clearly not in support of vaccines, tells adherents that if the law requires vaccinating, they should vaccinate.[16] Most people who refuse vaccines do it for reasons that are not religious.[17] Even for deeply religious people, the logic behind not vaccinating is usually secular.[18]

Against this background, recent decisions from the Supreme Court signaling increased protection for religious freedom raise the question of whether the Court will someday require a religious exemption from state-actors' vaccine mandates. This article contends that for children and school mandates, the new jurisprudence should not change the current legal situation, and that the arguments for not requiring a religious exemption remain extremely strong. For mandates applicable to adults, the argument for a religious exemption is more robust; but there are still good reasons not to require one. Among other reasons, vaccines mandates are adopted for public health reasons, clearly not targeting religion, are an area where free riding is a real risk, and policing religious exemptions to these mandates is very difficult. Even if strict scrutiny is applied, courts should not require that a religious exemption be added to a well-crafted law mandating a vaccine that clearly prevents death and other serious harms.

Two limits of this paper should be borne in mind. First, rather than provide a thorough discussion of the Supreme

Court's decisions, it focuses on the narrower question of vaccine mandates. The wonderful article by my colleague Professors Wendy Parmet provides in depth discussion of the decisions in a broader context. Second, the article focuses on mandates by state actors, not by private actors like employers, to which a different framework would apply.[19]

I. Vaccine Mandates and Religious Freedom in the United States Before the COVID-19 Pandemic

Vaccine mandates have existed in the United States for over 150 years. The first state-level school mandate, for a vaccine against smallpox, was adopted in Massachusetts in 1855.[20] In the 1960s and 1970s school mandates spread across states.[21] Multiple empirical studies have demonstrated that strong school mandates increase rates of childhood vaccination and reduce outbreaks of vaccine preventable diseases.[22]

The famous case of *Jacobson v. Massachusetts* focused on an ordinance adopted in 1902 referencing an earlier statute empowering local boards of health to require people be vaccinated against small pox "if, in its opinion, it is necessary for the public health or safety."[23] In 1905, the Supreme Court upheld the vaccine mandate on the grounds that individual liberty may, on occasion, have to give way for the public good, and that restraints on liberty in the common good are usual and expected in society.[24] The Court did make it clear that regulations limiting individual rights need to be reasonable and in the public health and safety interest. But within those limits, it specifically allowed a vaccine requirement.[25]

Jacobson did not address whether the state has to provide a religious exemption from a vaccine requirement, because at the time, the First Amendment did not yet apply to the states.[26] Extensive litigation explored whether incorporating the First Amendment changed the framework towards school immunization mandates. The pre-COVID-19 the consensus in the courts is that school immunization mandates do not have to include a religious exemption.[27] Several sources and arguments support that. Part of the picture is that, under current Supreme Court jurisprudence, primarily under *Employment Division v. Smith*, a law that is neutral on its face and generally applicable — like school vaccines mandates — does not have to provide a religious exemption.[28] But there is more to it. School vaccine mandates are different from adult mandates, because they not only protect the public health, they also affect children. Unlike adults, children do not make their own decisions concerning religion, and parental rights can be limited when their decisions put children at risk.[29] Because school mandates sit at the intersection of children's welfare — vaccines reduce the risks to children — and public health, they are on especially strong constitutional ground.[30]

In a case that long predated *Smith, Prince v. Massachusetts*, the Supreme Court allowed prosecution of a guardian — in that case, an aunt — for violating child labor laws by allowing her niece to distribute religious pamphlets.[31] The Court upheld the conviction in spite of the fact that the aunt relied both on her rights as a guardian (the parents left the child in her care) and on her right to free exercise of her religion. The Court reminded us that:

Parents may be free to become martyrs themselves. But it does not follow they are free, in identical circumstances, to make martyrs of their children before they have reached the age of full and legal discretion when they can make that choice for themselves.[32]

Addressing vaccines mandates for children directly, the Court also said:

[A parent] cannot claim freedom from compulsory vaccination for the child more than for himself on religious grounds. The right to practice religion freely does not include liberty to expose the community or the child to communicable disease or the latter to ill health or death.[33]

Prince v. Massachusetts had been cited in numerous cases upholding school immunization requirements since then, including, most recently, cases examining California's decision to repeal its non-medical exemption,[34] and cases examining New York's decision to repeal its religious exemption.[35]

In essence, parents opposing a school mandate are arguing not only for an unlimited right to not protect their child from disease, but also for a right to make their child's school less safe from disease for other children, their families, staff, and others. Courts have not been particularly sympathetic to that demand.

Adult mandates belong on a somewhat different footing. When it comes to adults, the tension is only between the subject's religious freedom and the public health, without the additional factors of a child's wellbeing and the lack of

a child's autonomous choice. Even for adults, though, current jurisprudence does not require a religious exemption from a state mandate. Under *Smith* (and its progeny[36]), a state is not required to provide a religious exemption from a generally applicable, neutral on its face law that otherwise meets rational basis review; vaccine requirements generally fit that bill — they are general, neutral laws, applicable towards the public health.[37] A longstanding exception is that laws motivated by hostility to religion must meet strict scrutiny. This exception was created in a case in which an ordinance was clearly passed to target a specific church.[38] It has since applied to a case where the hostility found by the Supreme Court in the government's application of an anti-discrimination law was more subtle.[39] Vaccines mandates aim to prevent outbreaks, not to target a specific religion or religion generally, and hence, fall squarely within *Smith* territory. That is, strict scrutiny should not apply to them. But changes to the jurisprudence — for example, overruling *Smith* — would directly affect them.

Vaccine state mandates for adults, outside the employment context, were extremely rare in the past century. As a result, there is almost no litigation in this context. The question of whether such laws are generally applicable was, however, raised in the context of childhood school mandates. In a case challenging New York's decision to repeal the religious exemption to its school immunization mandate, plaintiffs pointed to specific comments by legislators to allege that the repeal has been motivated by hostility to religion. The case has been rejected by the New York Supreme Court (the first instance) and by the appellate division, which found that the circumstances, and the legislative statements, did not support a claim of hostility to religion. Instead, the courts found that the context of a large measles outbreak better explained the legislation.[40] We can likely expect more challenges alleging hostility. As discussed in part II, recent Supreme Court Cases raise questions about the continued viability of *Smith*.

II. Supreme Court Jurisprudence on Religious Freedom Since 2014

Since at least 2014, Supreme Court decisions indicate that a growing majority on the Court seeks to strengthen protections for the free exercise of religion. This reflects growing tensions around religious freedom in our society, and increasing questions about the level of accommodation appropriate for religious freedom.[41]

In 2014, in *Burwell v. Hobby Lobby,* the Supreme Court held that requiring privately held companies to cover certain contraceptives for their employees, when the owners alleged the contraceptives were in tension with their religious beliefs, violated the federal Religious Freedom Restoration Act (RFRA).[42] Applying the federal RFRA was not remarkable, but protecting religious beliefs of corporations was an extension of previous law. Although the majority was cautious to state that the decision was focused on the RFRA, not the First Amendment, it suggested a move towards strengthening protection of religious freedom.[43]

In 2018, in *Masterpiece Cakeshop,* a majority of the Court overturned the Colorado Civil Rights Commission's sanction against a baker who refused to bake a wedding cake for a same-sex couple.[44] Here, too, the Supreme Court did not overturn *Smith*, instead finding that the Commission's comments showed hostility to religion, and hence fell under the hostile treatment exception to that ruling.[45] These cases set the ground for an increasing emphasis on religious freedom by the Court.

When the COVID-19 pandemic arrived in early 2020, one type of measure states adopted was to limit gatherings.[46] Many of these measures addressed houses of worship — some to limit their activities, a few to expressly exempt them from limits.[47] The limits on houses of worship were tightened after several outbreaks linked to churches, in response to risk factors applicable to church: a gathering of many people close together for long time, vocalizing and singing — activities that increase risk.[48]

Unsurprisingly, some churches brought legal challenges to these limits. The challenges to COVID-19 measures that reached the Supreme Court have been handled under the so-called "shadow docket." The term shadow docket was coined by law professor William Baude.[49] It is not a term used by the Supreme Court, but scholars and observers use it to refer unofficially to the "significant volume of orders and summary decisions that the Court issues without full briefing and oral argument."[50] Decisions under the shadow docket typically include decisions involving procedural matters such as whether or not to grant a stay or an injunction.

Professor Baude has explained that because the Court does not always issue opinions or explanations in these kinds of cases, and, shadow docket opinions do not always specify how each justice voted, lawyers do not know

what legal standards apply.[51] These features also make it unclear whether the decisions are consistent with prior precedent. Further, shadow docket decisions affect lower courts procedurally because they do not know how to interpret and apply those decisions in new situations, lacking a clear explanation.[52]

The first challenges by churches to COVID-19 measures were rejected by the Supreme Court in 5-4 decisions in the spring and summer of 2020.[53] The composition of the Supreme Court changed after Justice Ruth Bader Ginsburg died on Friday, September 18, 2020. Judge Amy Coney Barrett, who was quickly nominated by President Trump to succeed her, was confirmed in near-record time on October 23, 2020. The impact of the change was felt soon after. On November 25, 2020, with Justice Barrett now on board, the Supreme Court decided another shadow docket case, *Roman Catholic Diocese v. Cuomo*.[54] Five justices found that religious entities in New York were entitled to a preliminary injunction because New York had supposedly treated house of worship more severely than comparable institutions.[55] Chief Justice Roberts agreed with the majority on the merits, but would have dismissed the case as moot, since the state already changed the designation of the affected areas and the religious entities were no longer subject to the requirements. Justice Gorsuch wrote a concurrence arguing that the limits on houses of worship were extreme.

Some scholars saw *Roman Catholic Diocese* as a warning signal of a Court aggressively willing to undermine efforts to protect the public health for the benefit of religious groups. The Court was willing to intervene in spite of the expiration of the governor's order, and because the Court offered low deference to public health decisions, or to decisions based on local conditions.[56] Others saw it as an important counter to a trend of devaluing constitutional rights generally — or religious rights specifically — in the service of public health, and as an important reminder that the constitution stands even during a pandemic.[57]

The *Roman Catholic Diocese* decision and its (limited) progeny focused on situations where a state expressly treated houses of worship differently than other institutions. Scholars challenged the Court's treatment of other institutions, like stores, as similar to houses of Worship for this purpose.[58] But the shadow docket cases still examined rules specifically directed at houses of worship, and not the kind of generally applicable rules which fall under *Smith*.

The Supreme Court's general approach to religious freedom is, as yet, unclear. The Court has not expressly overturned *Smith*, and it has not provided a new standard. After *Fulton* and the shadow docket cases, is it inevitable that states will have to provide an exemption based on religion from a vaccine mandate?

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In two subsequent decisions, the Court, in short statements, struck down other limits on indoor gatherings, with little explanation.[59] But the real questions arose when the Court addressed cases where the rule was, arguably, general, and potentially in *Smith* territory. On April 9, 2021, in *Tandon v. Newsom* (another shadow docket case), the Court struck down California's limit on people who can gather in homes — for any reason.[60] The majority's short opinion suggested that what doomed the restrictions — which applied to any in-home gatherings, whether to pray or not — were the exceptions given to secular business. In a strong dissent, Justice Kagan argued that this comparison was flawed, since businesses like hardware stores and hair salons, she pointed out, were not similar to in-home gatherings and that a restriction on all at-home gatherings was generally applicable.

On June 17, 2021, the Supreme Court decided a case that could have dramatically changed the *Smith* framework. In *Fulton v. City of Philadelphia*, the Third Circuit Court of Appeals, affirming a district court decision, found that Philadelphia did not discriminate against Catholic Social Services (CSS), a foster care agency, in terminating its contract because CSS refused, on religious grounds, to certify same-sex couples as foster parents.[61] CSS appealed, alleging violation of its freedom to exercise its religion under the First Amendment. The Supreme Court granted certiorari on three issues, and heard oral arguments on November 4, 2020.[62] One of these issues was "whether to reconsider the standard that the Court set in *Smith* for courts to use to evaluate Free Exercise Clause claims."[63] The decision did not overturn *Smith.*[64] In brief, the Court unanimously reversed the Third Circuit's decision, but was split on the grounds for doing so.[65] A majority of six justices joined Chief Justice Roberts' opinion that the Court did

not need to overrule *Smith.* It found that the City of Philadelphia's actions fell into an exception to *Smith* because, in offering a discretionary exception from the non-discrimination provision, the contract was not generally applicable. Thus, if such exceptions exist and are not offered to those with religious objections, the refusal to offer them is subject to strict scrutiny.[66]

In concurrences that read like dissents, Justices Alito and Gorsuch, joined by Justice Thomas, strongly disagreed with the Court's choice not to overturn *Smith.* Justice Alito, in a 78-page concurrence (the majority's opinion was 15 pages), argued that *Smith* was flawed from its inception, that it could not constitutionally stand, and that it was inoperable.[67] Justice Gorsuch's concurrence went even further, arguing that the majority's analysis could not stand on the facts of the case, and that by refusing to address *Smith*, the Court created uncertainty and put people concerned about their religious freedom in a tight spot.[68] Justice Gorsuch was quite willing to overturn *Smith* immediately and sort out the implications later.

Justice Barrett, joined by Justice Kavanaugh and in part by Justice Breyer, explained in a concurrence that while she was also inclined to see *Smith* as flawed, she was unwilling to overturn it at present because she did not see a viable alternative.[69] Justice Barrett (and Kavanaugh), unlike Justices Alito, Thomas, and Gorsuch, was not yet willing to move to a regime in which any law that affects religion is subject to strict scrutiny.

