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SYMPOSIUM

Malingering & Health Policy

GUEST EDITED BY Daniel S. Goldberg

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INDEPENDENT ARTICLES

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Guest Edited by Daniel S. Goldberg

Cover Image: "Le malade imaginaire": Argan, a hypochondriac feigning illness in front of Béline, his wife and Dr. Purgon, his physician, in a scene from Molière's play. Etching by G. Schouten after J.B. Molière. Courtesy of the Wellcome Collection.

Symposium Articles

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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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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.

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.

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DETAIL

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Vaccine Confidence and the Importance of an Interdisciplinary Approach

Opel, Douglas J; Larson, Heidi J

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.

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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.

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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.

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Appendix 1

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

•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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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.

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

Rothstein, Mark A

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.

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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.

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34. See R. Copeland, D. Mattioli, and M. Evans, “Inside Google’s Quest for Millions of Medical Records,” Wall Street Journal, January 11, 2020, available at <https://www.wsj.com/articles/paging-dr-google-how-the-tech-giant-is-laying-claim-to-health-data-11578719700?reflink=desktopwebshare_permalink >(last visited July 20, 2021). It is debatable whether the arrangement was ethical. For example, it is questionable whether the records needed to be accessible in identifiable form. A technology company of Google’s sophistication could have deidentified the records without sacrificing the research significance of the data. Furthermore, patients should have been informed of the goals, methods, and parties involved in Project Nightingale and given the opportunity to opt out of the program. With 50

million records, the loss of a small percentage would not be detrimental and if a substantial number of patients elected to opt out, perhaps it would have convinced Ascension that the promised ends of the research did not justify the means.

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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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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.
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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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69. 42 U.S.C. §§ 12101-12213.
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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.

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(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

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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

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DETAIL

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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

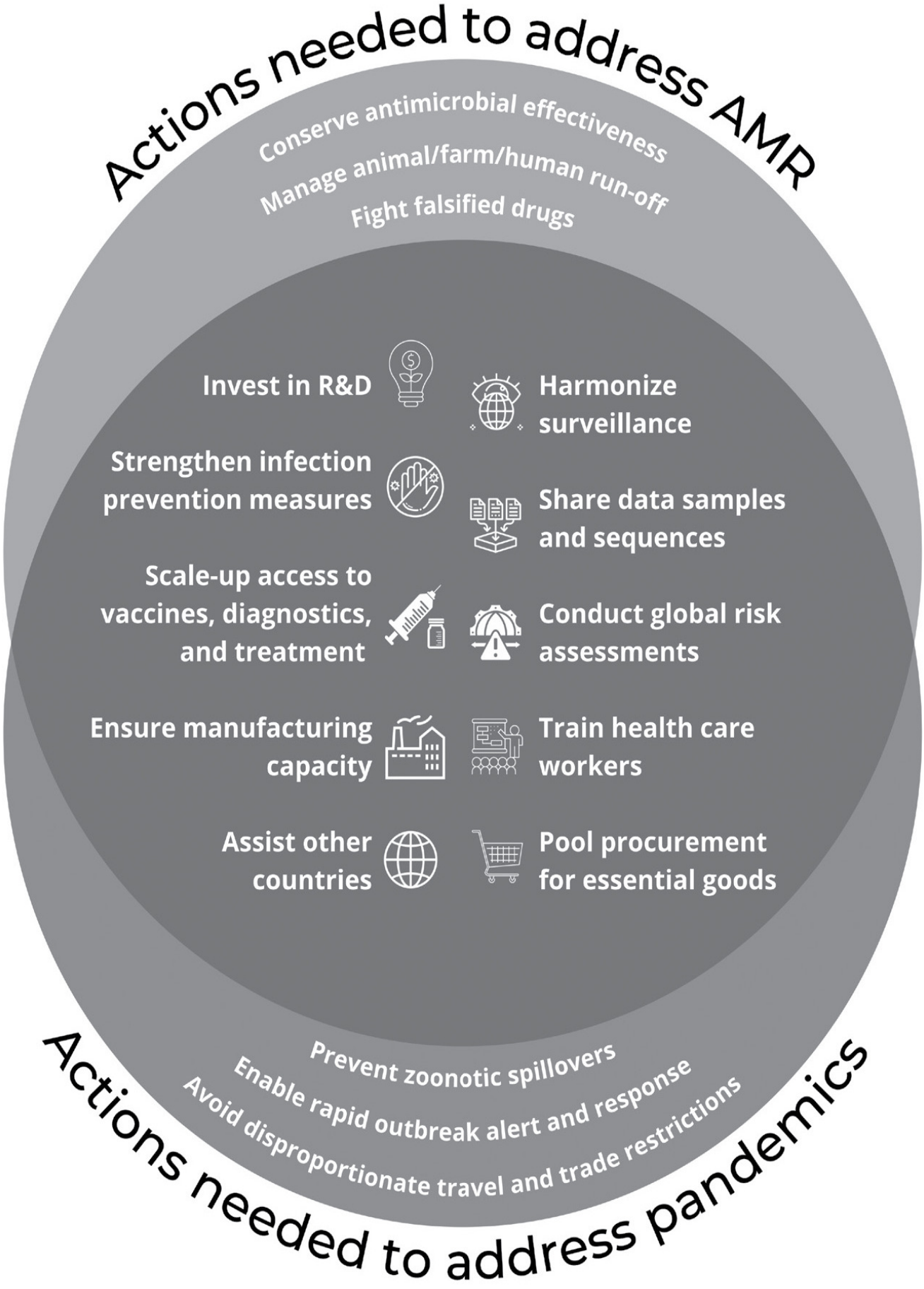
The COVID-19 pandemic has demonstrated that no single country can address global health threats alone.[1] As attention shifts to ensuring better preparedness for future disease outbreaks, a coordinated global strategy will be needed to address future pandemics and mitigate their human, economic, and 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.

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DETAIL

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Reproductive Technologies and Free Speech

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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.

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Note

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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

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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.

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

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

Nagar, Sarosh; Kesselheim, Aaron S

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.

TEKS LENGKAP

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

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About This Column

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

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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.

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

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20. Engel v. Vitale, 370 U.S. 421, 436 (1962).
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23. See Nelson, supra note 15, at 631-32.
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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

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“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
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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
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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.

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

Ashworth, Henry; Soled, Derek; Morse, Michelle

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.

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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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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

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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

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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.*

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Note

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About This Column

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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.

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.

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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.
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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.
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52. Id. at 7.
53. C alvary Chapel Dayton Valley v. Sisolak, 140 S. Ct. 2603 (2020); S. Bay United Pentecostal Church v. Newsom, 140 S. Ct. 1613 (2020).
54. Roman Catholic Diocese v. Cuomo, 141 S. Ct. 63 (2020).
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66. Id.
67. Id., (Aliton, J. Concurring).
68. Id., (Gorsuch, J., Concurring).
69. Id., (Barrett J., Concurring).
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72. Prince v. Massachusetts, 321 U.S. 158, 166-167 (1944).
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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.

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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.
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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).
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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

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DETAIL

Subjek:	Athletes; Discrimination; Testosterone; Females; Women; Human rights; Arbitration; Narratives; Gender
Lokasi:	South Africa
Orang:	Semenya, Caster
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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
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Transparency of Regulatory Data across the European Medicines Agency, Health Canada, and US Food and Drug Administration

Egilman, Alexander C; Kapczynski, Amy; McCarthy, Margaret E; Luxkaranayagam, Anita T; Morten, Christopher J; Herder, Matthew; Wallach, Joshua D; Ross, Joseph S

ABSTRAK (ENGLISH)

Based on an analysis of relevant laws and policies, regulator data portals, and information requests, we find that clinical data, including clinical study reports, submitted to the European Medicines Agency and Health Canada to support approval of medicines are routinely made publicly available.

TEKS LENGKAP

DETAIL

Subjek:	Business information; Research; Disclosure; Data; FDA approval; Clinical trials; Regulatory agencies; Drugs; Medical device industry; Biological products; Medical equipment; Product safety; Information sharing; Food; Product development; Statistical analysis
Ketentuan indeks bisnis:	Subjek: Disclosure FDA approval Medical device industry Information sharing Product development
Lokasi:	United States--US; Canada
Pengidentifikasi/kata kunci:	Transparency; Health Canada; US food and drug administration; Transparency; European Medicines Agency; Clinical Trials; Regulatory Data; Medical Product Regulation; Public Health
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Toward Complete, Candid, and Unbiased International Consensus Statements on Concussion in Sport

Casper, Stephen T; Bachynski, Kathleen E; Buckland, Michael E; Comrie, Don; Gandy, Sam; Gates, Judith; Goldberg, Daniel S; Henne, Kathryn; Hind, Karen; Morrison, Daniel; Ortega, Francisco; Pearce, Alan J; Philpott-Jones, Sean; Sandel, Elizabeth; Tatos, Ted; Tucker, Sally; Finkel, Adam M

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ABSTRAK (ENGLISH)

Five international consensus statements on concussion in sports have been published. This commentary argues that there is a strong need for a new approach to them that foregrounds public health expertise and patient-centered guidance. Doing so will help players, parents and practitioners keep perspective about these potentially life-altering injuries especially when they recur.

TEKS LENGKAP

Introduction

Over the last two decades, five international consensus statements on concussion in sports have been published. Reviewing these studies, our primary finding is that the process creating these documents has been narrow, compromised, and flawed. A careful reading of these studies suggests that the authors have adhered to a libertarian framing of causality, risk, and intervention, rather than considering a precautionary, public health and patient-centered point of view.

This commentary evaluates the creation of the prior consensus statements using the structural competency frameworks utilized in public health, medical sociology, the history of medicine, bioethics, medical ethics, economics, and healthcare policy and law.[1] It also explores how incorporating patient and caregiver perspectives could result in consensus recommendations that would bolster trust in future statements.

We suggest that greater attention to inclusion, sequestration, stronger forms of peer review, and procedural transparency would result in practice protocols and medical guidelines that would keep the patient firmly in view, procure better informed consent, and lead to an approach to concussion management informed by bioethical and public health standards.[2]

There is a strong need for a new approach to consensus statements on concussions in sports that foregrounds public health expertise and patient-centered guidance. Doing so will help players, parents, and practitioners keep perspective about these potentially life-altering injuries, especially when they recur.

Background of the Signatories

We are researchers, clinicians, humanists, advocates, and caregivers calling for a public health paradigm to inform new consensus guidelines on the causes, effects, and consequences of brain injury on society and individuals.

The upcoming 6th International Conference on Concussion in Sport will promise to assemble many of the world's concussion leaders together and charge them with producing an updated guideline. The process will be exclusionary, but this guideline will be tailored for all medical and allied health providers caring for the spectrum of athletes representing ages pediatric to geriatric, with skills from novice to professional.

We wish to foreground what might be termed a public health and patient-centered view of these efforts by drawing attention to evident limitations in both the consensus process and the substance of past versions of recommendations. We hope our efforts will aid in creating a representative consensus that reflects the current state of knowledge and uses patient well-being as the lodestar to guide policy recommendations. We propose that the following changes be included in a new consensus statement.

We Propose Broader Inclusion

Over the last twenty years the consensus statements that emerged from these conferences have been dominated by individuals with close relationships to professional and amateur sports organizations.[3] The documents have promoted sports-friendly viewpoints that could be construed to pronounce concussions and repeated subconcussive impacts more benign, recoverable, transient, and reversible injuries than we consider reasonable. In so doing, the guidelines have arguably compromised informed consent.[4] We would suggest, too, that these guidelines have almost certainly avoided the candor required for informed consent to be complete and frank.

Over the last twenty years the consensus statements that emerged from these conferences have been dominated by individuals with close relationships to professional and amateur sports organizations. The documents have promoted sports-friendly viewpoints that could be construed to pronounce concussions and repeated subconcussive impacts more benign, recoverable, transient, and reversible injuries than we consider reasonable. In so doing, the guidelines have arguably compromised informed consent. We would suggest, too, that these guidelines have almost certainly avoided the complete candor required for informed consent to be complete and frank.

Consider one outcome: the statements have been biased towards the experiences of exceptional, elite athletes at the professional, club, or collegiate levels. There is only modest contemplation of whether the recommendations make sense on a precautionary basis for the overwhelming majority of athletes whose participation in sports is exclusively recreational.[5] For such individuals, continued exposure to repeated traumatic brain injury increases risks

well beyond any foreseeable financial payoff —and there is much risk.[6] The trade-offs, and the risks and benefits, are different across these groups and the international consensus has made little effort to address this clear imbalance.

Equally of concern, the consensus statements have consistently failed to include experts with the diversity of training, experience, cultural competence, and affiliations it would be reasonable to expect for so common and ubiquitous an injury —a concern about consensus processes that has been voiced since the 1980s.[7] Experts in social medicine, bioethics, medical and sport anthropology, and clinicians with a range of experiences, including work with historically marginalized populations or in economically impoverished areas of the world, should all be included to provide deeper awareness about the lack of uniformity in the provision of and access to healthcare across cultures, geographies, and economic divides.

Since the 1970s, medicine has aspired to place medical evidence and consensus[8] in parallel conversation to the voice of the patient and caregiver.[9] It is noteworthy that parents who have lost a child, caregivers who have lost a spouse or parent, and indeed the voices of patients living with a tentative diagnosis of traumatic encephalopathy syndrome (TES) or persistent post-concussion symptoms are conspicuously absent among signatories on these statements. Including into the consensus process voices of individuals who have paid, or are paying, the high price that repeated exposure to concussion in sports can exact would provide a fuller, more balanced picture, especially since so many of the intended subjects have ended up as objects of sports research.[10]

Past statements have also included signatories who have consistently downplayed the risks of concussion injury and sought to emphasize all that we do not yet know rather than all that we do know, a pattern that was first established in concussion research for sports by the NFL MTBI Committee.[11] Such statements have ignored the precautionary principle, whose grounding in the concept of social responsibility requires scientists and researchers to act to protect the public from potential harm long before absolute metaphysical certainty has been achieved.[12] Indeed, the evidence linking collision sports to brain injury well exceeds the level at which this principle should inform policy.[13]

Further, we find it noteworthy that Dr. Ann McKee has never signed a consensus statement, although she has arguably done more than most researchers in the last twenty years to advance our understanding of what all athletes risk playing collision sports.[14] The numbers of reports on chronic traumatic encephalopathy by McKee alone far exceed the number of reports authored by the typical author of past consensus statements. Nor has, as far as we can tell, any expert on molecular neurodegeneration been sought to shape these documents.

Finally, there are other notable disciplines one would expect to find among a truly representative consensus statement. Where are frontline trauma surgeons, physical medicine and rehabilitation specialists, general practitioners, and experts in education and learning, public health, quantitative risk assessment, epidemiology, bioethics, and the sociology of medicine? The exclusion of all such experts restricts the generalizability of the consensus statements.[15]

We Propose Significant Additional Disclosure

Most signatories submit some form of disclosure. Many disclosures that we and investigative journalists have evaluated are far from complete.[16] This is concerning because of the significant history of influence that the sports industry has exerted upon brain injury research.[17] In light of a history of undue influence by industry in concussion research, the journals publishing these statements should conduct more than cursory due diligence to confirm the veracity and thoroughness of submissions. Further, each signatory should describe the amount of grants and their funders, including the source and amount of any funding provided directly to the journal to pay for open access. This is because advocates may have an interest in expanding readership for articles they favor, and because a funder's direct relationship to a journal may be a back door to getting rights of review after the article is out of the hands of the authors. Since industry funding contracts sometimes include provisions that limit disclosure and restrict publishing subject to funder approval, a blanket statement that indicates the existence of such non-disclosure agreements and details their various restrictions should also be entered in the record, including whether any contract (or even oral understanding exists) that gives consensus funders right of review prior to submission. With journals having the capacity to provide supplementary files online, it should be no onerous task for journals to achieve this

full and complete disclosure and it would help to dispel or at least diminish concerns that these consensus statements serve as works of agnotology.[18]

We Propose Additional Vetting

It is beyond question that sports industries are or should be duty bound to get the best information possible, and it makes sense that such authorities might wish for this reason to be involved in a consensus process. At the same time, such involvement creates inevitable conflicts and risks. These phenomena have been well-recognized by scholars.[19]

Whether real or mere appearance, these conflicts call into question the integrity of the documents and their suitability for generalization to all sports populations. Clinicians focused on professional athletes may have limited appreciation for the ministrations suited for children at play or those who engage in club sport on weekends. Clinicians with experiences of college and amateur sports, meanwhile, may not appreciate the legal requirements such a broad, international consensus statement may be seeking to fulfill for those who serve industry.

A more acceptable consensus statement might not exclude those with industry experiences, but it would identify them with fulsome transparency and would identify those with industry ties (past or present). *It would be even better, however, if the consensus conveners were sequestered and only fully unconflicted experts authored the end product.* We would suggest, either way, that the signatory in the masthead line explicitly indicate with an asterisk all experts with potential conflicts. However it is achieved, there should be a real effort to transparently explain any conflicts, which would help all readers and experts evaluate the generalizability of the document and suitability of its application to individual patients.

We have offered several remedies that can help all stakeholders resolve the challenge of concussions in sports through the bulwark of science. For well over a century the consequences of concussions have given rise to public controversy. The nature of these injuries is that they create adversarial points of view. Sports are deeply ingrained in our cultures. As a rule, most people do not like to contemplate their risks. No harm can be done by telling readers there are reasons for interpreting and implementing guidelines in a more precautionary way than the center of gravity of a consensus process unduly weighted by industries with a vested economic interest in the outcome might prefer.

We Propose Rigorous Peer Review

Our impression is that these Consensus Statements have not been externally peer-reviewed, except in the sense that they have been vetted by those involved in the consensus process. The most important thing that the signatories of these consensus statements can do is seek peer review substantially and substantively outside the consensus process. In addition to peers, athletes, patients, and caregivers might well be solicited for review as yet an additional safeguard. Such thorough peer review protects everyone.

We therefore also suggest that editors of the journals that publish these statements include open reviews of them by leading, sequestered experts in neurosurgery, trauma surgery, general medicine, public health, bioethics, and equipment standards. We also call on them to give patients or caregivers a public voice.

We think that a consensus statement like this should spell out to readers the mainstream view among clinicians who are in favor of doing absolutely everything feasible to avert any brain injury whatsoever. Everyone should recognize that there are sports that minimize the risks of brain injury while yielding the benefits of physical activity.

We Propose Procedural Transparency

We would suggest that each section and sub-section of these future consensus statements indicate who among the signatories agreed and who did not. This effort can be done easily by a tally of votes placed in italics beneath the title of the section and subsection —there is no reason that the vote should be anonymous. It is essential, we think, that each section then offer a broader enumeration of the evidence and counter evidence so readers may understand the nature of the controversy. Obviously, those sections where there was agreement would be important to identify. Those sections where agreement is divided need to be more transparent about the reason for those divided opinions. Doing so would help readers understand all stakeholder perspectives and decide for themselves whether a more precautionary or a more libertarian approach makes sense.

Conclusions

Improving the process of creating Consensus Statements will result in less biased content within the documents. For example, the section of the 2016 Statement discussing chronic traumatic encephalopathy (CTE) states perfunctorily that “the literature on neurobehavioral sequelae and long-term consequences of exposure to recurrent head trauma is inconsistent.” A more responsible summary, we believe, might have instead read “the literature on neurobehavioral sequelae and long-term consequences of exposure to recurrent head trauma suggests reason for serious concern, although much remains to be clarified.” Similarly, the statement that “A cause-and-effect relationship has not yet been established between CTE and sports-related concussions or exposure to contact sports” is incomplete: a more honest summary might have read “The strong statistical associations found between CTE and SRCs or exposure to contact sports may not represent a true cause-and-effect relationship, but at present attempts to attribute these associations to confounding, bias, or artifacts have not been persuasive”.[20] We also note that prospective longitudinal studies of a well-characterized cohort, the claimed sine qua non of the establishment of a causal link between repetitive head trauma and later-in-life neurodegenerative diseases, are not only impractical but also unethical in light of the significant probability of patient harm. As many as seven decades might separate a particular individual’s exposure and the emergence of neurological signs and symptoms. Waiting for results and conclusions from studies that require many decades is unethical in light of the significant probability of harm to at least some nonzero proportion of any collision sport cohort.[21]

We have offered several remedies that can help all stakeholders resolve the challenge of concussions in sports through the bulwark of science. For well over a century the consequences of concussions have given rise to public controversy.[22] The nature of these injuries is that they create adversarial points of view. Sports are deeply ingrained in our cultures. As a rule, most people do not like to contemplate their risks.[23] No harm can be done by telling readers there are reasons for interpreting and implementing guidelines in a more precautionary way than the center of gravity of a consensus process unduly weighted by industries with a vested economic interest in the outcome might prefer.

Competing Interests

Corresponding author STC discloses that he is retained in concussion litigation by firms representing plaintiffs against leading sports organizations worldwide. DCo previously advised the Morey Objectors on economic and health matters in the National Football League Players’ Concussion Injury Litigation, Case No. 12-md-02323-AB, U.S. District Court for the Eastern District of Pennsylvania between August 2013 and April 2015. AJP currently receives partial research salary funding from Sports Health Check charity. AJP has previously received partial research funding from the Australian Football League, Impact Technologies Inc., and Samsung Corporation. AF served as a consultant to the Football Players Health Study (Harvard University) in 2015 and 2016. RT and JG have been a caregivers for retired professional athletes. In the past, SG has served as a consultant to Roche and has held grants from Pfizer, Baxter, and Polyphenolics/Constellation Wines. None of these relationships is currently active. SG is a founder of Recuerdo Pharmaceuticals, also currently inactive. SG’s research on TBI and CTE was funded by the Alzheimer’s Drug Discovery Foundation. PET ligands for these studies were donated to SG by Avid and Lilly. The Mount Sinai Center for Cognitive Health and NFL Neurological Care is one of five centers designated to receive referrals from the NFL Neurological Care Program Player Care Plan http://www.nfl.com/news/story/0ap1000000228352/article/neurological-care-program.

Note

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Pharmaceutical Companies, Human Rights, and the Alien Tort Statute

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ABSTRAK (ENGLISH)

On January 3, 2019, U.S. District Judge Theodore D. Chuang of the U.S. District Court of the District of Maryland took a crucial first step in redressing one of the worst human subjects research ethics violations in U.S. history.

TEKS LENGKAP

On January 3, 2019, U.S. District Judge Theodore D. Chuang of the U.S. District Court of the District of Maryland took a crucial first step in redressing one of the worst human subjects research ethics violations in U.S. history. In *Estate of Arturo Giron Alvarez et al. v. The John Hopkins University et al.* (“*Alvarez*”), first filed on April 1, 2015, the Estate of Arturo Giron Alvarez and hundreds of other Guatemalan nationals brought suit against Johns Hopkins University, the Rockefeller Foundation, and the Bristol-Myers Squibb Company alleging that they “subjected them or

their family members to medical experiments in Guatemala without their knowledge or consent during the 1940s and 1950s, in violation of the law of nations."[1] Rejecting the Defendants' motion for judgment on the pleadings, Judge Chuang allowed the Plaintiffs to pursue relief (including damages) under the Alien Tort Statute ("ATS").[2] Central to Judge Chuang's decision and a subsequent appeal was the question of whether and when U.S. corporations can be held liable under the ATS. A recent June 2021 Supreme Court decision in another ATS case, *Nestlé USA v. Doe*,[3] gave new guidance on this question, but also raised new issues about what activities inside the United States permit plaintiffs to pursue liability for human rights violations such as those alleged in *Alvarez*. In this article, we discuss the *Alvarez* case and its implications in light of *Nestlé* for other litigation alleging U.S.-based conduct by U.S. corporations that committed research ethics and other international law violations.

The *Alvarez* case has its origins in the "Investigation of Venereal Diseases in Guatemala," a National Institutes of Health research study that was fortuitously unearthed and publicized by the scholarly efforts of Professor Susan M. Reverby.[4] Carried out between 1946 and 1948 by U.S. Public Health Service investigators, the study called for the inoculation of vulnerable Guatemalan nationals (male prisoners, female sex workers, and psychiatric inpatients) with syphilis, gonorrhea, or chancroid.[5] On October 1, 2010, President Obama offered an apology as well as deep regrets to the Guatemalan President and the Guatemalan people.[6] A comparable joint statement was issued on behalf of Secretary of State Hillary Rodham Clinton and Secretary of Health and Human Services Kathleen Sebelius.[7] A subsequent study by the Presidential Commission for the Study of Bioethical Issues, titled *"Ethically Impossible,"* found the study in question to have violated the "basic tenets bearing on informed consent and risk reduction" in force at the time.[8]

The ATS allows non-U.S. citizens ("aliens") to sue in U.S. federal court for civil damages (torts) that violate the "law of the nations."[9] In the portion of their lawsuit relevant here, the Plaintiffs alleged that the Defendants committed "crimes against humanity, in violation of well-established and customary norms of international law."[10] The Defendants sought to dismiss this claim arguing that the ATS does not permit a lawsuit against a U.S. corporation. In 2019, the district court in *Alvarez* disagreed.

To understand the importance of this decision and the issues that will now be litigated anew in light of *Nestlé*, some historical context is necessary. From its inception in 1789, the ATS lay dormant for almost two centuries before being resurrected in a series of human rights cases, starting with the landmark 1980 decision, *Filartiga v. Pena-Irala*.[11] The subsequent cases established that modern-day violations of the law of nations include the abuse of fundamental human rights, like torture and mass atrocities. Most ATS litigation initially focused on claims against direct government perpetrators, but in the 1990s, federal courts began to permit claims against non-state actors, including corporations and other institutions. Starting in 2004, the Supreme Court weighed in on the modern litigation, permitting ATS suits to proceed but indicating that only a limited number international law claims that were "specific, universal, and obligatory" in nature could be brought under the statute.[12] Starting in 2013, the Court has revisited the ATS three times, cutting back on this litigation each time but not closing the door completely. In 2013, the Court announced a rule in *Kiobel v. Royal Dutch Petroleum Co.* that there was a "presumption against exterritorial" application of ATS in a case involving foreign plaintiffs, foreign corporate defendants, and human rights violations that took place in Nigeria.[13] The Court expressed particular concern about the foreign policy implications of such suits and wanted to prevent U.S. courts from becoming a forum to judge violations for the "whole world."[14] On the facts in *Kiobel*, the Court specifically said that where "all relevant conduct took place outside of the United States," "mere corporate presence" in the United States would not suffice to create jurisdiction.[15] In 2018, the Supreme Court added another roadblock, holding in *Jesner v. Arab Bank, PLC*, that "*foreign* corporations may not be defendants in suits brought under the ATS."[16]

A recent June 2021 Supreme Court decision in another ATS cases, *Nestlé USA v. Doe*, gave new guidance on this question, but also raised new issues about what activities inside the United States permit plaintiffs to pursue liability for human rights violations such as those alleged in *Alvarez*. In this article, we discuss the *Alvarez* case and its implications in light of *Nestlé* for other litigation alleging U.S.-based conduct by U.S. corporations that committed research ethics and other international law violations.

In the wake of *Jesner*, the question raised by the case of the Guatemalan victims was whether the same limitation applied to *domestic* corporations, like Johns Hopkins University. Judge Chuang answered decisively "no." Before reaching that question, the court decided that "there is an international law norm barring nonconsensual medical experimentation on human subjects."[17] Moving on to the question of domestic corporations, Judge Chuang offered a careful analysis of the Supreme Court's decision in *Jesner*, including a close reading of the majority opinion, several concurring opinions, and the dissent. He also examined the decisions of a few other courts that had broached the question since *Jesner*. In his analysis, Judge Chuang focused particularly on the underlying policy issues and goals that arise through ATS litigation —namely foreign policy implications, separation of powers between the political branches and courts, and the aim of providing remedies for victims in U.S. courts. Ultimately, Judge Chuang decided ATS litigation against foreign corporations is different in kind from those against domestic ones in important ways, and "the need for judicial caution is markedly reduced" with such cases not likely to raise the same foreign policy concerns.[18] Unlike in *Jesner*, the judge concluded that allowing litigation to go forward "would 'promote harmony' rather than 'provoke foreign nations.'"[19] Judge Chuang's discussion and decision were prescient of the debate that ensued before the Supreme Court in *Nestlé*.

The *Alvarez* Defendants appealed the case to the U.S. Court of Appeals for the Fourth Circuit. After the case was briefed but before argument, the U.S. Supreme Court granted certiorari in *Nestlé* on the question of whether *Jesner* 's reasoning extended to U.S. corporations. On August 6, 2020, the Fourth Circuit filed an order placing the case in abeyance pending the decision in *Nestlé*.[20]

The U.S. Supreme Court decided the *Nestlé* case on June 17, 2021. That case was brought by "six individuals from Mali who allege that they were trafficked into Ivory Coast as child slaves to produce cocoa."[21] The Defendants were U.S.-based companies that engaged in the purchasing, processing, and selling of cocoa. According to the allegations in the complaint, they bought cocoa from local farms in the Ivory Coast and provided training, tools, cash, fertilizer, etc., in return for an exclusive right to purchase cocoa, even though the Defendants did not own or operate farms in the Ivory Coast. The Plaintiffs alleged that the Defendants knew or should have known that the farms were exploiting child labor but continued to provide those farms with resources and did not use their economic leverage to try to block children from working there.[22]

Turning to the legal analysis, the Supreme Court did not extend the reasoning of *Jesner* to categorically bar suits against U.S. corporations, instead returning to an exterritoriality analysis. In a majority opinion joined by every Justice except Justice Alito, the Court sided with the defendants and found the allegations in the complaint insufficient to allow the case to proceed. The Court specifically rejected the idea that "general corporate activity —like [corporate] decisionmaking" could be enough to establish jurisdiction under the ATS, and instead held that plaintiffs must allege something more in terms of a corporation's domestic conduct.[23] The Court categorized the allegations involving "major operational decisions" in the United States, and "generic allegations of this sort do not draw sufficient connection" between the claims and U.S. domestic conduct.[24]

In not extending *Jesner* to apply to U.S. corporations, however, the Court signalled that cases involving U.S. actors and U.S. domestic conduct require a different analysis than cases involving foreign corporations. Indeed, the Court has had three opportunities —in *Kiobel*, *Jesner*, and now *Nestlé* —to consider the question of corporate liablity under the ATS. Each time, it has declined to create corporate immunity or a categorical bar on all such cases. At present, there are five Justices who have expressed support for corporate liability under the ATS. Writing separately in *Nestlé*, Justice Gorsuch (joined by Justice Alito) wrote to express his view that "[t]he notion that corporations are immune from suit under the ATS cannot be reconciled with the statutory text and original understanding," and thus he would draw no distinction between corporate and personal defendants under the ATS.[25] Justices Sotomayor, Kagan, and Breyer have also expressed support for this position. Thus, there now appears to be a majority of Justices in favor of that position, even though the Court did not rest its opinion on that ground in *Nestlé.*

Now that *Nestlé* has been decided, we expect the Fourth Circuit to ask for briefing on how *Alvarez* should be decided in light of the Supreme Court's most recent pronouncement, or perhaps to remand to the district court to do a new analysis in light of *Nestlé*.

The *Alvarez* case will be critical arena to consider the implications of *Nestlé* and what relevant conduct in the United States will suffice to establish jurisdiction. The threshold question of corporate liablity for U.S. corporations should be of less concern in the case. Instead, the question of what these entities did in the United States and whether those actions involve a sufficient connection to the claims in question will be front and center in future proceedings.
No matter the outcome, any decision will have important implications in both the near and long term as to whether and how U.S.-based health care institutions may be held to account for both their current and historical practices at home and abroad that violate international principles such as undertaking nonconsensual experiments. For the *Alvarez* Plaintiffs themselves, there remains the hope that justice may be done for the victims of one of the worst atrocities in history perpetrated by the U.S. research community.

Note

Financial and Other Disclosures: Tyler Giannini filed an amicus brief on behalf of Professors of Legal History in *Nestlé USA v. Doe*.

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About This Column

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

DETAIL

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Legal Challenges Underlying COVID-19 Vaccinations

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ABSTRAK (ENGLISH)

Immunizing hundreds of millions against COVID- 19 through the most extensive national vaccine campaign ever undertaken in the United States has generated significant law and policy challenges.

TEKS LENGKAP

In response to the most impactful and costly public health event in U.S. history, federal authorities and pharmaceutical companies including Pfizer, Moderna, and Johnson &Johnson have collaborated to produce multiple safe and efficacious COVID-19 vaccines.[1] Pervasive allocation and monitoring of these vaccines are key to preventing further morbidity and mortality. Through his revitalized national COVID-19 strategy, President Biden emphasized the need for widespread access, uptake, and equity in distributing vaccines to assure Americans' health and economic prosperity.[2]

Immunizing 70% of eligible Americans against COVID-19 by mid-summer 2021 was the goal.[3] Achieving herd immunity, however, is complicated by substantial logistical, informational, political and, notably, legal challenges. Primary among legal issues are divergent approaches to the use of employer-based vaccine mandates and

"passports." The Biden Administration has not endorsed either concept even as international and state governments implement them.[4] Determining who and when persons should be vaccinated raises legal concerns among schools and universities considering immunization measures. As younger populations (ages 0-17) become eligible for vaccines, informed consent issues surface. Engrained notions of vaccine hesitancy among Americans have rekindled battles over perceived safety risks and personal liberty. Governmentally-supported "lotteries" designed to incentivize more Americans to get vaccinated are legally-suspect.[5] Persons of faith seeking religious exemptions from COVID-19 vaccines face contrary state policies and variable judicial responses. Health information privacy concerns underlie public health surveillance activities using personally-identifiable information. Omnipresent anxieties over potential liability for vaccine-related injuries may be dispelled via strong federal emergency liability protections. As explored below, addressing these legal and policy issues is pivotal to the success of the national COVID-19 vaccine campaign.

Employer-Based Vaccine Mandates

Employers across the country considered the legality of COVID-19 vaccine mandates long before the first vaccine received Food and Drug Administration (FDA) emergency use authorization (EUA). Public-sector vaccination mandates are constitutional under the U.S. Supreme Court's seminal 1905 decision, *Jacobson v. Massachusetts*.[6] In the private sector, the Equal Employment Opportunity Commission (EEOC) and Occupational Safety and Health Administration (OSHA) have previously approved workplace vaccine requirements.[7] Yet, employer-based vaccine mandates in the health care sector, schools, or other settings are controversial, principally because of the unique status of COVID-19 vaccines as FDA "authorized," but not fully "approved." The Food, Drug, and Cosmetic Act indicates Americans may refuse EUA vaccines.[8] Pending lawsuits argue that the Act prevents mandates.[9] While employer-based requirements impose conditions as incentives to participate, they do not legally compel employees to get vaccinated. Consequently, in May 2021, EEOC updated prior COVID-19 guidance, generally approving employer mandates that comply with civil rights protections and state/local laws.[10] In June 2021, OSHA encouraged workplace COVID-19 vaccination by requiring paid leave for immunizations and resulting side effects.[11]

In 2019, the World Health Organization classified vaccine hesitancy as a major threat to global health. Fueled by false or misleading messaging largely by anti-vax entities via social media, widespread resistance to COVID-19 vaccines poses direct threats.

Vaccine Passports

As COVID-19 vaccination rates increase nationally, public- and private-sector entities (e.g., entertainment venues, airlines, and other businesses) are considering whether to require proof of vaccination as a prerequisite, or "passport," to provision of services.[12] Vaccination verification is standard in certain settings. For example, international travelers must typically demonstrate compliance with specific country's vaccination schedules.[13] That COVID-19 vaccine passports may be required in other situations is logical. New York has already enrolled millions in an online vaccine "pass."[14] However, debates over autonomy and personal liberty have led other states (e.g., AL FL, MT, TX) to legislatively prohibit passports.[15] Widespread objections to passport requirements under the HIPAA Privacy Rule are unwarranted since only certain entities, namely health care providers, are covered by the Rule.[16]

School/University-Based Vaccine Requirements

No states currently require COVID-19 vaccination for K-12 students as a condition of their attendance, in part because children younger than 12 are not yet authorized to receive the vaccine. However, at least one state (Arkansas) has legislatively forbidden COVID-19 vaccine requirements as a condition of education;[17] other states may follow. In May 2021, the Superintendent of the Los Angeles Unified School District stated it is "likely" COVID-19 vaccines will be required once vaccines receive full FDA approval.[18] Among institutes of higher education, disputes over vaccine requirements are raging. Unlike for K-12 schools, state laws rarely dictate which vaccines universities and colleges may require among their students.[19] The American College Health Association recommends COVID-19 vaccine requirements for on-campus students, subject to certain exemptions.[20] While numerous universities plan to comply,[21] others are flatly refusing.[22] Some states like Arizona have legislatively proposed limits on universities to mandate COVID-19 vaccines.[23] A "patchwork" approach to COVID-19 vaccination requirements across higher

education may inevitably lend to preventable outbreaks in select locales.

Consent Among Minors

On May 10, FDA authorized Pfizer's COVID-19 2021 vaccine for use in minors (ages 12-17), immediately raising questions of consent among parents/guardians. According to the Kaiser Family Foundation, 41 states require adult consent for minors' vaccinations, while only four states (AL, OR, RI, SC) and DC allow children (of certain ages) to self-consent. Five other states (AR, ID, NC, TN, WA) grant medical providers some discretion in administering vaccines to children deemed sufficiently mature.[24] Though purposeful in assuring the safety of minors, consent laws may slow vaccine uptake nationally. Vaccination centers initially lacked procedures for securing consent. Marginalized children in foster care, juvenile institutions, or unaccompanied at the U.S. southern border may be compromised in securing consent.[25] Conflicts may also arise between minors seeking vaccination contrary to guardians' wishes.[26] In response, some localities have broadened minor self-consent provisions. On April 28, San Francisco's health officer ordered that minors 12 and older may consent to receive the COVID-19 vaccine and that healthcare providers may rely on such consent (with certain limitations).[27]

Vaccine Hesitancy

In 2019, the World Health Organization classified vaccine hesitancy as a major threat to global health.[28] Fueled by false or misleading messaging largely by anti-vax entities via social media, widespread resistance to COVID-19 vaccines poses direct threats.[29] Millions of Americans express concern about the long-term safety of vaccines unapproved by FDA, resist efforts assimilating mandates, promote their personal liberty over communal interests, and raise religious freedoms against their own vaccinations. Each of these positions is legally specious. To date COVID-19 vaccines are proving highly-efficacious and safe. No autonomous adult may be compelled to be vaccinated despite contrary allegations.[30] Constitutionally-protected liberty interests do not include actions that place others at direct harm. Further, First Amendment free exercise rights (as noted below) do not currently require vaccine exemptions, although most states allow them.

Vaccine Lotteries

In part to counter hesitancy, innovations encouraging COVID-19 vaccination have emerged including dispensing marijuana joints (AZ, WA), liquor (LA, NJ), and raffles for college scholarships (NY).[31] Among other states (e.g., CA, CO, OR), Ohio has established a vaccine lottery offering several $1 million payouts or full-ride in-state college scholarships to individuals newly seeking COVID-19 immunizations.[32] Persuading undecided persons to be vaccinated is the aim. Early results suggest lotteries provide ample incentives. Since the launch of Ohio's lottery, Governor Mike DeWine claims a 49% increase in vaccinations among individuals aged 16+, a 36% increase among minorities, and a 65% rise among rural populations.[33] Still, controversies swirl. Ohio lottery payouts are taken from federal coronavirus relief funds, suggesting a misuse of public resources. Federal authorities, however, have approved lottery funds if they are "reasonably expected" to increase vaccine rates.[34] Some hesitant individuals question the safety of COVID-19 vaccines if government must resort to lottery incentives to get public buy-in. Whether vaccine lotteries become commonplace after the pandemic (e.g., annual flu vaccine campaigns) depends on forthcoming public health assessments of their efficacy.[35]

Religious Exemptions

Further contributing to widespread vaccine refusal and hesitancy are specific exemptions to immunization requirements. Constitutionally, no one who is medically at-risk of harm may be required to be vaccinated.[36] Vaccine mandates often include as well religious or philosophical exemptions that vary across states.[37] Failures to respect religious exemptions may engender constitutional challenges under First Amendment free exercise principles. Currently, governments do not constitutionally have to respect religious exemptions to generally-applied vaccine requirements.[38] However, during the throes of the pandemic, the U.S. Supreme Court upheld several First Amendment religious freedom challenges to social distancing and closure orders.[39] Consequently, even arguably neutral public health laws may be closely scrutinized if they implicate free exercise principles. In future cases, the Court could determine that faith-based exemptions to vaccine mandates are required by the First Amendment, fundamentally altering the legal landscape.

Privacy Repercussions Related to Surveillance

Public health reporting and surveillance efforts involving sensitive conditions like COVID-19 heighten information privacy fears. Americans are quick to raise privacy concerns even though laws regularly permit disclosures of identifiable health information to public health agencies to prevent or control infectious diseases.[40] Other privacy concerns surface. Beginning in 2020, the Centers for Disease Control and Prevention (CDC) executed data sharing agreements with states to monitor COVID-19 vaccination status nationally.[41] Some states seek to limit information sharing, citing state privacy laws. New York will not disclose data to CDC that could be used to document citizenship.[42] California refuses to share potentially identifiable information.[43] CDC requests for specific vaccine data categorized by race and ethnicity help ensure equitable allocation of resources but may deter some communities from seeking vaccination.[44] Properly balancing access to identifiable health data and individual or communal privacy expectations is synergistic with accomplishing public health objectives.

Liability for Vaccine-Related Injuries

Despite numerous reports verifying the safety of FDA-authorized COVID-19 vaccines, the specter of liability pervades their production, allocation, and administration. The federal Public Readiness and Emergency Preparedness (PREP) Act[45] provides strong liability protections to persons or entities related to the manufacture or administration of vaccines and other medical countermeasures, absent claims of willful misconduct. Former U.S. Secretary of Health and Human Services Alex Azar issued a PREP Act declaration,[46] effective February 4, 2020, initiating these protections. This declaration helps insulate clinics, pharmacies, or other entities administering COVID-19 vaccines from claims of injury involving ordinary negligence. Americans suffering a serious physical injury or death as a direct result of their vaccination may be eligible for benefits through the federal Countermeasures Injury Compensation Program.[47] Benefits include compensation for unreimbursed medical expenses, lost wages, or survivor death payouts,[48] provided requests are filed within 1 year of receiving the vaccine.[49]

With the looming threat of additional variants of coronavirus impacting Americans in subsequent waves of disease,[50] rapidly achieving vaccination milestones and herd immunity is urgent. Identifying and resolving legal and policy challenges is essential toward accomplishing not only these immediate goals, but also the long-term viability of public health protections for the twenty-first century.

Note

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Seeking Conceptual Clarity in Organ Procurement Following Circulatory Determination of Death

Truog, Robert D

ABSTRAK (ENGLISH)

Murphy and colleagues have compiled a comprehensive yet concise analysis of conceptual issues surrounding the practice of cDCDD, or controlled procurement of transplantable organs after circulatory determination of death.1 The issues are interrelated in ways that that make them difficult to consider individually, yet the authors have effectively parsed out the key kernels of controversy that are at the core of each. As someone who has participated in these debates for decades, I found the authors' clear analysis to be a uniquely valuable contribution to the literature. At the same time, I have come to wonder whether the fascination of bioethicists with the complex ethical details of cDCDD are somewhat like the proverbial fascination of magpies with shiny objects, and that these details have distracted us from the bigger picture of what is ethically salient in the practice of cDCDD.
The Uniform Determination of Death Act requires that cDCDD donors be declared dead on the basis of the "irreversible cessation of circulatory and respiratory functions." Yet the authors clearly show that fulfilling these criteria requires answers to a host of contentious questions about how the cessation of these functions should be defined and determined. I suggest, however, that if we can step back from these details and adopt a broader vision about the ethical issues at stake, then it may be possible to discern a path towards greater clarity and simplicity. Consider, for example, the context of cDCDD donation. Typically, it involves a patient who has suffered a brain injury that is incompatible with meaningful neurological recovery, but not so devastating as to fulfill the criteria for the determination of brain death. Given the poor neurological prognosis, the patient's family has decided that the patient would not want life support to be continued if the patient were able to make that decision. Furthermore, the patient has either signed a donor card indicating the desire to be an organ donor, or the family believes that the patient would have wanted to be an organ donor if given the opportunity to do so. Finally, the family also believes that the patient would have agreed to certain alterations in end-of-life care that would enhance the likelihood of successful organ donation, provided these are not unduly burdensome (e.g., are not painful, do not substantially prolong the dying process, etc.).

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Murphy and colleagues have compiled a comprehensive yet concise analysis of conceptual issues surrounding the practice of cDCDD, or controlled procurement of transplantable organs after circulatory determination of death.[1] The issues are interrelated in ways that that make them difficult to consider individually, yet the authors have effectively parsed out the key kernels of controversy that are at the core of each. As someone who has participated in these debates for decades, I found the authors' clear analysis to be a uniquely valuable contribution to the literature. At the same time, I have come to wonder whether the fascination of bioethicists with the complex ethical details of cDCDD are somewhat like the proverbial fascination of magpies with shiny objects, and that these details have distracted us from the bigger picture of what is ethically salient in the practice of cDCDD.
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would have wanted to be an organ donor if given the opportunity to do so. Finally, the family also believes that the patient would have agreed to certain alterations in end-of-life care that would enhance the likelihood of successful organ donation, provided these are not unduly burdensome (e.g., are not painful, do not substantially prolong the dying process, etc.).

In this typical scenario, at least some of the most contentious debates about cDCDD can appear to be pedantic and excessively academic. For example, cDCDD patients all have do-not-resuscitate (DNR) orders in place, such that no attempt to restore circulation will be made once cardiac arrest has occurred. Under these circumstances, there are no known cases of “autoresuscitation” (defined as restoration of spontaneous circulation) following the onset of cardiac arrest. In other words, whether these patients are pronounced dead at 2 minutes or 5 minutes, or whether death is pronounced when the loss of circulation is considered to be “permanent” versus “irreversible,” their death is imminent and certain.

The dead donor rule requires that the organs not be removed until the patient is dead, but since there is no doubt that death is imminent, the rule is certain to be honored in spirit, even if not with respect to some of the details about timing. Decisions about how end-of-life care may be altered to facilitate the procurement of organs can, for the most part, be determined by common sense. Given the explicit or presumed desire of the patient to be an organ donor, routine types of procedures that are commonly performed on patients (such a placement of intravascular catheters, for example) should be permissible, provided they are done with standard techniques and medications to assure analgesia and comfort. And while maintaining the public trust should always be a core commitment of the medical profession, assuring the public that all of the above precautions are being taken should be enough to assuage any fears that patients are being killed for their organs.

Writing as someone who has passionately debated various sides of the many issues listed above, there is one issue that I think is absolutely central to the ethics of cDCDD. Before beginning the process of organ procurement, we need to be convinced that enough time has lapsed to be sure the patient is unconscious and insensate. Our actions would be unforgivable if the surgical procurement of the organs exposed the patient to pain and suffering. Perhaps surprisingly, this is an issue that has received little attention in the literature. We know, however, that the EEG is essentially flat within one minute of cardiac arrest. Unless evidence to the contrary exists or becomes known, I would suggest that this would be the minimal time that should elapse between the onset of cardiac arrest and the initiation of organ procurement.

The New England Journal of Medicine recently published research that is relevant to many of these issues.[2] The investigators studied patients during the dying process and found that 67 of 480 patients (14%) had resumption of cardiac activity after initial cardiac arrest, in one case as long as 4 minutes and 20 seconds after the onset of pulselessness. Many had ECG electrical activity that persisted for even longer. Yet “cardiac activity” was defined as generation of a pulse pressure of >5mm Hg, far below what would be required to restore circulation of blood to the organs, and the median duration of this activity was 3.9 seconds. Most importantly, none of these patients had return of circulation, regained consciousness, or survived.

What does this study tell us? Some might use these data to support use of the 5-minute rule for determining death after the onset of cardiac arrest. But given that none of the 480 patients had return of circulation or consciousness, I would argue that this interpretation of the data misses the point. Instead, I would be interested in seeing either EEG or other electrophysiological data indicating how long a period of pulselessness was necessary for these dying patients to be unconscious and insensate. This is much more important, it seems to me, than knowing how long we need to wait before we know that the cardiac muscle has made its last agonal twitch or fired its last electrical impulse.

As Murphy and colleagues discuss,[3] others have proposed that circulatory death is merely a proxy for the irreversible loss of consciousness and other critical brain functions. I suggest advancing this view one step further, which is to say that we can proceed with organ procurement in cDCDD donors as soon as we can be sure that the patient will be insensate at the time that organ procurement begins.

As Murphy and colleagues discuss, others have proposed that circulatory death is merely a proxy for the irreversible

loss of consciousness and other critical brain functions. I suggest advancing this view one step further, which is to say that we can proceed with organ procurement in cDCDD donors as soon as we can be sure that the patient will be insensate at the time that organ procurement begins.

Note

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DETAIL

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Medicaid Waivers, Administrative Authority, and the Shadow of Malingering

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ABSTRAK (ENGLISH)

From 2018 through 2020, HHS approved state Medicaid demonstration waivers to impose new eligibility conditions such as work requirements, connecting current “personal responsibility” rhetoric and historical suspicion of

malingering. The Biden administration reversed course but advocated to the Supreme Court for expansive administrative discretion. This approach supports health equity now but could enable reemergence of restrictive health policies down the road.

TEKS LENGKAP

On the last day of his presidency, the Trump administration filed a brief in the U.S. Supreme Court defending the legality of work requirements in the Medicaid program. Such requirements deprive the poorest Americans of access to care and are rooted in a long history of discriminating against individuals deemed undeserving of government assistance. The concept of deservingness reflects fear of “malingering,” that people feign need for government supports to avoid being responsible members of society. Fear of malingering is closely tied to the American myth of self-reliance, which stigmatizes government assistance in pursuit of idealized self-sufficiency. The two sides of this coin —fear of malingering and the myth of self-reliance —feed anti-Medicaid rhetoric, which flourished during the last four years but has much deeper roots.

The fear of malingering ignores extensive data that the majority of Medicaid beneficiaries who can work do work. Further, determinations of deservingness are contrary to the purpose of the Medicaid program, which has special rules to protect low-income individuals from the significant financial and other risks of medical care. The Biden administration reversed the work requirement policy, but low-income Americans may not be protected from a political turnaround in the long-term.

The Biden administration seeks to entrench broad authority for the Secretary of the Department of Health and Human Services (HHS) to approve demonstration waivers that have indirect benefits for the health of enrollees. Even when the goals are oriented toward health equity, HHS does not have authority to craft an alternative Medicaid program, and a broad read of secretarial authority leaves the interpretive door wide open for the next administration. The political pendulum swings from election to election, and the next swing could be in the direction of thwarting Medicaid’s statutory objectives and denying coverage to vulnerable populations.

Medicaid’s Purpose

Medicaid offers federal funds to states to provide medical assistance to low-income Americans. As federal courts have held, this means Medicaid pays for medical care for low-income individuals who fit in Medicaid’s categories of eligibility.[1] These have included children, parents, pregnant women, people with disabilities, and the elderly. The categories of eligibility drew on the old cash assistance welfare programs that were part of Medicaid’s original structure but separated by federal law during the Clinton administration. Despite that delinking, it was not until 2010 that Medicaid eligibility was expanded to cover other low-income, nonelderly adults under the Patient Protection and Affordable Care Act (ACA). The ACA eliminated the concept of deservingness for low-income people to qualify for Medicaid, though noncitizens are still treated differently.

The law is a structural determinant of health that can improve or stymie access to care for individuals and populations. The ACA’s statutory expansion of Medicaid has begun to erode barriers to medical care, especially for people of color, even though the Supreme Court allowed states to opt out of expansion.

The ACA’s Medicaid eligibility expansion was a change in the historical approach to accessing health care, shifting from a norm of exclusion to inclusion, and is central to the near-universal coverage goal of the ACA. Many other nations established universal coverage after World War II, but American medical care remained driven by private transactions and individual status. People who held jobs with no benefits, non-parents, non-white, and otherwise “undeserving” populations have been excluded from care in part because they were often unable to obtain coverage and could not afford to pay out of pocket.[2] Medicaid’s categorical eligibility was one aspect of exclusionary policy. Long-term downward trends in employer sponsored health insurance coverage (ESI), as well as continually increasing uninsurance rates, led Congress to recognize the substantial evidence that many people, especially part-time and low-wage workers, were unable to obtain ESI, could not obtain other commercial insurance, and did not qualify for Medicaid. Under the ACA, Medicaid expansion and federal tax subsidies for purchasing qualified health plans on a health insurance exchange are the two key ways that low-income people can obtain coverage, crafting a

universal approach to coverage for the first time in American history. While providing important synergy, these pillars are not actually equivalent. Medicaid has four core features that protect low-income populations in ways that commercial insurance does not.

First, in contrast to the limited open enrollment of commercial insurance and Medicare's penalties for beneficiaries who do not timely enroll in Parts B and D, Medicaid contains eligibility rules that accommodate income fluctuation and social vulnerability, such as continuous open enrollment, which allows anyone who is eligible to enroll at the moment they become impoverished enough. Second, patients cannot be denied coverage or care because of inability to pay, as the Medicaid Act limits out-of-pocket payments for those earning at or near the federal poverty level and premiums and deductibles are prohibited. Third, Medicaid provides comprehensive benefits beyond other insurers, such as non-skilled nursing home care (long term services and supports) and non-emergency medical transportation. Fourth, Medicaid contains due process and other structural protections. For example, states cannot delay enrollment for people who qualify, beneficiaries must receive notice before services are reduced or discontinued, and hearings to contest adverse actions include representation and a right to continued services until a decision is issued. Additionally, Medicaid's funding structure creates a statutory entitlement for states, which promises federal matching funds for the cost of Medicaid services and administration. By law, federal funds match state expenditures under the Medicaid Act and are not capped. This gives states crucial financial support, especially during events such as recessions or emergencies, protecting state budgets while also ensuring that individuals who are eligible can enroll and access care.

The law is a structural determinant of health that can improve or stymie access to care for individuals and populations. The ACA's statutory expansion of Medicaid has begun to erode barriers to medical care, especially for people of color, even though the Supreme Court allowed states to opt out of expansion.[3] More than six hundred studies[4] show that Medicaid expansion increases coverage, expands access to care, improves health, and improves underlying determinants of health including job and housing stability.[5] Medicaid expansion has reduced historic disparities in coverage and access and has improved health outcomes for Black, Hispanic, and other communities of color. Also, expansion is a financial benefit for states, with studies finding expansion leads to revenue gains and economic growth. Nevertheless, at the time of this writing, twelve states were refusing Medicaid expansion —despite the American Rescue Plan Act of 2021 sweetening the choice with an extra 5% federal funding match.

An important similarity between Medicaid and commercial insurance is often overlooked but relevant here: the substantial federal funding provided for both. Congress subsidizes commercial insurance in many ways, including not only startup funding provided to states to create exchanges and the ongoing spending to run the federal exchange, but also the individual tax subsidies for purchasing insurance on the exchanges, which cover most of the cost of subscribing for people at or near the poverty level. Additionally, ESI receives substantial federal tax benefits that inure to the benefit of both employers and employees, but this hidden tax subsidy of more than $200 billion in foregone tax dollars every year is often ignored. The desire to subject Medicaid beneficiaries to self-reliance scrutiny does not extend to ESI or exchange-based insurance coverage, even though both are also government-funded mechanisms for financing medical care.[6] In other words, Medicaid is treated differently, in part due to a fear of malingering and the misconception that playing by society's rules means having commercial insurance coverage, yet nearly all health insurance coverage, public and private, is heavily subsidized by the federal government.[7] The next part examines the expansion of administrative authority that resulted in renewal of exclusionary norms during the Trump administration, which reflected fear of malingering and the longstanding assumption that civic character is reflected in insurance coverage.

Pushing Boundaries through Waivers

The HHS Secretary has limited authority under Section 1115 of the Social Security Act to permit states to implement demonstration projects that are "likely to assist in promoting the objectives" of Medicaid by waiving certain statutory provisions.[8] Over time, the Secretary has approved demonstrations that expanded eligibility (for example, to pregnant women), increased covered services (such as prescription drugs), and altered delivery system models (managed care), all of which furthered Medicaid's objective: to furnish medical assistance.[9] Yet, in recent years

waivers have grown as a mechanism for implementing policies beyond the scope of Medicaid's enabling statute. From 2017 through 2020, HHS exceeded the waiver boundaries set by law and the policies of prior administrations by allowing states to limit medical assistance rather than furnish it. It is not uncommon for 1115 waivers to be used to implement policy preferences. But attempting to nullify the existing law of the ACA through administrative acts pushed waiver authority to a different level of policymaking. In sum: in 2017, then-HHS Secretary Tom Price and CMS Administrator Seema Verma challenged the purpose and existence of ACA Medicaid expansion in an open letter, calling Medicaid a program for the "truly vulnerable" and denying the need for covering the expansion population.[10] In January 2018, after Congress failed to repeal the ACA, HHS issued a State Medicaid Director Letter inviting waiver applications that propose "community engagement" requirements, a euphemism for work requirements. In January 2019, HHS issued a State Medicaid Director Letter inviting waiver applications to restructure Medicaid financing from a guaranteed federal match to a limited block grant or per capita caps in exchange for greater state regulatory freedom and reiterating work requirements as a goal.

To be clear, Congress never added work requirements to Medicaid, though they have been proposed and other social programs have been altered in this way. Recently, former Speaker Paul Ryan envisioned altering Medicaid to include work requirements as part of his plan for replacing the ACA, but such proposals failed. Congress is not neutral on this matter —Medicaid purposefully has not been amended to include work as a condition of enrollment; in fact, the ACA moved away from such deservingness determinations —in other words, away from the discourse of malingering and toward universalism. Likewise, even though politicians have tried to convert Medicaid to a block grant program, Congress never has done so. HHS is not empowered to act where Congress has declined or failed to amend the law.

Yet, rather than expand the scope of eligibility, coverage, access, or other programmatic features as prior administrations have done, the Trump administration undermined Medicaid's core features through administrative policies issued when Congress would not modify Medicaid and could not repeal the ACA. No prior administration attempted to implement work requirements through 1115 waivers. Nevertheless, recent waiver approvals were aimed at rolling back Medicaid expansion by limiting eligibility and transforming Medicaid from a safety net program to something that operates more like more limited welfare programs, imposing work requirements and "training" beneficiaries for commercial insurance, especially for the expansion population. HHS encouraged states to condition eligibility on novel "personal responsibility" rules, eventually extending work requirements beyond the expansion population to adults in nonexpansion states like South Carolina.

Federal courts have vacated these waivers, holding that the HHS process for approving demonstration projects with work requirements was arbitrary and capricious. Yet, the Supreme Court took Arkansas and New Hampshire's petitions for certiorari at the urging of the Solicitor General, and the federal briefs to the Supreme Court are informative for considering the breadth of waiver authority going forward.[11] The U.S. argued that courts must be utterly deferential to the administrative authority of the Secretary in the realm of demonstration projects. The degree of deference demanded by the brief is remarkable, calling judicial review of waivers "circumscribed" and insisting courts ask only if the Secretary has a "rational basis" for deciding a waiver will promote Medicaid objectives. While the language of 1115 grants the Secretary broad power, it does not provide unfettered authority. Rather, section 1902 of the Medicaid Act can be waived only if a state application furthers the purpose of the Medicaid program.

To that end, the brief also argued that work promotes fiscal stability for the state and shifting to private insurance for beneficiaries. The design of the waivers in question —requiring at least 20 hours of work per week that may be fulfilled with volunteering —conflicts with this claim. By definition, volunteering provides no income and no benefits, so the denial of Medicaid eligibility would result in no public coverage and no path to commercial coverage. Government labor statistics also contradict this position, showing year after year that ESI is unavailable to part-time and low-wage workers. Further, fiscal stability means lowering costs through disenrollment; but, the evidence weighs on the side of Medicaid expansion, which many studies show is a fiscal net benefit for states and a loss for nonexpansion states.[12]

The U.S. brief also asserted that these waivers teach beneficiary "personal responsibility," and claimed that work

requirements allow states to conserve resources to serve people who are “needy” —a distinction meant to express that the expansion population does not qualify as needy and therefore is not deserving. Here, the fear of malingering is particularly clear, and the Elizabethan Poor Laws echo loudly in this approach to social programs, having been the progenitor for American laws categorizing the poor as unable to help themselves and deserving of assistance or able-bodied and unworthy of assistance. The 1601 Act for the Relief of the Poor provided money and services to “deserving” poor but sent “undeserving” and “able-bodied” poor to workhouses to avoid dependence on handouts.[13] Deserving individuals included young children, the disabled, widows, elderly, and others unable to care for themselves. The colonies continued these classifications and categories of deservingness, which then carried into state welfare laws. These choices also appeared in early federal laws addressing health, such as the Sheppard-Towner Maternity and Infancy Act, and in grant-in-aid programs such as Aid to Families with Dependent Children (welfare) and Kerr-Mills, the precursor to Medicaid. The same categories are part of Medicaid today, though the ACA rejected deservingness for eligibility.

The use of “deserving” and “able-bodied” has become part of the law governing social programs despite the racialized history of these terms. Understanding this history is relevant to interpreting notions of self-reliance and the implications of such classifications in health policy today. The words “able-bodied” were used to advertise and valuate the sale of enslaved people, especially healthy men. After the Civil War, the Freedmen’s Bureau classified freed enslaved people as “able-bodied” to determine the degree of their eligibility for federal assistance, which was time-limited so they could not “forget how to work.”[14] The term able-bodied also was used in the South as part of the Jim Crow penal system, which sent able-bodied freedmen into “convict lease” programs providing involuntary free labor to private industry after conviction —effectively re-enslaving freedmen. Being deemed able-bodied was a double-edged sword, as the work performed by slaves and those caught in the convict-lease system was unpaid, yet able-bodied freedmen were expected to be self-reliant though they had no accumulated wealth or reliable source of income. Southern Democrats blocked efforts to create national health insurance after World War II out of fear that robust social programs would elevate agricultural, domestic, and other low-paid workers and help to eliminate segregation (which Medicare ultimately did).[15] Thus, return to the use of “able-bodied” to resist the universal coverage goals of the ACA is especially pernicious.

The Trump administration’s brief pointed to the work requirements in Temporary Assistance to Needy Families (TANF, cash assistance) and Supplemental Nutrition Assistance Program (SNAP, food assistance) as evidence of success. Statutorily, those programs include the option for states to implement work requirements but Medicaid does not. And, extensive evidence shows that work requirements hasten disenrollment and do not increase employment.[16] Further, the ACA already determined that people who qualify for Medicaid need government assistance, so HHS cannot reverse that legislative determination. In short, the words “personal responsibility” indicate self-reliance scrutiny of beneficiaries within social programs and echo historic fear of malingering.

In addition, the administration asserted that work “promotes health,” but this turns the evidence on its head. Barriers to health insurance coverage endanger health; many studies show that insurance coverage improves access to care and being uninsured causes people to delay or avoid care. Nevertheless, the brief stated:

Even accepting the court of appeals’ premise that the Medicaid statute’s sole objective is to provide health-care coverage, it does not follow that the Secretary may approve only demonstration projects that directly advance the provision of coverage —not those that may indirectly advance that goal. [the] text broadly authorizes “any *** demonstration project which, in the judgment of the Secretary, is likely to assist in promoting the objectives of ”Medicaid. The text contains no exception for projects to test measures that are intermediate means of advancing the Medicaid objective of furnishing medical assistance. To the contrary, by authorizing projects the Secretary deems “likely to assist in promoting” Medicaid’s objectives, the text naturally encompasses measures that are means of pursuing that end.[17]

Improvement of Medicaid beneficiary health was never the Trump administration’s goal. But the argument for deference to HHS authority to approve demonstrations that may indirectly support health is important to the Biden administration’s take on administrative authority, discussed in the next part.