Fulton left quite a few questions unanswered, but several things appear clear. First, there is not currently a majority on the Supreme Court for completely overturning *Smith,* if that means applying strict scrutiny to any law that affects religion. Second, there is broad support on the Supreme Court for stronger protection of the free exercise of religion than in the past. Third, the boundaries of *Smith* are, at present, uncertain. *Fulton* itself found *Smith* inapplicable because the provision argued by the City of Philadelphia to be generally applicable contained a discretionary exception. This caselaw raises the question whether any law that contains a secular exception that involves some discretion is not protected under *Smith*. If so, the exception is likely to swallow the rule since many laws have some kind of implied discretionary exception. In the alternative, if this exception is understood to be limited to situations where the law provides a broad, express discretionary exception — i.e., a provision that says specifically that an official has discretion to grant exceptions — the impact will be much less.

The analysis of school mandates below in Part III will address both interpretations. The combination of *Fulton* and the shadow docket cases may suggest that the Court will someday hold that any rule that has any secular exemption must also provide a religious exemption.[70] But it also may not. The COVID-19 shadow docket cases addressed instances where the claimant asserting religious motivation was a house of worship — clearly a religious actor, asking to engage in activities that are clearly religious. That may be different than identifying whether an individual is acting based on religious reasons.[71] Justice Barrett's concurrence in *Fulton* suggests that the distinction between religious entities and individuals is one of the concerns that led to her reluctance to overturn *Smith*.[72]

Finally, *Fulton* addressed religious freedom in a specific context — a context similar to that of *Masterpiece Cakeshop* — the tension between an anti-discrimination policy and free exercise of religion.[73] That tension is not the one in place with vaccine mandates. For that reason alone, it is an open question whether the analysis in *Fulton* will apply in that context.

III. Supreme Court Jurisprudence and Vaccines Mandates

The Supreme Court's general approach to religious freedom is, as yet, unclear. The Court has not expressly overturned *Smith*, and it has not provided a new standard. After *Fulton* and the shadow docket cases, is it inevitable that states will have to provide an exemption based on religion from a vaccine mandate? [74]

In answering that question, courts should separate the analysis for mandates requiring that children be vaccinated for school or daycare from other mandates usually directed at adults because there are meaningful differences between these two situations. First, childhood vaccine mandates long predated *Smith,* and were upheld in the face of free exercise claims even when the guiding Free Exercise precedents suggested that strict scrutiny should apply to laws touching on Free Exercise.[75] The rationale, as mentioned, is that there is a meaningful difference in regulating religion when it comes to adults as compared to children. The latter do not have the same autonomy to make religious choices, and there are already limits on what parents can do when it affects their child's welfare,

even for religious reasons.[76] These limits are not exclusive to vaccines. States regulate, for example, the ability of parents to deny treatment to their child.[77] States impose compulsory education requirements, and child labor laws.[78] States criminalize some religiously motivated practices, for example, female genital mutilation.[79]

As of yet, there is no indication that the Supreme Court is willing to require states to provide religious exemptions from laws that affect a child's welfare. The hesitation to overturn *Smith* may be strongest when it addresses these type of laws — directly affecting the welfare of individual children who cannot yet make the choice in question. As mentioned above, one argument against the City of Philadelphia's actions in *Fulton* is the negative effect on the children in question. In a real sense, Fulton is a case where the free exercise claim of CSS is, arguably, in line with children's interests, whereas in school mandates cases, they clash.[80] Further, school mandates have even stronger justification. The child welfare laws described above directly regulate behavior to protect the welfare of an individual child from parental choices. Vaccine mandates, however, protect not only the child but the community as well in serving public health.[81] Unvaccinated children are at a higher risk of contracting a potentially fatal preventable disease — and transmitting it.[82] At the end of the day, when parents of unvaccinated children argue for a religious exemption (even assuming the claim is sincere) they are asserting not only the right *not* to protect their own children from dangerous, preventable diseases, but also the right to bring that risk to school and endanger other people's children and other people who are in the school to receive education. Even before *Smith*, the jurisprudence did not interpret religious freedom to allow someone to make a choice that imposes this double risk. If there is any context in which it is advisable to preserve *Smith*, it is where parental choice arguably undermines both the child's welfare and the safety of others. Arguably, religious freedom claims are weakest when invoked to jeopardize a child's physical welfare and the welfare of others — i.e., when the believer is making the choice for others and not just for him/herself.

Preserving *Smith* would exempt general school immunization mandates from strict scrutiny. But even if *Smith* were overruled, school vaccine mandates might survive strict scrutiny, given that in recent years courts have upheld immunization mandates without religious exemptions. For example, in California, courts have found that school mandates serve a compelling interest in children's and community health, and are narrowly tailored because there is no real alternative.[83]

The situation for state adult mandates is more complex. In that case, the tension is directly between the believers' choice for themselves and the public health. As a result, the Supreme Court, may decide to apply strict scrutiny to adult vaccine mandates, especially since broad adult mandates are not currently in use, and would be a new intrusion into autonomy. As I argue below, however, if *Smith's* application of rational basis review is preserved for a least some contexts, it would be very appropriate to preserve it for adult vaccines. Further, even if *Smith* did not apply to adult mandates, and they were subjected to strict scrutiny, carefully drafted adult mandates should withstand analysis even under that exacting standard.

There are three reasons *Smith* should continue to apply to adult mandates. First, adult vaccine mandates are generally applicable and neutral — they are usually put in place to preserve public health. Further, vaccines really are a public good, where broad compliance matters. The choice not to vaccinate affects not just the individual but the community, in two ways. The unvaccinated person may herself become a vector for the disease; she is not just vulnerable to infection, but also vulnerable to transmitting the disease to others. Mandated vaccines are different from the restrictions that applied to churches in the shadow docket cases, where, arguably, the main risk is to other congregation members who chose to take the risk by attending church. The unvaccinated person also undermines herd immunity by lowering vaccine rates. As discussed earlier, higher vaccine rates lead to fewer outbreaks by stopping the germ from spreading in the population. Unvaccinated individuals benefit from herd immunity, even as they undermine it, which is a form of free riding.

Smith is an especially good fit for situations where a general law is adopted because of the importance of broad-based compliance to protect the general safety and welfare, where the nature of the law makes it unlikely that it targets religion, and where non-compliance leads to either free riding or harm to others. That is exactly the situation for vaccine mandates.

Second, in the case of vaccine mandates, the risk of false claims of religion is high, and policing the claims is challenging. Most people who choose not to vaccinate are not acting out of religious convictions, but out of a belief rooted in misinformation regarding vaccine safety (or other related misinformation). Decades of experience in the school mandate context suggests that people lie about the reasons for the refusal.[84] Our jurisprudence — appropriately — makes it hard to police sincerity (for example, you cannot require a letter from a religious leader to prove sincerity, since that discriminates in favor of organized religions).[85] Although limited, several cases predating *Smith* suggested that in contexts where there is incentive to claim religious beliefs to obtain a secular benefit and it is a challenge to police sincerity, there are grounds not to allow a religious exemption. For example, the Supreme Court concluded just that in a case upholding a statute prohibiting the sale of certain commodities on Sunday against a free exercise challenge, saying

To allow only people who rest on a day other than Sunday to keep their businesses open on that day might well provide these people with an economic advantage over their competitors who must remain closed on that day; this might cause the Sunday-observers to complain that their religions are being discriminated against. With this competitive advantage existing, there could well be the temptation for some, in order to keep their businesses open on Sunday, to assert that they have religious convictions which compel them to close their businesses on what had formerly been their least profitable day. This might make necessary a state-conducted inquiry into the sincerity of the individual's religious beliefs, a practice which a State might believe would itself run afoul of the spirit of constitutionally protected religious guarantees.[86]

The Court made a similar point in a case asking for a religious exemption from a statutory requirement that a social security number be provided by an applicant seeking to receive certain welfare benefits. The Court stated that

we know of no case obligating the Government to tolerate a slight risk of "one or perhaps a few individuals" fraudulently obtaining benefits in order to satisfy a religious objection to a requirement designed to combat that very risk. Appellees may not use the Free Exercise Clause to demand Government benefits, but only on their own terms …[87]

Bowen is not as good a fit. Many vaccine mandates would not involve conditioning a government benefit on vaccine status, though some will. Vaccines mandates are also not designed to prevent fraud. But the risk of lies to obtain a religious objection does come up in the context of vaccine mandates, and the argument that the government does not have to take even a slight risk of fraud to avoid harm to an important interest would apply here as well.

Although there are no additional Supreme Court cases on point, several scholars have argued against religious exemptions because of concerns about policing them.[88] Opponents, however, point out that a sincerity inquiry is not inherently different from other legal inquiries into mental state or credibility, and that there are other contexts in which sincerity of religion has to be examined.[89] This is true, but context matters. In some areas, such as intentional torts, one's mental state is an inherent part of the legal norm.[90] But with regard to a vaccine mandate, the sincerity inquiry is only necessary if a religious exemption is constitutionally required — and the concern about assessing sincerity is a reasonable argument against requiring it. When the risk of abuse is high — as it is with vaccine mandates — that is not a good idea. A serious concern is that people will claim religious exemption out of "pure selfishness — to enjoy herd immunity without undergoing the costs and risks of immunization."[91] That very real risk — coupled with the challenges in enforcing religious exemptions — argues against applying strict scrutiny in this context. And the mere existence of a sincerity requirement in other contexts does not justify importing it into a context where it may not be required.

Finally, as discussed by Justice Alito in *Fulton,* in cases before *Sherbert*[92] — which set the pre-*Smith* standard of strict scrutiny — courts rejected claims for religious exemptions when "'[t]he conduct or actions [in question] invariably posed some substantial threat to public safety, peace or order.'"[93] Justice Alito points out that this approach fits his understanding of the scope of free exercise at the time the First Amendment was adopted, suggesting an originalist interpretation of the amendment.[94] The Supreme Court's shadow docket decisions are concerning, suggesting lack of emphasis on public safety, as set out by Parmet. Ideally, however, cases fully argued, without the urgency of the shadow docket, would give the Court a chance to examine the implications of and

carve out appropriate exemptions, including a narrow public health exception.[95]

Compared to the extensive literature on school vaccine mandate, there is little empirical literature on adult mandates, maybe because they were so rare in the past. But as mentioned above, extensive literature shows that school mandates for children are correlated with fewer outbreaks.[96] Similarly, in the influenza context, studies show that workplace mandates reduce harms and deaths in hospitals.[97] This evidence suggests that vaccine mandates help prevent a real and substantial threat to public health (and safety), and therefore, it is appropriate not to apply strict scrutiny when there are no religious exemptions.

There is still the question of whether *Fulton* should be interpreted to apply strict scrutiny every time there is a secular exemption. Vaccine mandates — for children or adults — generally do (and should) offer medical exemptions when medical conditions make vaccination substantially more dangerous than average. One effect of mandates is to protect those who cannot safely be vaccinated by providing them with a protective ring of immunized people, who keep the disease away. As a result, those who cannot be safely vaccinated for medical reasons should be exempt from the requirement. Would the new Supreme Court apply strict scrutiny to vaccines mandates that offer a medical exemption?

The Supreme Court should not apply strict scrutiny if a vaccine mandate provides a medical exemption but not a religious exemption. First, medical exemptions are fundamentally different than other secular exemptions; they tend to apply to well defined medical conditions and require a doctor to determine their necessity. These exemptions involve medical discretion, but are not discretionary in the sense that the exemption in *Fulton* was. Medical exemptions involve professional discretion which, if misapplied, can lead to disciplinary charges (as happened to several doctors in California who wrote baseless medical exemptions).[98] This is different from the purely discretionary exemption mentioned in *Fulton.* A medical exemption is also different from a religious exemption, which is substantially harder to evaluate, as discussed.[99] Second, *Jacobson* implied, and is correctly understood to have decided, that medical exemptions are constitutionally required.[100] Constitutionally required medical exemptions are different than discretionary secular exemptions. In the latter case, the legislature does not choose to exempt categories of people for secular reasons, while failing to exempt those with religious objections. Instead, the legislature aims to preserve the logic of vaccine mandates.[101] The natural implication is that more finely tuned mandates that target specific populations may be held to strict scrutiny if they do not offer a religious exemption.[102]

The Supreme Court would have some ground to apply strict scrutiny to vaccine mandates for adults, though. An adult vaccine mandate requires an adult to undergo a medical procedure, albeit one that is minimally invasive and low risk. Nevertheless, it is still an imposition. Holding legislatures and agencies to a high standard in such cases may mean adult vaccines mandates are rarely imposed, and only when needed; in those circumstances, states should be able to meet strict scrutiny. Given the recent rulings on the shadow docket and *Tandon,* though, public health scholars, fear that courts will not give sufficient weight to public health in applying strict scrutiny, and will read the existence of any exemption as requiring a religious one, setting aside the judgment of public health officials.[103]

We have a long line of cases upholding vaccines mandates separate from religious jurisprudence, quite a few of them predating *Smith.* We can hope that courts will follow some of the guidance from previous vaccine mandate cases, acknowledging the special features of this context.

Jurisprudence concerning school mandates treats the prevention of disease as a compelling state interest.[104] Mandates should only be adopted when they are needed to prevent diseases that can kill and harm (though the jurisprudence — rightly — allows them to be used preventively, to avoid the occurrence of a disease outbreak, and not just to stop an ongoing outbreak). Such an appropriate mandate should meet the compelling interest standard. But an additional question will be whether the law is narrowly tailored. States can narrow these mandates in two ways; ideally, they will use a combination of both. First, states can impose the mandate only as needed. For example, in 2019, when New York City adopted an MMR mandate during a measles outbreak, it limited it to neighborhoods with high rates of cases.[105] In the context of COVID-19, for example, states could pass general laws empowering local boards to adopt a mandate if the locality becomes a hotspot or has an outbreak — somewhat like the law in *Jacobson.* Alternatively, states could adopt narrow mandates limited to specific professions or draw other

careful, and constitutionally permissible, distinctions. For example, a state could adopt a mandate directed at healthcare providers or correction offices, groups working with at-risk populations that may not be able to choose to distance themselves. States could also offer broad general exemptions, to more narrowly tailor the mandates. While adopting any exemption may subject mandates to strict scrutiny, providing broad exemptions and applying the mandate only where necessary may fill the requirement that the mandate be narrowly tailored. In the context of COVID-19, for example, it may be justified to exempt people with evidence of prior COVID-19 infection from the mandate.

The second way a mandate can be made less restrictive is by imposing a relatively low penalty for violations. For example, a moderate fine may increase the mandate's chances of surviving. In his concurrence in *Roman Catholic Diocese*, Justice Gorsuch suggested that one of the reasons for the holding in *Jacobson* was the low penalty — a $5 fine, which was modest even for its time.[106] I think that is an incorrect reading of *Jacobson*; although the penalty at issue was a fine, the Court's reasoning relied on decisions upholding school mandates that imposed the higher penalty of keeping a child out of school.[107] But modest penalties are another way for states to choose the least restrictive means to achieve the goal of preventing disease.

Conclusion

The Court's latest religious jurisprudence creates substantial uncertainty about the correct standard to be applied to laws that impose burdens on religion. This article addresses one narrow — but important — subset of laws, vaccine mandates. It argues that there are grounds to apply a lower standard of review than strict scrutiny to vaccine mandates. Even if courts use that higher standard of review, however, the mandates should survive strict scrutiny, if they are narrowly tailored to foster the compelling governmental interest of saving millions of lives and avoiding substantial harm to many more individuals.

Note

Dorit R. Reiss's family owns stock in GSK, a vaccine manufacturer. Reiss also served as a volunteer (unpaid) advisor on Moderna's ethics advisory group.

Acknowledgements

I am very grateful for the insightful and helpful feedback on previous drafts of this manuscript provided by David Levine, Ira Lupu, Wendy Parmet, Sonia Suter, and Robert Tuttle, as well as for the questions from participants in the First Amendment Conference in The George Washington Law School. I am also grateful to Aditi Asthana and Michele Ellson for their excellent research assistance. All errors are, of course, my own.

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4. V. K. Phadke, R.A. Bednarczyk, D. A. Salmon, and S.B. Omer, " Association Between Vaccine Refusal and Vaccine-Preventable Diseases in the United States: A Review of Measles and Pertussis," Journal of American Medical Association 315, no. 11 (2016): 1149–1158, at 1150. For specific examples, rates of exemptions in Connecticut increased over 1% between 2012-2019. That may not seem like much, but the starting point was 1.7% exempt, and the end 2.7% - over 60% growth. Further, the growth was entirely in the religious exemption category, not in the medical exemption, suggesting — since there's no indication Connecticut's religious composition changed dramatically in that time — that vaccine hesitancy increased. Connecticut State Department of Public Health, "School Immunization Survey Data," available at <https://portal.ct.gov/DPH/Immunizations/School-Survey >(last visited June 28, 2021). In California, prior to a change in law, nonmedical exemption rates increased dramatically

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9. D. R. Reiss, “ Litigating Alternative Facts: School Vaccine Mandates in the Courts,” University of Pennsylvania Journal of Constitutional Law 21 (2018): 207–263, at 216-218.
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11. L. Fay, “No Exceptions: New York, Washington, Maine Abolish Religious Exemptions for Measles Vaccine, California Looks to Limit Medical Exemptions,” The 74, June 17, 2019, available at <https://www.the74million.org/no-exceptions-new-york-washington-maine-abolish-religious-exemptions-for-measles-vaccine-california-looks-to-limit-medical-exemptions/ >(last visited June 28, 2021).
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13. D. R. Reiss, “ Litigating Alternative Facts,” supra note 10, at 240.
14. Id. at 239-243.
15. D. R. Reiss, “ Thou Shalt Not Take the Name of the Lord Thy God in Vain: Use and Abuse of Religious Exemptions from School Immunization Requirements,” Hastings Law Journal 65 (2014): 1573–1584, at 1551. (noting, for example, that Judaism, Catholics, most protestant churches and most Muslim strands do not prohibit vaccines, and in fact support them).
16. Id. 1583-1584.
17. Id. 1570-1573.
18. B. Kasstan, “ If a Rabbi did say ‘You have to Vaccinate,’ We Wouldn’t’: Unveiling the Secular Logics of Religious Exemption and Opposition to Vaccination,” Social Science and Medicine 280 (2021).
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Exemptions and Pertussis in California, 2010," Pediatrics 132, no. 4 (2013): 624-630. See also, for specific examples of outbreaks driven by exemptions: A. P. Fiebelkorn, S. B. Redd, K. Gallagher, et al., "Measles in the United States during the Postelimination Era," Journal of Infectious Diseases 202, no. 10 (2010): 1520–1528; V. Hall, E. Banerjee, C. Kenyon, et al., "Measles Outbreak — Minnesota, April–May, 2017," Center for Disease Control Morbidity and Mortality Weekly Report (MMWR) 66, no. 27 (2017): 713–717; J. B. Rosen, R. J. Arciuolo, et al., "Public Health Consequences of a 2013 Measles Outbreak in New York City," JAMA Pediatrics 172, no. 9 (2018): 811–817; R. McDonald, P. S. Rupppert, et al., " Measles Outbreaks from Imported Cases in Orthodox Jewish Communities — New York and New Jersey, 2018–2019," Center for Disease Control Morbidity and Mortality Weekly Report (MMWR) 68, no. 19 (2019): 444–445.

23. Jacobson v. Massachusetts, 197 U.S. 11, 12 (1905). The full quote is: The Revised Laws of that Commonwealth, chap. 75, § 137, provide that 'the board of health of a city or town if, in its opinion, it is necessary for the public health or safety shall require and enforce the vaccination and revaccination of all the inhabitants thereof and shall provide them with the means of free vaccination. Whoever, being over twenty-one years of age and not under guardianship, refuses or neglects to comply with such requirement shall forfeit five dollars.'

24. Id. at 25-26.

25. Id. at 29-30.

26. Reiss, "Litigating Alternative Facts," supra note 10, at 240. The First Amendment was incorporated into the Fourteenth Amendment towards the states in 1940, in Cantwell v. Connecticut, 310 U.S. 296, 306 –07 (1940).

27. Id. at 239-243.

28. Emp't Div., Dep't of Hum. Res. of Oregon v. Smith, 494 U.S. 872, 879 (1990).

29. D. R. Reiss and L. A. Weithorn, " Responding to the Childhood Vaccination Crisis: Legal Frameworks and Tools in the Context of Parental Vaccine Refusal," Buffalo Law Review 63, no. 4 (2012): 881 –9, at 912–915.

30. Id.

31. Prince v. Massachusetts, 321 U.S. 158, 170 (1944).

32. Id.

33. Id. at 166-167.

34. Reiss, "Litigating Alternative Facts," supra note 10, at 229-230.

35. F.F. ex rel. Y.F. v. New York, 65 Misc. 3d 616, 108 N.Y.S.3d 761 (N.Y. Sup. Ct. 2019) was the first instance, F.F. v State of New York, 194 A.D.3d 80, 143 N.Y.S.3d 734 (2021), decided March 18, 2021, is the appellate court's decision, available at <https://law.justia.com/cases/new-york/appellate-division-third-department/2021/530783.html >(last visited July 28, 2021); V.D. v. State of New York, 403 F. Supp. 3d 76 (E.D.N.Y. 2019).

36. E.g. City of Boerne v. Flores, 521 U.S. 507, 513-514 (1997); and a much larger jurisprudence in the lower courts, for example Tenafly Eruv Assn., Inc. v. Tenafly, 309 F. 3d 144, 168, n. 30 (CA3 2002) and San Jose Christian College v. Morgan Hill, 360 F. 3d 1024, 1032–1033 (CA9 2004), for two examples.

37. Smith, 494 U.S. at 878-879. The court held was that "an individual's religious beliefs [do not] excuse him from compliance with an otherwise valid law prohibiting conduct that the state is free to regulate." Id., at 878-879.

38. Church of Lukumi Babalu Aye, Inc. v. Hialeah, 508 U.S. 520, 531-32 (1993) ("[A] law that is neutral and of general applicability need not be justified by a compelling governmental interest even if the law has the incidental effect of burdening a particular religious practice … [but a] law failing to satisfy these requirements must be justified by a compelling governmental interest and must be narrowly tailored to advance that interest.") In that case, a seemingly neutral ordinance prohibiting animal sacrifice was, evidence showed, enacted to target a church belonging to the religion of Santeria.

39. Masterpiece Cakeshop, Ltd. v. Colo. Civil Rights Comm'n, 138 S. Ct. 1719, 1729-31 (2018).

40. F.F. ex rel. Y.F. v. New York, 65 Misc. 3d 616, 108 N.Y.S.3d 761 (N.Y. Sup. Ct. 2019) was the first instance, F.F. v State of New York, 194 A.D.3d 80, 143 N.Y.S.3d 734 (2021), decided March 18, 2021, is the appellate court's decision, available at <https://law.justia.com/cases/new-york/appellate-division-third-department/2021/530783.html >(last visited July 28, 2021).

41. M. L. Movsesian, " Masterpiece Cakeshop and the Future of Religious Freedom," Harvard Journal of Law and Public Policy 42, no. 3 (2019): 711 –50, at 713-716.
42. Burwell v. Hobby Lobby Stores, Inc., 134 S. Ct. 2751, 2760-62 (2014). The Religious Freedom Restoration Act of 1993, 42 U.S.C. §§ 2000bb –1(a), 1(b).
43. I. C. Lupu, " Hobby Lobby and the Dubious Enterprise of Religious Exemptions," Harvard Journal of Law and Gender 38, (2015): 35–100, at 92-100. Extensive literature addressed Hobby Lobby and its effects, mostly expressing concern. E.g. P. Horwitz, "The Hobby Lobby Moment," Harvard Law Review 128, no. 1 (2014): 154-189; J. C. Pizer, "Navigating the Minefield: Hobby Lobby and Religious Accommodation in the Age of Civil Rights," Harvard Law &Policy Review 9, no. 1 (2015): 1-23; S. J. Levine, "A Critique of Hobby Lobby and the Supreme Court's Hands-Off Approach to Religion," Notre Dame Law Review Online 91, (2015): 26-49; S. Rosenbaum, "When Religion Meets Workers' Rights: Hobby Lobby and Conestoga Wood Specialties," Milbank Quarterly 92, no. 2, (2016): 202-206.
44. Masterpiece Cakeshop, Ltd., 138 S. Ct. at 1731-34.
45. Id.
46. L. F. Wiley, " Democratizing the Law of Social Distancing," Yale Journal of Health Policy, Law &Ethics 19, no. 3 (2020): 50–121.
47. D. Rubinstein Reiss and M. Thomas, " More than a Mask: Stay-At-Home Orders and Religious Freedom," San Diego Law Review 57, no. 4 (2020): 947–972.
48. A. James et al., "High COVID-19 Attack Rate Among Attendees at Events at a Church—Arkansas, March 2020," Centers for Disease Control and Prevention: Morbidity and Mortality Weekly Report, M ay 19, 2020, available at <https://www.cdc.gov/mmwr/volumes/69/wr/mm6920e2.html >(last visited July 28. 2021); S. Becker, "At Least 70 People Infected With Coronavirus Linked to a Single Church in California, Health Officials Say," CNN, April 4, 2020, available at <https://www.cnn.com/2020/04/03/us/sacramento-county-church-covid-19-outbreak/index.html >(last visited July 28. 2021); R. Burkard, "Church at Center of COVID-19 Outbreak Responds," The Messenger, April 7, 2020, available at <https://www.the-messenger.com/news/local/article_59dcb9b2-063a-56fe-a89a-e72ee157483f.html >(last visited July 28. 2021); K. Conger et al. "Churches were Eager to Reopen. Now They Are Confronting Coronavirus Cases," New York Times, July 8, 2020, available at <https://www.nytimes.com/2020/07/08/us/coronavirus-churches-outbreaks.html/ >(Last visited July 29, 2021).
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50. S. I. Vladeck, " The Solicitor General and the Shadow Docket," Harvard Law Review 133 (2019): 123–163, at 125.
51. Baude, supra note 48, at11-15.
52. Id. at 7.
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54. Roman Catholic Diocese v. Cuomo, 141 S. Ct. 63 (2020).
55. Id. The case stated, "businesses categorized as 'essential may admit as many people as they wish. And the list of 'essential' businesses includes things such as acupuncture facilities, camp grounds, garages … all plants manufacturing chemicals and microelectronics."
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58. W. E. Parmet, supra note 56.
59. S. Bay United Pentecostal Church v. Newsom, 141 S. Ct. 716, 716 (2021) (mem); Gateway City Church. v. Newsom, 141 S. Ct. 1460 (2021) (mem). For a much more thorough discussion of these cases see W.E. Parmet, supra note 56.
60. Tandon v. Newsom, 141 S. Ct. 1294, 1294-99 (2021) (per curiam).
61. Fulton v. City of Philadelphia, 320 F. Supp. 3d 661 (E.D. Pa. 2018) (No. 18-2075), aff’d, 922 F.3d 140, 165 (3d Cir. 2019), rev’d and remanded sub nom. Fulton v. City of Philadelphia, Pennsylvania, 141 S. Ct. 1868 (2021).
62. M. S. Chavez, “ Employing Smith to Present a Constitutional Right to Discriminate Based on Faith: Why the Supreme Court Should Affirm the Third Circuit in Fulton v. City of Philadelphia,” American University Law Review 70, no. 3 (2020): 1165 –216.
63. Id. at 1169, footnotes omitted.
64. W. E. Parmet, supra note 56.
65. Fulton v. City of Philadelphia, Pennsylvania, 141 S. Ct. 1868 (2021).
66. Id.
67. Id., (Aliton, J. Concurring).
68. Id., (Gorsuch, J., Concurring).
69. Id., (Barrett J., Concurring).
70. An interpretation raised previously in a decision by Judge Alito, as he was then, on the Third Circuit in Fraternal Order of Police Newark Lodge No. 12 v. City of Newark, 170 F.3d 359, 364-66 (3d Cir. 1999).
71. W. P. Marshall, “ Extricating the Religious Exemption Debate from the Culture Wars,” Harvard Journal of Law and Public Policy 41, no. 1 (2018): 67.
72. Prince v. Massachusetts, 321 U.S. 158, 166-167 (1944).
73. On that tension, see M. S. Chavez, supra note 62; C. Figueroa, “Fulton v. City of Philadelphia: The Third Circuit’s Bittersweet Advancement of LGBTQ+ Rights,” Tulane Journal of Law and Sexuality 29 (2020): 51-58; one alternative concern by a scholar in relation to Fulton is that that the discussions of the case ignore the interests of the children in question; J. G. Dwyer, “The Child’s Rights Forgotten, Again: Reframing Fulton v. City of Philadelphia,” November 12, 2020, available at <https://ssrn.com/abstract=3737686 >(last visited July 28, 2021).
74. For some views, see W.E. Parmet, supra note 56, suggesting that Roman Catholic Diocese (let alone Gateway) puts vaccine mandates at risk. But see, M. Hoernlein and R. Gauthier, “Clues Mandatory Vaccines Would Pass Muster At High Court,” Law360, December 15, 2020, available at <https://www.law360.com/articles/1335601 >(last visited July 28, 2021); and see Z. B. Pohlman, “Fulton and Government-Mandated Vaccination,” CANOPY Forum 2021, April 9, 2021, available at <https://canopyforum.org/2021/04/21/fulton-and-government-mandated-vaccinations/ >(last visited July 28, 2021) (While all of these sources predated Fulton, their analysis applies, and will be discussed individually).
75. Sherbert v. Verner, 374 U.S. 398, 405-409 (1963); Wisconsin v. Yoder, 406 U.S. 205, 207-209 (1972).
76. Reiss and Weithorn, supra note 29 at 905-911.
77. W. H. Hawes IV, “ Faith Healing Prosecutions: How Religious Parents Are Treated Unfairly by Laws that Protect their Liberty,” American Criminal Law Review 54, no. 3 (2017): 885; S. F. Peters, When Prayer Fails: Faith Healing, Children, and the Law (Oxford: Oxford University Press, 2007): at 185-195.
78. Reiss and Weithorn, “Responding to the Childhood Vaccination Crisis,” supra note 29, at 911-915.
79. K. Hughes, “ The Criminalization of Female Genital Mutilation in the United States,” Journal of Law and Policy 4, no. 1 (1995): 321–370.