Indirect Health Benefits and Proxies

On February 12, 2021, the Biden administration began notifying states it was evaluating whether to withdraw authorization for work requirements. HHS eliminated the 2018 policy inviting waiver applications for community engagement requirements and used the novel coronavirus pandemic as a lens for reevaluating the dangers of causing Medicaid disenrollment through work requirements. HHS then began notifying states with such waivers that it determined work-related requirements "would not promote the objectives of the Medicaid program" and approval was withdrawn.[18]

The individual state revocation letters, which began with Arkansas and New Hampshire (litigants before the Supreme Court), are heavily footnoted with extensive evidence regarding the harms enrollment barriers cause Medicaid beneficiaries. These letters contrast sharply with the lack of evidence for the Trump administration's assertion that work requirements are a way to promote health. HHS also included the evidence that most beneficiaries who can work already do so, highlighting the sham reasons for instituting work requirements, which were predicted by every state to limit Medicaid enrollment —also a policy goal of HHS, which had asserted that the expansion population was not truly needy and so not deserving of Medicaid.

Yet, the Biden administration did not petition the Supreme Court to dismiss the work requirement case in its entirety, which would have left the circuit court's decision in place. Rather, the new federal position sought to vacate the appellate court's finding that work requirements could not satisfy the purpose of Medicaid and remand to the Secretary of HHS for further consideration.[19] This procedural posture was a surprise to scholars and advocates, because the Biden administration is contesting the judicial decision that the Secretary does not have authority to approve waivers that indirectly "improve" health outcomes, much like the Trump administration had done. In short, the administration asserts that the scope of the Secretary's authority to grant demonstration project waivers is broad, the D.C. Circuit's decision threatens that broad power, and the Secretary's authority should not be curtailed given how circumstances are substantially changed due to both the pandemic and HHS policy shifts.

The question of the HHS Secretary's authority to issue waivers that may have an indirect benefit for the health of enrollees is the same claim underlying the Trump administration's assertion that work requirements support health. This point of alignment is notable and worth analyzing.

As noted above, demonstration projects imposing work requirements are not authorized by the Medicaid Act and create an unlawful condition of enrollment for individuals who are entitled to medical assistance. The Trump administration's assertion that work benefits health and serves the purpose of the Medicaid program was plainly a sham. Extensive evidence from other social programs that statutorily allow work requirements, such as SNAP, shows that work requirements hasten disenrollment and deepen poverty but do not increase employment.[20] As such, when states predicted in their Medicaid waiver applications that thousands of people would be disenrolled by virtue of work requirements, they were relying on the very evidence put forth by the Trump administration in its defense of work requirements. Also, Arkansas' brief implementation of work requirements almost immediately disenrolled 18,000 people, many because the administrative burden was too great, and the disenrolled neither found work nor enrolled in commercial insurance.[21] (New Hampshire had the same experience but halted implementation before disenrollment occurred, as did Indiana.) This is the kind of deceptive administrative reasoning rejected by the Supreme Court in 2019, when the Census Bureau attempted to add immigration status to census documents.[22]

Executive orders and agency actions have made it clear the Biden administration has a different approach that includes centering health equity, rebuilding the ACA, and encouraging completion of Medicaid expansion in its health policy. The claim for broad secretarial discretion may be operationalized to support states submitting waiver applications to pay for determinants of health such as food and housing. Plenty of good evidence demonstrates that food security and housing improve health, but the question is whether such a broad read of administrative authority is necessary to pursue demonstrations supporting underlying determinants of health. Good nutrition directly impacts health, and poor nutrition can cause certain diseases such as type 2 diabetes. Low quality housing and being unhoused can exacerbate chronic conditions such as asthma. These are direct effects on health, and may be within the scope of secretarial authority to grant state requests to cover such services —without making broad claims about

indirect effects on health.

Broad secretarial authority under the Biden administration likely would support social programs and beneficiary health and seems unlikely to rely on sham reasoning based on regulatory issuances such as the withdrawal of work requirement approval letters. But extending the reach of Medicaid, which has a statutorily defined purpose and limited funding, should not become a proxy for difficult policy debates about amending or revising other social programs. And expanding secretarial authority around the concept of indirect health effects could become a dangerous game.

For example, Arkansas has granted a waiver to provide premium assistance for the expansion population to purchase insurance on the exchange, and the state posted a waiver application for public comment on June 14, 2021 that asks HHS exercise this “indirect benefit” authority. More specifically, Arkansas would have HHS exercise its authority in multiple and potentially conflicting ways: the application seeks to pay for connecting beneficiaries to social supports with a focus on particular vulnerable populations but also wants to require beneficiaries to show they “value” having coverage through Medicaid by paying out of pocket while also having health plans link beneficiaries to work through “economic independence initiatives.”[23] The waiver application does not seek work requirement approval, but Arkansas states it would do so should such a policy return to favor. These features seek to institute protocols that target fear of malingering.

Fear of malingering is not strictly policy that breaks along political lines. For example, President Clinton encouraged welfare reform that helped to usher in work requirements under the Personal Responsibility and Work Opportunity Reconciliation Act (PRWORA).[24] Welfare was based on old-fashioned Mothers’ Pensions, later Aid to Dependent Children, which prevented recipients from working to preserve women’s limited role in society. Both Democrats and Republicans came to see this approach as problematic, but PRWORA embraced an anti-malingering policy that ended the cash assistance statutory entitlement, encouraging states to institute work requirements and time-limited eligibility while limiting federal funds. Researchers have found that PRWORA made low-income populations more vulnerable to the Great Recession, because many low-income individuals became more impoverished yet had no path to the safety net and no possible employment when the economy crashed.[25]

Advocates who support the Biden administration’s broad administrative authority should bear such examples in mind, as the Arkansas waiver application and others like it may put the Biden administration’s approach to the test. How far can the Secretary go in supporting “indirect effects” on health? Many who want to support vulnerable populations see Medicaid as a source of funding for basic needs, understanding that all determinants of health are relevant factors in the health of low-income people and are difficult to address individually. But, another administration could share the perception that Medicaid is not public insurance, and it could use the very same authority to shred the safety net —a lesson that must be learned from the last four years.

Conclusion

Singling out “able-bodied” adults for self-reliance scrutiny through work requirements reverted to a pre-ACA, exclusionary approach to accessing health care that has deeply discriminatory roots. This is an approach that defies the law as well as data regarding work and insurance coverage, and it is harmful to low-income people who rely on social programs. Though the Biden administration may have evidence-based individual and public health policy goals, advocacy before the Supreme Court arguing for a very broad and largely unreviewable scope of administrative authority raises questions. Section 1115 is not a green light for administratively implementing an alternative Medicaid program. The policy pendulum swings with each administration, and the next one may contradict Medicaid’s statutory objectives and deny coverage to vulnerable populations.

Note

The author has no conflicts to disclose.

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DETAIL

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No Excuses: A Brief History of Playing Through Risk in College Football

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ABSTRAK (ENGLISH)

Celebrations of playing through risk, skepticism of athletes perceived as faking injuries, unregulated training regimens, the mythos of amateurism, and lack of accountability for preventable health harms have long characterized many college football programs. Setting policies that effectively prioritize player health will require taking this history into account.

TEKS LENGKAP

In the early 1930s, the American Football Coaches Association (AFCA) was closely tracking public alarm over the hazards of college football. Calls for reform grew particularly loud following the death of Richard Brinsley Sheridan, Jr. in 1931. In the fourth quarter of that year's Army-Yale football game, the young cadet sustained a broken neck while making a tackle. He never regained consciousness and died several days later.[1] Dr. Mal Stevens, then-president of the AFCA, warned attendees at the association's annual meeting that "all the furore" would adversely affect recruitment efforts: "we can anticipate that a lot of mothers are not going to let their sons play football."[2] The public might begin to perceive the sport as unacceptably dangerous.

In response, Stevens announced that the AFCA would initiate a survey of injuries and fatalities.[3] He also co-authored a 1933 text, *The Control of Football Injuries*, to directly address safety concerns. Reviewers at the time noted that this work "grew out of the criticism of the game of football and its associated injuries."[4] Alongside its specific health guidance, ranging from best dietary practices to how to set up a locker room, *The Control of Football Injuries* also reveals deep-seated beliefs about player safety. These included the conviction that some players were prone to fake injuries, and that a stoic approach was appropriate for minor or commonplace injuries that were presumably of little consequence.

Even in a medical text written in the wake of a highly publicized college player's death, physicians reinforced the view that exaggerating or faking an injury was shameful. In conjunction with powerful financial and institutional pressures, this longstanding cultural perception continues to inform attitudes toward risk in college sports today. From brain trauma to heat stroke, and most recently Covid-19, such narratives have facilitated the exposure of young athletes to the risks of serious health harms under the aegis of educational institutions. Setting policies that effectively prioritize player health will require taking this history into account.

"A Spartan Attitude"

In their overview of football's hazards, Dr. Stevens and his colleague Dr. Winthrop Morgan Phelps highlighted the importance of promptly reporting and treating injuries. They warned against a popular idea of "guts" that might incline athletes to attempt playing through serious injuries.[5] On this view, hiding an injury and continuing to compete was a sign of honor.

While acknowledging that this notion was a mistake, Stevens and Phelps contended that attempting to conceal an injury was "more admirable" than "to feign one." Consequently, they urged athletic trainers to adopt a "Spartan attitude" toward "ordinary injuries." Explaining that younger boys were particularly apt to fake injuries, the doctors attributed this tendency to boys' desire for publicity, and in some cases an attempt to escape from their failure to develop into first class athletes. "A Spartan gains the respect and affection of his intimates and the malingerer only incurs their contempt."[6] Even this overview of football injuries prompted in part by a player's death reminded readers that seeking treatment for a small or non-existent injury was associated with disgrace. To help prevent such malingering on the part of athletes, Stevens and Winthrop advised that physicians and trainers curtail "sentimentality and self-pity in private or public."[7] While the two doctors urged athletes to neither hide nor feign injuries, they reserved their sharpest censure for the "pseudo-athletes" they claimed engaged in the latter.

Such suspicions of feigned injuries often accompanied beliefs that competitive sports helped build moral character in ways that included playing through injuries. These norms permeated understandings of the "life lessons" imparted by football. As Carl Snavely, the head football coach at Cornell University, put it in 1936, "If these values can be taught

on the field of play rather than on the field of war, what difference does it make if the boy gets a few bruises and sprains?"[8] Seemingly minor injuries were considered negligible in comparison to such values as courage, discipline and loyalty that coaches believed football imparted.

The specific social concerns put forward to justify the importance of a stoic form of character building through contact sports varied over the decades. For example, the threat of totalitarianism in the late 1930s and 1940s contributed to an emphasis on football as a means to prepare boys to defend the country.[9] While competitive athletics offered a way to teach young athletes desired social values at a lower risk than active military service, key virtues in both contexts included the importance of withstanding physical risk and a willingness to sacrifice for the greater good. In 1940, Lafayette College president William Lewis Mather told the AFCA that

It is trite, of course, to say that the Battle of Waterloo was won on the playing fields of great private schools, of Eton, in England; but it isn't trite to say that the athletic officers of the American colleges today have it in their hands to decide whether or not the young men of America will go forth prepared, either for warfare when the guns are booming, or in the other warfare that we must face, economic and social and political.[10]

In the 1950s, Cold War anxieties and social concerns, such as the potential for juvenile delinquency, loomed larger after the booming guns of World War II had ceased.[11] In 1958, Brandeis football coach Benny Friedman stated that rather than joining a gang or wearing a leather jacket, boys "should be out on the playing fields, knocking heads."[12] The perceived character building benefits of football were so powerful that they enabled coaches to frame hits to players' heads as healthy and as a far better alternative to life on the streets. Sports medicine doctors promulgated similar views. Physician Thomas B. Quigley, former chair of the American Medical Association's Committee on the Medical Aspects of Sports, wrote in 1966 that "the playing field is better than hot rod activities, or the tavern."[13] Teen car culture, gangs, joy riding, and drinking were all associated with irresponsibility and idleness. Feigning an injury to avoid football participation was seen as particularly suspicious in a context where the specific character building advantages of the sport were explicitly framed in opposition to the indolence of the streets and barrooms.

With "knocking heads" conceived as a more wholesome activity for youth than donning a leather jacket, coaches often expressed greater concern about the possibility of an athlete malingering than the possibility that he might have sustained brain injury. Writing in the *Journal of School Health* in 1953, physical educator R. T. DeWitt described witnessing one high school football player fail to get up after a hard tackle during a practice session. The head coach, however, "apparently believed that the boy was feigning unconsciousness" and sought to pull him to his feet and insist that he return to the game.[14] DeWitt made clear that it was obvious to him, "a lay person having only a smattering of knowledge regarding the symptoms of brain injury, that something was wrong with the boy." The player was subsequently diagnosed with a concussion. DeWitt described other similar incidents, and contended that only a national movement might effectively address the flawed social structure in which authorities responsible for player safety rationalized away serious injuries.[15]

The refocusing of interscholastic athletics that DeWitt called for did not occur. Instead, for decades, the hazards of football provided not only entertainment appeal, but also prominently featured in coaches' justifications of the sport's moral benefits. The "bumps and bruises" of football were characterized as inherent to the game and even as crucial to a team's success.[16] College administrators and policymakers did not mandate national protocols to prevent injuries. Instead, persistent narratives that relatively young, healthy athletes could and should overcome the hazards of competitive athletics contributed to the absence of more rigorous safety protections for athletes. In a culture that celebrated "knocking heads" as wholesome for football players, a "Spartan attitude" predominated and policies to minimize the physical risks were not prioritized.

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"A Revered Tradition"

In conjunction with these social attitudes toward risk, financial incentives crucially motivated the NCAA to eschew legal responsibility for player injuries. The very history of the term "student athlete" derives from the NCAA's effort to

avoid paying worker's compensation benefits. In the 1950s, the widow of Ray Dennison, an athlete who died of a head injury sustained while playing football for the Fort Lewis A&M Aggies, filed for compensation. As writer Taylor Branch explained in an influential 2011 commentary, coining the term "student athlete" helped the NCAA successfully contend to the Colorado Supreme Court that there was no employer-employee relationship between students and their schools. Consequently, colleges were "not in the in the football business" and did not have a duty to compensate athletes for injuries.[17]

Dennison's widow lost the case, and the "student athlete" defense featured in subsequent influential cases involving the NCAA.[18] The framing of college athletics as a noble exemplar of amateurism persisted even as the money involved in big-time college sports grew. Notably, a 1984 Supreme Court decision contended that the NCAA "plays a critical role in the maintenance of a revered tradition of amateurism in college sports."[19] In this case, the Court ruled that individual colleges and universities could negotiate their own television contracts, opening the college football television market to free competition with multimillion dollar contracts at stake. Yet writing for the majority in this decision, Justice John Paul Stevens emphasized that "the preservation of the student-athlete in higher education adds richness and diversity to intercollegiate athletics" and that this ideal was key to the place of college sports in American life.[20]

These two ideologies —the belief that the NCAA was responsible for upholding ideals of amateurism, and the view that one of the key lessons of college sports was how to persevere through adversity —both profoundly influenced expectations that athletes play through risk. From the NCAA's inception following a spate of high-profile college football injuries and deaths in the early twentieth century, the physical risks of athletics were treated as essential and desirable components of the game. In 1905, President Roosevelt, who helped lead the reforms, gave a widely quoted commencement address at Harvard in which he affirmed his belief in "rough sports." He expressed his scorn for young men who avoided risk while wrapped "in cotton wool," adding that he had "a hearty contempt for him if he counts a broken arm or collar bone as of serious consequence, when balanced against the chance of showing that he possesses hardihood, physical address, and courage."[21] These were the qualities that college sports leaders sought to inculcate in students. Conversely, the message to athletes who avoided risk, or who took injuries seriously, was that they would be subject to disdain.

One of the life lessons college amateurs were expected to learn, then, was that broken bones were negligible in comparison to ideals of "hardihood" and toughness. Yet a longstanding view remains that the NCAA was established in order to safeguard athletes' health. The NCAA itself has promulgated this narrative, contending on its website that the association was founded in 1906 "to keep college athletes safe."[22] As Michael Oriard has argued, however, the early twentieth century reforms that led to the creation of the NCAA sought to address some of football's most brutal elements without lessening its spectator appeal, and ultimately "without making it truly safer for the players."[23] The NCAA's failure to implement enforceable safety protocols is consistent with its founders' view that conceptions of courage ultimately took priority over injury prevention. Through the present, American college sports programs continue to lack basic oversight to protect players. Notably, "there are no NCAA rules with penalties governing coaches' behavior and player injuries, only guidelines."[24] In 2021, NCAA president Mark Emmert testified before the U.S. Senate that there was no national enforcement system for health protocols.[25]

Occasionally, legal or policy pressures have prompted the NCAA to mandate measures to protect athletes against life-threatening conditions. For example, a legal settlement with the family of Rice football player Dale Lloyd II, who collapsed and subsequently died from complications related to sickle cell trait in 2006, led the NCAA to implement a universal screening program for this genetic condition.[26] Apart from such reactive measures, however, neither the NCAA nor policymakers have required proactive, national policies to protect athletes from the broad range of known risks associated with college sports. In this vacuum of accountability, nearly a century after Sheridan, Jr.'s death, colleges have frequently gambled with athletes' welfare. This policy gap has proved especially consequential for college football, where both the physical hazards and the financial stakes are particularly high. The risks range from the cumulative and long-term —notably repeated traumatic brain injuries —to the immediate and devastating. Heatstroke fatalities are a particularly striking example of the latter category because they are entirely preventable

through proper training precautions. Since the 2001 death of Minnesota Vikings offensive tackle Korey Stringer drew attention to the issue, no NFL players have subsequently died of heatstroke.[27] Yet amateur college players lack the workplace protections available to professional athletes. Instead, many college football coaches continue to insist on high-risk preseason workouts that are "deeply embedded in the football culture," based on the belief that pushing players to their physiological limits will lead to "mental and physical toughness, discipline, and accountability."[28] In the absence of enforceable safety standards, as athletic trainer Scott Anderson has observed, an average of two NCAA football players die these types of preventable deaths each season.[29]

The 2018 heatstroke death of University of Maryland offensive lineman Jordan McNair drew public attention to the broader toxic culture surrounding such high-risk workouts. ESPN described an atmosphere of fear and belittlement, in which a player deemed overweight was forced to eat candy bars and in which players unable to complete particular workouts or drills were subjected to taunts mocking their masculinity.[30] Underlying such an environment was the threat of players being perceived as weak, inadequate or exaggerating injuries. Centuries-old American histories of racist stereotypes meant that black athletes were more likely to be perceived by white coaches, staff and spectators as lazy or lacking a work ethic.[31] As writer Tyler Tynes observed in an essay on McNair's death, black athletes remain disproportionately subjected to the expectation that they repeatedly "prove they are not weak," to deadly effect.[32]

In a training environment such as Maryland's, staff disbelieved the most blatant evidence of serious health harms. For example, a former Maryland player recalled witnessing an injured player pass out during a tug-of-war competition: "I saw his body slowly giving away, and the strength coach was like, 'Keep pulling, keep pulling!'"[33] Even a player in the process of losing consciousness might be accused of malingering and expected to continue with a drill. Implicit bias makes the pain and distress of black athletes even more likely to be disregarded or mistrusted. These factors have all contributed to a college sports environment where "kids like McNair will die in the hot sun," with the coaches responsible for their well-being subsequently offered jobs elsewhere.[34]

Moreover, the tragic death toll of college football represents only the tip of the iceberg when it comes to the policy vacuum that fails to protect athletes. While student deaths are the most devastating and visible outcome of unsafe sports environments, many more students are regularly exposed to serious non-fatal risks while competing. Brain injuries in football and associated neurological diseases, from chronic traumatic encephalopathy to amyotrophic lateral sclerosis, have received growing medical and legal attention in recent years.[35] In addition, bone and joint injuries remain extremely common in this collision sport. A 2016 study found that on average, half of college football players experienced at least one injury per season that required an absence of at least one day, representing a high burden of injury.[36]

"A Little Covid Problem"

Celebrations of overcoming physical risk, skepticism of faking or exaggerating injuries, unregulated training regimens, the mythos of amateurism, and lack of accountability for preventable health harms have long characterized many college football programs. In 2020, a novel pandemic virus entered into this already dangerous mix. In many ways, rather than forcing a reckoning with this history, the virus that causes Covid-19 was simply added to the lengthy list of preventable health harms to which players were routinely exposed.[37] Despite the cautions of public health experts and numerous outbreaks associated with summer football workouts, many administrators determined to proceed with the fall 2020 season. As the athletic director at University of California, Berkeley put it, "we're going to make it work. And we're not going to be fazed by a little Covid problem."[38]

Not only did numerous conferences strive to "play through" the virus in the fall 2020, but some put forth the view that pre-season exposure to the virus and subsequent immunity would yield a "competitive advantage" for teams.[39] Clemson University head football coach Dabo Swinney even expressed skepticism of game cancellations due to Covid-19 protocols: "COVID was just an excuse to cancel the game."[40] Teams that bowed out of a match due to Covid-19 protocols were accused of faking cases.[41] Guidelines that prioritized caution following a positive Covid-19 test contradicted the "no excuses" ethos that has been associated with college football for decades.

The NCAA did not track Covid-19 cases among athletes at its member schools. By December 2020, the *New York*

Times estimated that at least 6,629 college athletes, coaches and staff had tested positive for coronavirus. Yet numerous schools failed to share data, making the total number unknowable.[42] Although many athletes who contracted Covid-19 had relatively mild symptoms, others experienced season- and even career-ending symptoms. For example, after testing positive for Covid-19, Clemson defensive end Justin Foster struggled with ongoing symptoms and missed all of the fall 2020 season. Due to a combination of asthma, allergies and Covid-19, he announced his decision to retire from football in February 2021. “The decision came after months of recovery and treatment,” he explained.[43]

This most recent failure to protect athletes from known, direct risks to their short and long term health is consistent with the past behavior of the governing bodies of college sports. It is also consistent with longstanding cultural expectations that athletes “play on” and overcome physical risk. Of course, the nature of an infectious disease meant that the hazard was not limited to the playing field. The Covid-19 risks imposed upon athletes extended “outward to trainers, coaches, staff, families, and ultimately the broader community,” making the failure to prioritize athlete health all the more consequential.[44] Yet consistent with its approach to brain injuries, heat stroke and other health risks, the NCAA implemented no enforceable policies to control the spread of Covid-19. For instance, athletic programs did not have to conduct a minimum number of tests or adhere to consistent quarantine protocols.[45]

Keeping College Athletes Safe

Although health and safety policies for college athletes remain few and far between, hints of challenges to the NCAA’s narratives surrounding the student-athlete tradition have begun to emerge. In June 2021, the Supreme Court ruled that college athletes could receive “enhanced education-related benefits,” rejecting the NCAA’s argument that such payments represented a threat to amateurism.[46] But this decision did not address protections for athlete health. As Representative Lori Trahan (D-Lowell) observed, “we must go further by guaranteeing them [athletes] the right to organize and collectively bargain for the compensation, safety, and playing conditions they’re owed.”[47] Martin McNair, the father of Jordan McNair, a college football player who died of heat stroke in 2018, expressed a similar view. “How do we pay a kid if we can’t keep him safe?” he asked.[48]

Ninety years after the death of Sheridan, Jr., the NCAA remains unwilling and unable to ensure the basic safety of its participants. These failures have been particularly devastating for the health of football players engaged in a collision sport with little oversight for coaches and administrators who have failed to adhere to minimal safety standards. The preventable deaths of young athletes from heatstroke epitomize this institutional disregard for health. Permanent change is necessary in order to truly make college athletes’ health as well as the public’s health a priority. But this will not happen without fundamentally reckoning with the values that celebrate “playing through” risk and that cast suspicion upon athletes who speak up about health hazards.[49] Since the origins of both tackle football and the NCAA, overcoming physical hazard has been promoted as one of the key character building benefits of college sports. Consequently, to a great degree the possibility of an athlete shirking or receiving undue “coddling” has been regarded as a greater threat than depriving an athlete of needed medical attention.[50] Coaches and even doctors warned that feigning an injury was shameful and worthy of contempt. Under this prevailing framework, the alternative —acknowledging, treating, and ultimately preventing the routine hazards associated with football —might undermine the value system that had justified incorporating a collision sport into schools.

As the experience of athletic programs navigating Covid-19 has made clear, it is past time to insist that college sports leaders embrace and act upon another value system. To truly protect athletes, an entirely different set of “life lessons” from those associated with warfare and a “Spartan” mentality is required. For decades, coaches and administrators have claimed “no excuses” for athletes, even when their very physical safety was threatened. Instead, there ought to be no excuses for continuing to tolerate preventable deaths, acute injuries, and long-term chronic disease in institutions of higher education.

Note

The author has no conflicts to disclose.

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Beyond COVID-19: The State of Telehealth Equity and Best Practices in Underserved Populations

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ABSTRAK (ENGLISH)

Telehealth is now a fundamental health approach to address health-related needs in a way that is consistent with the restrictions imposed by the coronavirus pandemic (COVID-19) globally.

TEKS LENGKAP

COVID-19 is causing the world to embrace telehealth like never before. The state of telehealth among vulnerable populations globally provides best practices and examples for telehealth implementation. From live-interactive video conferencing to remote patient monitoring, many different types of care settings benefit from telehealth technology.[1] In underserved populations, particularly low-income urban and rural US, African American communities, and developing countries, telehealth can help expand access to health care by connecting patients to providers and services from a distance while promoting patient-centered care.[2] With improved widespread broadband connectivity and large use of mobile phones and social media in underserved populations, the opportunity to grow telehealth seems ripe and exponential. To combat the COVID-19 outbreak and health disparities in vulnerable communities, offline telehealth and mobile social media should be safely expanded and normalized.

The US and Telehealth

One fifth of Americans live in rural areas and are at increased risk of losing access to some type of health care.[3] Without sufficient capacity due to provider recruitment/retention difficulties, low patient volume, or inadequate local resources to provide access to crucial services, rural communities are not adequately equipped to address their unique health needs.[4] Low-income populations in cities live in poverty with few affordable healthy alternatives for food and diet (food deserts), and difficulty accessing quality health-care facilities and telehealth services. Hospital emergency rooms and urgent care centers are often utilized for primary care, which lead to hefty patient expenses. These obstacles inhibit this vulnerable population from seeking initial and follow-up care.[5] Therefore, the ability to receive care in rural and low-income urban communities that avoid long travel times and exorbitant costs are extremely valuable. Telehealth expands access to services and addresses health-care disparities including those based on socioeconomic status, geographic isolation, an aging population, and race and ethnicity. With greater acceptance of health-care delivery through virtual connections, the utilization of telehealth services has dramatically increased in the US.

In rural Maryland, Frederick Memorial Hospital has launched a remote patient monitoring telehealth platform to improve care management for chronically ill patients. Before the COVID-19 pandemic, the program had decreased ER visits and cost of care by half, and reduced hospitalizations by nearly 90% among chronically ill patients.[6] In addition, enrolled patients receive a tablet with mHealth software and connectivity to Bluetooth-enabled digital health devices; hospital care providers collect, monitor, and communicate information to their patients through video, phone, or text. This initiative is successful and enables providers to identify health issues before they become emergent.[7]

Philadelphia's Jefferson Health Hospital uses Jeff-Connect telemedicine platform to successfully cut health care costs. The program has found new utilization of the platform was uncommon because most health concerns could be resolved in a single consultation. Each Jeff-Connect visit is a $49 flat fee, leading to cost savings ranging from $300 to more than $1,500 for 650 patients.[8] Before the coronavirus pandemic, no insurer covered Jeff-Connect charges, but that has since changed. Now, insurers are covering the telemedicine bills. This serves as a cost prevention measure and enables urban-based patients to participate in a health-care system they would not otherwise.[9]

Unfortunately, in the wake of the COVID-19 outbreak, barriers to widespread use of telehealth still remain. Many factors such as statutory and regulatory restrictions on how Medicare covers telehealth, inadequate broadband connectivity, cross-state practitioner licensure hurdles, and cost of equipment acquisition and maintenance have been illuminated during this pandemic. According to the Federal Communications Commission (FCC), 34 million Americans still lack access to quality broadband and affordable infrastructure that impedes health care delivery.[10] Given the shortage of health and medical resources, a mixed online-offline focused plan should play a central role in ensuring underserved communities can routinely access the care they need through telehealth.

On April 22, 2020, the Health Resources and Services Administration (HRSA) at the U.S. Department of Health and Human Services (HHS) received nearly $165 million to combat the COVID-19 pandemic in rural communities. Some of this funding is earmarked to support 14 HRSA-funded Telehealth Resource Centers (TRCs) for telehealth technical assistance to help rural and underserved areas during the pandemic.[11] Additionally, the US Centers for Medicare &Medicaid Services (CMS) has pledged to expand Medicare's telehealth benefits to cover emergency needs. Under this provision, healthcare providers in a physician's office, hospital, nursing home or rural health clinic, as well as from their own homes can offer telehealth to Medicare beneficiaries, of whom 23% are rural Medicare beneficiaries.[12]

Recently, Congress also passed the $2 trillion Coronavirus Aid, Relief, and Economic Security (CARES) Act, allocated $200 million for the FCC to expand telehealth services nationally. This monetary support allows for the purchase of medical devices and telecommunications equipment to enable remote care. An additional $100 million from the Universal Service Fund administered by the FCC will finance the Connected Care Pilot program to expand connectivity for health-care providers.[13] This federal funding recognizes that telehealth plays a significant role in the

response to COVID-19 and health care resilience in rural and low-income urban US populations.

There is a critical need to understand how African Americans perceive health services and digital solutions. Current research on routine medical care suggests that African Americans are less likely to engage in health seeking behavior. While health insurance coverage can play a role, other factors such as low trust in providers, high stress, high daily discrimination, and low burden of lifetime discrimination influence this behavior

African Americans and Telehealth

There is a critical need to understand how African Americans perceive health services and digital solutions. Current research on routine medical care suggests that African Americans are less likely to engage in health-seeking behavior. While health insurance coverage can play a role, other factors such as low trust in providers, high stress, high daily discrimination, and burden of lifetime discrimination influence this behavior.[14] Notably, only 8% of adults over 35 years old in the US have received all high-priority, appropriate clinical preventive services recommended for them.[15] Therefore, the US generally does poorly with individuals accessing clinical preventive services. Solutions to help get individuals to access important preventative services, particularly those covered by insurance, are key. Smartphone use is widespread in the US at 81%, with the share of African Americans owning them at a similar level.[16] Social media use among African Americans is high and also reflects the rate of use among US adults at 69% vs. 72%, respectively.[17] At the same time, African Americans are less likely to report owning a home desktop or laptop computer (58% vs. 82% for Whites) or having high speed internet at home (66% vs. 79% for Whites).[18] As a result, African Americans tend to rely more heavily on their smartphones for accessing the internet, for example, 23% of Blacks are “smartphone only” internet users —meaning they lack traditional home broadband service but do own a smartphone. Meanwhile, 12% of Whites are in this “smartphone only” internet category.[19] With these differences in reliance on smartphones for internet access, it is not surprising that there are racial and ethnic differences in how individuals use mobile technology.