80. J. G. Dwyer, supra note 72.
81. Prince, 321 U.S. at 166-67.
82. Reiss, supra note 10, 222-223 and the footnotes there. Unvaccinated adults pose a similar risk, as discussed below, but the point here is that the combination of risk to the child and risk to others is what makes this especially strong.
83. See Brown v. Smith, 24 Cal. App. 5th 1135, 1146, 235 Cal. Rptr. 3d 218, 226 (Cal. Ct. App. 2018) (rejecting plaintiff's "complaint that Senate Bill No. 277 is not narrowly tailored to meet the state's interest, because there are less restrictive alternatives (such as alternative means (unspecified) of immunization, and quarantine in the event of an outbreak of disease)" because "compulsory immunization has long been recognized as the gold standard for preventing the spread of contagious diseases"); Whitlow v. California, 203 F. Supp. 3d 1079, 1089-1091 (S.D. Cal 2016); Love v. State Department of Education, 29 Cal. App. 5th 980, 996, 240 Cal. Rptr. 3d 861 (Cal. Ct. App. 2018). Note that strict scrutiny was not applied in New York: F.F. v. State of New York, 194 A.D.3d 80, slip. op. at 87 (3d Dep't 2021). Although the argument that a medical exemption is a secular exemption that requires a religious one may be applicable here as well, I left that discussion for under the adult mandates, to avoid repetition.
84. Reiss, "Thou Shalt Not Take the Name of the Lord Thy God in Vain," supra at 1570-1588.
85. Id. at 1568-1570.
86. Braunfeld v. Brown, 366 U.S. 599, 608-09 (1961). Braunfeld was positively cited in a few other state cases challenging similar laws. Marks Furs, Inc. v. City of Detroit, 365 Mich. 108, 117, 112 N.W.2d 66, 70 (1961); Miles-Lee Supply Co. v. Bellows, 197 N.E. 2d 247, 250 (1964) (Held for defendant on unrelated grounds.)
87. Bowen v. Roy, 476 U.S. 693, 709, 711 -12 (1986).
88. E. West, " The Case Against a Right to Religion-Based Exemptions," Notre Dame Journal of Law, Ethics, and Public Policy 4, no. 3 (1990): 591–638, at 603-604; J. E. Ryan, "Smith and the Religious Freedom Restoration Act: An Iconoclastic Assessment," Virginia Law Review 78, no. 6 (1992): 1407-1462, at 1427-1428; G. Epps, "What We Talk About When We Talk About Free Exercise," Arizona State Law Journal 30, no. 3 (1998): 563-601, at 570; Ira C. Lupu, "The Failure of RFRA," University of Arkansas Little Rock Law Journal 20, no. 3 (1998): 575-619, at 593; W. P. Marshall, "Extricating the Religious Exemption Debate from the Culture Wars," Harvard Journal of Law and Public Policy 41, no. 1 (2018): 67-77, at 70-71.
89. D. E. Steinberg, " Rejecting the Case against the Free Exercise Exemption: A Critical Assessment," Boston University Law Review 75, no. 2 (1995): 241–320, at 278.
90. Id. at 278-279.
91. R. B. Collins, " Too Strict? " First Amendment Law Review 13, no. 1 (2014): 1–70.
92. Sherbert v. Verner, 374 U.S. 398 (1963).
93. Fulton, 141 S. Ct. at 1883-1926.
94. Id.
95. W.E. Parmet, supra note 56.
96. See, for a larger collection of such studies, Immunization Action Coalition, Personal Belief Exemptions for Vaccination Put People at Risk. Examine the Evidence for Yourself, available at <https://www.immunize.org/catg.d/p2069.pdf >(last visited July 28, 2021).
97. T.L. Wang, L. Jing, and J.A. Bocchini, Jr., " Mandatory Influenza Vaccination for All Healthcare Personnel: A Review on Justification, Implementation and Effectiveness," Current Opinion in Pediatrics 29, no. 5 (2017): 606–615.

98. D. Rubinstein Reiss, "Dr. Kenneth P Stoller Requests Stay of Punishment for Fake Vaccine Exemptions — Judge Says No," Skeptical Raptor, March 21, 2021, available at <https://www.skepticalraptor.com/skepticalraptorblog.php/dr-kenneth-p-stoller-requests-stay-of-punishment-for-fake-vaccine-exemptions-judge-says-no/ >(last visited July 28, 2021); P. Sisson, "Three Doctors Face Medical Discipline for Vaccine Exemptions, and More Could be on the Way," San Diego Union-Tribune, October 24, 2019, available at <https://www.sandiegouniontribune.com/news/health/story/2019-10-24/three-doctors-face-medical-discipline-for-

vaccine-exemptions-and-more-could-be-on-the-way >(last visited July 28, 2021).
99. Reiss, “Thou Shalt Not Take the Name of the Lord Thy God in Vain,” supra at 1557.
100. D. Farber, “ The Long Shadow of Jacobson v. Massachusetts: Public Health, Fundamental Rights, and the Courts,” San Diego Law Review 57, (2020): 833–858; B. Horowitz, “A Short in the Arm: What a Modern Approach to Jacobson v. Massachusetts Means for Mandatory Vaccination During a Public Health Emergency,” American University Law Review 60, no. 6 (2010): 1715-49, at 1742-1743.
101. Horowitz, supra note 100.
102. W.E. Parmet, supra note 56.
103. Id.
104. Workman v. Mingo Cnty. Bd. of Educ., 419 F. App’x 348, 353 (4th Cir. 2011) (per curiam), cert. denied, 132 S. Ct. 590 (2011) (“[T]he state’s wish to prevent the spread of communicable diseases clearly constitutes a compelling interest.”); Whitlow v. California, 203 F. Supp. 3d 1079, 1089-90 (S.D. Cal. 2016); Brown v. Smith, 24 Cal. App. 5th 1135, 1146 (Cal. Ct. App. 2018).
105. J. D. Cantor, “ Mandatory measles Vaccination in New York City — Reflections on a Bold Experiment,” New England Journal of Medicine 381, (2019): 101–103.
106. Roman Catholic Diocese of Brooklyn, 141 S. Ct. at 69.
107. Jacobson, 197 U.S. at. 32-34.

DETAIL

Subjek:	At risk youth; Public health; COVID-19 vaccines; Supreme courts; Adults; Disease; Freedom of religion; Immunization; Pandemics; Religious exemptions; Jurisprudence; Children &youth; First Amendment-US; Children; Coronaviruses; Religion; Supreme Court decisions; Childrens rights
Ketentuan indeks bisnis:	Subjek: Religious exemptions
Lokasi:	New York; United States--US; Massachusetts; California
Pengidentifikasi/kata kunci:	Vaccines; Public policy; Vaccine; Mandate; Public health; Public Health; Freedom of Religion; Supreme Court; Children’s Rights
Judul:	Vaccines Mandates and Religion: Where are We Headed with the Current Supreme Court?
Pengarang:	Reiss, Dorit R
Judul publikasi:	The Journal of Law, Medicine &Ethics; Boston
Volume:	49
Edisi:	4
Detail sumber:	First Amendment Values in Health Care
Halaman:	552-563
Tahun publikasi:	2021

Tanggal publikasi:	Winter 2021
Bagian:	Symposium Articles
Penerbit:	Cambridge University Press
Tempat publikasi:	Boston
Negara publikasi:	United Kingdom, Boston
Subjek publikasi:	Law, Medical Sciences
ISSN:	10731105
e-ISSN:	1748720X
Jenis sumber:	Jurnal Akademik
Bahasa publikasi:	English
Jenis dokumen:	Journal Article
DOI:	https://doi.org/10.1017/jme.2021.79
ID dokumen ProQuest:	2730847310
URL Dokumen:	https://www.proquest.com/scholarly-journals/vaccines-mandates-religion-where-are-we-headed/docview/2730847310/se-2?accountid=211160
Hak cipta:	© 2021 The Author(s)
Terakhir diperbarui:	2023-11-27
Basis data:	Public Health Database

Of Athletes, Bodies, and Rules: Making Sense of Caster Semenya

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ABSTRAK (ENGLISH)

This article aims to systematically deconstruct four distinct narratives derived from the case of *Caster Semenya v. IAAF (Court of Arbitration for Sport).*

TEKS LENGKAP

This article helps navigate through *Mokgadi Caster Semenya et al. v. International Association of Athletics Federations (IAAF)*, a case decided by an arbitral panel of the Court of Arbitration for Sport (CAS) in 2019[1] and on appeal, by the Swiss Supreme Federal Tribunal (SFT) in 2020.[2]

In *Semenya*, Athletics South Africa (ASA) and the globally famous South African runner Caster Semenya contended that the IAAF's Eligibility Regulations for the Female Classification (Athletes with Differences of Sex Development) (DSD Regulations) violated Semenya's right to participate in sport without discrimination. Semenya and the ASA claimed that the DSD Regulations unnecessarily, disproportionally and unreasonably discriminated against people with Differences of Sex Development (DSD) by preventing them from competing in the female category unless they underwent testosterone-suppressing treatment.[3]

In particular, the DSD Regulations require women athletes with DSD and testosterone levels higher than 5nmol/L to lower them for a six-month period prior to a competition and continuously thereafter.[4] Building on the principle of non-discrimination contained in the Olympic Charter and in the IAAF's Constitution,[5] the CAS found that the DSD Regulations did discriminate on the basis of genetic characteristics, sex and gender, but nonetheless considered them a "necessary, reasonable and proportionate means of attaining a legitimate objective."[6] The SFT eventually upheld the award and denied Semenya's claim that the CAS award had violated public policy.[7]

This article complements the existing academic literature on the case, which consists of two strands of criticism, respectively approaching the award under human rights law and critical legal theories. According to the former view, the DSD Regulations entail multiple violations of the rights of athletes with DSD, which are sidelined by the CAS award.[8] The United Nations Human Rights Council has adopted this perspective in a resolution calling for the respect of female athletes' "rights to bodily integrity and autonomy."[9] The latter view reproaches the CAS for having mobilized science over legal concerns, ignoring the multiple ethical issues raised by the DSD Regulations. This analytical approach criticizes more generally the "technocratization" of law, which relies on the assumption that science reveals "absolute truths" about athletic performance and sex/gender boundaries.[10]

Against any absolute truth about sex and gender, we conceive both sex and gender as cultural constructs. As our examination of *Semenya* will demonstrate, not only gender but also sex vary across time and space. Sex traits are biological and concrete facts. The scientific gaze on bodies is always distant. Far from being the direct representation of what it observes, science translates what it sees through human and non-human intermediaries that "stand in for what actually is."[11] The way in which the human eye interprets and categorizes sex characteristics is, therefore, far from natural[12] but rather imbued with cultural expectations. Hence, in this paper we refer to "sex/gender," unless the analysis requires the separate use of one of the two terms or the term is contained in a quotation from another source.

In *Semenya*, Athletics South Africa (ASA) and the globally famous South African runner Caster Semenya contended that the IAAF's Eligibility Regulations for the Female Classification (Athletes with Differences of Sex Development) (DSD Regulations) violated Semenya's right to participate in sport without discrimination. Semenya and the ASA claimed that the DSD Regulations unnecessarily, disproportionally and unreasonably discriminated against people with Differences of Sex Development (DSD) by preventing them from competing in the female category unless they underwent testosterone-suppressing treatment.

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In this article, we offer an original analysis of *Semenya* that looks at a set of narratives that the adjudicators used to make sense of the case, by deconstructing them as legally flawed and ethically questionable. We elaborate this argument in two parts. Part I presents the case's factual and legal background. Part II offers an analysis in four sections, respectively dedicated to each of the abovementioned narratives. Particularly, we challenge that:

•Deciding on eligibility is not deciding about sex/gender.

•Testosterone is an accurate predictor of athletic performance.

•The required testosterone-suppressing treatment is safe and harmless.

•*Semenya* now protects women as a whole.

Despite the adjudicators' attempt to offer an objective, neutral and apologetic narrative, the way they made sense of Semenya's excellent performance is stereotyped, gendered and stigmatizing. We conclude that the narratives presented in *Semenya* are inherently flawed and contradict the principle of fairness in sport. In fact, by precluding athletes with DSD from competing in the same way as the other athletes, the outcome of the case contradicts the very essence of equal participation in sport.

I. A Longstanding Dispute On Gendered Bodies

A . Before Semenya

On August 19, 2009, eighteen-year-old South African runner Mokgadi Caster Semenya set a new world record in women's 800-meters finals at the World Athletics Championship in Berlin, winning the gold medal with a time of 1:55.45. As she excelled eight seconds beyond her prior record, her performance was perceived as a "double transgression" for both her young age and common standards of preparation.[13] While the antidoping tests failed to mark any irregularity, Semenya's peers objected that she should not compete with them as "she is not a woman, she is a man."[14]

To placate the storm, the IAAF announced further tests on Semenya under their 2006 Policy on Gender Verification (PGV), a one-page instruction set for "handling cases of gender ambiguity."[15] A regime based on mere suspicions of gender non-conformity, the PGV targeted female athletes based on the assumption that they "should not be enjoying the benefits of natural testosterone levels normally seen in a male."[16] Such testing had already been heavily criticized a few years earlier, when Indian athlete Santhi Soundarajan, a champion in the 800-meter race at the 2006 Asian Games in Doha, was stripped of her medal on the alleged grounds that she "did not possess the sexual characteristics of a woman."[17] Her career in sport being interrupted without formal explanations, she attempted suicide, with the IAAF's silence feeding speculations by the media for months.[18] Caster Semenya was subject to the same treatment. She was described as having "male sex organs and no wombs or ovaries"[19] and being "too strong and muscular to be a woman."[20] In response, South African media criticized the IAAF's policy as "a lingering artifact of South Africa's apartheid past and the racist history of Global North/Western culture's scientific scrutiny of African Women's bodies."[21]

Following these polemics, in 2011 the IAAF replaced the PGV with the Regulations Governing Eligibility of Females with Hyperandrogenism to Compete in Women's Competition (Hyperandrogenism Regulations).[22] By refusing the label of "gender verification" and "gender policy,"[23] this new regime restricted its own scope to female athletes with suspected or diagnosed "hyperandrogenism." This was defined as the excessive production of testosterone above the normal male range, which was conventionally fixed at 10 nanomoles per liter (nmol/L).[24] After qualifying hyperandrogenism as "a risk to health,"[25] these regulations envisaged a threefold investigation procedure to be carried out by a panel of independent medical experts.[26] As in the PGV, the assumption behind the Hyperandrogenism Regulations was that the condition generated an advantage in terms of muscle development that nullified the athletic difference between male and female athletes.[27] The new regime also revived the suspicion regime that existed under the PGV, although now suspicion was formally required to come "from any reliable source."[28]

In 2014, the Indian athlete Dutee Chand challenged the Hyperandrogenism Regulations for the first time before a

CAS arbitral tribunal.[29] A sprinter and 100-meters national champion at the age of sixteen, Chand had been disqualified at the last minute from the Commonwealth Games upon suspicion of hyperandrogenism. After medical personnel performed two-round tests on her, the Athletics Federation of India (AFI) suspended her from any competition and recommended she follow the Hyperandrogenism Regulations if she planned to compete again.[30] Notwithstanding the absence of clear-cut answers regarding Chand's medical conditions, the media speculated that Chand had "failed a gender test" and therefore was not a "normal" woman.[31]

Before the CAS, Chand argued that the Hyperandrogenism Regulations disproportionately discriminated against female athletes with particular biological characteristics based on flawed scientific assumptions about the impact of testosterone on athletic performance.[32] The CAS eventually issued an interim award and suspended the Hyperandrogenism Regulations. In particular, the CAS accepted the IAAF's argument that "the Regulations do not police the male/female divide but establish a female/female divide within the female category."[33] Moreover, the CAS rejected Chand's contention that testosterone was irrelevant in explaining the difference in athletic performance between men and women and confirmed it as a scientifically sound marker for eligibility.[34] However, because the parameter against which hyperandrogenism was measured was not men's testosterone level but that of non-hyperandrogenic females, the CAS required the IAAF to produce sufficient evidence about the degree of athletic advantage enjoyed by hyperandrogenic athletes.[35] As a result, in early 2018, the IAAF withdrew the Hyperandrogenism Regulations and enacted a completely new set of rules, the DSD Regulations, allegedly supported by the strongest scientific evidence and with a more limited scope, resulting in the arbitral proceedings being terminated.[36]

B . Caster Semenya, the DSD Regulations and the CAS Award

Compared to the Hyperandrogenism Regulations, the DSD Regulations provide more details about the imperatives supporting their provisions. Their self-proclaimed objective is "[t]o ensure fair and meaningful competition in the sport of athletics" while at the same time maintaining the male/female categorization "[b]ecause of the significant advantages in size, strength and power enjoyed (on average) by men over women from puberty onwards, due in large part to men's much higher levels of circulating testosterone, and the impact that such advantages can have on sporting performance."[37] Nonetheless, the DSD Regulations recognize possible "atypical" developments in chromosomal, gonadal and anatomical sex characteristics — the so-called "differences of sex development:" (DSD) — which do not perfectly match the traditional male/female categorization.[38]

The DSD Regulations require the affected individuals — athletes with "46,XY DSD" — to undergo testosterone-suppressing treatment if they wish to continue to compete. Specifically, 46,XY DSD results from a discordance between the genetic sex, the gonadal sex (testes or ovaries), the external genital sex (vulva or penis and scrotum) and/or the initial sex ducts existing at birth. Endocrinology identifies a spectrum of 46,XY DSD conditions which include, *inter alia*, the 5a-reductase type 2 deficiency (5-ARD). Shortly, 5a-reductase (5-AR) is an enzyme that helps testosterone metabolize into dihydrotestosterone (DHT), an androgen that in turn contributes to the proper formation of the typical male external genitalia (penis and scrotum). The 5-ARD results in a newborn child's genitalia looking atypical or female-typical, while developing testosterone levels closer to the male range from puberty onwards.[39] The DSD Regulations target athletes with 5-ARD and other DSD, including "any other genetic disorder involving disordered gonadal steroidogenesis."[40] Additionally, for ineligibility to apply, the athlete must have circulating testosterone levels in blood of 5 nmol/L or above and sufficient androgen sensitivity to a "material androgenizing effect."[41] It is an eligibility condition for the athlete to maintain her blood testosterone level below that threshold "for a continuous period of at least six months (e.g., by use of hormonal contraceptives)" and thereafter "continuously […] for so long as she wishes to maintain eligibility."[42]

Before these new provisions formally entered into force, Caster Semenya and Athletics South Africa (ASA) tried to have them invalidated by CAS on the grounds that they unnecessarily, disproportionally and unreasonably discriminated against people with DSD.[43] Semenya and ASA, as the claimants, argued that the DSD Regulations breached the athletes' fundamental rights, exposing them not only to stigmatization but also to adverse physical and mental health risks as a consequence of the mandatory testosterone-suppressing treatment.[44] In response to these claims, the IAAF argued that the DSD Regulations were necessary for providing the so-called biological females with the same sporting opportunities as male athletes. The IAAF also explained that the DSD Regulations were reasonable in their scope and considerably narrower than the previous regimes.[45]

The CAS agreed with the claimants that the DSD Regulations were discriminatory but found them necessary, proportionate and reasonable for the IAAF to pursue the objectives of ensuring fair competition and protecting the integrity of the female category. In particular, the CAS observed that, insofar as a binary system was maintained, sex segregation should necessarily be based not on legal status but on "human biology" — biological factors such as the level of endogenous testosterone.[46] In the CAS' view, the DSD Regulations were necessary because athletes falling within their scope — androgen sensitive female athletes with 46,XY DSD — enjoy "a significant performance advantage over other female athletes" due to their greater levels of circulating testosterone.[47] Such an advantage had been determined by two academic papers which integrated the need for evidence underlined by the CAS in *Chand*.[48] Furthermore, the CAS found that the DSD Regulations were reasonable in light of their limited scope to specific events where the athletic advantage enjoyed by DSD athletes is particularly evident.[49] Finally, the CAS concluded that, with the DSD Regulations requiring athletes with diagnosed DSD to take oral contraceptives to reduce testosterone, the side effects of such a treatment, albeit generally unknown, would not be different in nature from those experienced by the many thousands of XX women who take such oral contraceptives.[50] Thus, these side effects did not render the Regulations disproportionate.

At the same time, however, the CAS expressed grave concerns relating to: (i) the paucity of evidence justifying the Regulations material scope;[51] and (ii) the possibility of the affected athletes not being able to maintain a natural testosterone level below 5 nmol/L, even after complying with the DSD Regulations, due to unintentional fluctuations in their endogenous testosterone levels.[52] Although the CAS recommended the IAAF to address both concerns swiftly, the IAAF ignored these recommendations. Semenya decided therefore to quit athletics and register in soccer competitions instead, a discipline unaffected by the DSD Regulations.[53]

Semenya and ASA subsequently sought a review of the award by the Swiss Supreme Federal Tribunal (SFT), whose jurisdiction over CAS awards is limited to public policy (*ordre public*).[54] According to the SFT's decade-long judicial practice, an award is contrary to public policy if it disregards "essential and widely recognized values which, according to the prevailing views in Switzerland, should underlie any and all systems of law."[55] The SFT found that the CAS award did not disregard such values. The SFT indeed upheld all the conclusions reached by the CAS regarding the necessity, proportionality and reasonableness of the DSD Regulations.[56]

II. The Four Narratives

There are four narratives that emerge from *Semenya*: (1) deciding on eligibility is not deciding on sex/gender; (2) testosterone is a reliable predictor of athletic performance; (3) the required testosterone-suppressing treatment is safe and harmless; and (4) *Semenya* now protects female athletes as a whole. These narratives reflect the ways sport authorities and adjudicators make sense of the case. We, nevertheless, challenge them.

Methodologically, we deconstruct these narratives using both legal and ethical arguments. These narratives are described in the literature covering the subject in various ways.[57] Here we intend "narratives" to be understood as "ordered representation[s of] the way we think."[58] Scholars of different disciplines have highlighted the enormous

powers attained to narratives. Narratives are not just vehicles of communication or instruments that help describe the world, but behavior-shaping techniques that influence our lives.[59] Given the importance of law in shaping behaviors, the power of narratives becomes particularly important when it comes to legal matters and decisions. As one the foremost experts in legal narratology, Peter Brooks, puts it, a judicial decision may "activate conviction that its narrative is the true and the right one."[60]

The narratology we derive from *Semenya* depicts an apparently logical sequence of objective, neutral and apologetic considerations. These justify a regime of conditions for athletes with DSD for the sake of highly priced values in sports including equality, fairness and the common good. Against this logic, we maintain that the outcome of the case sidelines equally important notions for sports such as gender and race (as in narratives 1 and 4) and expresses extremely narrow views of the surrounding scientific and ethical dynamics (as in narratives 2 and 3). As Australian sociologist and former middle-distance runner Madeleine Pape showed in her in-depth analysis of *Chand* , sidelining certain important dimensions of a case is a way for the CAS to deal with complexity.[61] Her analysis persuasively found that sidelining manifested itself in *Chand* when the CAS replaced one gendered dichotomy with another one. The CAS, indeed, substituted the male *versus* female dichotomy with "a new binary" female-with-DSD *versus* female-without-DSD, which "simulate the sex categories of male and female in all but name."[62] The same phenomenon, we argue, occurs in *Semenya*, where the CAS is able to: transform complex questions about sex/gender into a simple eligibility matter (narrative 1); amplify the reliability of the deeply flawed research produced by the IAAF while downgrading the criticisms raised by the claimants as "insufficient" (narrative 2); affirm that a completely unethical medical treatment is nonetheless safe (narrative 3); and downplay the experience of the claimant for the sake of principles (narrative 4).