Data shows that African Americans are more likely than whites to use their phone to seek information about a health condition (67% vs. 58%).[20] The prevalence of online health information-seeking, and existing health disparities inspired an examination of health information on the internet targeted at African Americans; it suggested the importance of not just access to information, but the significance of quality in helping to address the digital divide.[21] Social media can provide health consultations or appointments for patients, instant non-contact doctor-patient communication, quick decision-making, and follow-up services. High telehealth utilization acceptance among African American women suggests the need for additional research into its use, affordability, accessibility, and convenience going forward.[22] Coupled with the high ownership of smartphones and underrepresentation in clinical trials and research studies, African Americans are in a unique position to be recruited into eHealth and mHealth interventions. “According to World Health Organization, eHealth is the cost-effective and secure use of information and communications technologies in support of health and health-related fields; and mHealth is the use of mobile and wireless technologies to support the achievement of health objectives. A systematic review of African Americans’ participation in such studies revealed low representation and the need to engage African Americans by going beyond a one-size fits all approach.[23] The increased likelihood of seeking health information and services through mobile means is promising for African Americans, especially in light of studies that have demonstrated the efficacy and impact of mobile health programs grounded in behavioral theory to effect changes in beliefs among all who seek health services.[24]

Telehealth Global Implementation and Its Future

The emergence of telehealth has aided an increase in access to care. Typically, a conversation via social media concerning health begins with a user contacting a health provider or the health provider providing information about acquired symptoms via mobile application. Thereafter, the mobile application or the health provider acknowledges the inquiry by providing a response, which may include one of the following: (1) a request for a photo which captures the problem described; (2) a recommended course of action or treatment; or (3) a referral or transfer to visit a clinic or hospital. A user, in sharing such individualized health information, avails oneself to privacy and data protection concerns that lead to the need for protective measures.[25]

Nonetheless, nations must strike a balance between the positive effects and the safeguards to implementing telehealth through policy and legislation. Globally, privacy and data protection laws influence how mHealth applications are developed.[26] In the United States, consumers are protected by health privacy laws at both the federal and state levels. The US has made efforts to exceed the parameters of protecting health information in health-care settings by implementing the use of supplemental upstream protective methods in addition to the Health Insurance Portability and Accountability Act of 1996 (HIPAA),[27] a downstream protective method. In other words, there is a chain of policies from health-care providers to the state government to federal government and so forth. Although HIPAA and additional protections provided by state law exist in the US, resource-constrained areas face significant barriers in the implementation of mHealth applications in the absence of privacy and data protection laws. South Africa has taken the lead in Africa in its efforts to recognize the right to privacy in healthcare and telehealth in part to its thriving telecommunication industry.[28] Nonetheless, challenges including cost, education, and cross-cultural perspectives of the right to privacy persist. Many other nations are forced to either diminish health privacy laws to address emergency circumstances or simply continue using unregulated and unprotected telehealth applications. The U.S. Department of Health and Human Services (HHS) has issued rulings to address the immediate needs of COVID-19, broadening the scope of providers that may offer services.[29] Additionally, HHS has "relaxed" HIPAA requirements allowing for the use of devices and systems such as Skype which would otherwise be prohibited. These measures risk violating patient privacy when health professionals exceed their privileges with patient medical care data.

In the first quarter of 2020, Nigeria ranked 6th among the top 20 countries with the highest number of internet users.[30] The use of mHealth through informal platforms such as WhatsApp has become more common.[31] Stigmas associated with diagnoses of diseases such as HIV and sickle cell disease and natural cure beliefs have led many to rely on social media platforms. Currently, new mothers have formed groups on Facebook Messenger and WhatsApp to exchange information on postnatal care in order to learn how to properly feed and clean their newborn babies. Such support groups assist in risk reduction of disease and infection in youth. These groups also provide mothers in remote areas access to a doctor, who may be located far away. Not only are patients using these platforms, but health professionals are using these networking tools to disseminate information to their patients and amongst provider team members in hospitals or during emergencies.[32] Sessions facilitated by health professionals combat potential advancement of harmful misinformation.

In underserved populations, the widespread use of telehealth can deliver quality health care by connecting providers and services to patients remotely. Despite the benefit and convenience of telehealth, sharing health information offline, on social media, and via mobile increases privacy and data protection concerns. As immediate COVID-19 concerns encourage greater telehealth access, safe and uniform implementation is necessary to combat the COVID-19 outbreak and general health disparities going forward. Studies on understanding how to fully engage underserved populations in telehealth are critical to expanding equity in telehealth usage.

Note

The authors have no conflicts to disclose.

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DETAIL

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The Intertwined History of Malingering and Brain Injury: An Argument for Structural Competency in Traumatic Brain Injury

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ABSTRAK (ENGLISH)

Every year millions of people suffer minor brain injuries, many of which occur in collision sports. While there has been substantial commentary and debate about the nature of this public health crisis, it is clear that the scientific and clinical arguments reflect values preferences and judgments that are often invisible in documents which combine artful language with undue focus paid to sources of uncertainty at the cost of clarity and transparency. This essay gives a brief history of these patterns and proposes a remedy.

TEKS LENGKAP

Introduction

Scholars estimate that every year tens of millions of people globally suffer brain injuries.[1] While substantial research has investigated this silent public health crisis for decades,[2] debates in traumatic brain injury (TBI) research often reflect deeper values, preferences, and judgements which in contexts of uncertainty, and particularly in the area of sport become catalysts for controversies that often result in victim-blaming.[3] The difference historically between the patient with TBI and the malingering patient starts fundamentally with a judgment call by a clinician: either the invisible injury is real and explains the patient's troubles or it does not. That diagnostic and prognostic call has historically been structured by several overarching, implicitly-held and sometimes explicitly practiced practitioner beliefs including whether the injury is the victim's fault.[4] Different populations experience TBI stigma differently and in different ways by different people.[5] These manifest historically in discussions of class, gender, race, sport, and legal and cultural representation.[6]

Alone such matters can present brain injured patients and their caregivers with substantial challenges.[7] TBI patients must manage substantive divisions within therapeutics. Patients encounter practitioners in orthopedic surgery, psychology, psychiatry, physical therapy, occupational therapy, and neurology that themselves navigate profound differences about the importance of structure and function in these injuries, and each specialty dichotomizes differently bodily, mental, and environmental dimensions of trauma.[8] Add to this that individual cases have historically often fallen into both medical and legal domains, and it is easy to see that historical and sociological tensions between medicine and law emerge around such patients, with personal sympathies towards putative claimants and defendants resulting in profound differences of clinical experience.[9]

The specter of the malingering patient haunts this altogether messy picture.[10] Concerns about malingering patients have long been productive of stigma in neurology and that history is highly detrimental in clinical care domains and legal contexts.[11] Stigma changes the treatments patients receive. It structures their legitimacy. The existence of widespread, stigmatizing knowledge about individuals who simulate injury encourages self-harming behaviors because normative pressures assert the importance of carrying-on and keeping a stiff upper lip.[12] Stakeholders add to these pressures in ways that place coercive pressures on people to tax themselves unnecessarily or overlook injury. In litigation these matters become exacerbated and cynicism about patient claims can frustrate patient care generally and in the courts result in substantive downplaying of harm that was nonetheless real.

Over the last sixty years these issues have played out in TBI medicine and litigation. Medicine and the law have at once echoed culture currents and simultaneously shaped them, facts that imply the need for structural competency to inform TBI research and diagnosis now.[13] On one hand, the motivations that drove patients in other walks of life to seek help from doctors and redress from lawyers have structured patient encounters, experiences, and legitimacy. On the other hand, research and litigation on sport injuries has flowed back towards non sport injuries and accidents often in ways that have worked to downplay harm.[14] Exploring this historical interplay across these many domains, this paper builds on extensive research in to the history of TBI to show schematically through a few choice examples the remarkable resilience of biases and prejudices that historically shape and shaped and undermine/undermined brain injured patients' life experiences in Britain and America. The result likely led patients into further harm in their efforts to accommodate normative pressures to conform to their normal roles rather than identify with chronic

sickness.[15] Normative pressures should be understood in this essay as commonly accepted traditions and behaviors that structure behavior and that are difficult to challenge without critical reflection. In the conclusion, this paper calls for a reflexive turn in TBI research to make these axiological and economic structures radically visible and introduces one remedy.

Representations of Values in Britain and America

The concept of malingering resulted from nineteenth-century social and economic contexts in Britain and America. Suspicions of poverty were high. Relations between employer and employee were changing. Industrial accidents that caused traumatic injuries fell into a grey area of jurisprudence as new workers compensation laws took shape in statutes, torts, and contract negotiations.[16] Lawyers for plaintiffs brought actions in the nineteenth century. Employers resorted to a common defense that emphasized the "contributory negligence of the employee, assumption of risk, and common employment."[17] Was the victim blameless, a question which meant that the plaintiff's character, associations, and legitimacy deserved investigation.[18] Whether the injured patient was a hereditary defective was also considered a legitimate question. Malingering filled these special rabbit holes. As historian Roger Cooter has shown, malingering became a medical and psychological problem during the First World War,[19] yet the malingerer emerged as a category of social existence from the mid-nineteenth century.

Normative pressures should be understood in this essay as commonly accepted traditions and behaviors that structure behavior and that are difficult to challenge without critical reflection. In the conclusion, this paper calls for a reflexive turn in TBI research to make these axiological and economic structures radically visible and introduces one remedy.

Inevitably occupational injuries implied head injuries and brain injuries. TBIs brought immediate incapacities and potentially worrying longer impacts.[20] Nineteenth-century medical publications and public information made this clear from the mid nineteenth-century on. Personal character and contributory negligence were always central issue. How injuries occurred and to whom heightened the importance of context decisively.[21] The context mattered for assessing prognosis and claims of permanent disability. Doctors' roles in providing those diagnoses and prognoses implied vast powers. Doctors increasingly made decisions about legitimacy that mattered materially in patients' futures. Insurers, relying upon clinical judgment, appear to have felt themselves besieged by cases of subjective symptoms, fraud, and malingering. Payouts also corresponded often with what cynics called miraculous cures.[22]

Brain injury legitimacy and expertise occurred in contexts with normative class pressures (highly variable across Britain and America and generationally) and economic deployments that changed with industrialization and warfare. Stakeholders' interests in Britain and America were often finely tailored to accord with the letter of the law. In a quite significant sense, concussion in the courts was tantamount to the making of scientific knowledge throughout courtroom dramas, a fact that left an indelible mark on the science and medicine of TBI. While many clinicians and investigators sought to insulate themselves from those deep influences, each judgment that required expertise made concussion science and medicine that much more uncertain.

The Intersections of Traumatic Brain Injury: Class, Gender, and Stigma in the 19th Century

The spectacle of the malingerer evoked significant prejudice against chronic patients, and TBI made these intersections highly visible in the nineteenth century and after. Two instances suffice to illustrate the broad trend in nineteenth century Britain and America. Consider the August 1878 issue of *Pall Mall Gazette*, an evening newspaper published in London, which took up the troubling subject of the malingerer "or simulator of disease." Published under the ominous title "Sketches from Shady Places" the author described unpleasant figures at "common lodging-house," or on the "sick-list" of many a reputable employer, haunted London dens and preyed "on the public." The hospitals were altogether too pleasant, the author remarked. To "the man of soft and indolent disposition," the taste of "hospital life" provided the purest of temptations:

… the demoralization is intense in proportion to the severity of the habitual labours of the individual. The coal-heaver or a dock-porter always makes a more inveterate malinger than a house-painter or bricklayer. Be his trade however what it may, the new developed malingerer is always hankering after the hospital and always maneuvering to retain his place therein.[23]

The malinger, the author stated, was a beggar, a corpulent fellow likely surviving on the labor "of his daughters —a pair of weak-looking girls, seamstresses", an indolent, and indeed the tendency ran "in the blood" for "hereditary paupers" formed a class in the workhouse populations "all of them inveterate malingers."[24]

Perhaps the most singular form of malingering —which takes almost every form —is that which puts on the appearance of insanity. I have seen one such instance —that of a soldier charged with a serious offense —who, taking a hint from a comrade, assumed the mask of a lunatic, and wore it so naturally as to escape all the consequences of his misdeed. I have good reason to believe that the same sort of thing is much more frequent than most people would be inclined to suspect. I know that a good many people designedly work for the reputation of being "a little cracked," because it is an admirable excuse for all sorts of follies and most vices. I know, too, that a good many look upon the lunatic asylum as rather a pleasant sort of retreat, whence all care for the morrow is excluded.[25]

The source shows a whole worldview manufactured in an instance. It displays resentments typifying class relations in British and American industrialization, a time when with hindsight it should be recalled that: "Social insurance was unknown. Local poor relief was cruel, sporadic, and pinchpenny. Institutions for the helpless were indescribably filthy and heartless …the whole system was shot through with …an inordinate fear of the spread of idleness and a perverse notion that pauperism generally arose out of the moral failings of the poor."[26] But the argument I am offering is that these representations would be as familiar now as they would become in that period, and that far from being accurate, they signal prejudices that shape structures determining clinical and legal encounters. Laziness, poverty, obesity, sinful licentiousness, mentally illness, and cowardice —all pointed to the conclusion that it was easy to feign sickness for monetary reward.

Women TBI patients experienced these matters in similar ways.[27] Consider this second source. In 1886 a case history in the United States appeared in the *Boston Medical and Surgical Journal*. The source points to the way normative attitudes could result in self-injurious behaviors. The author Arthur H. Nicols recounted how in 1884 a freight train flipped over tracks and tumbling over brought up against this house, knocking a hole in the side-wall of the kitchen where Louisa Russell "was at the time engaged in her ordinary housework."[28] The box car did not destroy the house. Nicols noted that Russell had "not been thrown down, rendered unconscious, or even nauseated" which indicated that "the blow received was not of great severity." Indeed "there was no satisfactory evidence to show whether she was in reality struck on the head."

For the period of about a fortnight after the accident she appears to have been dressed and about the house each day. Though doing no house-work, she was able to attend to the adjustment of the award for damage to the house …It will thus be understood that when at a subsequent date, having in the meantime felt aggrieved at the same sum awarded by the referees on account of damage to the house, she preferred a claim for personal injury, it was not unnatural that her allegation should be viewed by the corporation with suspicion and held to be an after-thought.[29]

Nicols explained that the chief symptom complained of and seen by her personal physician "sixty-five" times was headache. The suspicions of others are certainly noteworthy. Nichols wrote: "The exercise involved in hanging out clothes must be pronounced at least injudicious, if there existed, as it assumed, any lesion of the brain. To interpret, however, this indiscretion as evidence of fraud or exaggeration, would indicate an imperfect knowledge of the eccentricities of the patient."[30] Nicols explained that the case appeared to be "concussion of the brain." The cause of the patient's long term problems was that "the real nature of the trouble was not for a time suspected, and consequently absolute rest, the essential element in the treatment of such lesions, was not enjoined." It would be impossible, Nicols said, "to assume this to be a case of malingering" because "stimulation of organic brain trouble is not admitted as within the range of possibility by any treatise on malingering."[31]

These two cases reflect schematically, as I have shown elsewhere with more detail, a commonplace reality that shaped personal injury law, workplace compensation, insurance claims, and after World War I public policy on psychiatric and psychological injuries suffered during warfare. These coincidently often overlapped with the burden of traumatic brain injury that had left no visible mark on the soldier. The case of Louisa Russell personalizes rather sharply the way that the expectation of the suffering individual was that they would carry-on in their houses but that

also the fact of their continued efforts could result in worsening of symptoms and suspicion of exaggeration. Public and private worlds made such distinctions. TBI patients routinely encountered a limiting argument in court that if they had the capacity to argue and advocate for themselves then the conclusion could only be that they were better than they believed. Those unable to advocate for themselves or those seen contributing effort to their households thus confounded the sick role —the expectation that people who are sick will be sick in ways that confirm illness meant the TBI patient with persistent symptoms fit no specific category of invalidism.

The Intersections of Traumatic Brain Injury: Gender, Sport and Stigma in the 20th Century

Sport plays a peculiar role in the history of TBI and stigma, because the frequency of presumed mild brain injuries shapes these constructs but the dangers of sports are equally worsened by normative assumptions about the ability of people, mainly men, to take punishment with their bodies. These facts are seen clearly in the entangled history of TBI and sport in twentieth century Britain and America. As Bachynski has beautifully noted in her study of boys and American football, the pressures to discipline the body to survive and play through its pain is packaged by domestic understandings about gender roles in American society in which boys are meant to differentiate themselves from girls through pain and militaristic pageantry.[32] The same pressures existed in Britain during the period of Bachynski's analysis in rugby and soccer, but they have a longer history, dating from the nineteenth century when the absence of fathers off on colonial pursuits demarcated that sports would teach boys to be men.[33]

Collision sports proved remarkably adept for heightening the ability for people to deny the consequences of injuries they deemed minor. A degree of manly apathy and chumminess in collision sports about these injuries inculcated in sports playing men stoicism and reticence about the seriousness of the injuries, and as these young men came of professional age, it seems likely that more than a few viewed similar injuries suffered in other contexts with similar apathy and bravado. In other words, reticence about injury created a culture in which playing through pain in sport taught stoicism about injury wherever and however it occurred.

Two chapters in a 1969 volume entitled *The Late Effects of Head Injury b*rings these matters into the open.[34] One study by John B. Cook explored the effects of minor head injury sustained in sports resulting in postconcussion syndrome, a collection of persistent, often debilitating, symptoms following longer after a head injury than would normally be expected. Cook reported that something akin to postconcussion symptoms were seen in head injured sports players but noted that they were "shortlived" and "absence from work is only occasional and is not prolonged." Cook's conclusion from this study was that it implied that hospitalization of non-sports cases could result in poor recovery and lead to an unshakeable conviction of unfitness for work. He concluded: "The postconcussional syndrome with its stereotyped and persistent symptoms relates neither to concussion or brain injury, nor possibly even to the frightening aspect of the accident; its existence depends upon by whose hand the injury was caused." Blame avariciousness, he moralized.

It is important to see that Cook's argument could not have been viewed as farfetched. Injuries in sport were so common that whole books devoted to the prevention of athletic injuries had already been published for decades by the time he elaborated his argument. He was also toiling familiar British soil, pointing for example to neurologist Henry Miller's coinage of "accident neuroses" as a pithy means of situating patients who allegedly could not be as hurt as they imagined or purported.[35] Yet some thought about the way that British sports had evolved by the 1960s would make it fairly easy to see that the coercive pressures on sportsmen were vastly larger than those on other populations. In this sense, Cook was unable to see through the limitations of his own cultural preferences. From the adulation of fans and families, to the pressures to represent national and working cultures, to the love of teammates in a martial sense, and indeed to the threat of being replaced by a younger player, the average elite athlete in the 1960s and after had good reasons to play through injuries and to deny the seriousness of neurological symptoms hidden from view by the skull. Footballer's migraine might have been annoying, but it was not necessary to tell anyone about it and it could be treated with narcotics. Who would know?

Sport thus shaped the representation of non-sport injuries by ignoring the way in which sport created, celebrated, and concealed self-harm. This fact became a source of stigma non-sport TBI patients, particularly in the courtroom. The second chapter investigated here was by Sir Frederick Lawton titled "An English Judge's View of Some Medical

Problems to be Met in the Courts" explored the various claims made by workers and others in accidents —symptoms like headaches, inability to concentrate, decreased libido and the like.[36] Lawton appears to have been beyond contemptuous of such claims. He complained about clinicians' courtroom testimony, remarking: "Need you accept as often as you do what the patient tells you?"[37] His suspicions, he noted, were shared by the infamous British neurologist F. M. R. Walshe, who had often asked rhetorically in court in defense testimony, who "has ever come across functional disorder without clinical signs of lesion in jockeys or professional footballers" who "frequently have knocks on the head while following their employments."[38] In this way, then, masculinity in sport became a structural determinant of health and healthiness in non-athletes. The fact that normal people in their normal lives had little in common with young, strong, and coerced athletes became a reason for distrusting them rather than distrusting the atmosphere of sport in which the downplaying of harm implied a gender identity.

Stigma about malingers in normal population worked its magic on sport too. The familiar tone that Lawton and Cook adopted became a significant means of questioning athletes' pain. Consider one contemporaneous American example from a profile of American footballer and fullback Jim Brown published in *Ebony Magazine* in 1964. Reflecting on Brown's stoicism, club house director Morris Kono stated "He never asks for thing. On a cold day you have to give him a coat. I don't even know if he wants it. He never takes a sip of water during a game. You never know if he's hurt. He doesn't complain. The guy was a Spartan the day he showed up and he's exactly the same now."[39] Brown's wiliness to work was noted by the reporter who then described a moment when Brown "suffered a brain concussion in a pileup and spent one quarter on the bench." In that circumstance, Brown recalled that his "coach hinted he was gold-bricking." Brown remembered that he couldn't remember the plays and recognized after the fact that his coach basically "didn't seem to care if you lived or died, so long as you played."[40]

The ability to even recall this episode could well have been deemed evidence that Brown was malingering, another word for goldbricking. More likely, however, is that this anecdote captures a whole different world in a moment. It makes clear that athletes are re-exposed to harm by sports doctors, coaches, trainers, and other responsible authorities downplaying that harm and by intimating a comparison with the shadowy figure of the malingerer or simulator. In 1969 two clinicians suggested that such malingers were familiar to high school coaches and usually took the form of a boy who was scared to play but under peer and parental pressure to do so. In such instances, they argued, the nice thing to do was pretend with the boy that he was so injured it was necessary to retire from sport forever.[41] Athletes who did not or could not take the pain were considered too frail for the sport. No one challenged the notion that it was the sport that was in the wrong.

It is essential to see that in all of these situations a moral economy prefigured what Dominic Malcolm calls an axiological question.[42] The sporting world, a martial morality, required a particular kind of body calibrated for spectacle and its economic impacts, all of which were predicated on erotic desire, violence, and heroism. In the medical world, a morality of healthiness and stoicism, required a body that desired its own health and denied a place for itself as a burden on others and called this quality of life.[43] In the legal domain, the existence of these bodies pointed to virtues of stoicism and healthiness that framed economic realities of necessity, responsibility, liability, and settlements. Sloth and greed were moral hazards faced by all in all of these domains. To look at this with competency, it should be clear that the structures of this practice of stigma promoted self-harm by making people overwork themselves at the demand of others or by downplaying the harm they had experienced for the reward of not living up to the stigma itself. In order to see these harms, it is necessary to name and understand these stigmas.

What to do? A Proposal to Aid Structural Competency on TBI in Sport and Beyond

In this short essay I have sought to explore the ways stigma, traumatic brain injury, and sport compound and unify risks across several social and professional domains. Structural competency in brain injury research requires recognizing that these long histories of courtroom battles, cultural concern about fakers, shirkers, and effeminacy, and economic resentments created through the compensability of workplace injuries, place large burdens on TBI patients to prove their own clinical and legal legitimacy. Many of them end up trapped in two ways. They are either too injured to address the burden and cannot. Or they possess the personal wherewithal or support structures to call attention to their difficulties but by so doing make experts question whether they are as bad as they report. In this

area of clinical care and law, working at the least to make these social contexts and social pathologies structured in the clinical and legal system visible for all is good social medicine, not least because it invites clinicians particularly to question their own assumptions about what sick people might have to do in order to survive in a society with scant resources dedicated to chronic patients daily needs and support.

Many of the central themes of this essay are extant broadly in the history of neurology. These concerns have revealed themselves periodically in the treatment of nervous diseases women, in the cultural understanding of post-traumatic stress disorder, and in the way that harm is downplayed in the manufacturing of uncertainty. In the world of traumatic brain injury they have evoked numerous stigmatizing labels over the years in psychology and medicine, from malingering to iatrogenic disease to miserable minorities. These characteristics of stigma in this context are that they remain structurally determining of health and well-being and produce unhealth in myriad ways, including public toleration of violence, acceptance of unnecessary exposure to head impacts, and an expectation that little about brain injuries will be discussed clearly and transparently.

How should researchers in social medicine respond to the challenge of the circularity of harm posed by the story elaborated above? In the essay that follows this contribution, a collection of authors adopt a position statement on consensus documents about sport concussion. They argue for person-centered and player-centered guidelines that adopt precautionary recommendations and use strong transparent languages about risk as a way of breaking this axiological cycle. Furthermore, the signatories call for a reflexive turn in evidentiary standards by arguing for strenuous disclosure of conflicts of interest, sources of bias and omission, and radical transparency about risk. In offering this position statement, the signatories seek not only to redress the harm that is baked into these decontextualized positions, but also to remedy a now century long collection of circumstances and facts that have culturally positioned these consensus guidelines and other documents like them in ways that deny the material circumstances in which elite and non-elite athletes play and the ways their experiences shape the lives of normal TBI patients. By asking researchers to confront their own values and preferences and sources of motivated bias, the essay that follows proposes that it is possible to break down axiological barriers that perpetuate harm across the whole traumatic brain injury space, including sports but transcending them as well.

Note

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DETAIL

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Global Regulatory Agencies and Data Transparency

Plott, Caroline F; Sharfstein, Joshua M

ABSTRAK (ENGLISH)

Egilman et al. review the current data sharing practices of three global regulatory agencies — Health Canada, the European Medicines Agency and the Food and Drug Agency. While there has been progress towards increasing transparency over the past decade, progress has been slow.

TEKS LENGKAP

To decide whether to permit the marketing of medical products, national regulatory agencies rely upon vast quantities of information from clinical trials. Growing recognition that this information has value, apart from the regulatory decisions themselves, has led to a global movement for greater data transparency.[1] Among the benefits of broader access to research data are deeper understanding of disease progression (from combining the placebo arms of clinical trials), insights from novel comparisons of different treatments, and new ideas for promising avenues of research.[2]

In this issue, Egilman and colleagues report on the status of data transparency efforts at three major national regulatory agencies —the European Medicines Agency (EMA), Health Canada (HC), and the US Food and Drug Administration (FDA).[3] Each of these agencies releases certain information from clinical trials in response to requests, applying its own standards for redaction of confidential information.

In recent years, the agencies have each developed programs to release data proactively. In 2014, the European Medicines Agency gained the authority to release clinical study reports and patient level data for studies submitted after January 1, 2015. In 2018, the US Food and Drug Administration launched a pilot program to release clinical study reports. In 2019, Health Canada launched a major effort to release clinical reports (but not individual patient data) for drugs, biologics, and devices.

The results so far? The EMA is the clear leader in proactive data release. To date, EMA, HC, and FDA have proactively released data on 119, 16, and 1 therapeutics, respectively. FDA's pilot program ended after just one report was made public. EMA and HC's disclosures were comparable in scope for the same drugs, with minimal redactions. The length of time between making the decision to release data and the actual data release is 522 for the EMA, compared to 135 days for HC.

Egilman et al. did not compare directly the three agencies in their responsiveness to data requests. Where the researchers were able to evaluate releases for the same drugs, the FDA appeared to disclose more information for comparable medications than EMA, although the time from request to release for both agencies exceeded 900 days.

The findings reflect both the progress of data transparency over the last decade and the challenge of making large amounts of trial information accessible quickly. In particular, the burden of review and redaction for historical documents seems to be quite large, substantially limiting the speed of release. The authors suggest a "harmonized approach for clinical report disclosure to help reduce inefficiencies." Such an approach could eventually lead to standards for companies to submit "releasable" documents soon after sending the originals, easing the burden of redaction. FDA has the opportunity to learn from the best practices of EMA and HC and to help lead the global conversation on how best to make useful information more widely available quickly.

In this issue, Egilman and colleagues report on the status of data transparency efforts at three major national regulatory agencies —the European Medicines Agency (EMA), Health Canada (HC), and the US Food and Drug

Administration (FDA). Each of these agencies releases certain information from clinical trials in response to requests, applying its own standards for redaction of confidential information.

As the movement for transparency advances, however, two additional issues will come to the fore. The first is the extent to which greater transparency feeds the disinformation crisis. Poor quality research on newly released clinical study information could lead to mistaken conclusions that spread across the world and confuse patients and clinicians alike. One approach to mitigating this danger is to utilize trusted intermediaries, such as the Yale University Open Data Access (YODA) initiative, which only permit individual patient level data access to qualified researchers.[4] Scientific journals will play a critical role in assuring the soundness of the methodology of submitted research. To justify the risks and costs of transparency, it will be important for the research community to track the use of newly available clinical trial data to improve the health of populations.

A related matter is the impact of data transparency on the credibility of regulatory agencies themselves. Certainly, transparency will lead to greater appreciation of the vast work of regulatory agencies in reviewing complex clinical studies. It is also predictable, however, that academic and independent scientists will re-analyze data submitted to agencies and challenge the resulting regulatory decisions. Regulators will have to adapt to a new set of demands for explaining their decisions.

A companion project, then, is a different type of openness: transparency in regulatory decision making. Regulatory agencies differ in their policies on release of key documents outlining their standards and decision making. These include guidance for industry; complete response letters that outline why medical products are not approved (a practice at the EMA, but not the FDA); statistical analyses from withdrawn applications; and explanations for clinical holds.[5] Agencies also have different styles of responding to criticism from academic researchers, industry groups, and consumer advocates.

At a time of doubt in many social institutions, the public's confidence in the safety and effectiveness of medical products is very much at stake. Greater data transparency has the potential to enhance not only scientific progress, but also public understanding and confidence in the safety and effectiveness of a wide range of medical products. Engaged and capable regulators are necessary to bring this potential to reality.

Note

Dr. Sharfstein reports that he served as Principal Deputy Commissioner of the US Food and Drug Administration from March 2009 to January 2011. The authors have no other potential conflicts of interest to disclose.

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DETAIL

Subjek:	Clinical trials; Regulatory agencies; Research; Transparency; Disclosure; Food; Decision making
Ketentuan indeks bisnis:	Subjek: Disclosure
Lokasi:	United States--US
Perusahaan / organisasi:	Nama: Food &Drug Administration--FDA; NAICS: 926150; Nama: Health Canada; NAICS: 923120; Nama: European Medicines Agency; NAICS: 922190
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Pandemic “Disability Cons”

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ABSTRAK (ENGLISH)

Disability rights law has made issues of access and accommodations much more visible in American life. Yet a byproduct of the increased awareness of disability rights has been “fear of the disability con,” that is, the common apprehension that people are abusing the law to gain an unfair advantage. Many times, this moral panic creates an invisible, oft-overlooked barrier for people with disabilities who desire to utilize their rights. They either are refused the right altogether or give up asking for it in the first place because they are afraid of being accused of being fakers. This Article shows how fear of the disability con surfaced along the progression of the COVID-19 pandemic. It describes the schism between the ways in which people with disabilities generally fared under the pandemic and some popular perceptions regarding the “privileges” they allegedly received because of their protected legal status. Those so-called privileges include mask exemptions, vaccination priority, and permission to continue remote work. The Article concludes with lessons the COVID-19 pandemic experience can teach us about the nature and scope of the fear of the disability con.

TEKS LENGKAP

Introduction

In her 1984 book *The Disabled State*, published before disability was formally recognized as a civil rights matter through the Americans with Disabilities Act (ADA), Deborah Stone acknowledged disability to be a “special

administrative category" that gives disabled people some "privileges." She wrote: "[] a social observer cannot fail to notice that disability entails (or may entail) at least as much political privilege as it does social stigma. It is a political privilege because, as an administrative category, it carries with it permission to enter the need-based system and to be exempted from the work-based system. It can also provide exemption from other things people normally consider worth avoiding: military service, debt, and criminal liability."[1]

As I have written elsewhere,[2] after the "disability rights revolution,"[3] the so-called privileges given to individuals with disabilities became no longer limited to receiving public benefits and being exempt from working, as Stone suggested originally. Nowadays, the status of disability awards privileges that are omnipresent in everyday lives.[4] Designated disabled parking,[5] exemptions from standing in queues,[6] getting extra time on exams, and being able to take a service dog into public places that don't allow pets[7] are just a few examples. While those types of privileges are in fact accommodations and modifications put in place to help disabled persons navigate a world not designed with them in mind,[8] for the layperson those are often perceived as "special rights"[9] that are prone to abuse by those who fake disabilities.[10]

Those perceptions about abuse of disability rights by "fakers," which I called *Fear of the Disability Con,* are also fueled by the common misconception of disability as dichotomous and one-dimensional: one is either disabled or not. In reality, however, disability is a fluid state.[11] It fluctuates, manifests itself in visible and invisible forms, and is formed through a complex interaction between the pathology and the social environment.[12] The moral panic of disability con has consequences for people with disabilities who are trying to utilize the disability law and are often questioned and harassed. Rights claimants with disabilities also need to navigate defensive policies informed by the fear of the disability con.[13] Therefore the public suspicion of abuse and fakery serves as an oft-overlooked barrier to preventing the proper implementation of disability rights law and disabled people from fully taking part in society.

While the dust has not yet settled on the COVID-19 pandemic, it is clear that the pandemic has exacerbated or shed new light on myriad social and legal phenomena: from the politicization of public health measures to discussions of triage and the value of life. In this article, I show how the socio-legal phenomenon of the fear of the disability con has manifested itself in different ways through the progression of this global public health crisis.

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A schism exists between the ways in which people with disabilities generally fared under the COVID-19 pandemic and some popular perceptions regarding the "benefits" they allegedly received because of their protected legal status.

An estimated 83% of people under the age of sixty-five who died from COVID-19 were people living with underlying medical conditions that meet the legal definition of disability, including heart disease, cancer, kidney disease, diabetes, and lung disease.[14] This is because some disabled people are at an increased risk of infection or severe illness because of underlying medical conditions.[15] The rationing of medical care and resources on the basis of disability in state Crisis Standards of Care plans also threatened the lives of patients with disabilities and served as a reminder of the societal devaluation of disabled lives.[16] Disabled workers were also laid off at higher rates compared with their nondisabled peers during the pandemic.[17]

On the other hand, people with certain disabilities were exempted from wearing masks, were given priority in the queue to get vaccinated, and were also allowed to continue to work remotely when others were called back to the workplace in person. Those "privileges" were the source for a moral panic around pandemic disability cons, which added strain on people with disabilities who wanted to use these accommodations but were thought to be fakers and malingerers.

In the rest of the article I will describe this new manifestation of the fear of the disability con in chronological order that fits with the progression of the pandemic and will demonstrate the effects it had on disabled individuals during that time. I will conclude with some suggestions regarding what the pandemic experience can teach us about the

nature and scope of this socio-legal phenomenon.

I. Pandemic "Disability Cons"

A. Mask Exemptions

Along with stay-at-home and social distancing orders, requirements to wear masks or face coverings were a significant public health measure aimed at stopping the spread of coronavirus issued by the Centers for Disease Control and Prevention (CDC). The original CDC recommendations, promulgated in April 2020,[18] advised that every person over the age of two should wear face coverings in public unless that person "has trouble breathing, or is unconscious, incapacitated, or otherwise unable to remove the cover without assistance."[19] Similar to what happened with the definition of disability under the original 1990 ADA,[20] this open-ended exemption category combined with the fluid nature of disability (which could take on an invisible form or a periodic nature), yielded suspicion of disability con alongside some instances of abuse.

Mask mandates quickly became (and continue to be) a highly contentious and polarizing matter, which crossed partisan divides.[21] Ideals of personal liberties and skepticism about the existence or severity of the pandemic generated resistance to mask wearing specifically among the Right. To avoid wearing face covering, "anti-maskers" —a small yet vocal group —evoked the exemptions they perceived as the "benefits" or "special rights" that follow the legal status of disability.

Misinformation regarding mask exemptions under the ADA and under the Health Insurance Portability and Accountability Act (HIPAA), which was falsely interpreted by anti-maskers to allow a person the right not to disclose their disability, started surfacing online.[22] As one anti-masker advised in a viral online video: "*so you can say that you have a medical condition. And the medical condition might be that wearing a mask is strangling your sense of free speech …*"[23]

Legally, however, the HIPAA privacy rule was designed to safeguard individually "identifiable health information," only as it applies to covered entities (insurance companies, clearinghouses, and health-care providers with access to information) and their business associates.[24] The rule regarding privacy of health information does not apply to vendors or business owners who may ask patrons to put on masks when entering the store.

The irony of the situation is clear: anti-maskers were coopting rules put in place to protect people with disabilities in a way that puts this vulnerable population at greater risk of contracting the virus.

As with other manifestations of disability con, the ones to bear the brunt of attempts (no matter how sporadic and uncommon) to abuse the law were disabled people themselves. Many people with genuine disabilities that prevent them from wearing face coverings, like those with sensory processing disorders, developmental disabilities, or facial deformities,[25] were subjected to harassment and exclusion because of others thinking they are "faking it."[26] Disabled people not able to wear masks were turned away from stores and shouted at, and there were even reports of violent confrontations over this issue.[27] Those threats and suspicion created a chilling effect on the possibility of those with genuine needs to ask for the exemption in the first place, thus making them even more isolated during the pandemic.[28] In other words, it is this public suspicion that creates a barrier for disabled individuals to safely participate in society, even though black-letter policy (in the form of the CDC exemptions) was put in place to help them achieve that goal.

The fight against mask exemptions and fear of the disability con has also reached the courts. In May 2020, Kimberly Pletcher filed a disability discrimination complaint under Title III of the ADA in the United States District Court, Western District of Pennsylvania. Pletcher claimed that Giant Eagle, a grocery chain store in the Pittsburgh area, discriminated against her because she could not wear a mask due to her respiratory impairment.[29] This is because the chain had a strict policy not allowing customers into the store without masks, without any exemptions, offering curbside services instead as a reasonable disability accommodation.[30] In response, Giant Eagle states that it does not have enough information about Ms. Pletcher's disability to be able to address it.[31] The complaint was then amended with additional plaintiffs joining the case.

On October 23, 2020, the court denied a motion for preliminary injunction to modify Giant Eagle's policy and permit the plaintiffs to enter the store without masks as a reasonable accommodation. This motion was made by another

plaintiff, Josiah Kostek, who claimed to have “mental health impairments” that prevent him from wearing masks due to severe anxiety and difficulty breathing.[32] In denying the motion, the court determined that Kostek did not prove his inability to wear a face covering using appropriate medical records, nor did he prove he could not comply with the secretary of the Pennsylvania Department of Health’s as well as the store’s policy allowing people to wear a full face shield in lieu of a cloth face covering.[33] The court also concluded that Kostek’s claims of disability exemptions are undermined by numerous inconsistent statements he made in social media posts and on video where he says that he is in fact able to wear a mask “but merely believes he has a right to refuse to comply with mask policies.”[34] As of June 2021, the case was continuing and seems especially contentious, with a special master being appointed to handle ongoing discovery disputes.

Mask exemption, the first arena of pandemic disability con, is illustrative of the phenomenon as a whole. Masks could be considered the most obvious, visible symbol representing the COVID-19 pandemic. Even though they were found to be efficient in halting the spread of coronavirus, and have become a part of people’s routine for almost two years now, masks are uncomfortable, cumbersome, and shown to create a barrier to mutual empathy, communication, and quality social engagement.[35] To be exempt from masks is exactly the type of “privilege” attributed to disability that is prone to misunderstanding as to the real nature of the accommodation. The moral panic around those faking disabilities to get this “special right” is thus similar to the exemptions Deborah Stone pointed to decades ago.

B. Jumping the Vaccine Queue

Queues are a system of ordering in conditions of scarcity designed to enforce social order and increase efficiency.[36] Although queuing is based on the premise of “first come, first served,” research has shown that laypersons perceive procedures that use a “weaker first” mechanism —one that promotes allocation based on need, status, or identity —as the fairest system.[37]

In previous work, I showed how people were willing to give another individual the right to cut in line based on the status of disability, yet they needed to make sure that the person was in fact worthy of the right. When there was some doubt as to that person’s deservingness, others were significantly more suspicious of them being a “cheater” who is “gaming the system.”[38] Due to such suspicion of fraud, the concept of “jumping the queue” has been negatively associated with disability in examples that range from getting accommodations for learning disability in schools[39] to getting priority in lines at a theme park.[40] The COVID-19 vaccine allocation has extended the connection between the metaphor of queue jumping and disability.

The COVID-19 vaccination rollout started in the U.S. in mid-December 2020[41] and since then has been described by commentators as “chaotic.”[42] After health-care workers and residents of nursing homes were vaccinated in the first few weeks, the fragmentation of the American health-care system once again proved itself as states differed on what groups should be given priority next. While New York, for example, decided to have persons 75 and older and essential workers, including school teachers and in-person college instructors, in the next eligibility category,[43] Florida prioritized persons 65 and older, skipping over essential workers altogether.[44] Montana, on the other hand, included “American Indians and other people of color who may be at elevated risk for COVID-19” in its next eligibility category.[45]

Questions regarding who should be given priority next based on medical conditions and disability status became urgent. In March 2020, the CDC promogulated a list of high-risk conditions more likely to make a person severely ill if contracting the coronavirus.[46] While the CDC never meant for this list to be exhaustive, it had not been updated for months until well into the vaccine rollout. This created problems for people with disabilities like quadriplegia, cerebral palsy, Type 1 diabetes, intellectual-developmental disabilities other than Down syndrome, or rare conditions that were absent from the original list. Those conditions still posed grave danger of complications from COVID-19 but were not included in states’ distribution plans that looked to the CDC list almost exclusively for guidance.[47]

The variations in eligibility criteria, regarding age, occupation, and preexisting medical criteria, created much confusion among the population.[48] In the midst of this uncertainty, stories about those taking advantage of the situation and faking their eligibility to get ahead and jump the vaccination queue began to dominate news media.[49]

Once again, as happens with other examples of fear of the disability con, the media played a role in creating a discourse that centers on fakery and disability status.[50]

National news outlets ran stories about two women in their thirties and forties disguising themselves as “grannies” to try to get a second dose of the vaccine,[51] on “young, seemingly healthy college students” in Texas who lined up to get vaccinated,[52] and on a celebrity SoulCycle instructor in New York City who presented herself as an “educator” to get a vaccine appointment.[53] As one news article in Philadelphia simply put it: “healthy 30-year-olds will lie about being sick to get vaccinated.”[54]

In reality, however, the situation was painfully ironic, as many people with disabilities experienced difficulties getting vaccine appointments due to inaccessibility of the scheduling websites and the actual vaccination sites.[55] The slow vaccine rollout also led to tragic consequences. Vincent Welch, a 35-year-old Michigan resident with Down syndrome, died from pulmonary complications related to COVID-19 while waiting to get a vaccine that was not yet fully available in the state in April 2021.[56]

While it is impossible to precisely estimate how many people did fake eligibility on the basis of disability or age, those with disabilities had to bear the brunt of the increased suspicion around cheating. In California, a mother of 15-month-old triplets who has chronic lung disease, and was thus eligible for the vaccine, had to try three times before getting vaccinated because “workers at the [vaccination] site denied her the shot. The letters [she presented to prove eligibility], they said, could be fake.” The health professionals did not agree to give her the vaccine in the first two appointments even when the woman presented additional documents.[57] One could only assume what would have been the situation for a person from an underserved community with fewer resources, in other words, less time to spend on this issue, or lack of access to doctors to gather further documentation. This is therefore yet another situation in which the fear of the disability con creates a barrier preventing an eligible person from getting the benefit they deserve in a timely manner. Another example of a person who expressed frustration over the situation is journalist Louis Peitzman who turned to Twitter to share his experience being suspected of vaccine line hopping. He wrote: “Thinking about the stranger who replied to me, ‘It’s none of my business, but what underlying conditions qualify you for the vaccine?’ Hope she’s well!”[58] All the while, Michael Brendan Dougherty, a senior writer for the conservative news outlet *The National Review*, publicly pondered in a tweet: “So what’s the reason I shouldn’t judge all the under 40 people I see posting their vaccinations?”[59]

In March 2021, Katherine Wu published a news article based on interviews with people with less apparent disabilities, like chronic illness, who decided to conceal the fact they were vaccinated due to the fear of being blamed of jumping the queue. Alongside stories of people with disabilities being shamed on social media after posting their “vaccine photos,” the story included testimonies of people with stigmatized conditions, like HIV or Type II diabetes, who did not want to disclose their vaccination status, as it meant “coming out” with a disability they had not previously revealed to others.[60]

Beyond fear of the disability con, this phenomenon of “covert vaccinees,” as Wu referred to it, is yet another manifestation of dilemmas about navigating self-identification as disabled in our society because of fear of being considered vulnerable[61] or being stigmatized.[62] Legal scholars have explored these dilemmas in a variety of contexts, from claiming Social Security benefits,[63] to students in public school[64] or in law school,[65] to the adjudication of workplace discrimination cases.[66]

Although the dilemma of whether to disclose a disability in the context of vaccine priority was fleeting as the vaccine rollout picked up pace, it clearly demonstrates both the emotional toll people with disabilities have to endure when exercising rights[67] as well as the difficulty in reducing bias and progressing the disability justice agenda more generally.[68]

C. Return to In-Person Teaching

As the pandemic progressed and the return to work and to schools grew closer, another type of suspicion of disability con developed, though this one has been more covert. While many employees do not want to go back to the office full time and give up the flexibility that comes from working remotely,[69] some expressed health concerns due to disability or caring for someone else who is at high risk. Such concerns are protected under the Occupational

Safety and Health Act's (OSHA) general duty clause (Section 5), which requires employers to keep their places of employment "free from recognized hazards that are causing or are likely to cause death or serious physical harm."[70] In those circumstances, under the ADA, the employee and employer should also discuss possible reasonable accommodations such as continuing remote work. Nevertheless, pre-pandemic courts were generally hostile to such an idea, as they treated full-time "in-person" norms as essential functions of the job.[71] One arena in which the return to in-person work was specifically contentious was public school teaching.

About 20 percent of public school teachers are 55 or older, and many of them live in communities that were hit hardest by the pandemic, like Black Americans and other persons of color, and have caregiving responsibilities.[72] While the CDC published recommendations to ensure the safety of school staff,[73] many of the teachers who still expressed concerns about health risks were backed up by strong unions. Teachers' unions across the country demanded that better safeguards be put in place (including mask mandates, social distancing, and contact tracing) and that the return to in-person instruction only occur once transmission rates decline, a difficult demand considering the nascent steps for vaccinating children. They were not shy about threatening to strike should their demands not be fulfilled.[74] Those threats became a reality in Chicago in January 2021 when more than half of the public school teachers did not appear at work in protest of inadequate COVID-19 protocols. The Chicago Teachers Union supported those teachers who wanted to continue to teach remotely.[75] In February 2021, the Chicago Teachers Union reached a tentative agreement to reopen the schools.[76] By the end of April 2021, all states started offering vaccines for teachers in an effort to get the return to in-person teaching finalized.[77]

Since schools went fully remote in March 2020 and until they returned to the classrooms in February-March 2021, the discourse around teachers' objection to go back to in-person teaching had a "suspicion of disability con" undertone to it. Very early into the pandemic, in April 2020, reports of an FBI report distributed to companies warned them about employees faking COVID-19 infections through falsified documentation and doctors' notes. The report cited an incident in an undisclosed "critical manufacturing company" where allegedly an employee presented falsified documentation claiming he had COVID. As a consequence, the company had to shut down its facility, send all its other employees who had been in contact with that malingerer to quarantine, and incur significant financial losses.[78] Teachers occupy an important role for the economy to properly function, as they allow parents to engage in gainful employment. It was therefore unsurprising that such narrative regarding possible fraud by teachers soon appeared.

The "idea" that some teachers are just faking their high-risk status to not return to the classroom has probably been bolstered by the animosity toward the strong teachers' unions and anti-union ideology. For example, in response to prioritizing teachers for vaccination, including those who objected to schools reopening, the right-wing blog Empower Wisconsin wrote: "[T]eachers who considered faking COVID-19 symptoms to protest the return to in-person learning will get their shots before teachers in schools that have safely been educating students for months in classrooms."[79] As one commentator who identified as a teacher in Colorado noted in a blog for a school district: "There are teachers with real issues but a hella lot are faking and we all know it."[80]

A key point in the Chicago negotiations was expanding the criteria for medical conditions that are high risk and have people with those impairments teach remotely as an accommodation.[81] Discussions on such eligibility of teachers living with or caring for someone who has hypertension, cancer, and heart disease were at the heart of the discussion with the school district and mayor of Chicago. According to the union, as of January 2021, the district had denied 85 percent of the requests for remote work accommodations based on high-risk status of the teacher or their care recipients.[82]

Ensuring one's deservingness for an accommodation or codified disability rights is a driving force in the decision-making process behind fear of the disability con.[83] As I showed elsewhere, when the disability in question is less visible, and thus perceived to be easier to fake, public suspicion of disability con increases.[84] Although it is hard to say for certain, it seems that in the case of teachers asking for remote work accommodations, the fact that the disabilities in question were in the form of less apparent chronic illnesses made the suspicion against them for "faking it" stronger. The case study of remote work accommodations during the pandemic generally, and the specific

circumstances of public school teachers, therefore illustrate once more the dynamic of the fear of the disability con.

II. What Can We Learn from the Manifestation of the Fear of the Disability Con in the COVID-19 Pandemic?

Disability rights law has made issues of access and accommodations visible in everyone's lives. A byproduct of the increased awareness of disability rights is fear of the disability con and the constant worry that people are abusing the law to gain an unfair advantage.[85] In the vast majority of cases, the rate of actual fraud is hard to assess, yet it is also crucial to examine how the suspicion of fakery itself serves as a "social problem" that affects the lives of people with disabilities.[86] Many times, this moral panic creates an invisible, oft-overlooked barrier for people with disabilities who desire to utilize their rights. They either are being refused the right altogether or give up asking for it in the first place because they are afraid of being singled out as fakers. The fear of disability con thus jeopardizes the law's goal of inclusion.[87] The COVID-19 pandemic seems to have pushed many aspects of the human experience to the extreme. This article shows how fear of the disability con played into and surfaced within the "new normal."

This article first contributes to the theoretical project of exposing and drawing attention to the fear of the disability con by demonstrating how this socio-legal phenomenon influenced public health policy. The concerns of people using disability status to be exempt from preventative measures, like wearing face coverings or getting priority in vaccination efforts, were not previously explored using the disability con framework. The implementation of the suspicion also becomes urgent, as COVID "long-haulers" may increase the number of disabled persons in the population, and this challenges Social Security disability benefits policy as well as the number of people utilizing disability rights law.[88] In addition, the case study of the public school teachers (and other workers) faking disability to get the remote work accommodation exposes how anti-union sentiment blends into, and may even exacerbate, suspicion, opening the door to a more intersectional as well as structural view of the phenomenon.

These perceived "pandemic disability cons" once again bring to bear a fundamental question: how much fraud are we as a society willing to endure to make sure that those who are in real need of the right or benefit actually recieve it? Admittedly, this is more of a political and cultural question than a legal one. This article's goal is to help evaluate the fear of the disability con phenomenon in the public health and health-care arenas and to draw attention to it among researchers and practitioners in these fields. My hope is that this article can contribute to the debate on the presented question, which has a significant influence on the implementation and development of health policy as well as disability law.

Note

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4. This is while malingering is usually done by nondisabled people who are not recognized to have the status of disability. It is the recognition that someone is disabled and thus deserves the privileges that differentiates disability con from malingering.

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Shared Decision Making, Vaccine Guidelines, and Public Health Authority: Reading Between the Lines

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ABSTRAK (ENGLISH)

When the president's commission first voted to endorse shared decision-making in 1981, they were not envisioning it being used to implement vaccination guidelines like those the Advisory Committee on Immunization Practices and the Centers for Disease Control and Prevention now offer.

Fast forward 40 years. Now, in their article entitled "Shared Decision-Making and Government Prevention Guidelines: Evolution, Implications, and Impediments" Lawrence and Schwartz should prompt us to wonder how it is that we got to this point. The emergence of what they call shared clinical decision-making (SCDM) as a recommendation category, particularly in vaccine guidelines "aim to acknowledge limited available data or inconclusive findings regarding key considerations such as long-term effectiveness, risk benefit ratio, or safety." Fair enough. Almost obvious.

However, stepping back a little, the recent trend of recommending SCDM implies a subtext exists to the emergence of that possibility within guidelines — a subtext that can be cyphered if not entirely decoded. That cyphering led me to wonder again about shared decision-making, the ethics of medicine, and how each fits into the authority and ethics of public health.

In my cyphering, I noted that SCDM was not always plausible as a recommendation category; it only became plausible, recently. We should at least wonder how that came to be. What in the public imagination or the evolution of public health ethics, or the grading of evidence led us to this point? Perhaps vaccine guidelines need a short course in the history and sociology of science.

TEKS LENGKAP

When the president's commission first voted to endorse shared decision-making in 1981, they were not envisioning it being used to implement vaccination guidelines like those the Advisory Committee on Immunization Practices and the Centers for Disease Control and Prevention now offer.

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plausible, recently. We should at least wonder how that came to be. What in the public imagination or the evolution of public health ethics, or the grading of evidence led us to this point? Perhaps vaccine guidelines need a short course in the history and sociology of science.

The shared decision-making bandwagon has now swelled so greatly, that the fact that some guidelines do not recommend SCDM may feel the oddest. At least for a generation of primary care doctors attentive to their information-hungry consumer-patient, even the most efficacious vaccine may entail a detailed conversation about risks and benefits —a kind of odd Portlandia of primary care, reflective of our moment.

Either way, my cyphering also prompted a wondering about how the implicit norms guidelines espouse about what SCDM is and is not —a concept that has been debated for decades that retains a certain resilient resonance and a disturbing slipperiness.[1] Most physicians think they do shared decision making, most patients aren't quite sure.[2] Most researchers, when they observe patients see little evidence of it.[3] And so for vaccine guidelines, absent a more transparent articulation of their lens, we as guideline readers are left to wonder whose version of shared decision making they deem desirable.

Using SCDM as a public health recommendation —as good and right as that may be at our particular moment in history, ought also to remind us of a crucial though somewhat unfashionable normative distinction —that the ends of public health and those of clinical medicine, though overlapping in the sphere of population health, diverge.[4] Public health takes group harm as its referent, seeking the good of the many, even at times at the expense of the liberty of a few. Clinical medicine begins more micro —striving for individual good, and occasionally zooming out to ensure its primary pursuit is not at cross-purposes with broader justice concerns. And the means each uses to pursue those ends may also diverge.

Such reflections and distinctions might then start making their way into how we think about the authority and ethics of public health. What then to make of the now routine recommendation of SCDM for vaccines like HPV or the pneumococcal vaccine in certain populations? The thoughts that came to mind for me bifurcate —at times toward the salubrious and at others toward the haunting.

Salubrious because, given the public confusion and outcry associated with vaccine hesitancy, conspiracy theories, and a strident faux-libertarian fad in our public life, who wouldn't want public health policymakers to wield the pen carefully. We should only make a strong recommendation when there is both strong evidence or imminent public health need. That guideline panels would exercise modesty in a middle way seems fitting, right, even good. When the evidence is unclear, don't overreach.

But skulking in the background of these seemingly flexible and accommodating maneuvers rests a different sort of worry, one that at least for me haunts. If policymaking bodies for guidelines get too comfortable offering soft recommendations, perhaps under pressure from advocacy groups, perhaps less confident in their role and worried about their legitimacy, or perhaps too attentive to growing public discontent with assertive centralized authority in the wake of a pandemic, then, down the road, even when it may be needed, that tendency to soften may metastasize to the point where governing bodies shrink from or altogether shirk their responsibility —to assert the right sort of public health authority when it is needed. An unused muscle soon becomes an atrophied one.

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And with this atrophy grows a different sort risk germane to the middle way of SCDM —a risk of outsourcing. If we ask SCDM to bear all the burden, we ask it to do too much. Shared decision making should help patients and doctors navigate uncertainty, but it should not be a scapegoat for inexact science. Doctors like the support and certainty that guidelines recommend. And in the realm of vaccination discussions, these should be the easier part of

a general medical exam, with built-in defaults —“unless you say otherwise, we’ll go ahead and give X, Y, and Z.” Making SCDM do more work than it should not only adds more conversation burden to otherwise overwhelmed primary care providers, but would tacitly shift the blame when (not if) vaccination rates decline, putting doctors on the hot seat for prevention metrics. Dumping all the uncertainties about vaccine risks and benefits onto primary care doctors’ for point-of-care adjudication seems both wimpy and unfair. And doing so could quickly become an unfunded public health mandate that would, over time, only weaken public health authority. It would amount to asking primary care doctors to routinely recite the vagaries they already have to navigate in, say, prostate cancer screening discussions, but now all day long with every demographic stratum. Spending one’s whole day saying “the evidence is unclear, it may help, it may not; it depends in part on whether you are a risk taker, or a proactive type” —over and over again, doth not a fulfilling career make.

Instead of asking SCDM do all that work, we should insist on better evidence so that we can make stronger recommendations, ones that give reliable practice defaults, not ones that just acknowledge the uncertainty, throw up our hands, punt to doctors, and then walk away.

That SCDM emerged as a routine category within public health prevention recommendations mirrors important trends that have swept across medicine and our broader society. Those trends toward empowerment, transparency, and less paternalism have done a lot of good. But even as that trend continues, let’s hope that more participation and empowerment do not devolve into abrogation of responsibility, outsourcing the hard work or becoming so comfortable with inconclusive evidence that we stop seeking a solid basis for strong public health recommendations when they are needed the most.

We’ve learned a lot in the last year and a half. There are and will continue to be times when public health authority will need to be exercised, even amidst evidentiary uncertainty and even if unpopular. That exercise is right and good. Doing so is a moral and prudential necessity.

Note

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DETAIL

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Letter From The Editor

Hutchinson, Ted

TEKS LENGKAP

As I finish my second decade as the editor of the *Journal of Law, Medicine &Ethics*, it is sometimes hard to remember I once led a very different academic life. A long time ago I was a student studying for a Ph.D. in 19th-century American history, with an abiding interest in the Civil War and the way it was remembered and commemorated. I recall being struck even then by how difficult it was for even some of the great heroes of the Union to receive the appropriate pension benefits related to their wartime wounds and injuries. Unless one had an extremely visible injury or amputation, it seemed, one was never above the suspicion of trying to defraud their government, no matter how nobly that person defended it during the war.

Because of this interest I was excited to learn my friend Daniel Goldberg and a group of his acclaimed colleagues were conducting a study on the concepts of malingering and social policy throughout American history. We quickly came to an agreement to publish the papers coming out of this study in the pages of *JLME*, and the results are the issue you now hold in your hands, featuring the symposium “Malingering and Health Policy,” guest-edited by Daniel and spotlighting a stellar group of interdisciplinary scholars. This team explores the theme of malingering from its inception at the very beginning of literature through its blossoming in Victorian England and 19th century America, as both nations begin to build the social safety nets of the modern state. The authors continue the story into the 20th and 21st centuries, with thoughtful explorations of war, sport, welfare, Medicaid, and even how the concepts of malingering and deceit inform our response to COVID-19. And recall how I was struck twenty years ago by the difficulty of white soldiers and officers receiving proper pensions after the Civil War? A recurring theme of this collection is that if this group often had to fight accusations of malingering, the challenge was tenfold for women and racial minorities, a challenge that certainly persists today.

Containing in addition to this symposium our usual collection of independent articles, commentaries, and columns, (many of which continue to explore the continual challenges COVID is inflicting upon all of us) we are deeply proud of this issue of *JLME*. And reflecting the importance of the subject matter, we are very pleased to announce that the symposium papers in this issue will be free and open-access to everyone. We hope you all share this important work widely. And as always, we thank you for reading our journal.

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Telehealth to Address Health Disparities: Potential, Pitfalls, and Paths Ahead

Simon, David A; Shachar, Carmel

ABSTRAK (ENGLISH)

Telehealth has the potential to address health disparities, but not without deliberate choices about how to implement it. To support vulnerable patients, health policy leaders must pursue creative solutions such as public-private partnerships, broadband infrastructure, and value-based payment. Without these initiatives or others like them, health disparities are likely to persist despite telehealth's tantalizing potential.

TEKS LENGKAP

As COVID-19 spread and strained our health systems, large sectors of the economy, including healthcare, went remote. But closing doors also meant opening screens —smartphone, tablet, and computer. Blake et al. argue that telehealth, and remote health care delivery in general, is a key tool to mitigating health inequities, even beyond the pandemic.[1] Because telehealth can reach beyond traditional office locations, it can be used even in communities where many doctors never set foot. Patients spend less time traveling and waiting; physicians may be able see a greater number, and more diverse array, of patients. Not only can telehealth increase access to health services, but telehealth also promises to be cheaper than in-person care —both for the patient and the provider.

But making good on telehealth's potential to address health disparities requires several assumptions, which, as the authors point out, cannot always be assumed. One is technological. Many of those who could benefit most from telehealth are the least likely to have the technology required to use it. Sometimes this is because of affordability: they lack the resources to purchase a smartphone, tablet, or stable internet access. Even if lower-income patients own a smartphone or computer, they may live in communities that lack access to technological infrastructure, like high-speed internet, necessary to use many dominant telehealth services, such as virtual video visits.

In some cases, alternative modes of communication (such as using phone calls, text messaging, or online questionnaires) rather than video conferences for consultation and ancillary services, can mitigate technological concerns.[2] Where a computer program automatically translates text from English to a foreign language, for example, non-visual communication can actually increase healthcare accessibility. But some consultations require devices with a particular kind or quality of visual display, which patients may not have. Finally, some populations like the elderly or persons living with disabilities may not have the technological aptitude or physical ability to use digital tools if accessibility features are neither required by law nor built-in by developers.

To ensure that the benefits of telehealth are not drowned by the weight of these challenges, policy makers will need to consider creative technological, attitudinal, and financial solutions. On the technology side, existing infrastructure could be repurposed to address concerns about affordability and access. Community centers, houses of worship, and public libraries could dedicate space, technology, and resources to telehealth. This would reduce overall investment costs in high-speed internet and technology by centralizing access points. Using centralized telehealth locations like houses of worship and senior centers would also move telehealth to familiar environments, which may increase uptake.

It is important to be mindful of not reproducing or reinforcing health disparities when using existing infrastructure to build out access to telehealth. Senior centers, for example, already play a significant role in providing community and educational activities, including home-based activities to those with physical disabilities, to the elderly or disabled. But they tend to play this role most prominently for certain demographic groups (mostly white, single/widowed older women with moderate to low incomes and minimal physical disability) who tend to use senior centers the most. Increasing the role of senior centers ccounting for current access issues, then, could exacerbate, rather than reduce, current inequities in access to telehealth.[3]

It is important to be mindful of not reproducing or reinforcing health disparities when using existing infrastructure to build out access to telehealth. Senior centers, for example, already play a significant role in providing community and educational activities, including home-based activities to those with physical disabilities, to the elderly or disabled. Certain demographic groups (mostly white, single/widowed older women with moderate to low incomes and minimal physical disability) tend to use senior centers the most, however, increasing the role of senior centers without additional build-out could exacerbate current inequities in access to telehealth.

When such access points are not feasible or would fail to meet the needs of underserved populations, there are opportunities for other public-private partnerships. Big-Box stores, pharmacies, and insurers —like Walmart, Target, CVS, Walgreens, and Express Scripts —may also provide affordable access points within marginalized or rural communities. Another solution is to supply the required technological devices, as the Veteran's Administration has recently done by providing patients with physical devices (tablets) to increase telemedicine uptake.[4] Combining these solutions as the delivery of prescription pharmaceuticals becomes more popular —by, for example, subsidizing companies to distribute technological hardware with prescriptions —could further increase telehealth uptake. Municipal-owned broadband rollout would also help increase the ability of low-income patients to utilize such devices. Given the current administration's proposal to spend $100 billion to expand broadband access, there appears to be both the political will and financial support to do so.

Another concern is social. Patient attitudes toward telehealth vary.[5] Some patients may be more hesitant than others to adopt telehealth because of distrust, cost, or contextual factors, such as age, income, and education. These attitudes may differ not only across demographic groups, but also across technology. Relatedly, and importantly, all of these issues also affect provider use of telehealth.[6] Put another way, technological and attitudinal factors influence whether providers, not just patients, adopt and use telehealth services.

Changing attitudes will in some ways be a more significant challenge than building out infrastructure. One truism of telehealth is that aversion decreases as exposure increases,[7] but high aversion makes repeat exposure difficult. COVID-19 has, in part, overcome this difficulty by forcing many providers to operate remotely, increasing public exposure, and decreasing public aversion, to telehealth. But the pandemic telehealth boom has focused largely on translating existing care relationships, rather than establishing new healthcare relationships. Unfortunately, this can disadvantage Black, Indigenous, and People of Color (BIPOC) populations, who are less likely to be connected into care in the first instance. Continued, widespread use of telehealth will require additional educational efforts and community outreach to help ameliorate these concerns. Patient education should include information about the various types of telehealth and how they can be adapted to meet their needs. Provider education on telehealth should also focus on establishing new relationships and diagnoses, rather than only translating chronic care, to ensure that no individuals are left behind.

Incentivizing payors to adopt telehealth will also require different techniques. Payors, of course, will need evidence that telehealth is as effective as in-person healthcare, or at least less expensive. While some payors, such as the Centers for Medicare and Medicaid Services,[8] have been willing to expand telehealth coverage during the pandemic, it is not clear how their reimbursement policies will change once the pandemic ends. Providers, too, will need assurance of profitable reimbursement, especially because telehealth visits can result in fewer diagnostics, procedures, and interventions to charge for.[7] This suggests that payment parity requirements alone are not sufficient to make telehealth financially attractive to fee for service providers.