1. The case is about eligibility and not about sex/gender

The idea that one can decide on an athlete's eligibility without deciding on their sex/gender is expressed very clearly by both the IAAF and the CAS. On the one hand, the DSD Regulations state that "[i]n no way are they intended as any kind of judgment on or questioning of the sex or the gender identity of any athlete."[63] On the other hand, the CAS stipulates that "nothing in this Award is intended to question, determine, or pass judgment upon any aspect of any person's sex or gender"[64] — a conclusion that is shared by the SFT.[65]

According to Judith Butler, "we can invoke certain standards for admission to compete under a particular gender category without deciding whether or not the person unequivocally "is" that category."[66] The problem with these statements, however, is that the question of eligibility and that of sex/gender in sports are so profoundly intertwined that it becomes difficult, if not impossible, to judge an athlete's eligibility without making assumptions about her sex/gender. In fact, while defining the eligibility of certain athletes with DSD to compete within the female category, both the DSD Regulations and the CAS award implicitly determine who is a woman and who is not. They do not simply describe or recognize an athlete's sex/gender. They define it to mean "a real woman does not have a DSD." The whole eligibility system is grounded on a form of collective surveillance over the athlete's body which valorizes the simple *suspicion* of gender non-conformity.[67] While the IAAF Medical Manager is the only person who can initiate an investigation, the DSD Regulations are imprecise as to those who may raise "concern," referred to, in Section 3.3 thereof, as:

sources, such as (for example, but without limitation) the athlete herself, the team doctor of the National Federation to which the athlete is affiliated, results from a routine preparticipation health examination, and/or information/data (including but not limited to blood testosterone levels) obtained from the collection and analysis of samples for anti-doping purposes.[68]

Clearly, such a system leaves the door ajar to gender stereotypes and biases to drive the eligibility process.

Borrowing from Rebecca Cook and Simone Cusack, a stereotype is "a generalized view or preconception of attributes or characteristics possessed by, or the roles that are or should be performed by, members of a particular group."[69] Stereotyping is everywhere. Gender stereotyping, in particular, dominates sport competitions as much as our everyday lives. Both explicit and implicit gender stereotyping is heavily implicated in sport behaviors.[70] In this respect, particular body morphologies and above-average levels of strength represent powerful triggers for implicit gender stereotyping, especially in the case of gender nonconforming bodies. A stereotype builds on the "salient representatives of a given category."[71] Consequently, appearance replaces great athletic performances with non-stereotypical characteristics being targeted as signs of gender non-conformity. For instance, media speculations surrounding Caster Semenya's victory in Berlin in 2009 reflected the idea that Semenya's voice, way of dressing, muscles, short hair and attitude render her a man,[72] an argument that the IAAF did not hesitate to buy.[73]

In the context of sport competitions, well beyond the measurement of hormonal levels, "appropriate" female bodies are those meeting the aesthetics and expressions of normative femininity, reporting the beholder — acting as the supposed "source" under the DSD Regulations' investigation provisions — to culturally-coded ideas of femininity. These are the lenses through which higher testosterone levels are interpreted.[74] Specific characteristics or modes of behaving may therefore be perceived as signs of high testosterone so that the tone of voice, the size of muscles, facial and other features which do not fit the typical feminine traits become the target of a widespread surveillance of female athletes by different actors and entities like national federations, doctors, doping officials and other official personnel. In this context, striking performances are not interpreted as deserving victories but as gender non-conformity accidents, with talent and stubbornness turning into ambiguous or anomalous components of the athlete's femininity to be extirpated. Hence, rather than expanding the category of woman, the goal is to more narrowly define it in a way that leads to stigmatizing DSD outliers.[75]

Ironically, both the IAAF and the CAS insist on the prevention of stigmatization to which they actually contribute. By upholding the legitimacy of the DSD Regulations, the CAS turns a blind eye to the inconsistency of the above mentioned Section 3.3, describing the process through which any person or entity may provide information to the IAAF Medical Manager for initiating the investigation, with the prescription, contained in the subsequent Section 3.4, to respect of the "dignity and privacy of every individual."[76] The latter provision also sets forth the specific prohibition for any person or entity providing information to the Medical Manager to "stigmatize or otherwise injure an athlete."[77] This reflects the more general prohibition of stigmatization and "improper discrimination on the grounds of sex or gender identity."[78] Among the conducts that will not be "tolerated" is the "persecution or campaigns against athletes simply on the basis that their appearance does not conform to gender stereotypes."[79]

As a matter of fact, stigmatization almost automatically follows gender stereotyping. In particular, the DSD Regulations do not target all women with hyperandrogenism, but only women with a subset of DSD variations with higher natural testosterone levels and androgen sensitivity sufficient to have "a material androgenizing effect."[80] This last expression incorporated in the DSD Regulations constitutes *per se* a gender stereotype. Higher testosterone levels, indeed, produce certain traits which are considered not feminine and make women androgenized. The "androgenizing effect" is the key albeit vague criterion to selecting the athletes who look "masculine" or do not look "feminine enough."[81] This is the premise of the DSD Regulations, which encourage stigmatization of those who look not like the standard(ized) feminine athlete and do not fit gender stereotypes. This claim is further substantiated by the content of the predecessor of and model for the DSD Regulations, the Hyperandrogenism Regulations. These Regulations expressly stated that women with higher testosterone "often display masculine traits and have an uncommon athletic capacity in relation to their fellow female competitors."[82] By upholding the DSD Regulations, the CAS reinforces the stigmatization of athletes with DSD, perpetuating the vulnerability of female athletes whose

bodies do not conform to common gender stereotypes. The risk of the DSD Regulations' scope being overinclusive is real. While targeting women with DSD with sensitivity to high level of testosterone, the DSD Regulations reinforce stereotypes as to how women more generally should behave and look like.

A second manifestation of the confusion between eligibility and gender determination comes from the CAS' focus on the gender binary which is at the basis of sex segregation in sport. For the CAS,

[o]nce it is recognized that the reason for organizing competitive athletics into separate male and female categories rests on the need to protect one group of individuals against having to compete against individuals who possess certain insuperable performance advantages derived from biology rather than legal status, it follows that it may be legitimate to regulate the right to participate in the female category by reference to those biological factors rather than legal status alone.[83]

This statement reflects a view according to which sex segregation in sport is commanded by the apparently meritorious goal of protecting women from the "insuperable performance advantage" enjoyed by men. However, sociologists have unveiled the hypocrisy laying behind this view. According to this view, women appear as the protected category while, in reality, the purpose of sex segregation is, and has always been, that of policing sex/gender boundaries to protect male physical superiority.[84] What eligibility rules actually do is to "provide an upper limit for women's sporting performance"[85] which does not operate for men.

In the Western world, women were admitted to sport competitions since the 1860s under the dominant medical discourse that justified their access to exercise and training as a way to reinforce the nation's strength. Women's resulting muscular benefits, it was believed, would be inherited by their (male) children.[86] Systematic and deeply invasive physical examinations were put in place, which effectively restricted women's access to competitions, with the clear purpose of verifying that sport "cannot in any way injure the woman."[87] This theory predicates women's inherent fragility and perfectly fits the eugenic narrative of capitalism relegating women to a reproductive function.[88] As such, it has been shared for decades by the Olympic Games ideologues, who vigorously opposed the idea of female athletes as "inconvenient, uninteresting, un-aesthetic and not correct" — women's role had to be relegated to crowning the winners.[89] When, at the end, women were "admitted" (*admises*) at the Olympic Games,[90] it was not for the sake of gender equality. Instead, so many female sport associations had blossomed locally that it was ultimately impossible to ignore them.[91]

Once this had happened, a new narrative was construed to support the sequence of "crude and unpleasant,"[92] "inappropriate"[93] and ultimately "obsolete"[94] set of sex/gender verification tests enacted by sport authorities from the 1930s to the 1990s. Ranging from "femininity certificates" to the infamous "naked parades,"[95] to the Barr Body (or Chromatin) test,[96] these tests were formally justified with the intention of identifying "gender frauds" and "gender cheaters."

However, the number of cases that academic research has progressively revealed to the public tells a completely different story. On the one hand, more often than not, suspicions of gender frauds have been highly politicized, especially during the Cold War, with Western media targeting Eastern athletes in an attempt to discover the highest number of gender cheaters.[97] On the other hand, as has been showed by a recent study, the various changes in IAAF's sex segregation regime were actually demanded not by cases of cheating but rather by "social anxieties over sex/gender binary breakdown" and the need to police women's bodies.[98] The Olympics' experience with sex testing reflects both these anxieties for sex/gender boundaries and the connected geopolitical influences.

In sum, the eligibility regime drawn by the DSD Regulations and validated by the CAS construes a "female" category that is: (a) necessarily physically weaker than the "male" category; (b) based on anatomical features and differences between male and female athletes; and (c) arbitrarily drawn upon a line between what is typically female and non-

female. Therefore, the category of "female" is treated monolithically as if no differences existed within the group of women. This stance ignores that there is always a particular segment of the sport community which remains difficult to label.[99] Where a difference is present, the DSD Regulations impose athletes with DSD to assimilate to the male or the female category, in the latter case subject to testosterone-suppressing treatment. In this framework, the Regulations' statement that "in no way are they intended as any kind of judgement on or questioning of the sex or the gender identity of any athlete"[100] is nothing more than a theoretical dictate built on shaky grounds.

2. Testosterone is a predictor of athletic performance

The second narrative scrutinized here is the CAS' conclusion of testosterone being a biological predictor of athletic performance. In this regard, the CAS shares the IAAF's view that "androgen sensitive athletes with 46,XY DSD enjoy a significant performance advantage over other athletes without such DSD, and that this advantage is attributable to their exposure to levels of circulating testosterone in the adult male range."[101] The CAS also responds affirmatively to the question as to whether this advantage is "insuperable," thereby resulting in the justifiability of DSD Regulations as necessary.[102] We hereby criticize this narrative as an exercise of "opportunistic epistemology," that is, an approach that formulates conclusions before searching for evidence.[103]

Let us start with the integrity of the scientific process that supports the alleged causal relationship between testosterone and the athletic advantage enjoyed by athletes with DSD. In *Chand*, the CAS adopted a rigorous approach in the evaluation of the scientific evidence by explicitly warning the IAAF that the "degree or magnitude of the advantage" must be scientifically determined as "substantial," while "it is not enough simply to establish that the characteristic has some performance enhancing effect."[104] Against this approach, according to which "numbers matter[ed],"[105] the majority of *Semenya*'s panel went loose on the exact weight of the athletic advantage and limited its findings to considering that the latter "cannot be characterized as minimal or marginal."[106]

Given such stunning level of disenfranchisement from *Chand* — which the CAS omitted to justify[107] — one should have expected the scientific evidence brought before the CAS to be methodologically sound, that is resilient to criticism. Yet, despite the CAS' enormous efforts to elaborate on the scientific evidence provided by the IAAF, an accurate time analysis of the proceedings reveals that the evidence used in support of the DSD Regulations in the first place, *i.e.*, the 2017 paper by IAAF's medical experts Stéphane Bermon and Pierre-Yves Garnier[108] ("BG17") was firstly amended to fit the IAAF's purposes and subsequently complemented with more research – namely, Professor David J. Handelsman's expert testimony and paper, coauthored with Bermon,[109] published *after* the publication of the DSD Regulations. This explains why, as has been observed, the BG17 was "relegated to the periphery, out of sight and scrutiny, because that's where the IAAF were the weakest,"[110] and why the CAS reported at length on Handelsman's data and findings.[111]

Now, the BG17 examined 1,332 blood samples made available to the IAAF in 21 women's events in Daegu and Moscow IAAF World Championships and found a competitive advantage from 1.8% to 4.5% in female athletes with high testosterone over female competitors with normal androgen levels, with different margins depending on the discipline.[112] A substantial number of authors highlighted flaws in the paper's methodology and data analysis, concluding that "it is reasonably likely that the correlations presented in [BG17] (even the largest ones) occurred by chance."[113] These authors also found that only in 12 over 21 of the examined events athletes with high testosterone performed better on average and that, given the absence of publicly available raw data, the paper filed with the arbitral tribunal failed to meet the standard of proof required by the CAS.[114] Other authors contended that BG17 failed to address "the issue of causality" between the testosterone level and athletic performance. They criticized the idea that the asserted competitive advantage could be measured by testosterone alone without considering "other relevant variables."[115] Finally, one author questioned whether it was ethical to use the blood samples the athletes

consensually provided in the context of antidoping testing for further research on athletic performance.[116] Analogous criticisms have been raised with regard of an amended version of the BG17 produced before the CAS.[117] As to Professor Handelsman's paper, the authors not only declared that their research provided "incomplete evidence," but also remarked that, in order to fill the existing "lack of well-designed study" on the sex/gender differences in athletic performance, the more research that is needed may raise "ethical concerns over short and long-term adverse effects" of administering exogenous testosterone to "healthy" adults.[118] Moreover, when Professor Handelsman's independence was questioned before the CAS, he admitted that his remuneration by the IAAF was contingent on the outcome of the case.[119]

Concerns have also been raised regarding a possible conflict of interest since the research supporting the conclusions of the IAAF has been conducted by its own in-house researchers, which is tantamount to "cigarette companies [providing] the scientific basis for the regulation of smoking".[120] While sports governance necessarily requires robust evidence, the evidence in this case simply does not fulfil the standard criteria for courtroom admissibility due to the use of flawed scientific data which has not even been subject to peer-review.[121]