Here value-based care payment structures can help align incentives to promote telehealth, including to underserved populations. Because providers receive a monthly ("capitation") payment based on patient outcomes, providers have incentives to provide patients the most effective, rather than the most expensive, care. At least one provider focused on lower-income patients reports that a value-based payment model enabled it to shift quickly and seamlessly to telehealth without sacrificing significant care.[9]

Blake et al. are right to flag that telehealth as a useful tool to address health disparities. But without focused policy initiatives to promote its use in BIPOC communities, it will not realize this potential. These policies can and should vary. Developing alternate sites of telehealth delivery, expanding community broadband access, educating providers

to utilize telehealth at the start of care relationships, and utilizing alternate payment structures can all contribute to normalizing and expanding telehealth in vulnerable communities.

Note

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Informed Consent for Secondary Research under the New NIH Data Sharing Policy

Rothstein, Mark A

ABSTRAK (ENGLISH)

The new NIH data sharing policy, effective January 2023, requires researchers to submit a data management and data sharing plan in their grant application. Expanded data sharing, encouraged by NIH to facilitate secondary

research, will require informed consent documents to explain data sharing plans, limitations, and procedures.

TEKS LENGKAP

Policies of the National Institutes of Health (NIH) increasingly have required federal grantees to share data broadly.[1] The latest and most comprehensive policy was published in the *Federal Register* on October 30, 2020, with an effective date of January 25, 2023.[2] The Final NIH Policy for Data Management and Sharing was designed to promote the management and sharing of scientific data generated from NIH-funded or conducted research, subject to certain limitations or exceptions. “Data sharing enables researchers to rigorously test the validity of research findings, strengthen analyses through combined datasets, reuse hard-to-generate data, and explore new frontiers of discovery.”[3]

Researchers planning to generate scientific data[4] will be required to submit a data management[5] and data sharing[6] plan[7] to the funding NIH institute, center, or office as part of the budget justification section of their grant application. The plan should explain how data will be managed and what data will be shared. The actual plan submitted to the NIH is limited to two pages.

Although there is no requirement that all data be shared by all researchers in all circumstances, data sharing is urged. “NIH expects that in drafting Plans, researchers will maximize the appropriate sharing of scientific data, acknowledging certain factors (*i.e.*, legal, ethical, or technical) that may affect the extent to which scientific data are preserved and shared.”[8] NIH also “strongly encourages” the use of established data repositories to the extent possible for preserving and sharing scientific data, and data should be available for as long as the researchers anticipate it will be useful to the research community, institutions, or the public.

For many researchers and their potential research participants, changes in data management and sharing promoted by the new NIH policy will alter traditional arrangements of the parties regarding possible secondary research using data acquired by or derived from the study. These new expectations regarding access to data are likely to affect disclosures in informed consent documents. “NIH strongly encourages researchers to plan for how data management and sharing will be addressed in the informed consent process, including communicating with prospective participants how their scientific data will be used and shared.”[9] This article considers some of the fundamental assumptions and applications of informed consent implicated by this new policy.

Controls on Data Sharing

The NIH Data Sharing Policy leaves many questions unanswered, including whether the data will be open access or accessible only by credentialed researchers. In its Supplemental Information accompanying the Data Sharing Policy, NIH strongly suggested that data need not be open access. Thus, in describing the characteristics of repositories for storing human data, NIH emphasized the importance of fidelity to consent and documented procedures to communicate and enforce data use agreements.[10] Furthermore, another important characteristic of a data repository is that it “[m]akes use of an established and transparent process for reviewing data access requests.”[11] The Secretary’s Advisory Committee on Human Research Protections (SACHRP) recommended that “NIH consider requiring data requesters to agree to terms and conditions under which the requester must protect data privacy, refrain from attempting to identify individual participants, and not share the data with individuals outside of those who are listed in the data access request.”[12] A requirement of data use agreements, however, is not in the NIH Data Sharing Policy.

NIH is expected to issue additional guidance documents, which will clarify the important relationship with consent provisions of the Common Rule, including the new broad consent provision.[13] Other controls on the secondary use of scientific data, such as tiered consent,[14] registered access,[15] and dynamic consent,[16] also emphasize the importance of informed consent to discern and respect the choices of participants for sharing their data. In many respects, informed consent is the first step in data management and sharing.

Some Specific Concerns

Although there is a robust literature questioning the effectiveness of informed consent,[17] it remains the ethical touchstone for research with human participants.[18] Thus, any changes in the elements or applications of informed

consent will have widespread ramifications. Four of the most challenging —and sometimes overlooked —implications are deidentified data, Big Data, unregulated research, and consent bias.

Although there is a robust literature questioning the effectiveness of informed consent, it remains the ethical touchstone for research with human participants. Thus, any changes in the elements or applications of informed consent will have widespread ramifications. Four of the most challenging —and sometimes overlooked —implications are deidentified data, Big Data, unregulated research, and consent bias.

Deidentified Data

Identifiability plays an important part in the regulation of research under the Common Rule, no doubt reflecting the view that there is little risk to data sources if their data are not identifiable. Based on this principle, if researchers deidentify primary research data or clinical data, then secondary research can proceed without regulation under the Common Rule[19] or the HIPAA Privacy Rule.[20]

During the protracted rulemaking for the Common Rule revisions that took effect in 2018, several fundamental provisions of the Common Rule were reassessed, including the limited applicability of federal research regulations to: (1) research funded by a Common Rule signatory department or agency or research intended to support an application to the FDA for approval of a drug or medical device;[21] and (2) individually identifiable data or specimens. Ultimately, both controversial yet fundamental principles limiting the applicability of the federal research regulations were retained.

The new NIH Data Sharing Policy does not extend regulatory coverage to deidentified data, but it raises the issue of whether researchers should nonetheless consider providing some level of protection to deidentified data for use in secondary research. “Researchers should consider whether access to scientific data derived from humans, even if de-identified and lacking explicit limitations on subsequent use, should be controlled.”[22]

There are several concerns in the use of deidentified data, especially because such research can be conducted without any notice to or consent from the data source.[23] First, a frequently mentioned concern, but perhaps not the most important one, is that deidentified data could be reidentified, especially individual DNA analyses.[24] Nevertheless, it is not clear how many people would have the technical ability and motivation to engage in such conduct.[25] Second, deidentification does not eliminate the risk of group harms. A well-known example involves the Havasupai Tribe in Arizona, where all tribe members and not just research participants suffered from unauthorized research on schizophrenia, inbreeding, and ancestral migration.[26] Third, deidentification does not protect against research that individuals view as objectionable, such as research on psychiatric conditions, gene therapy, or fetal development.[27] Fourth, many individuals are concerned if their data or specimens, regardless of identifiability, are used for a commercial purpose without prior disclosure.[28] Fifth, deidentified research conducted without consent can lead to a loss of trust in health research and health care generally,[29] and loss of trust is a particular concern in minority communities.[30]

The wide range of risks associated with research using deidentified data raise the issue of whether the NIH exhortation in the Policy for Data Management and Sharing that researchers “should consider” limitations on access to deidentified data will result in voluntary disclosure controls imposed by researchers.

Big Data

Big Data may be defined as “a large collection of disparate data sets that, taken together, can be analyzed to find unusual trends.”[31] An assumption of Big Data analytics is that it is not known what individual or combination of data will be valuable, so the default rule is to collect all possibly relevant data.

Perhaps the best example of Big Data health research is the NIH All of Us Research Program, which is enrolling at least one million individuals in the United States.[32] In addition to whole genome sequencing, All of Us participants are asked to share data from (1) health surveys (sociodemographic, lifestyle, and substance use); (2) physical measurements (blood pressure, heart rate, weight, height, and body-mass index); (3) biospecimens (blood and urine); (4) electronic health records (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).[33]

Even such a comprehensive list does not include all the data of possible relevance to health research. Thus, Big Data health research (and possible future clinical applications) also could include one or more of the following sources: (1) vital statistics of family members; (2) military service records; (3) employment records; (3) financial and consumer information; (4) educational records; (5) travel information and geo-location data; (6) social media postings; and (7) government records.[34]

Secondary researchers might combine identifiable research information shared by repositories with other accessible data, resulting in a highly detailed compilation of data about the individual. Thereafter, algorithms developed by researchers could analyze the data to discover unexpected associations. To prevent such unauthorized compilation and aggregation, informed consent in the age of Big Data and data sharing should expressly disclose the possibility of further data compilations and analyses.

Unregulated Research

An emerging and contentious issue involves the types of researchers who should be permitted to access health data for secondary research. On the one hand, some researchers and institutions might assert that only responsible, credentialed researchers subject to federal research regulations ought to have access to individually identifiable health records. On the other hand, some researchers and patient advocates might assert that health data derived from publicly funded research ought to be widely available to maximize the likelihood of scientific discovery. In considering these positions it is important to distinguish regulated from unregulated research.

Unregulated research may be defined as research not subject to the Common Rule[35] or FDA research regulations.[36] Although a few states have their own research laws,[37] almost all of them have limited applicability and utility, and therefore regulation of health research is overwhelmingly a federal government responsibility. The category of unregulated researchers is diverse and includes research by commercial entities (e.g., employers conducting health research with their employees), independent or self-funded researchers, citizen scientists, patient-directed researchers, do-it-yourself (DIY) researchers, and self-experimenters.[38] Unregulated research is believed to be growing because many individuals and disease-specific organizations regard traditional research as slow, expensive, unresponsive, and dominated by biotech and pharmaceutical companies; social media, crowdsourcing and online communities facilitate new collaborations; and direct-to-consumer genetic testing, open-source data, and widely available smartphone applications for capturing biometric and other health information can generate a vast trove of data for analysis.[39] Unregulated researchers could gain access to research repositories in one of the following ways: (1) if NIH regulations require open access to data from NIH-funded research; (2) if additional research repositories are established on open access principles; or (3) if more lenient access rules are developed by primary researchers or their institutions. Assuming that access to individual health data is not restricted to researchers subject to federal research regulations, this information should be disclosed to potential research participants in the informed consent process. For example, a typical disclosure statement might read: “Your data will be available to other investigators, including those who are not subject to the federal research regulations.” If unregulated researchers will have access to their data, potential participants might prefer limitations on the types of research conducted (e.g., through tiered consent), but it might be difficult to enforce any restrictions against unregulated researchers.[40]

Consent Bias

If researchers add disclosures about deidentified information, Big Data, and, possibly, even unregulated research, the length and complexity of the informed consent process will increase. It is foreseeable that some researchers will assert that the additional disclosures will cause potential research participants to suffer from information overload and comprehension will decrease, the percentage of potential participants who decline to participate will increase, and studies will be less accurate due to consent bias.

Consent bias is a type of selection bias that occurs when those who consent to participate in research differ in important ways from those who decline to participate.[41] The concept of consent bias, however, is widely misunderstood. Consent bias only occurs when those who consent for research and those who decline differ along a dimension measured by or affecting a particular research study. Consent bias is not the same as

unrepresentativeness of the participants or their data. There are many legal, ethical, and policy reasons, including NIH funding requirements, why research participants should be representative of the population. But consent bias would arise only if the opinions or health characteristics of those who declined to participate in research differed from those who agreed to participate in ways measured by the research. Even then, researchers could use a variety of standard statistical methods, such as inverse probability weighting, to reduce the effects of any residual selection bias.[42] Therefore, any additional provisions in a consent document to satisfy new data sharing disclosure requirements are highly unlikely to bias well-designed, administered, and analyzed studies.

The Evolving Role of Informed Consent

Informed consent for research was developed in the mid-twentieth century to protect the autonomy and dignity interests of research participants whose consent was lacking or obtained through coercion or deceit. Such practices exposed many vulnerable individuals to risks that were mostly physical. At the time, research was typically small-scale, location-specific, and under the direction of physician-investigators. Most of the studies were interventional, including clinical trials of new treatment methods and new drugs. The relative simplicity of research allowed potential research participants to understand, in at least general terms, the research plan and the potential risks and benefits. Thus, they were able to decide whether to give or refuse permission to participate.

Today's biomedical research is often quite different, and its scale can involve many thousands of participants at numerous sites. In addition to interventional research, research is increasingly informational, with researchers aided by modern computational methods analyzing millions of data points related to participants' health status as well as sociodemographic, environmental, and behavioral measures. The risks to individual participants today are often dignitary in nature, involving the personal, relational, and economic consequences of researchers generating and disclosing sensitive information.

The new characteristics of research have led some experts on research ethics to regard informed consent as anachronistic for twenty-first century, informational research.[43] Measures that previously were sufficient to protect the interests of research participants are now ineffectual. For example, removing individuals' names from medical records or coding them is insufficient to protect privacy when the research involves genomic data and is subject to sophisticated computer attacks.[44] Research participants also may be asked to consent to unspecified future research, either by primary enrollment in a research repository or through secondary research. Critics assert that one-time consent, even when modified by participant-designated limitations or external oversight, is problematic for data-based research.

Although informed consent can certainly be improved, it is much too important to discard even for informational research. Informed consent should not be considered too narrowly, or its success judged on how much information is retained by research participants. Focusing only on *getting consent* from potential participants, fails to capture the essential symbolic and interpersonal dimension of informed consent. Especially now that it is increasingly difficult or impossible to provide potential participants with detailed information about possible future research uses of their data, the process of *asking for consent* takes on greater significance.[45] This may be especially important for research with participants who are members of racial or ethnic minorities with a history of mistreatment in research or persistent health inequity.

Asking for consent by an investigator demonstrates respect for the autonomy and dignity of the potential research participant, serves to build trust, and is a symbolic expression of the moral equivalence of the researcher and research participant in an otherwise asymmetrical relationship. In the context of modern data management and sharing, informed consent should do more than add some new disclosures by also emphasizing the asking for consent by researchers. Regardless of the specifics recalled by participants, informed consent will be viewed as a success if participants are assured of the trustworthiness of the researchers and the researchers commit to protecting the participants' privacy and other important interests.

Conclusion

The NIH Policy for Data Management and Sharing is intended to be flexible so that researchers can design policies depending on the type of research, data generated, legal and ethical limitations, concerns and preferences of

research participants, and interests of other researchers and the public. The flexible sharing admonition of the NIH will require thoughtful consideration by researchers, institutional review boards, research administrators, and data repositories in balancing these multiple interests to develop responsible data management and sharing practices and policies. NIH should supplement its Data Sharing Policy with guidance documents, use case descriptions, best practices, and sample documents to serve as guardrails for the increasingly broad range of researchers. Informed consent documents and processes will be important in explaining the data sharing plans, limitations, and procedures to potential participants.

Informed consent disclosures about deidentified data and Big Data will have increased significance. Although the NIH Policy does not apply to unregulated research, public and private stakeholders should consider a range of measures to facilitate ethical conduct of research and data utilization.[46] Concerns about possible consent bias attributable to data sharing disclosures should not be a major concern. Finally, explaining informed consent procedures and documents should not be viewed as ministerial tasks assigned to lower-ranking members of the research team, but as important steps in the essential relationship and trust building of the research enterprise.

This article is an expanded and annotated version of the author's remarks at a conference of the National Academies of Sciences, Engineering, and Medicine on April 29, 2021.

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1. These include the Data Sharing Policy, 68 Fed. Reg. 37369 (2003); Genomic Data Sharing Policy, 79 Fed. Reg. 51345 (2014); and NIH Policy on the Dissemination of NIH-Funded Clinical Trials Information, 81 Fed. Reg. 64922 (2016).
2. Final NIH Policy for Data Management and Sharing and Supplemental Information, 85 Fed. Reg. 68890-68900 (2020).
3. Id. at 68896 (footnote omitted) (Section I).
4. "Scientific Data: The recorded factual material commonly accepted in the scientific community as of sufficient quality to validate and replicate research findings, regardless of whether the data are used to support scholarly publications. Scientific data do not include laboratory notebooks, preliminary analyses, completed case report forms, drafts of scientific papers, plans for future research, peer reviews, communications with colleagues, or physical objects, such as laboratory specimens." Id. at 68896-68897 (Section II).
5. "Data Management: The process of validating, organizing, protecting, maintaining, and processing scientific data to ensure the accessibility, reliability, and quality of the scientific data for its users." Id. at 68897 (Section II).
6. "Data Sharing: The act of making scientific data available for use by others (e.g., the larger research community, institutions, the broader public), for example, via an established repository)." Id. (Section II).
7. "Data Management and Sharing Plan (Plan): A plan describing the data management, preservation, and sharing of scientific data and accompanying metadata." Id. (Section II).
8. Id. (Section VII).
9. Id. (Section VII).
10. Id. at 68900 (provisions II-A and II-B).
11. Id. (provision II-G).
12. Secretary's Advisory Committee on Human Research Protections, Attachment A —NIH Data Sharing Policy at 7, available at <https://www.hhs.gov/ohrp/sachrp-committee/recommendations/august-12-2020-attachment-a-nih-data-sharing-policy/index.html >(last visited July 27, 2021).
13. 45 C.F.R. §46.116(d). See H.F. Lynch, L.E. Wolf, and M. Barnes, "Implementing Regulatory Broad Consent under the Revised Common Rule: Clarifying Key Points and the Need for Evidence," Journal of Law, Medicine &Ethics 47, no. 1 (2019): 213–231 (discussing legal and practical issues with the broad consent provisions of the

Common Rule that will limit the utilization of this new option by researchers).
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20. 45 C.F.R. §164.514.
21. The FDA regulations, note 36 infra, are not part of the Common Rule because they differ in some respects, but are joined here because of the jurisdictional effect of the FDA’s role.
22. Final NIH Policy, supra note 2, at 68898 (Section VII).
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34. See M.A. Rothstein, “Structural Challenges of Precision Medicine,” Journal of Law, Medicine &Ethics 45, no. 7 (2017): 274–279 (discussing the possible elements of precision medicine research).
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39. Id.
40. See id. at 207-218 (recommending policies on unregulated health research for adoption by state governments, NIH, FDA, Federal Trade Commission, Consumer Product Safety Commission, consumer technology companies and app developers, and organizations of unregulated researchers).
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About This Column

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Person Under Investigation: Detecting Malingering and a Diagnostics of Suspicion in Fin-de-Siècle Britain

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ABSTRAK (ENGLISH)

In 1889, The *British Medical Journal* published a piece titled, “Detective Medicine,” which describes feats of medical detection performed by physicians attending malingering prisoners. Though simulating illness had a long history, the medicalization of malingering at the *fin de siècle* led to a proliferation of such case histories and cheerful records of pathological feigners thwarted.

TEKS LENGKAP

An 1897 watercolor by H.S. Robert shows two physicians —one lean and mustachioed, another plump and bald, scrutinizing a chamber pot. It reads: “Deux princes de la science furent chargés àleur tour de se rendre exactement compte …de …l’état de l’illustre malade …”and “The Panama Canal: to determine whether he was fit to be extradited, two eminent physicians examine the stools of Dr Cornelius Herz, who had fled France to escape the results of his mismanagement of the canal’s financing.”[1] The Compagnie Universelle du Canal Interocéanique (French Panama Canal Company) collapsed in 1889, and a few years later a judicial inquiry unearthed bribery, extortion, and government complicity. Among its chief figures was Paris-trained physician and businessman Cornélius Herz (1845-1898), who liaised between the company and fraudulent government officials. Hounded by detectives, Herz fled to England and fought France’s persistent attempts at extradition by claiming that his advanced diabetes was life-limiting. Sequestered in the seaside town of Bournemouth, he soon transitioned from being the poster child for corruption to one for malingering, as jaundiced and antisemitic portrayals in the European press turned his medico-legal struggles into a *cause célèbre.* Robert’s eleven-watercolor series, titled “Un diabétique,” embraces various aspects of Herz’s alleged medical con-artistry, including: “An English doctor takes Dr Herz’s pulse to see if he is seriously ill” and “Dr Cornelius Herz escapes extradition on the ground that he has a terminal illness,

and lives happily in Bournemouth for fifteen years," augmented by the caption "Ils ne lui donnèrent que quelques heures àvivre et …il y a 15 ans de cela …on n'en parle plus. Mystère !!! …"[2] These glib portraits aside, numerous medical practitioners examined Herz to assess his state of health and condition for prosecution. In 1893, Paris physicians Jean-Martin Charcot and Paul Brouardel visited upon the request of the French government and pronounced him too ill for extradition.[3] Though Brouardel returned with Paul Georges Dieulafoy later that year and judged the patient much improved, he was never transported.[4] In 1896, the Home Office commissioned British neurologists Thomas Barr and Thomas Buzzard to re-evaluate him. Practically all specialists agreed that Herz was too ill to travel, even to nearby London, and —in contrast to popular media —British clinical accounts were uncharacteristically sympathetic, whether due to inflamed anti-French sentiment or because they were dealing with a fellow physician.[5] Herz died in 1898, long before the fifteen-year period archly predicted.

Centering the detection of malingering in Britain from the late nineteenth- to early twentieth-centuries, this paper argues that malingering not only secured distinctly clinical attachments in the fin de siècle, but that those operated *in conjunction* with its ongoing social and cultural connotations. The Herz case exemplifies this, sitting at the crossroads of medico-legal and forensic issues, and suturing the private and public spheres.

The case of Cornélius Herz is an illuminating episode in *fin-de-siècle* approaches to malingering, one which highlights the period's fascination with the meta-diagnosis of the condition, for to expose a malingerer was not only to diagnose along the continuum of illness and health, but to refine individual symptoms and signs into an understanding of how they cohered, organically or artificially. Malingering reverberates through the classical and historical lore: from Odysseus to King David and Hamlet, and military recruits to the working poor, the act of feigning illness to avoid obligations, disrupt boundaries, and unsettle social structures has persisted in the cultural and political realm.[6] But a transformation occurred in Western Europe and Britain in the nineteenth century, when malingering came under the purview of the physician, a bio-political power we see evidenced in the procession of eminent doctors who visited Herz. This "medicalization of malingering," to use Simon Wessely's phrase, had broad effects upon the cognitive and professional roles of medical practitioners and the diagnostic episteme itself, an effect that I argue has had downstream impact on clinical relationships and health and social policies surrounding diagnosis even today.[7] Detecting malingering entered a new forensic and investigative space, and became a way of ordering the social through the clinical.[8]

Centering the detection of malingering in Britain from the late nineteenth- to early twentieth-centuries, this paper argues that malingering not only secured distinctly clinical attachments in the fin de siècle, but that those operated *in conjunction* with its ongoing social and cultural connotations. The Herz case exemplifies this, sitting at the crossroads of medico-legal and forensic issues, and suturing the private and public spheres.[9] Though feigning illness had a long history, this period witnessed a proliferation in the clinical literature: of sensational case histories and cheerful records of pathological feigners thwarted. Malingering also assumed significance as a node for thinking about diagnosis writ large. Drawing from popular media, fiction, and clinical reports, this paper traces two key prototypes. It shows how the detection of malingering became part of a methodology ascribed to a particular sort of physician: the "malingering detective," a role bound up with diagnostic proficiency and practitioner skill, existing debates on generalists versus specialists, and the physician investigator model on the rise since the early part of the century.[10] Malingering was a whetstone. It sharpened competency. Consequently, it bolstered professional authority.[11] At the same time, it generated a secondary phenomenon: as a clinical appraisal, it also informed clinical humility. Diagnosing malingering proved one's mettle or exposed one's deficiencies, and shaped constructions of the ideal physician: a clinical, investigative, and ethical being.[12] To identify it was not only to hone diagnostic technique, but to pit one's knowledge of the more "subtle signs of disease" against an ingenious adversary, against whom one might readily fail.

Yet it was not all down to investigator skill. If disease was traditionally cast as the criminal, in cases of malingering the patient —especially those viewed as prone to degeneracy such as the incarcerated, working class, neurasthenic, and foreign —was definitively culpable, a "person under investigation." As such, malingering implanted itself among the "new social diseases" of the end of the century, including contagious and public health threats, neuroses, and

childhood ailments, problems which put medical expertise front and center at the intersection of health and policy.[13] Out of these interactions emerged a diagnostics of suspicion: distinguishing "legitimate" from "feigned" illness informed not only the identification of so-called fakers, but also the very act of diagnosis even as it pertained to non-factitious disorders. In doing so, it generated debates about practitioner roles and clinical ethics, and produced unease about where clinicians sat in an emergent medico-legal framework. In these fin-de-siècle formations of diagnosis, malingering was central to physicians' place in a new regime aligning diagnosis with detection and aiming it not merely toward therapeutic discovery, but suspicious surveillance.

The Malingering Detective

The case of Cornélius Herz consumed the Anglo-American imagination. Debates about whether he was malingering were parleyed in the UK Parliament, splashed across newspapers from New York to New Zealand, parodied in cartoon, and scrutinized in medical journals.[14] Himself a highly skilled physician, Herz was believed to be singularly capable of feigning illness, turning his repeated medical evaluations into a "whodunit" that played out on the public stage. His pathography became the object of collective curiosity, and introduced malingering as a site where medical, criminal, and legal structures intersected on an individual and societal level. In her study on the masculine body, Joanna Bourke argues that it was during World War I that doctors began to assume the overt role of detectives, policing the bodies and behavior of shirking servicemen. She cites an army surgeon's response when asked if he was a doctor: "No…I am a detective," as well as Dr. Henry Cohen's "admission that it was 'tempting to compare the methods of diagnosis with those of crime detection.'"[15] I locate this triad of malingering, detection, and diagnosis earlier in the mid-nineteenth century, especially during the fin de siècle where it becomes more fevered. Arising from this moment is a literary example notable for a malingering detective and an exploration of malingering's clinical, investigative, and cultural facets.

"Malingering is a subject upon which I have sometimes thought of writing a monograph," remarks Sherlock Holmes after a successful run at it in "The Adventure of the Dying Detective" (1913, *His Last Bow*). Published twenty years after "The Final Problem," where the Baker Street sleuth fakes his own death ("The Final Problem," 1893), "The Dying Detective" bares the ligaments between clinical diagnosis, criminal detection, and malingering. The narrative is reflexive and promiscuously fascinated with these entanglements: a physician (Arthur Conan Doyle) fictionalizes a physician playing detective (John Watson), diagnosing a malingering detective (Holmes), who malingers in order to entrap a criminal (Culverton Smith). At the story's outset the reader is invited to inhabit the role of the skeptical but baffled Watson, worried physician friend. We are summoned to the bedside of a dying Holmes. The case is plausible. Stigmata are present: "His eyes had the brightness of fever, there was a hectic flush upon either cheek, and dark crusts clung to his lips; the thin hands upon the coverlet twitched incessantly, his voice was croaking and spasmodic." So alarming is his appearance that his landlady Mrs. Hudson consults Watson ("For three days he has been sinking, and I doubt if he will last the day"). But what Watson sees at a respectable contagious distance is exactly what Holmes wants him to see: a very good piece of method acting. Holmes' adversary, a British Sumatran planter named Culverton Smith, is equally fooled and —overconfident —confesses his crimes to someone he believes is dying. After duping Smith, Holmes describes his scheme to a shocked Watson: "With vaseline upon one's forehead, belladonna in one's eyes, rouge over the cheek-bones, and crusts of beeswax round one's lips, a very satisfying effect can be produced…A little occasional talk about half-crowns, oysters, or any other extraneous subject produces a pleasing effect of delirium."[16]

"The Dying Detective" is an unusual Sherlock Holmes adventure. It disrupts the genre formula Conan Doyle burnished, and which his *Strand* readership had come to expect, opening with the consultation of a doctor, rather than a client approaching the detective. The detective himself, a paragon of stoic vigor, is seemingly debilitated. It is one of the few where the solution turns on a medical diagnosis, even though diagnostic epistemologies are baked into Holmes' methods via Conan Doyle's medical training and homage to his professors (i.e. Joseph Bell).[17] At the same time, it represents a malingering apotheosis. Throughout his repertoire, Holmes establishes himself as a master of disguise and trickery, assuming and shedding identities as varied as sailors, clergymen, and elderly women, and ultimately counterfeiting his own death. Police inspector Athelney Jones tells him in *The Sign of Four*

(1890), “you would have made an actor, and a rare one”; the skill is also bidirectional, with Holmes remarking, “the first quality of a criminal investigator [is] that he should see through a disguise” (*The Hound of the Baskervilles*, 1901). “The Dying Detective” seems almost inevitable when considering the epidemic of feigning in the rest of the Holmes canon.[18]

Just as the investigator prides himself on being able to “see through a disguise,” a fin-de-siècle physician might view the clinical guise of malingering as a test of diagnostic acumen. “The Dying Detective” is rare in its focus upon Watson’s skill as a doctor, not merely as trusty sidekick, loyal friend, or foil for Holmes’ brilliance. Of chief importance are the twin questions of clinical expertise and ethics —here, where the usual roles are reversed and Holmes is incapacitated, is Watson’s field. The bedside is his stage, just as the consulting room is Holmes.’ Yet when Watson tries to examine him, an apparently delirious Holmes entreats him to keep his distance due to his ailment, “a coolie disease from Sumatra …infallibly deadly and horribly contagious.” Spurred on by a sense of responsibility as both physician and friend, Watson insists: “Do you suppose that such a consideration weighs with me of an instant? It would not affect me in the case of a stranger. Do you imagine it would prevent me from doing my duty to so old a friend?” When threats of contagion fail, and Watson advances undeterred, Holmes turns caustic, undermining his clinical abilities: “If I am to have a doctor whether I will or not, let me at least have someone in whom I have confidence.” Mocking him as a mere generalist —“you are only a general practitioner with very limited experience and mediocre qualifications” —he cites esoteric medical knowledge: “what do you know, pray, of Tapanuli fever? What do you know of black Formosa corruption?” “Shall I demonstrate to you your own ignorance?” he asks brusquely. “There are many problems of disease, many strange pathological possibilities, in the East …I have learned so much during some recent researches which have a medico-criminal aspect.” Holmes identifies himself as a medico-criminal expert, a specialist in contrast to Watson’s humble generalist. Watson knows domestic and quotidian disease; Holmes researches “foreign” and outlandish afflictions, a clear alignment of the consulting detective and the medical specialist.[19] Despite Holmes’ stinging remarks, Watson offers to seek out tropical disease experts, a convincing example of the character’s subordination of ego to virtue. Later, Holmes tells Watson that he kept him at a distance *because of* his clinical skills, certain that he would intercept his performance and stymie Culverton Smith’s capture: “Do you imagine that I have no respect for your medical talents? Could I fancy that your astute judgment would pass a dying man who, however weak, had no rise of pulse or temperature?” At the end of this episode, Watson comes through the crucible of malingering as an idealized physician detective: clinically astute (Holmes’ insults notwithstanding), upstanding, and humble. Yet it is Holmes who, as a forensic specialist, intends to write a monograph on the topic.

The traits which Conan Doyle lionizes in “The Dying Detective” appear in contemporary clinical literature about malingering. The word itself appears in 268 *Lancet* articles between 1800 and 1900. The first time it appears in a title is 1885. Notably, many of the malingering descriptions take the form of a “strange” or “curious” case, highlighting their kinship to the detective genre.[20] Malingerers are often cast as having criminal intelligence, or in many instances, being criminals themselves, with the doctor diagnostician serving as super sleuth. This is exhibited in an 1889 article “Detective Medicine,” reporting from Her Majesty’s Convict Prisons:

There can be no doubt that the variety and multiplicity of devices resorted to by the more confirmed exponents of this imposing art show a remarkable degree of ingenuity, perverted, it is true, and cases arise where special opportunity of gaining knowledge of the more subtle signs of disease have been found, and fully and intelligently turned to account.[21]

It describes feats of medical detection performed by physicians attending malingering prisoners.[22] By exercising their “diagnostic powers,” they familiarize themselves with the “infinite varieties of physical malingering” and “many forms of assumed insanity.”[23] They develop a comprehensive nosology of disease across a continuum of legitimate and fictitious, gaining knowledge with each encounter and standing up their expertise against the “expert class of malingerers.”[24] Framing these encounters as competing forms of prowess and virtuosity, the *British Medical Journal* indexes clinical authority to rooting out malingering and announces an adversarial relationship between physician and patient, where the patient’s body and mind become loci of suspicion. Physicians caution each other to remain

vigilant and on multi-sensory alert, aware that penetrating the disguises of malingering indicates superior skill. Writing on feigned insanity, Henry Wentworth Acland (1815-1900) argues that, “if masters of our art, we ought always to detect an imitation of this disease.”[25] Specialists also staked their expertise upon being able to identify malingering within their exclusive ambit, as when English dermatologist F. Parkes Weber (1863-1962) comments on malingerers presenting with esoteric skin conditions, or New Jersey surgeon B.A. Watson discusses central nervous system concussions and lesions.[26] Such differentiation was also viewed as critical to general medical education, wherein the diagnosis of malingering served as a doppelgänger to the diagnosis of legitimate illness, testing the same skills but through inversion. Acland wrote that malingering examples should be presented to advanced medical students, “if a case of supposed feint were offered to him for diagnosis.”[27] Outwitting such tactics was not initially considered part of a garden-variety medical education, nor part of the ethos of a physician, as when Holmes explains why he couldn’t share his secret with Watson: “among your many talents dissimulation finds no place.”

As the century turned, medico-legal pedagogy reinforced unraveling patient artifice and detecting malingering as tricky, yet necessary challenges. For with malingering one was not merely contending with natural histories of disease, but the evasions of the investigated subject themselves. Whether these feints were the “normal” and understandable behavior of “normal” individuals under extraordinary circumstances (as in the case of prisoners of war), the normal and calculated behavior of allegedly abnormal individuals (the avaricious, criminal, or cowardly), or the abnormal behavior of the assuredly and involuntarily abnormal (the insane or otherwise pathological), was a matter of iterative debate and a cardinal feature of the clinical literature.[28] Coterminous with emergent social theories such as Emile Durkheim’s differentiation of the normal and pathological (in *The Rules of Sociological Method*, 1895), which postulated that even something that seemed intuitively “abnormal,” such as crime, was indisputably “normal” given its presence and frequency in society across numerous contexts, malingering problematized traditional categories of well and ill, suggesting the contingency of the normal and pathological in a way that Canguilhem would articulate some years later. For the “genuine” was not necessarily normal, nor was the counterfeit necessarily pathological.[29] Irreducibly contextual and phenomenological, the “normal” counterfeiter and the “pathological” genuine sufferer could not be reduced to binary heuristics, but existed along a continuum. Indeed, the upending of these categories of illness and wellness was part of what made malingering so epistemologically and affectively challenging for practitioners, and their dissolution triggered uneasiness about how and where physicians ought to intervene, as well as more existential questions about the rightness of such interventions.[30]

Malingering narratives went hand in hand with other diagnostic narratives of this period, including those of early detection and systematic clinical approach. Practitioners needed to recognize the tempo and progression of illness and refine their diagnostic method. One could not hope for success without “an analytical mind” and a “carefully arranged system of examination.”[31] In the case of infectious diseases in particular such vigilance would be rewarded, as Robert Farquharson, Rugby School medical officer offered in 1869: “to discriminate between trifling complaints and those of a more serious character is at all times desirable, but especially so when the slightest error of judgment may encourage the spread of contagion …”He argues that it is easy to be a good diagnostician when confronted with florid symptoms, “when the skin, and the throat, and the eyes, and the tongue tell their plain story.” but that detecting subtlety “tries the skill of the most accomplished observer,” and therefore the “value of premonitory symptoms stands in danger of being overlooked amid the more brilliant and exciting investigations of modern medicine.” Unlike many other ailments, for which early detection offered little but a longer duration of illness (in a pre-therapeutic era), infectious diseases could actually be warded off through such attentiveness. The process of distinguishing between “trifling” and “serious” complaints suggests a linked program between the detection of malingering and apprehending infectious disease early, expressing that both crime and disease are epidemic, and that the same techniques which might expose malingering could also detect “the first entrance of infection into our system” and “enable us to state with absolute fidelity whether any group of phenomena indicates serious disease or superficial derangement.”[32]

Above all, malingering offered an exercise in clinical humility. Tracts cautioning against overconfidence, bias, and prejudice come up more frequently with malingering than with non-factitious diagnoses. Some writers warned that

such diagnostic hubris would abet the malingerer and reflected poorly upon the profession itself. Here, B.A. Watson: "it is unfortunately too frequently the case that a surgeon commences his examination in medico-legal contests after having fully formed an opinion, or at least a bias or prejudice…[a] serious defect frequently observed in the members of our profession, which sometimes has its origin in laziness, although occasionally in an inordinate greed, where the physician has been accustomed all his life to given an opinion to a patient without either an examination or thought …I have not yet reached the case of the malingerer; but I have thus far merely paid my respects to those who aid and assist the malingerer."[33] Another admonishes physicians to develop qualitative aptitudes: "opportunity, discretion, and tact." Doses of clinical humility delivered, many textbooks of medical jurisprudence and forensic medicine highlighted the juridical role of diagnosing malingering, devoting entire sections to its nosologies and the role of the medical expert in transmitting these diagnoses to the extra-clinical/legal world, for without the medical jurist as a liaison, "avenues of fraud are opened up and capital, lawyers and courts are practically at the mercy of a clever malingerer."[34] Some viewed the diagnosis of malingering as merely a prelude to the physician's ethical obligation and an explicitly moral duty: the "task of inducing in such a creature the moral change which shall incline him to return to the ordinary course of the duties and customs of life around him," for this second, paramount phase tests the true character of a physician, the subtle skills that "no science taught in schools" can aid.[35] They associate a great responsibility with identifying a malingerer, or wrongly accusing an innocent person.

Conan Doyle was evidently preoccupied with contemporary debates on malingering as well, importing them not only into his fictional practice, but his clinical prose. Like Watson, a veteran of the Anglo-Afghan war, Conan Doyle's military experiences were formative. In 1900, he published on an outbreak of enteric fever during the Boer War, and singled malingering out as something he saw uncommonly among military recruits. Indeed, the piece devotes substantial effort to rescuing the reputation of soldiers, often maligned as "skulkers and shirkers." He writes, "of the courage and patience of soldiers in hospital it is impossible to speak too highly …I have not had more than two or three cases in my wards which bore a suspicion of malingering, and my colleagues say the same."[36] Catherine Wynne believes Doyle's South African experiences to have been determinative, shaping the ways in which Dr. Watson —post Boer War —becomes a more "primary investigative figure" in texts such as *The Hound of the Baskervilles* and "The Adventure of the Dying Detective."[37] What is clear is that malingering becomes a way for Conan Doyle to refract contemporary debates around physician authority and virtuosity, diagnostic acumen, vigilance, and surveillance, and draw a clear line from the Baker Street consultation and the medical practices of Harley Street to the specialized medicine practiced by a growing cadre of domestic and colonial physicians. Indeed, "The Dying Detective" pays homage to several such medics when Watson offers to consult them: tropical specialists Dr. Ainstree (an adaptation of William Francis Ainsworth (1807-96), surgeon, cholera specialist, traveler, editor, and one of the founders of the Royal Geographical Society) and Penrose Fisher, likely a portmanteau of a few doctors who trained at Edinburgh with Conan Doyle; even the police officer, Inspector Morton, may have been named for Charles J. Morton, an 1886 Edinburgh medical graduate).

Packing so many doctor investigators into a story about a malingering detective raises the question: what did it mean to be at the receiving end of such scrutiny? What did this generation of malingering detectives mean for patients?

Person Under Investigation

"The Adventure of the Dying Detective" is unorthodox precisely because the detective himself becomes the patient and subject of medical and criminal investigation.[38] As with Cornélius Herz, the expert becomes an object of study. The transformation of patient to person under investigation is a kind of cosmological shift not accounted for in Jewson's famous ontology of the sick-man, nor in his reappearance at the center of patient-centered medicine toward the end of the twentieth century.[39] David Armstrong has located the "rise of surveillance medicine" in the early twentieth century based on the reconnaissance of normal populations and an extra-corporeal spatialization of diagnosis, reconfiguring the relationship between symptom, sign, and illness into a series of health factors, an "infinite chain of risks."[40] Armstrong carves a sharp boundary between the nineteenth-century diagnostics of hospital medicine, with its lesion-centric pathological approach, and surveillance medicine's monitoring of healthy

populations to “identify the precursors of future illness” and distribution of lifestyle factors. He sees this as medicine’s entrance into the social sphere: no longer content to confine itself to the individual patient in a hospital bed, “medical surveillance would have to leave the hospital and penetrate into the wider population.”[41] But I posit that these ideas root themselves in the nineteenth century, and that rather than the total dissolution of a somaticist and localizing structure giving way to chains of risk, diagnostic entities such as malingering took on especial relevance at the century’s pivot, reflecting more fluid models integrating discourses of localization, risk and vulnerability, the individual and public, clinical and social. Nineteenth-century precursors like the diagnostics of suspicion as exercised in the work of malingering detectives prototype surveillance ways of thinking. For malingering existed in a liminal space between lesion and symptom, between organic pathology and presentation, and therefore taxed physicians in a very specific way. These continuities suggest that fin-de-siècle formations of diagnosis were negotiating illness semiology, pathological anatomy, and physiology while also veering toward the detection of the “normal,” i.e. the healthy individual feigning illness, a behavior pathologized in association with specific traits, alleged predispositions and susceptibilities, and in many instances a perceived lack of moral and physical fitness.

Holmes’ malingering is aided by the fact that he is mimicking not only a tropical ailment unknown to most European medical practitioners, but an entirely fictitious one. This creates an epistemic rift between himself and Watson. Not only is Holmes is acting, and Watson in earnest, but Holmes’ behavior draws him closer to the marginalized classes and criminals he is devoted to ferreting out. It also associates him with many others, who in the mainstream view, were guilty of such pathological acts. Taxonomies stratifying risk for malingering cropped up around the turn of the century. This surveillance medicine tracked those who made a “career of imposture” versus the unwitting feigners or the mentally ill, and generated probabilities of guilt depending on individual and social factors. The “Detective Medicine” report argues that feigners are found more frequently amongst the “criminal classes,” while in 1890 J.T. Eskridge classes malingerers as “the tramp, criminal, and mercenary.” Unlike many of his colleagues, Eskridge believed that it was less important to generate a differential diagnosis of malingering than it was to classify the malingerer: the “tramp class” try to “‘dead-beat’ their way …to gain sustenance in hospitals, or to eke out a miserable existence by imposing upon the charitably inclined.” The criminal malingerer “hope to escape their deserved punishment,” while the mercenary “feign injury for the hope of gaining remuneration.”[42] Such wariness only increased in the setting of the Workmen’s Compensation Act (1898) and the growth of such workers’ compensation schemes in industrializing nations, so that by the early 20th century clinicians across domains maintained a similar administrative roster of offenders: duplicitous workers, “soldiers, prisoners, schoolboys, conscripts …‘hospital birds,’ hysterical young women, club patients, persons injured or supposed to be injured in railway accidents, and persons who have been accused of some crime,” according to neurosurgeon Byron Bramwell (1847-1931), or as F. Parkes Weber attested, “young women with abnormal psychical states,” and prisoners of war attempting to achieve repatriation.[43]

By inhabiting the role of a malingerer suffering from a mysterious tropical disease, Holmes occupies a pathologized identity, one associated with dock workers, global migrants, and colonial subjects. Mrs. Hudson tells Watson that Holmes had been in Southwark, “working at a case down at Rotherhithe, in an alley near the river, and he has brought this illness back with him,” while Holmes himself calls it a “coolie disease from Sumatra.”[44] Pablo Mukherjee views Holmes’ malingering as confirmation of the “pathological proximity” between the detective responsible for “the defense of the imperial status quo” with the global laboring class —not only working class English but indigenous laborers everywhere. The allegations of laziness and the racialization of malingering amongst “coolies” (especially in the colonial context) is an “almost reflexive taxonomic move,” harbored in the imperial archive of “official reports, plantation diaries, medical treatises, parliamentary debates, or private correspondences.” Reading “The Dying Detective” through Freudian and Kristevan poetics, Mukherjee argues that Holmes’ physical deterioration (albeit self-imposed) joins him with the abject bodies victimized by Culverton Smith’s horrific medical experiments (collapsing Holmes’ final illness with that of these indigenous subjects, Smith brutally says: “Yes, the coolies used to do some squealing towards the end”). In order to uphold British imperial stability and to contain threats, Holmes must himself become subversive and peripheral.[45]

Despite being insulated by wealth, education, professional status, and Euro-American caché, Cornélius Herz did not fare much better as a person under investigation, his Jewish heritage making him a ready target in a structurally racist society. A full century later some historians still associate his name with malingering, and his English tenure as a ploy "sheltered under the cloak of invalidism."[46] Accounts of his financial speculations and corruption, dosed with antisemitism, bled into his medical assessment, and it is hard to separate where one begins and the other ends. In the Robert caricatures as well as French political cartoons depicting then Prime Minister Georges Clemenceau as his puppet (or "L'ex copain de Cornelius Herz"), Herz is shown as a "a stereotyped Jewish figure" with a large nose and swarthy features, juggling money bags and tweaking marionette strings.[47] Edouard Drumont's *Le Libre Parole* is exemplary even among the generally skewed French press for its antisemitism, leveraging the Panama Scandal (Cornelius Herz and Baron Jacques Reinach) and *l'affaire Dreyfus* of 1894-1906 (Alfred Dreyfus), both featuring prominent Jewish protagonists, toward a surge of French nationalism and religious intolerance.[48] As the medico-legal literature suggested qua malingerers, Herz's criminal intelligence, Jewishness, and foreignness, were thought to enhance his expert counterfeiting. Per Eskridge's taxonomy, he would exist somewhere between the criminal and the mercenary.

Herz's reception in England, while still skeptical, was tempered. British physicians, in particular, were more supportive than was their wont. The same qualities undergirding French characterizations of his "pathological proximity" to criminality became their authenticating arguments. They defended Herz as a colleague, an Anglophile (who had spent time in both England and America), and a cosmopolitan global citizen. His status as a French exile fueled more fervent advocacy, as when *The British Medical Journal* avowed "the French press have never ceased to ridicule the reality of the illness, have published the most fanciful accounts of the patient's outdoor doings, and generally the most indecent misrepresentations and charges against the patient and his physicians."[49] These accusations of malingering were viewed as an attack on the professional guild itself, for they were dually directed against a fellow practitioner and the acumen of his examining physicians. The media coverage of Herz was also deemed an ethical violation: *The Lancet* remarked that the intersection of the private, clinical sphere and the politically exigent showed how "the first principle of social ethics may be overborne," and that this treatment was not only immoral, but dangerous:

The unfortunate object of this legal persecution has been for the past two years confined to his bed by a mortal illness, which has been gradually advancing towards its inevitable termination; and yet during the whole time he has been kept under police surveillance and has been practically condemned unheard. Surely no course could be better calculated to hasten the end of a sufferer from advanced cardiac disease complicated with diabetes.[50]

Similarly, angina specialist Lauder Brunton (1844-1916) wrote after examining Herz that "unless the strain which is at present weighing upon him is diminished, and his worry and anxiety lessened, the cardiac disease will progress and lead to an utter and irremediable ruin of his health, or even to death itself."[51] These characterizations of Herz as a desperately unwell man, condemned "unheard" through ill will and unable to defend himself, a victim of "legal persecution" under a panoptic regime of surveillance, mark him as both person under investigation and martyr to malingering rhetoric. Unlike the anonymous malingerers distributed across contemporary clinical literature, he is regarded with sympathy. I would argue that this operates in tandem with the ideal of the "malingering detective" we have seen elaborated in both medical and cultural sources —a clinically astute, skeptical, and virtuous being. The conjunction of testimonies from well-regarded specialists, iterative clinical examinations, congratulatory rhetoric on the superiority of English good will and ethics, all operate to reconfigure and uplift this professional ideal in response to Herz's malingering case. As such, the British medical establishment largely viewed the accusations leveled against Herz as violating these principles. When Herz died, *The Lancet* published a brief but compassionate obituary, remarkable for its eagerness to vindicate British physicians while subtly denouncing colleagues across the Channel: "his death was due to angina pectoris and in its mode of onset sufficiently justified the opinion of the well-known English physicians who refused to take the responsibility of saying that he was in a fit state to appear at the Extradition Court"[52]

Many also critiqued the ways in which Herz's body and suffering were put on display; the cynical disbelief of his

symptoms and scrutiny of every physical sign presented on the European stage. As one writer noted, “we have always regretted that it should have been ever deemed necessary to parade before the public the particular details of the malady of Dr. Herz.”[53] Legal proceedings in Paris provoked further outcry across the Channel, as repeated attempts at extradition countervailed what was considered impeccable English medical guidance. In response to this, Malcolm MacDonald McHardy (1852-1913), along with a number of other practitioners who examined Herz, sent “authenticated” clinical impressions to the Cour d’Appel in Paris and the Home Office in London and replicated them in the pages of *The Lancet*, pointing to the “cruel hardship of the situation,” and the “falseness and indecency of the comments in the lay press of France [which] are as disgraceful as incredible.”[54]

Despite these calls for privacy and decency, however, even sympathetic British accounts of Herz’s ailments were cast in an explicitly investigative light. In their enthusiasm to refute the malingering allegations, respected medical journals offered competing “authentic statements” upon the “case of Dr. Cornelius Herz.” Thomas Barlow described his visit with Thomas Buzzard: “It is fair to state that Dr Herz bore our investigation of one and a quarter hour’s duration extremely well. We were told by those present that he was at his best and that at previous investigations he had acquitted himself with great success, but that he had suffered much afterwards.”[55] Lauder Brunton conducted and publicized a meticulous physical exam, including cardiac auscultation, splenic palpation, and urinoscopic analysis.[56] These bedside case histories were arduous and detailed, and evidently taxing for the patient. Because they were iterative, the slightest changes or improvements were noted and tabulated, affixing tiny shifts in constitutional symptom (appetite, weight, fatigue) or sign (auscultation, palpation) to the legal apparatus awaiting Herz.

When Brouardel and Dieulafoy visited Herz, a few months after Brouardel’s initial exam with Charcot, they noted that their subject was significantly improved, notably “dans la plénitude de ses facultés intellectuelles. Il n’est plus l’homme anémié el amaigri du mois de juin; iln’est plus l’homme tombant d’inanition et de faiblesse,” and that as a result he could be extradited.[57] For the French press, this was further evidence of a “faux Cornelius Herz,” “montré aux médecins experts lors de leur mission, le vrai, le seul, jouant au crocket, voyageant en France.” When the British raised an outcry, the French responded on medical grounds: “Il semblait que l’on n’avait ja mais vu un malade atteint de diabète, d’albuminurie ou d’affection du cœur, avoir une rémission dans la marche de sa maladie.” [58] Perhaps their British counterparts were simply unfamiliar with the natural histories of diabetes and cardiac disease, and not so skilled at detecting malingerers, after all.

Dwelling upon the nineteenth and early twentieth century, this paper has made the case that during this period, malingering transforms into an entity around which the medico-legal establishment constructed an entire clinical, epistemological, and ethical structure. It fixes the fictional and historical case studies of Sherlock Holmes and Cornélius Herz in the broader context of malingering. Framing malingering as an act of detection, its diagnosis becomes part of a methodology ascribed to a certain sort of physician —the “malingering detective” —a figure characterized by clinical acuity, ethical rigor, and a broad forensic sphere of influence bridging the clinic and the courtroom.

A Diagnostics of Suspicion

When Paul Ricœur characterized a “hermeneutics of suspicion” distinguished by skeptical reading, circumventing obvious meanings in favor of occult or unflattering truths, he triggered a half-century debate in literary and historical criticism.[59] For isn’t this self-evident? Are we not always panning for meaning amidst the dross? The same can be said for diagnosis; housed in its very etymology is the praxis of sifting truth from appearances. In her landmark study of medical narratology, Kathryn Montgomery identifies a “diagnostic circle” akin to Heidegger’s hermeneutic circle, an iterative process of interpretation where multiple narratives intersect, scaffolding clinical thought and relationships and centering the physician as reader and interpreter.[60] Diagnostician and critic share this fascination for the concealed —unearthing profound meanings and mapping relationships between surface and depth —a genealogy of suspicious reading. Diagnosis is also socially constructed, and as Charles Rosenberg famously described, it “structures practice, confers social approval on particular sickness roles, and legitimates bureaucratic relations.”[61] In this regard, it informs a number of policy frameworks. What then is the meaning of a diagnostics of suspicion, and

what ramifications might this have for contemporary social policy?

Dwelling upon the late nineteenth and early twentieth centuries, this paper has made the case that during this period, malingering transforms into an entity around which the medico-legal establishment constructed an entire clinical, epistemological, and ethical structure. It fixes the fictional and historical case studies of Sherlock Holmes and Cornélius Herz in the broader context of malingering. Framing malingering as an act of detection, its diagnosis becomes part of a methodology ascribed to a certain sort of physician —the "malingering detective" —a figure characterized by clinical acuity, ethical rigor, and a broad forensic sphere of influence bridging the clinic and the courtroom. Alongside we witness the mutation of the patient into a person under investigation, a term which still carries epidemiological heft, signaling both contagious danger and medicalized surveillance in recent outbreaks from Ebola (2014-2016) to the ongoing SARS-CoV-2 pandemic (2019-).[62] As such, it is even attached to diagnostic and billing codes, as when the Centers for Disease Control updated ICD-10 taxonomies to reflect the category of COVID-19 "PUI."[63] This interaction between diagnosis in the clinic, classificatory schemes, public health policy, and business and legal apparatus mirror the networks of malingering in the fin de siècle.

For the late Victorians, the person under investigation was often pathologized, racialized, and distanced from the investigator due to alleged predispositions and susceptibilities. Simultaneously, the practitioner developed a sense of social and ethical responsibility beyond the clinical, to address a condition thought to present risk to the population and medico-legal system at large. The interplay between these figures contributed, in turn, to a diagnostics of suspicion. In contemporary biomedicine on the individual and population health scale, such dynamics operate in subtle, but pervasive ways. Though malingering was expunged from the Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-V) but remains a "V" code (a numeric code used for visits to a health care professional for purposes other than for illness), its afterlives continue and have ramifications for almost all forms of diagnosis. Doctors are coached to be skeptical of patients or to distrust their reports —before the advent of patient-centred medicine in the last few decades of the twentieth century, this was overt and endemic in published clinical literature, even as late as a 1979 *Journal of the American Medical Association* piece which counsels physicians to model themselves on the "detective prototype" in order to "detect deception on the part of a patient."[64] Such deception, writes the author, is not just deliberate malingering but anything that threatens the physician's authority, from subconscious undermining to non-compliance. Since the 1980s, a growing body of literature has addressed physician distrust of patients, including major works in the health humanities and bioethics, such as Jay Katz' *The Silent World of Doctor and Patient* (1984), Susan Sherwin's *No Longer Patient: Feminist Ethics and Health Care* (1992), and health communications and health equity scholarship addressing distrust mediated by racial, gender, and cultural bias.[65] Nevertheless, the legacy of the malingering detective endures in the medical "hidden curriculum," that cues trainees to doubt patients, though such language might never appear in overt form.[66] Such a diagnostics of suspicion is embedded even in the seemingly benign aspects of quotidian medicine, such as the conventional "SOAP" note (Subjective/Objective/Assessment/Plan) which assigns subjectivity to the patient's story and symptoms, but objectivity and primacy to diagnostic and laboratory data and physician impression. Medical care is billed according to this fault line, practically effacing the patient's account from the critical/billable portion of the chart. These social and cultural views of diagnosis therefore have substantive clinical, epidemiological, and policy effects, tied to diagnostic error and bias, insurance models and compensation, and global health outcomes.[67] This framing of doctors as suspicious readers and patients as evasive or untrustworthy subjects, whether actively cynical toward patient reports and motivations or more subtly undermining of them, carries forward from the long nineteenth century a consequential paradigm: that of virtuous doctor and unvirtuous patient. One to be believed and trusted, the other to be investigated.

Note

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References

1. "Two princes of science are charged in turn with providing an exact account…of…the state of the illustrious invalid," H.S. Robert, "The Panama Canal: To Determine Whether He was Fit to be Extradited, Two Eminent

Physicians Examine the Stools of Dr Cornelius Herz, Who had Fled France to Escape the Results of his Mismanagement of the Canal's Financing," watercolour drawing, (ca. 1897), Wellcome Collection, available at <https://wellcomecollection.org/works/xre3xmfu >(last visited August 4, 2021).
2. H.S. Robert, "The Panama Canal: Dr Cornelius Herz, Having Fled to Bournemouth to Escape the Results of His Mismanagement of the Canal's Financing, Simulates Illness to Avoid Extradition to France," watercolour drawing (ca. 1897), wellcome Collection, available at <https://wellcomecollection.org/works/srfgf4zx >(last visited August 4, 2021); "They gave him only a few hours to live…that was 15 years ago…We don't talk about it anymore. A puzzle!"
3. E. Dete and Bertrand, "La Chambre de Cornélius Herz àBournemouth," wood engraving, black and white, (Paris, 1893), National Library of Medicine, available at <http://resource.nlm.nih.gov/101459165 >(last visited August 4, 2021); R. Hierons, "Charcot and His Visits to Britain," BMJ 307, no. 6919 (1993): 1589–1591, available at <https://doi.org/10.1136/bmj.307.6919.1589 >(last visited August 4, 2021).
4. P. Brouardel, Etat de santé de Cornélius Herz (Paris: Baillière, 1893): at 2-3; La Chronique Médicale (Paris: Rédaction &Administration, 1898).
5. "The Case of Dr. Cornelius Herz," British Medical Journal 2, no. 1711 (1893): 858–859.
6. Odysseus may have been the first malingerer. Performing madness to avoid serving in the Trojan War, he tills an empty field with salt instead of seed; but he is ensnared by his countryman Palamedes, who tricks him into revealing the deception. He does not forget Palamedes' trick and is revenged upon him at Troy, when he forges a letter suggesting that he has betrayed Greece, invoking the wrath of Agamemnon, who has Palamedes stoned as a traitor. As related by Apollodorus and Hyginus, this tale of Odysseus' malingering and Palamedes' death becomes part of the classical and historical lore, but is also a cautionary tale of the consequences for those who divulge the deception. For more on the historical and bioscientific afterlives of Odysseus' malingering, see P. Kheirkhah, "Malingering: A Historical Perspective," in Neurological Malingering (Boca Raton, FL: CRC Press, 2018): at 1–6; A. Núñez, et al., "Pseudodementia, Malingering and Revenge in Ancient Greece: Odysseus and Palamedes," Neurosciences and History 4, no. 2 (2016): 47-50; H. M. Hackford, "Malingering: Representations of Feigned Disease in American History, 1800–1920," PhD. dissertation, American University (2004); L.D. Hankoff, "The Hero as Madman," Journal of the History of the Behavioral Sciences 11, no. 4 (1975): 315-333.
7. There is a continuous thread through the late nineteenth-century to early twenty-first century diagnostic literature, concentrated around particular entities: occupational injury, disability and social security assessments, military medicine, traumatic brain injury, neuropsychiatric disorders, pain, forensic trauma, post-traumatic stress disorder, and illness deception (malingering/factitious disorder/Munchhausen's Syndrome) itself. Yet little has been written specifically about the epistemologies of malingering detection and diagnostic reasoning more generally, physician professionalization/identity formation, and medico-disciplinary power. The late twentieth-century and early twenty-first century clinical database reflects the empirical impulse, with a growing number of validated instruments and quantification tools: see G. Young, "Toward a Gold Standard in Malingering and Related Determinations," in Malingering, Feigning, and Response Bias in Psychiatric/Psychological Injury (Dordrecht: Springer, 2014): 53–87; R. Rogers, et al., "Standardized Assessment of Malingering: Validation of the Structured Interview of Reported Symptoms," Psychological Assessment: A Journal of Consulting and Clinical Psychology 3, no. 1 (1991): 89.
Secondary literature reveals a tension between sociolegal and biomedical analyses of malingering. For example, in their introduction to Malingering as Illness Deception (Oxford, 2003): 3-31, Peter Halligan, Christopher Bass, and David Oakley contest the prominent role that medicine and the biomedical model continue to play in "shaping and defining current discussions of illness deception," as this facilitates a merging of the "language of medicine" and the "language of morality." They reframe illness deception as a "volitional act" that can be conceptualized within a sociolegal framework, rather than a deterministic disease model, therefore foregrounding the human capacity for free will. Though their intervention attempts to free "illness deception" from its diagnostic and clinical moorings and physicians from their roles as gatekeepers, embedding malingering further in sociolegal and social responsibility frameworks still yokes the detection of malingering to morality. Though there is a small body of ethics scholarship addressing the clinician's duties in cases of suspected malingering (via a bioethics/informed consent framework, cf.

P. J. Candilis, “Ethics, Malingering, and a Lie-Detector at the Bedside,” Journal of Forensic Science 43, no. 3 (1998): 609-612; J. D. Seward and D. J. Connor, “Ethical Issues in Assigning (or Withholding) a Diagnosis of Malingering,” Neuropsychology of Malingering Casebook (New York: Psychology Press, 2008): 535-547, the necessary critique frequently comes from the humanities and social sciences, including C. E. Rosenberg, “The Tyranny of Diagnosis: Specific Entities and Individual Experience,” The Milbank Quarterly 80, no. 2 (2002): 237-260 and L. Grubbs, “Lauren Slater and the Experts: Malingering, Masquerade, and the Disciplinary Control of Diagnosis,” Literature and Medicine 33, no. 1 (2015): 23-51, and Ian Hacking’s discussion in Mad Travelers (Cambridge: Harvard, 1998) on the politics of assigning diagnoses (distinguishing between hysteria and epilepsy in Charcot’s time). Clearly the health humanities has something to say about this intersection of medical jurisprudence, diagnosis, power, and critique.

8. S. Wessely, “Malingering: Historical Perspectives,” in Malingering and Illness Deception (New York: Oxford University Press, 2003): 31–42, at 36.

9. The historiography and health humanities scholarship on medical jurisprudence and forensic or legal medicine (an inversion and distinction that is itself worth exploring) is too vast to encompass in a single footnote or even this entire paper, but I am including some key sources which have informed my thinking for this article as well as a forthcoming book on diagnosis and detection. Most recently, work on forensic cultures (epistemologies, institutions, and technologies in conjunction with techniques and methods) featured in a special issue of Studies in History and Philosophy of Science (2013) and Global Forensic Cultures, ed. I. Burney and C. Hamlin (Johns Hopkins, 2019) have influenced my view of the diagnostic space as a forensic space, and textured the motif of “doctor as detective” into the cross-cutting figure of investigating professional, bridging clinic, courtroom, and culture. On the spatialization of diagnosis, see also G. Mooney, “Diagnostic Spaces: Workhouse, Hospital, and Home in Mid-Victorian London,” Social Science History 33, no. 3 (2009): 357–390, and D. Armstrong, “Public Health Spaces and the Fabrication of Identity,” Sociology 27, no. 3 (1993): 393–410. Foundational scholarship on legal medicine and views of the juridical/disciplinary apparatus, especially suturing the private and public spheres, include Legal Medicine in History, eds. M. Clark and C. Crawford (London: Cambridge, 1994), J. Goldstein’s Console and Classify: The French Psychiatric Profession in The Nineteenth Century (Chicago: University of Chicago Press, 1987), and “Framing Discipline with Law: Problems and Promises of the Liberal State,” AHR, 1993, and T. Golan’s Laws of Men and Laws of Nature: The History of Scientific Expert Testimony in England and America (Cambridge: Harvard, 2007), among others. I have also drawn from Simon Cole’s Suspect Identities: A History of Fingerprinting and Criminal Identification (Cambrdge: Harvard, 2001) particularly in the “Person Under Investigation” section which engages “criminal identity” more explicitly, ranging from the postcolony to the metropole. I am grateful to Mitra Sharafi and Samuel Scharff for generative conversations on forensic medicine, and their own work, including Sharafi’s article, “The Imperial Serologist and Punitive Self-Harm: Bloodstains and Legal Pluralism in British India,” in Global Forensic Cultures: Making Fact and Justice in the Modern Era, cited above, and Scharff’s dissertation, “The Mask of Expertise: Hervey Cleckley, Psychiatry, and Law in 20th Century America,” (Dissertation: Johns Hopkins University, 2021.) Finally, on co-production of scientific and social discourses, an assumption which undergirds much of this work: S. Jasanoff, States of Knowledge: The Co-Production of Science and the Social Order (New York: Routledge, 2004).