The centrality of quantitative evidence in proceedings before the CAS acquires a further meaning if seen from the angle of what that evidence is expected to prove. The reasons underlying the two-year temporary suspension of the Hyperandrogenism Regulations in 2015 in the *Dutee Chand* interim award provide the background for understanding the narrative of testosterone being a predictor of athletic performance in *Semenya*.[122] The narrative upheld in *Semenya* was conditioned by the combination of the burden of proof being on the IAAF and the CAS' assumption of testosterone being an indicator of improved performance in the *Dutee Chand* interim award. The panel assumed that, had the IAAF proven the testosterone-driven athletic advantage, the Hyperandrogenism Regulations should have been reinstated. In that ruling, the CAS suspended the regulations to allow the IAAF to provide scientific proof about the correlation between increased testosterone levels in hyperandrogenic athletes and a competitive advantage in athletic performance. By giving the IAAF the opportunity to provide scientific evidence about improved performance, the CAS, therefore, confirmed the IAAF's assumption regarding the causal link between high testosterone levels and athletic advantage. The panel explicitly stated that this link "may well be proved valid"[123] although sufficient evidence of the correlation between testosterone and performance was not provided, with the onus of proof remaining with the IAAF.[124]

We see the CAS' approach in assessing the scientific evidence advanced by the parties as reflecting a power imbalance between the IAAF and its athletes. While the IAAF is allowed to produce, amend, contradict and provide further support to its own data and findings, the claimants are left unarmed against such a powerful expenditure of money and resources on the opposite side. It seems that the same dystopic dynamics highlighted by Pape in the *Chand* award are replicated in *Semenya.* Here, claimants are cornered into the awkward position of having to prove "the negative claim that testosterone does *not* confer an advantage of *any* size."[125] Furthermore, as Pape argued, under this approach "legitimate expertise could only be that which constructed testosterone — and the sexed/gendered athletic bodies it was taken to approximate — in binary terms."[126] This is exactly what both the BG17 and Professor Handelsman's paper do. In fact, their research on testosterone is always gendered. It is led not by the genuine intent of discovering unexplored dimensions of testosterone but by the goal of biologically confirming the male-female binary. In other words, the focus of the IAAF's research altogether is to confirm sex/gender boundaries so that male above-average performances are never considered but only female ones are. All this completely neglects the fact stressed by UN Special Rapporteurs, that "[n]atural physical and biological traits as well as social and economic factors also influence the performance of men athletes."[127] We argue that this is the essence of opportunistic epistemology. The CAS fell into the same conceptual trap when it asserted that testosterone, in its

own view, remains “the primary drive of physical advantages and therefore of the sex difference in sports performance between males and females.”[128]

Overall, the expertise evidence claimed by the CAS as decisive in deciding about the role of testosterone in athletic performance appears extremely flawed. Contrary to what the CAS stated, there exists no clear scientific consensus that high testosterone levels actually produce a performance advantage in athletics. The equation at the core of the IAAF’s argument, that “more testosterone equals more ability,” is inaccurate and therefore makes the argument untenable. Studies even demonstrate that positive and negative relationships between testosterone and performance exist in a wide range of sports.[129] Additionally, as this article goes to print, Bermon and Garnier issued a correction to the BG17, clarifying that the results they reached regarding the relationship between testosterone level and athletic performance are “exploratory, nothing else, that is, not confirmatory of evidence for a causal relationship”, praising for “an independent, prospectively designed, randomly controlled trial […] to establish confirmatory scientific evidence”.[130] This further strike at the core of IAAF’s significant competitive advantage claim which is at the basis of the DSD Regulations confirms the weakness of the narrative surrounding the athletic advantage, which remains very far from being supported by solid scientific evidence, no matter the conclusions reached by the CAS. At any rate, one thing is to say that there is a significant advantage deriving from specific physical condition,[131] like the CAS argued, another thing is to argue that such an advantage is unfair. A performance difference is not necessarily unfair, unless it leaves gender binary unquestioned.

3. The required testosterone-suppressing treatment is safe and harmless

That bodies are (easily) malleable is the assumption underlying the third narrative. The body malleability narrative is expressed very clearly at multiple levels. First, the DSD Regulations plainly require athletes with DSD who have testosterone levels higher than 5 nmol/L to lower them for a 6-month period prior to a competition and continuously thereafter.[132] Second, the CAS accepted that “the use of oral contraceptives to reduce testosterone levels can cause a range of unwanted side effects”[133] such as “weight gain, feverish symptoms and consistent abdominal pain,”[134] making focus during training impossible and performance low. Yet, the CAS asserted that these side effects “are not different in nature to those experienced by many thousands, if not millions, of other XX women, who take oral contraceptives.”[135] Finally, the SFT recognized that “the assumption of oral contraceptives causes significant side effects and does not lay on a completely free and clear consent, to the point of constituting a grave violation of the athlete’s right to physical integrity.”[136] Nevertheless, the SFT upheld the mandatory testosterone-suppressing treatment as it was proportional and ultimately justified by the need to pursue the objectives prefixed by the IAAF.

Two premises are implicitly stated here, which make the required medical treatment look minimal or insignificant. The first premise is that *the artificial lowering of testosterone is a negligible medical treatment*; the second is that *the medical procedure attained to obtain this result is both safe and effective*. In fact, whereas generally speaking testosterone levels may be lowered either surgically or pharmacologically,[137] the DSD Regulations expressly forbid the former possibility, so that “surgical anatomical changes are not required in any circumstances.”[138]

Both premises, however, are false. To begin with, despite said prohibition, there is no certainty that an athlete could not be required to undergo surgical operations, making the medical treatment uncertain and possibly dangerous. If the prohibition of surgical treatment is, on the one hand, the law on the books, then on the other hand, the genealogy of the implementation of the DSD Regulations’ predecessor dismantles this statement. In accordance with the Hyperandrogenism Regulations, indeed, four female athletes with “excessive” testosterone underwent medical investigations. Following the discovery of a 46 XY karyotype, doctors recommended partial clitoridectomy, vaginoplasty and estrogen replacement therapy.[139] Gonadectomy (*i.e.*, the removal of gonads) had been the condition that the IAAF imposed for the athletes to compete.[140] That the surgical solution remains a concrete

possibility for athletes with DSD exceeding the required threshold for testosterone is made clear by the CAS itself, which after taking into consideration both the use of GnRH antagonists and gonadectomy in case the oral contraceptives failed to achieve the expected result, simply recommended, in this event, “a different analysis of proportionality.”[141] The CAS did not seem concerned with the fact that the use of GnRH in combination with oral contraceptive may not bring the expected results.[142] In any case, it implied that, besides the different proportionality standard that would be applied, gonadectomy nonetheless remains a feasible option in medical practice.

This is confirmed by the genealogy of the implementation of the DSD Regulations’ predecessor. In accordance with the Hyperandrogenism Regulations, indeed, four female athletes have been reported as having excessive testosterone levels and being subjected to the Hyperandrogenism Regulations.[143] They were all aged between eighteen and twenty-one and came from rural areas of developing countries. The doctors who examined them found a 46,XY karyotype and recommended partial clitoridectomy followed by vaginoplasty and estrogen replacement therapy.[144] The IAAF allowed these athletes to compete one year after gonadectomy, despite the fact that a paper authored by IAAF officials discouraged gonadectomy for eligibility purposes while recommending keeping eligibility and therapeutic options distinguished.[145] By making permanent anatomical modifications a concrete option, while at the same time denying them as a condition to compete, both sport authorities and adjudicators have been able to minimize the costs that these operations entail on the athlete’s body and psyche.

This narrative on body malleability is accompanied by what Susie Orbach in a different context called “a rhetoric of empowerment.” This is the idea that not abiding by the testosterone-suppressing provision would signal the athlete’s *voluntary* exclusion from the competition. According to this rhetoric, no athlete would be actually “forced” to do anything against their own will, with the medical treatment following the discovery of testosterone levels beyond the prescribed threshold being just a part of the athlete’s stubbornness and prowessness.

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These challengeable postures on bodily modifications show that nature is a concept prone to misrecognition and misunderstanding depending on the interests and the power dynamics at stake. In the CAS decision, the sport competition moves the focus from one’s identity to their bodily parts as components of a performing machine. Relatedly, the CAS conflates sex with gender. “Ms. Semenya is a woman,” the CAS argues. “At birth, it was determined that she was female, so she was born a woman.”[146] This is the opposite of Simone de Beauvoir’s well-known conception of gender as a non-innate feature but a becoming: “one is not born a woman, but rather becomes one.”[147] The confusion produced by the CAS conveys the idea that gender is inextricably determined by sex — because “gender is sex,” and “sex is gender.” It is undeniable that sex characteristics are natural in their origins. Yet the way in which a certain society or societal circle, such as the Westernized international sport arena, interprets, understands and thereby categorizes sex traits is anything but natural. Perceptions and interpretations change across times, spaces and cultures.[148]

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In connection with that, the DSD Regulations specify that the medical investigation and the possible subsequent treatment depend on the athlete’s willingness and responsibility, as if no coercive assessment and treatment were ever imposed on the athlete. The DSD Regulations state, precisely, that “[n]o athlete will be forced to undergo any

assessment and/or treatment under these Regulations [and i]t is the athlete's responsibility, in close consultation with her medical team, to decide whether or not to proceed with any assessment and/or treatment."[150] Despite this statement, in practice the DSD Regulations leave no real choice to the athlete who wants to compete in the female category. *Either* the athlete agrees to undergo invasive medical investigations involving intimate parts of her body and undertake medical procedures with potentially physically and psychologically harmful consequences, *or* she has to quit the competition.[151]

It is undisputable that the mere acceptance of the medical intervention is not equivalent to informed consent: such a consent must be voluntary and sufficiently informed to make a free decision. In 2018, the UN Special Rapporteur on the right to health addressed a letter to the IAAF, stressing the key element of making the athlete's consent vitiated. The consent that the athlete gives to the intrusive investigation is indeed far from free, as the athlete makes the decision under pressure *vis-à-vis* the alternative of being excluded from competition without a viable choice.[152] The same UN Special Rapporteur had already explained in 2009 that informed consent is invalid if, *inter alia*, it is subject to "undue influence," which corresponds to situations where the person "perceives there may be an unpleasant consequence associated with refusal or consent."[153] There is no reason to doubt that ending an elite sport career amounts to an unpleasant consequence, an "impossible set of choices,"[154] a subtle form of double bind. Either you conform, or you cannot perform. Damned if you do, doomed if you don't.

The side effects of the hormonal treatment imposed on the athlete whose testosterone level is over 5 nmol/L are equally unfortunate. The treatment has a great impact on the athlete's health, which goes beyond the IAAF's minimizing suggestion about contraceptives.[155] Paradoxically, the CAS recognizes that the side effects of hormonal treatment would make compliance with the DSD Regulations practically impossible, alerting the IAAF that:

[i]f the DSD Regulations cannot be implemented fairly in practice, that could render them disproportionate at a later stage since a regulation which is impossible or excessively difficult to apply fairly cannot be characterized as a proportionate interference with the rights of those who are subjected to it.[156]

The CAS (followed by the SFT) moved from a strict proportionality analysis to a lighter standard requiring the mere lack of an evident disproportion in the prescribed measure.[157] This approach may be explained in light of the CAS' decision to defer to the IAAF's legislative competence. The CAS held that evaluating the IAAF's policy making process or rewriting its rules was not their problem.[158] Nonetheless, we see a contradiction between CAS upholding the DSD Regulations' exclusionary regime, on the one hand, and its assessment of the actual harm that is caused to the athlete's body, on the other hand. Such a harm may attain the *practical impossibility to participate in sport*. This practical impossibility cannot be left to future cases and future proportionality assessments, as unfair implementation of the DSD Regulations in practice is already a reality today. By attempting to fix the standard to be applied in future cases, the CAS acted, probably unintentionally, as a constitutional adjudicator. Yet it declined to play this role in all respects, leaving the IAAF's legislation completely untouched without considering any less harmful alternative, or even the possibility of a time percentage handicap.[159] This consideration undermines the CAS' necessity analysis. How can a measure be deemed necessary if the adjudicators refuse to examine possibly less harmful alternatives? The CAS' approach appears shy at best, reverential to IAAF policy orientations at worst. One would expect that the intensity of the CAS' legal review of the IAAF's decision-making power would have been greater in the light of the IAAF's public function in creating rules and impacting athletes' lives. This is even more problematic given that a decision of such importance, for the control over powerful decision-makers and for the implications on athletes' physical integrity, was reached with a two out of three majority.

The CAS' narrative of the athletes' easily malleable bodies is that of machines whose performance can be not just accurately measured but also remotely controlled through pharmacological treatment. As machines that are required

to function perfectly, their suffering becomes either irrelevant or part of the inherent dynamics of their own working. In such a world, calling for these machines to consent to the burdens that are assigned to them is simply unconceivable.

4. The case is about protecting the integrity of the female category

The argument that it is fair to exclude certain athletes from the female category in order to protect the integrity of the category itself is made by both the IAAF and the CAS. In particular, the DSD Regulations clearly establish that they "exist solely to ensure fair and meaningful competition within the female classification, for the benefit of the broad class of female athletes."[160] The CAS accepts this argument subject only to the IAAF proving the existence of an athletic advantage to the benefit of the considered subgroup,[161] a proof it considered reached anyway. The STF also upheld this argument when dealing with Semenya's petition for annulment.[162]

We wonder whether the resulting separation between "the broad class of female athletes" and a minority of women sensitive to high testosterone levels reflects ethno-racial boundaries. To dig deep in this direction, we resort to an intersectional analysis and therefore look at how sex/gender interact with other markers such as ethnic origins and race.[163] The type of discrimination arising from this interaction is peculiar in that it does not correspond to the simple sum of the different discriminatory grounds, but to their coalescence. Understanding these intersections helps appreciate the different subordination discourses underlying discrimination.[164]

Several authors have remarked that a common trait of the female athletes targeted by the DSD Regulations and their antecedents — including Semenya — is that they *all apparently come from the Global South.*[165] This circumstance makes these athletes "structurally vulnerable for 'failing' gender eligibility regulations."[166] The United Nations High Commissioner for Human Rights asserted that "[t]he existing data do not show much about the intersection between gender and race discrimination in sport, global and local resource inequities and exclusionary community practices."[167] However, the apparent overrepresentation of athletes from the Global South among those subjected to the IAAF's scrutiny under the DSD Regulations and their predecessors should raise attention across the board. For instance, by considering that allowing athletes with DSD to compete in the female category would amount to a defeat for the entire female category, the IAAF and the CAS open the door to a majority-minority dynamic. In this context, the logics of power take the shape of the "tyranny of the majority"[168] and the oppression of the minority.

This category-defeating narrative conceals an exercise that sociologists Pierre Bourdieu and Loïc Wacquant would define as "cultural imperialism." This is "the power to universalize particularisms linked to singular historical tradition by causing them to be misrecognized as such."[169] Instead of being celebrated as exceptional athletes, athletes from the Global South are cornered with their bodies being obsessively scanned in search of biological explanations of their strength and stunning performances. These explanations build on understandings of body and sexuality that conform to the Western culture. In this perspective, globalized Western conceptualizations of the shape of sex traits and health (so-called) normality prevail over local dimensions of access to health and sexuality.[170] It is therefore not surprising that "the majority of medical experts named in the 2011 and the current [IAAF] policy include mainly men and a few women in Western research and medical institutions who have long-standing relationships with the [IAAF, International Olympics Committee and] national sporting organizations."[171]

Furthermore, the story of Caster Semenya has a parallel in that of Sarah/Saartjie Baartman, derisively known as the "Hottentot Venus."[172] Born in Candeboo Valley, South Africa, in 1789, Baartman was brought to Europe in 1810 under the false pretense of a regular employment contract. There she was exhibited half-naked for years, with her body systematically examined by anatomists, zoologists and physiologists. After her death in 1815, her excised genitalia and brain were preserved in formaldehyde and, along with her skeleton, exposed at the Jardin des Plantes

and the Musée d'Orsay in Paris.[173] Obviously, the two centuries that separate Semenya from Baartman — whose remains were returned to South Africa only in 2002 [174] — account for completely different historical and geopolitical contexts. Nonetheless, in both cases, the Global North's eye dehumanizes the Black body, portrayed as the dangerous site of fear and fascination.[175] In both cases, the European gaze submits individuals to analogous exhibition and enfreakment.[176] Sexualization, pathologization and medicalization are the perfect ingredients for dehumanization of Black bodies.

The main problem with the category-defeating narrative is that it frames the question of the exclusion of athletes with DSD as a simple male-*versus*-female opposition. A champion of this narrative is certainly Duke law professor Doriane Lambelet Coleman, who acted as a witness expert before the CAS and has written extensively about women in sport and the *Semenya* case.[177] Coleman's main argument is that athletes with DSD are so strong that, if they are not excluded somehow, "most of the women who will lose out will be biological females of color."[178] She also denies that the overrepresentation of athletes from the Global South has any relevance, claiming that "[b]ecause our sport is mostly populated at the elite levels by athletes of color, it is this group that will be most impacted however the women's category is defined.'[179] In her opinion, the case is actually more about women's empowerment and economic opportunities than race.

Although greatly articulated, arguments of this kind tend to adhere to a narrative dominated by "[a] perception of a "tsunami" of men coming to destroy women's sport."[180] This narrative neglects both the cultural imperialism that characterizes sport competitions in general, and the suffering of individual athletes in particular. In fact, what remains unclear within the broad discussions surrounding the category-defeating argument is how the stigmatization of athletes with DSD and the imposition of a highly invasive medical treatment to their bodies could do any good to the majority of female competitors.

Consider the story of Uganda's 800-meter champion Annet Negesa, gold medalist at the 2011 All-Africa Games. After being alerted by her medical team that she could no longer compete, she went to Nice for medical tests and once back in Kampala, underwent an allegedly "simple" surgery, which she knew nothing about.[181] Having been identified in the media as an "intersex," Negesa petitioned for — and obtained —the refugee status in Germany as she risked the death penalty in Uganda because of her condition.[182] Consider also Equatorial Guinean footballer Genoveva Anonma, whom the Confederation of African Football has forced to do a naked parade in front of her team to show that she was a woman;[183] or Kenyan runner Maximilla Imali, who was sidelined at the IAAF World Championship after her blood tests revealed that she had hyperandrogenism;[184] or, finally, her peer Margaret Wambui,[185] who dropped from competing internationally after the CAS ruled on *Semenya*. That the policing of gender categories brings detrimental harm is patent.

What remains unsolved is the question of how all these dramatic experiences of discrimination, stigmatization, humiliation and exclusion could actually help the majority of women foster their lives in sport. This question remains unsolved after *Semenya* because for the CAS, the *expertise* evidence produced by the IAAF on testosterone's impact on athletic performance has a different weight than the *experiential* evidence shown by Semenya regarding the side effects of testosterone-suppressing treatment. While the former is praised at length in the award, the latter is trivialized as irrelevant and perhaps even disturbing. After all, how dare Semenya complain about contraceptive-subsequent migraine when there are millions of women out there facing the same? It is unsurprising, then, that in the CAS award, testosterone-driven putative advantage prevails over the evidence of concrete harm suffered by individuals.[186]

In sum, the category-defeating narrative is based on a sort of zero-sum consideration. The more a minority of outcast athletes is framed and suppressed, the better the majority's chances to access to the podium. This narrative

raises unsolved social justice matters that are worthy of further reflections at all levels.

Conclusion

This article offers a narratological perspective of the *Semenya* case. We have problematized the narratives generated by the CAS award and the SFT judgment on Semenya's discrimination claims. The adjudicators have attempted to present the case outcome as the necessary conclusion of a smooth logic driven by objective, neutral and apologetic considerations.

Yet, the CAS left a large margin of manoeuvre to the IAAF concerning the level of "reasonableness" of scientific evidence, without problematizing the effects of the IAAF acting as a policy maker. What is peculiar is the lack of accountability in relation to an entity exerting broad policy-making powers such as those described in this case. This lacuna of accountability is unique in the international landscape and therefore requires close scrutiny.

The way adjudicators made sense of Semenya's excellent performance is as flawed as it is stereotyped, gendered and stigmatizing. Sport authorities and adjudicators would like us to believe that the conversation about the DSD Regulation is over. We don't think this is the case. To the contrary, we believe that a genuine conversation should start at all levels — sport authorities, adjudicators, media, governments, societies — regarding, *inter alia*, the key actors and networks influencing decision-making processes, the alleged scientific basis supporting eligibility regulations and decisions, and the interplay in sport between adjudication, science, and human rights.

One crucial point, which deserves not just to be stressed, but to be made the object of further research, is why sex/gender-related dimensions of sport are given more attention than other bodily traits. The world is filled with athletes having bone, heart, blood, and muscles advantages, but sport authorities do not look at them as they look at sex/gender-related aspects. Why are some of these advantages celebrated as gifts while others as anomalies? If we believe in fairness, talent, respect, integrity and solidarity, we should pursue these conversations.

Note

The authors have no conflicts to disclose.

Acknowledgments

The authors are grateful to Daniela Alaattinoglu, Florencia Amorena, Michela Balocchi, Coralie Boissel, Mauro Bussani, Giada Di Stefano, Jack Drescher, Marta Infantino, Anna Lorenzetti, Stefano Osella, Graziella Romeo, and Martin Scheinin for their deep insights on earlier drafts of this paper. This paper greatly benefited from the invaluable support provided by Romit Kohli throughout the research and drafting process.

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24. Hyperandrogenism Regulations, supra note 22, Sec. 6.5 (2011); IOC Regulations, supra note 22, Art. 8.F (2012).
25. Hyperandrogenism Regulations, supra note 22, preamble (2011).
26. The three levels are: (1) an "initial clinical examination" with physical examinations and the compilation of specific clinical and anamnestic data under particularized guidelines; (2) a preliminary endocrine assessment of the athlete's urine and blood samples for a series of androgenic hormones, among which testosterone; and (3) the athlete's full examination and subsequent diagnosis.
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DETAIL

Subjek:	Athletes; Discrimination; Testosterone; Females; Women; Human rights; Arbitration; Narratives; Gender
Lokasi:	South Africa
Orang:	Semenya, Caster
Pengidentifikasi/kata kunci:	Discrimination; Body; Rule; Narrative; Caster; Caster Semenya; Athlete; Arbitration; Court; Intersex; DSD; Court of Arbitration for Sport; Gender; Sex
Judul:	Of Athletes, Bodies, and Rules: Making Sense of Caster Semenya
Pengarang:	Winkler, Matteo; Gilleri, Giovanna
Judul publikasi:	The Journal of Law, Medicine &Ethics; Boston
Volume:	49
Edisi:	4
Detail sumber:	First Amendment Values in Health Care
Halaman:	644-660
Tahun publikasi:	2021

Tanggal publikasi:	Winter 2021
Bagian:	Independent Articles
Penerbit:	Cambridge University Press
Tempat publikasi:	Boston
Negara publikasi:	United Kingdom, Boston
Subjek publikasi:	Law, Medical Sciences
ISSN:	10731105
e-ISSN:	1748720X
Jenis sumber:	Jurnal Akademik
Bahasa publikasi:	English
Jenis dokumen:	Journal Article
DOI:	https://doi.org/10.1017/jme.2021.89
ID dokumen ProQuest:	2730847278
URL Dokumen:	https://www.proquest.com/scholarly-journals/athletes-bodies-rules-making-sense-i-caster/docview/2730847278/se-2?accountid=211160
Hak cipta:	© 2021 The Author(s)
Terakhir diperbarui:	2023-11-27
Basis data:	Public Health Database

Shared Decision-Making for Implantable Cardioverter-Defibrillators: Policy Goals, Metrics, and Challenges

Rao, Birju R; Merchant, Faisal M; Howard, David H; Matlock, Daniel; Dickert, Neal W

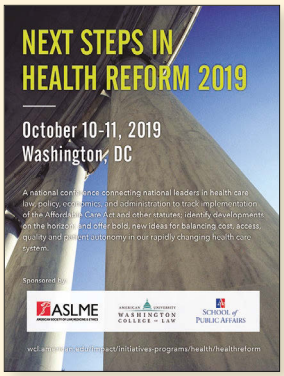
ABSTRAK (ENGLISH)

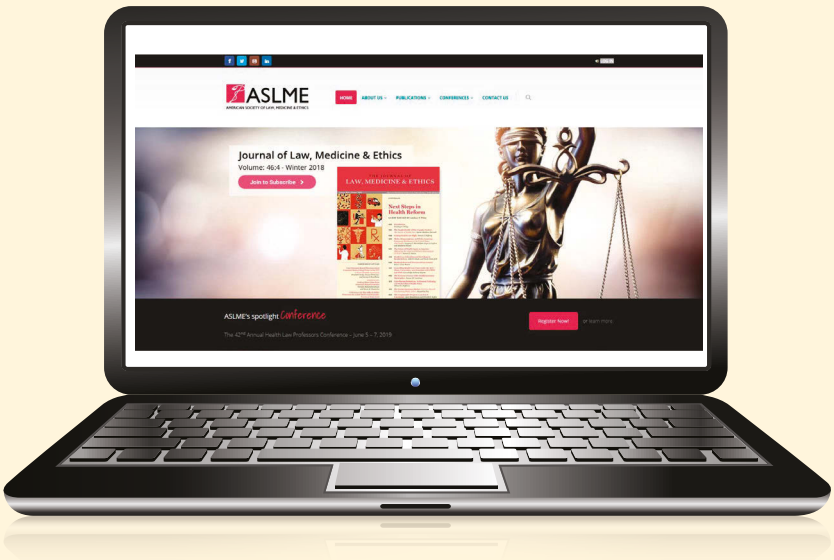
Shared decision-making has become a new focus of health policy. Though its core elements are largely agreed upon, there is little consensus regarding which outcomes to prioritize for policy-mandated shared decision-making.

TEKS LENGKAP

DETAIL

Subjek:	Success; Health care policy; Decision making; Heart failure; Medicare; Patient satisfaction
Ketentuan indeks bisnis:	Subjek: Medicare
Pengidentifikasi/kata kunci:	Shared Decision-Making; Challenge; Implantable cardioverter-defibrillator; Metric; Health policy; Defibrillation; Implantable Cardioverter-Defibrillator; Decision Aids; Cardiovascular Disease; Health Policy
Judul:	Shared Decision-Making for Implantable Cardioverter-Defibrillators: Policy Goals, Metrics, and Challenges
Pengarang:	Rao, Birju R; Merchant, Faisal M; Howard, David H; Matlock, Daniel; Dickert, Neal W
Judul publikasi:	The Journal of Law, Medicine &Ethics; Boston
Volume:	49
Edisi:	4
Detail sumber:	First Amendment Values in Health Care
Halaman:	622-629
Tahun publikasi:	2021
Tanggal publikasi:	Winter 2021
Bagian:	Independent Articles
Penerbit:	Cambridge University Press
Tempat publikasi:	Boston
Negara publikasi:	United Kingdom, Boston
Subjek publikasi:	Law, Medical Sciences
ISSN:	10731105
e-ISSN:	1748720X
Jenis sumber:	Jurnal Akademik





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https://doi.org/10.1017/jme.2021.97 Published online by Cambridge University Press

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https://doi.org/10.1017/jme.2021.97 Published online by Cambridge University Press