10. A paradigmatic model that weaves throughout clinical literature as a relatively unexamined assumption, see N. Y. Hoffman, “The Doctor and the Detective Story,” JAMA 224, no. 1 (1973): 74-77; R. E. Peschel and E. Peschel, “What Physicians have in Common with Sherlock Holmes: Discussion Paper,” Journal of the Royal Society of Medicine 82, no. 1 (1989): 33–36. Being a diagnostician is central to the physician’s contemporary role, and detective methods are often used to promulgate and consolidate diagnostic reasoning. This is so ubiquitous that it appeared even in 21st century Medical Grand Rounds at the National Institutes of Health: diagnostician Faith Thayer Fitzgerald charged her clinical audience to read Sherlock Holmes because his fictional methods are archetypal of the diagnostic process (F. Fitzgerald, Clinical Center Grand Rounds, “Mysterious Cases,” National Institutes of Health, 2002). Though the canonical doctor-detective motif is familiar to most humanists (vis-a-vis Sherlock Holmes and Joseph Bell, diagnosis and semiology, see also C. Ginzburg, “Clues: Roots of a Scientific Paradigm,” Theory

and Society 7, no. 3 (1979): 273-88; C. Ginzburg, “Morelli, Freud, and Sherlock Holmes: Clues and Scientific Method,” History Workshop Journal 9, no. 1 (1980): 5–36; U. Eco and T. A. Sebeok, eds., The Sign of Three: Dupin, Holmes, Peirce (Bloomington: Indiana University Press, 1988), it has wider ramifications and points up a more fundamental forensic shift in clinical epistemology and professional identity formation.

11. An excellent analysis of clinical authority as it specifically pertains to medical jurisprudence and railway injury trials in the late nineteenth century in K. M. Odden, “Able and Intelligent Medical Men Meeting Together’: The Victorian Railway Crash, Medical Jurisprudence, and the Rise of Medical Authority,” Journal of Victorian Culture 8, no. 1 (2003): 33–54.

12. This construction was also explicitly gendered (masculine). For more on how the medical profession invoked visions of masculinity, heroism, and self-sacrifice, often through martial metaphors or explicitly military formulations, see M. Brown, “‘Like a Devoted Army’: Medicine, Heroic Masculinity, and the Military Paradigm in Victorian Britain,” Journal of British Studies 49, no. 3 (2010): 592–622; M. J. D. Roberts, “The Politics of Professionalization: MPs, Medical Men, and the 1858 Medical Act,” Medical History 53, no. 1 (2009): 37–56; S.E.D. Shortt, “Physicians, Science, and Status: Issues in the Professionalization of Anglo-American Medicine in the Nineteenth Century,” Medical History 27, no. 1 (1983): 51-68, and of course Joanna Bourke’s work, cited below.

13. Almost thirty years ago, D. Armstrong argued that the “new social diseases” emerged in the early 20th century, generating novel targets for health care intervention and shifting from the lesion-based pathological medicine of the hospital to the extra-corporeal risk factors of surveillance medicine. But as I will demonstrate throughout this paper, I believe these shifts to have started much earlier and to be more fluid and contingent in the dynamic late nineteenth century. (See D. Armstrong, “The Rise of Surveillance Medicine,” Sociology of Health and Illness 17 (1995): 393–404).

14. “Cornelius Herz Summoned in Paris,” New York Times, March 13, 1895, at 7; “The Case of Dr. Cornelius Herz,” British Medical Journal 2, no. 1711 (1893): 858-859; “DR. CORNELIUS HERZ,” Sacramento Daily Union, June 3, 1898, at 1; “Dr. Cornelius Herz,” Wanganui Herald, March 17, 1893, at 3; See Dr. Cornelius Herz, UK Commons, at Volume 28, debated on Tuesday, August 14, 1894 (statement by Mr. Scott Montagu and Mr. Asquith); “The Case of Dr. Cornelius Herz,” Lancet 142, no. 3664 (1893): 1265.

15. J. Bourke, Dismembering the Male: Men’s Bodies, Britain, and the Great War (University of Chicago Press, 1996).

16. A. Conan Doyle, “The Adventure of the Dying Detective,” His Last Bow: A Reminiscence of Sherlock Holmes (New York: George H. Doran Company, 1917): 179–205, at 203. See as well A. Conan Doyle, “The Adventure of the Final Problem,” The Strand Magazine 5, no. 12 (1893).

17. So effectively does Conan Doyle mimic the case report that several physicians have attempted to retrospectively diagnose Holmes’ fictitious “Tapanuli fever” in medical journals (see Setu K. Vora,“Sherlock Holmes and a Biological Weapon,” Journal of the Royal Society of Medicine 95, no. 2 (2002): 101–3; W.A. Sodeman, Jr., “Sherlock Holmes and Tropical Medicine: A Centennial Appraisal,” American Journal of Tropical Medicine and Hygene 50, no. 1 (1994): 99–101; N.J. Ehrenkranz, “A. Conan Doyle, Sherlock Holmes, and Murder by Tropical Infection,” Reviews of Infectious Diseases 9, no. 1 (1987): 222-225; See also: J. Bell, “A Note on Mr. Sherlock Holmes,” Preface to A Study in Scarlet (London,1887); P. Accardo, Diagnosis and Detection: The Medical Iconography of Sherlock Holmes (London: Associated University Presses, 1987); E.P. Scarlett, “The Old Original: Notes on Dr. Joseph Bell Whose Personality and Peculiar Abilities Suggested the Creation of Sherlock Holmes,” Archives of Internal Medicine 114, no. 5 (1964): 696–701; M. Boruch, “Diagnosis, Poetry, and the Burden of Mystery,” New England Review 36, no. 2 (2015): 23-36.

18. See also B. Poore, “The Trickster, Remixed: Sherlock Holmes as Master of Disguise,” in Sherlock Holmes in Context, ed. S. Naidu, Crime Files (London: Palgrave Macmillan UK, 2017): 83–100.

19. For more on medical specialization in the late nineteenth century Euro-American context, enabling both closer observation of a fewer number of cases and administrative shepherding, see G. Weisz’s numerous articles: “The Emergence of Medical Specialization in the Nineteenth Century,” Bulletin of the History of Medicine 77, no. 3 (2003):

536–575; “The Development of Medical Specialization in Nineteenth-Century Paris,” Clio Medicine 25 (1994): 149-188; “Mapping Medical Specialization in Paris in the Nineteenth and Twentieth Centuries,” Social History of Medicine 7, no. 2 (Aug 1994): 177-211; L. Premuda, “La Specializzazione in Medicina: Aspetti Storici e Considerazioni [Medical Specialization: Historical Aspects and Considerations],” Medicina nei Secoli 16, no. 2 (2004):219-36; D. Echenberg, “La Spéciatisation Médicate: Aussi Vieille Que l’Antiquité! Médecine Interne Générale: Perspective Canadienne [A History of Internal Medicine: Medical Specialization: As Old as Antiquity],” Revue Médicale Suisse 28, no. 3 (2007): 2737-2739.

20. For the casuistic disciplines —medicine, jurisprudence, ethics —“strange” or “peculiar” cases serve as a shared epistemic genre see G. Pomata, “The Medical Case Narrative: Distant Reading of an Epistemic Genre,” Literature and Medicine, 32, no. 1 (2014): 1–23. I discuss this in detail in a forthcoming Literature and Medicine article with Iro Filippaki: “The Case of the Peculiar Story: Medical Investigation and the Detective in Edgar Allan Poe and Marguerite Duras.” There is a robust humanities scholarship on the cross-pollination between literary/scientific case narratives ranging from Gothic literature to Realism, sensation, and speculative fiction. For more see J. Tougaw, Strange Cases: The Medical Case History and the British Novel (New York: Routledge, 2006); A. Stiles, Popular Fiction and Brain Science in the Late Nineteenth Century (London: Cambridge University Press, 2011); M. Coyer, Literature and Medicine in the Nineteenth-Century Periodical Press: Blackwood’s Edinburgh Magazine, 1817-1858 (Edinburgh: Edinburgh University Press, 2017); M. Kennedy, Revising the Clinic: Vision and Representation in Victorian Medical Narrative and the Novel (Columbus: Ohio State University Press, 2010).

21. “Detective Medicine,” British Medical Journal 2, no. 1507 (889): 1108–17, at 1109.

22. For more see: A. E. Dembe, “The Medical Detection of Simulated Occupational Injuries: A Historical and Social Analysis,” International Journal of Health Services 28, no. 2 (1998): 227–239.

23. See “Detective Medicine,” supra note 21.

24. The psychopathology of malingerers sits in a broader literature of psychological development, criminality, and contemporary concerns about the porous boundaries between normal and pathological (see discussion of Canguilhem and Durkheim below). Around this period, heightened medical surveillance starts surveying not only the avowedly pathological —the monomaniac, neurasthenic, unstable, and criminal —but healthy populations (see Armstrong on surveillance medicine). The malingerer points up the precarity of the normal, and - continuous with other susceptibilities and pressure points —becomes a subject of exaggerated medical vigilance.

25. Anatomist, Fellow of the Royal Society, and Regius Professor of Medicine at Oxford, Acland was principally responsible for the University Museum at Oxford, and was also curator of university galleries and the Bodleian Library. He wrote a number of textbooks, including (with William Stokes) A Treatise on the Diagnosis and Treatment of Diseases of the Chest, Vol. 98, (New Sydenham Society, 1882), and accounts of cholera in Oxford: H. W.h Acland, Memoir on the Cholera at Oxford, in the Year 1854: With Considerations Suggested by the Epidemic (J. Churchill, 1856).

26. F. Parkes Weber, “Possible Pitfalls in Life Assurance Examination, and Remarks on Malingering,” British Medical Journal 1, no. 2980 (1918): 167–169; B.A. Watson, The Diagnosis of Traumatic Lesions in the Cerebro-Spinal Axis: And the Detection of Malingering Referred to this Centre (New York, 1891).

27. H. W. Acland, Feigned Insanity, How Most Usually Simulated, and How Best Detected: An Essay to Which Was Awarded the Gold Medal in the Class of Medical Jurisprudence in the University of Edinburgh, July, 1844 (London: R. Clay, 1844): at ix–xi.

28. J. Herold, A Manual of Legal Medicine: For the Use of Practitioners and Students of Medicine and Law (Philadelphia: JB Lippincott Company, 1898).

29. E. Durkheim, Rules of Sociological Method (New York: Simon and Schuster, 1982); G. Canguilhem, On the Normal and the Pathological (New York: Springer Science &Business Media, 2012).

30. A. M’Kendrick, Malingering and its Detection Under the Workmen’s Compensation and Other Acts (Edinburgh: E. &S. Livingstone, 1912).

31. See Watson, supra note 26.

32. R. Farquharson, “On The Early Detection of Infectious Diseases,” The Lancet 94, no. 2415 (1869): 798–800, at 798-800; Eighteenth and nineteenth-century entanglements between hygiene, epidemic surveillance, and criminal detection (i.e. medical police, public health and sanitation regimes, and contact tracing) are beyond the scope of this paper, but notable is the introduction of malingering into this dyad —where the methodology of hypervigilance associated with curtailing early contagion (cf. Farquharson, before it spreads rapidly through the population) is applied to exposing feigners. See also P. E. Carroll, “Medical Police and the History of Public Health,” Medical History 46, no. 4 (2002): 461–494; C. Hsien-Yu, “Colonial Medical Police and Postcolonial Medical Surveillance Systems in Taiwan, 1895-1950s,” Osiris 13 (1998): 326-338; A. Bashford, ed. Medicine at the Border (London: Palgrave Macmillan, 2006).
33. See Watson, supra note 31.
34. See Herold, supra note 28; “Department of Medical Jurisprudence,” Chicago Law Times 3, no. 1 (1889): 87–104.

35. See “Detective Medicine,” supra note 23.
36. A. Conan Doyle, “The War In South Africa,” The British Medical Journal 2, no. 2062 (1900): 49– 53, at 49.
37. C. Wynne, “Sherlock Holmes and the Problems of War: Traumatic Detections,” English Literature in Transition, 1880-1920 53, no. 1 (2010): 29–53, at 39.
38. Post-Conan Doyle, the trope of the detective as suspect or criminal recurs as a formal feature of the genre, i.e. in twentieth-century successors such as Agatha Christie (The Murder of Roger Ackroyd, 1926), Rudolph Fisher (The Conjure Man Dies, 1932), and Dorothy Sayers (Clouds of Witness, 1926) among others. Additionally, in Curtain, The Conjure Man Dies, and Clouds of Witness, feigning illness, debility, or death are central plot structures.
39. Jewson’s prototype of Laboratory Medicine, while investigative, focuses on the methods of the natural sciences and the atomization of the patient into material/biological phenomena, rather than the person themselves as a direct object of study and surveillance; N. D. Jewson, “THE DISAPPEARANCE OF THE SICK-MAN FROM MEDICAL COSMOLOGY, 1770-1870,” Sociology 10, no. 2 (1976): 225–244; S. Gillam, “The Reappearance of the Sick Man: A Landmark Publication Revisited,” The British Journal of General Practice 66, no. 653 (2016): 616–617; D. Armstrong, “The Invention of Patient-Centred Medicine,” Social Theory &Health 9, no. 4 (2011): 410–418.
40. D. Armstrong, “The Rise of Surveillance Medicine,” Sociology of Health &Illness 17, no. 3 (1995): 393–404, at 400.
41. For more on contemporary connections between Armstrong’s “surveillance medicine” and personalized medicine, self-monitoring, and the paradoxes of a health system that treats patients and enjoins patients to view themselves as composites of risk profiles, see S. Samerski, “Individuals on Alert: Digital Epidemiology and the Individualization of Surveillance,” Life Sciences, Society and Policy 14, no. 13 (2018); See Armstrong, supra note 40, at 398.
42. J.T. Eskridge, Some Points in the Diagnosis of Certain Simulated Mental and Nervous Diseases (New York, 1890): at 2–3.
43. B. Bramwell, “Malingering: Discussion On,” Transactions: Medico-Chirurgical Society of Edinburgh 32 (1913): 26–56; See Weber, supra note 26.
44. Rotherhithe is south of the Thames, a shorthand for shipyards, docks, and the port, telegraphing Holmes’ proximity to the working classes “south of the river” as well as an influx of global migrants to the metropole; see C. Doyle, “The Adventure of the Dying Detective,” supra note 16: at 180–182.
45. U. Pablo Mukherjee, “‘Out-of-the-Way Asiatic Disease’: Contagion, Malingering, and Sherlock’s England,” in Literature of an Independent England: Revisions of England, Englishness, and English Literature, ed. C. Westall and M. Gardiner (London: Palgrave Macmillan UK, 2013): 77–90.
46. F. Brown, For the Soul of France: Culture Wars in the Age of Dreyfus (New York: Anchor Books, 2011).
47. V. Lenepveu, “No. 10 L’ex copain de Cornelius Herz / Musée des Horreurs / Duke Digital Repository,” 1899, Rubenstein Library, available at <https://idn.duke.edu/ark:/87924/r4w08wp59 >(last visited August 4, 2021); D. R. Watson, “Clemenceau’s Contacts with England,” Diplomacy &Statecraft 17, no. 4 (2006): 715–730.

48. In 1894, French army captain Alfred Dreyfus was wrongly accused of transmitting military secrets to the Germans and subsequently of espionage and treason. The resultant scandal has become a watchword for nationalism and antisemitism in the Third Republic. Author Émile Zola's famous screed "J'accuse" was written to the President of the French Republic in an attempt to exonerate Dreyfus, and was instrumental in generating a public and global response. For more see: C. Forth, The Dreyfus Affair and the Crisis of French Manhood (Baltimore: Johns Hopkins University Press, 2006); E. Cahm, The Dreyfus Affair in French Society and Politics (New York: Routledge, 2014); R. Celestin and E. DalMolin, "Scandal and Innovation in the Third Republic (1871–1899)," in France From 1851 to the Present: Universalism in Crisis, ed. R. Celestin and E. DalMolin (New York: Palgrave Macmillan US, 2007): 89–126; H. Arendt, "From the Dreyfus Affair to France Today," Jewish Social Studies 4, no. 3 (1942): 195–240.
49. See "The Case of Dr. Cornelius Herz," British Medical Journal, supra note 14
50. "The Case of Dr. Cornelius Herz," Lancet 145, no. 3743 (May 25, 1895): 1328.
51. See supra note 49.
52. "Deadly Ice-Creams," The Lancet 152, no. 3907 (1898): 164.
53. See supra note 51.
54. See supra note 50.
55. T. Barlow, "Notes and Correspondence Relating to the Medical Examination of Dr Cornelius Herz, at Bournemouth," Wellcome Collection PP/BAR/F/4 (April 1896).
56. See supra note 53.
57. See Brouardel, Etat de Santé de Cornélius Herz; "…that he is in full possession of his intellectual faculties. He is no longer the anemic and emaciated man from June; he is no longer the man collapsing from weakness and starvation," at 3.
58. See La Chronique Médicale, "[the fake Cornelius Herz,] shown to the medical experts during their mission, while the real one, the only one, plays croquet, and travels in France;" "It would appear that they [the English physicians] had never seen a patient with diabetes, albuminuria, or cardiac afflictions experience a remission in the trajectory of his illness," at 480.
59. P. Ricoeur, Freud and Philosophy: An Essay on Interpretation (Yale University Press, 1970).
60. On the multiplicity of clinical narratives —phenomenological, written, and embodied —and a robust critique of biomedicine's refusal to acknowledge its hermeneutic self-understanding, see D. Leder, "Clinical Interpretation: the Hermeneutics of Medicine," Theoretical Medicine and Bioethics 11, no. 1 (1990): 9–24. For a historical and philosophical survey on Heidegger and hermeneutics structuring medical knowledge and practice see F. Svenaeus, The Hermeneutics of Medicine and the Phenomenology of Health: Steps Towards a Philosophy of Medical Practice (Dordrecht, The Netherlands: Kluwer, 2000); M. Heidegger, Sein und Zeit (Halle: M. Niemeyer, 1927); K. Montgomery Hunter, Doctors' Stories: The Narrative Structure of Medical Knowledge (Princeton: Princeton University Press, 1991).
61. P. Brown, "Naming and Framing: The Social Construction of Diagnosis and Illness," Journal of Health and Social Behavior, Extra Issue (1995): 34–52; C. Rosenberg, "The Tyranny of Diagnosis: Specific Entities and Individual Experience," The Milbank Quarterly 80, no. 2 (2002): 237–260.
62. For more on Ebola PUI, see M. C. Wadman et al., "Emergency Department Processes for the Evaluation and Management of Persons Under Investigation for Ebola Virus Disease," Annals of Emergency Medicine 66, no. 3 (2015): 306–314; H. Wu et al., "The Potential Ebola —Infected Patient in the Ambulatory Care Setting: Preparing for the Worst Without Compromising Care," Annals of Internal Medicine 162, no. 1 (2015): 66-67. COVID-19: A. J. Singer et al., "Cohort of Four Thousand Four Hundred Four Persons Under Investigation for COVID-19 in a New York Hospital and Predictors of ICU Care and Ventilation," Annals of Emergency Medicine 76, no. 4 (2020): 394-404. I am also influenced by Adia Benton's work on Ebola and public health surveillance: "Ebola at a Distance: A Pathographic Account of Anthropology's Relevance," Anthropological Quarterly (George Washington University Institute for Ethnographic Research) 90, no. 2 (2017), 495–524 and "International Political Economy and the 2014

West African Ebola Outbreak," African Studies Review 58, no. 1 (2015): 223-236. Thanks to Lorenzo Servitje for our conversations about "PUI" and clinical investigation from the individual to the scalar, as well as for his book Medicine is War: The Martial Metaphor in Victorian Literature and Culture (New York: State University of New York Press, 2021), which offers excellent paradigms and critiques of how metaphors structure medical epistemology.
63. "CDC Updates Criteria to Guide Evaluation of Persons Under Investigation for COVID-19, Provides ICD-10," American Trauma Society (February 28, 2020), available at <https://www.amtrauma.org/news/491215/CDC-Updates-Criteria-to-Guide-Evaluation-of-Persons-Under-Investigation-for-COVID-19-Provides-ICD-1.htm >(last visited August 4, 2021).
64. S. Vaisrub, "Monitoring for Mendacity," JAMA 241, no. 20 (1979): 2194.
65. One of the avowed aims of narrative medicine is to ameliorate these tensions, to "fortify health care with the capacity to skillfully receive the accounts persons give of themselves —to recognize, absorb, interpret, and be moved to action by the stories of others." See R. Charon, "Introduction," The Principles and Practice of Narrative Medicine (London: Oxford, 2016). The newer wave of critical medical humanities articulates a more incisive critique as well as an embrace of clinical and humanistic complexity (see W. Viney et al., "Critical Medical Humanities: Embracing Entanglement, Taking Risks," Medical Humanities 41 (2015): 2-7; See also S.D. Goold, "Trust, Distrust and Trustworthiness," Journal of General Internal Medicine 17, no. 1 (2002): 79-81; S. Peters et al, "What Do Patients Choose to Tell their Doctors? Qualitative Analysis of Potential Barriers to Reattributing Medically Unexplained Symptoms," Journal of General Internal Medicine 24, no. 4 (2009): 443 -449; W.A. Rogers, "Is There a Moral Duty for Doctors to Trust Patients?" Journal of Medical Ethics 28 (2002): 77-80; K. Hawley, "Trust and Distrust Between Patient and Doctor," Journal of Evaluation in Clinical Practice 21, no. 5 (2015): 798-801.
66. H. Lempp and C. Seale, "The Hidden Curriculum in Undergraduate Medical Education: Qualitative Study of Medical Students' Perceptions of Teaching," British Medical Journal 329 (2004): 770; J. Peng et al., "Uncovering Cynicism in Medical Training: A Qualitative Analysis of Medical Online Discussion Forums," British Medical Journal Open 8, no. 10 (2018): e022883; There is little literature extant on this topic, but this excellent op-ed by a medical trainee unravels the connections between perceived patient deceit, subjectivity, and the medical hidden curriculum: B. Saaquib, "Liars, Alcoholics, and Malingerers: Medicine's Hidden Curriculum," Op-Med Doximity Network, available at <https://opmed.doximity.com/articles/liars-alcoholics-and-malingerers-medicine-s-hidden-curriculum?_csrf_attempted=yes >(last visited August 2, 2021).
67. Engineering National Academies of Sciences, Improving Diagnosis in Health Care, 2015; H. Singh et al., "The Global Burden of Diagnostic Errors in Primary Care," BMJ Quality &Safety 26, no. 6 (2017): 484–494.

DETAIL

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“The Offspring of Drunkards”: Gender, Welfare, and the Eugenic Politics of Birth Control and Alcohol

Reform in the United States

Lauren MacIvor Thompson

ABSTRAK (ENGLISH)

The social politics of women's alcohol use is controversial given current debates over maternal-fetal health, fetal alcohol syndrome, and debates about welfare. Exploring the early twentieth century intersections of Prohibition, birth control reform, and alcohol politics reveals the historical roots of current recommendations surrounding women, alcohol, and public assistance.

TEKS LENGKAP

Alcohol use has always been a persistent social concern in the United States, rife with the stigmas of laziness, poverty, and dependence that endure alongside its more recent medicalization. But the potential for pregnancy adds yet another layer of complexity regarding public health policy on women and alcohol use. In summer 2021, the draft Global Alcohol Action Plan 2022-2030 released by the World Health Organization advised, "Appropriate attention should be given to …prevention of drinking among pregnant women and women of childbearing age." In doing so, they joined the Centers for Disease Control in the United States, who in 2016 had also officially recommended that sexually active women refrain from drinking unless using contraception. In both cases, the recommendations were met with public skepticism, with critics noting that men who consume alcohol were not mentioned in either case (even though recent studies have shown an increase in birth defects related to men's use of alcohol prior to conception).[1]

Despite this resurgence in awareness and controversy, the regulatory guidance on these issues is not new. Indeed, examining the historical relationship between the movement to legalize birth control and the simultaneous attempts to regulate alcohol in the twentieth century can illuminate rationales behind modern policies on alcohol and welfare reform, as well as concomitant understandings of dependency and disability. After all, public health protocol has long linked the social costs of alcohol with both the protection of women and fears of non-marital births or disabled children. In nineteenth-century America, much of the temperance movement's strength rested upon notions of women as victims of both male drunkenness and their responsibilities for maintaining domesticity and purity. This meant that women who drank, to excess or not, were especially vulnerable to accusations that not only were they harming themselves and their families, but also damaging the feminine obligation to keep society itself moral.[2] Physicians and reformers warned that women who drank could pass on the tendency toward drunkenness as well as disease, disability, and bad moral temperament to their children. Later, these concerns were reformatted with the identification of Fetal Alcohol Syndrome in the early 1970s. The recent CDC and WHO guidance extends the longstanding idea that women's responsibility for a healthy pregnancy is hers and hers alone, and that it begins before conception.[3]

Although much of this guidance centers on improved maternal-child health, deeper concerns about disability and dependence are underneath the surface of the concerns about alcohol and pregnancy. The connection between alcohol use, labor, and welfare dependency remains fraught and understudied, especially in the context of gender. Women with dependent children who have alcohol and substance abuse issues often encounter significant barriers in applying for and receiving federal aid. Although there is not much contemporary data to assert definitively that women with alcohol or drug dependency are more likely to be welfare recipients or unemployed, the perception that welfare itself promotes alcohol and drug use informs public thinking around federal aid programs and the need to incorporate personal responsibility as a central requirement for public assistance.[4] These perceptions also extend to gendered understandings of women's roles as mothers and the social impact of non-marital births and single-parent

households.

The historical context behind these ideas and polices can be partially traced to the relationship between the various factions of the temperance, birth control, and anti-Prohibition civil liberties groups of the 1920s. In the age of Prohibition, the overlapping politics of alcohol reform and the movement to legalize birth control coalesced in a shared rhetoric. Both movements associated drinking and disability together in a set of compelling arguments for the protection of the family and American society from drunken men. Both sides argued that their pursuit of laws governing the public's use of either alcohol or contraception constituted a gain for eugenics, influencing the "health, sanity, and stamina of generations yet unborn" as eugenics reformer Albert Wiggam phrased it.[5] Yet temperance and birth control were not always compatible bedfellows. Their respective advocates clashed over questions of morality, health, and the public good in their simultaneous pursuits to either maintain or remove the legal prohibitions on alcohol and birth control.

Temperance had long made arguments about health and home to win Prohibition. In the antebellum period, the burgeoning anti-alcohol movement had its roots in women's general moral reform associations. Yet the temperance movement went beyond mere moral suasion, linking their fight against alcohol directly to the politics of the suffrage movement. Although not all temperance advocates were suffragists, many of them were "relatively willing to express what [reformer] Amelia Bloomer called 'a strong woman's rights sentiment'" and insisted that gaining the right to vote was the most important key to accomplish their aims. By the late nineteenth century, the Women's Christian Temperance Union (founded in 1874) had become a major political force as the largest women's organization of the post-Reconstruction era. By the 1920s, it had a membership of nearly 350,000, only declining after 1933 when Prohibition was repealed. The organization taught that "alcohol is a poison; that its use breaks down the physical nature and harmfully affects the blood, the nerves, the heart, and makes the drinker an easy prey to disease …alcohol attacks the moral nature, and its use causes an increased need of institutions for the dependent, the delinquent and the criminal classes."[6]

Indeed, the WCTU attracted enormous support in their crusade against the liquor industry and cannily framed women's rights through the lens of the dangers of male vice. Men who drank failed to live up to the marital bargain that called for female subordination in exchange for physical protection and economic security. As one newspaper editor pointed out, "Many …men believe that their wife is as much their property as their dog and horse and when their brain is on fire with alcohol, they are more disposed to beat and abuse their wives than their animals…. Every day, somewhere in the land, a wife and mother —yes, hundreds of them —are beaten, grossly maltreated and murdered by the accursed liquor traffic, and yet we have men who think women should quietly submit to such treatment without complaint."[7] Reformers argued that women needed protection from the violent sexual advances of drunken husbands —a situation that placed "women in a slavery worse than that of chains" by "brutal and designing men."[8] In an age in which marital rape law did not exist, nor legal birth control, temperance and women's rights advocates insisted that alcohol contributed more than its fair share to female misery, both emotional and reproductive. The idea of "voluntary motherhood," in which women had the right to refuse their husbands' sexual advances in order to only bear children they welcomed, rested in part on women's enforcement of temperance in the home. "Woman gives birth to man; alcohol destroys man …It is impossible then, that woman, better instructed, should not be the irreconcilable enemy of a poison that is destructive of her offspring" one reformer reminded her audience.[9]

The organized movement for Prohibition not only relied on these gendered framings, but also nativist and racist sentiments about drink. As temperance crusader Annie Wittenmyer observed in her *History of the Woman's Temperance Crusade*, published in 1882, "I cannot close this volume without calling attention to the relation of foreign emigration to the liquor traffic, and to crime and pauperism …more than two-thirds of the entire liquor business is in the hands of a low class of foreigners, although the entire foreign population of the country constitutes less than one-sixth."[10] The WCTU, with their motto, "For God and home and native land," told its members that the "incoming tide from the old world" was leaving its "vicious portions in the city centers," and to tell the foreign-born, "If you don't like our institutions, take the first boat and go home."[11]

The dangers that alcohol presented in the form of violent husbands and drunken immigrant mobs were also neatly incorporated into fears about the larger effects of alcohol on the health of future generations. The popularization of the theory of eugenics provided a persuasive scientific framing for publicizing alcohol's dangers to heredity.

Eugenics first made its debut in 1865 after the British scientist Francis Galton (who also happened to be Charles Darwin's second cousin) published his essay "Hereditary Talent and Character" in *Macmillan's Magazine*. The paper argued that humans could control and improve their offspring's mental qualities and "natural ability" through picking partners as carefully as breeders did for livestock.[12]

Ideas about heredity had long been part of scientific understandings of reproduction and inheritance of traits, but the idea that humanity could breed deliberately for particular traits was new. Galton did not use the word "eugenics" (derived from the Greek word *eugenes*, meaning "good in birth,") until 1883 in his book *Inquiries into Human Faculty and Its Development* and would define the term succinctly in 1904 for the *American Journal of Sociology* as "the science that which deals with all influences that improve the inborn qualities of a race; also with those that develop them to the utmost advantage."[13] As Paul Lombardo has noted, "…it is difficult to describe all the things that eugenics meant to the public." A concept that "became concrete in a variety of ways, from political movements to voluntary social programs" and beyond into restricting reproduction of the unfit, eugenics came to mean different things to different groups.[14]

For eugenic reformers, they speculated on various (and often competing) theories about the relationship between alcohol and soft and hard heredity. Discussion about the dysgenic effects of liquor on women and children proliferated, as newspapers and journals trumpeted the results of eugenic family studies in which hordes of unwanted children were born to drunkard parents. As one report concluded, "This fact of inherited disease is a terrible contradiction of the argument that a man has a right to drink if he wants to."[15] Physicians like William Healy theorized that the alcohol circulated through membranes of a pregnant women's womb and entered into the fetus' developing brain, bathing its cells in alcoholic poison. He noted that the "drinking mother stands a very good chance, by all accounts, of bringing forth children with defective or unstable nervous systems. We know the relation, in turn, of these abnormalities to inefficiency and to criminalism." Healy also noted the Lamarckian nature of alcohol's general immoral effects, observing that often "there was so much else that might account for a child's bad conduct" that it was often difficult to tell if alcohol was even the main factor.[16]

Indeed, for many researchers, the question of exactly how alcohol affected offspring remained unclear. "Does alcohol affect the germ plasm injuriously, producing hereditary defects, or does it have a selective effect, as some of held, killing off the weaker germ cells and allowing only the better to survive?" wondered University of Pennsylvania geneticist Phineas Whiting. He explained, "In the former case it would be dysgenic, in the latter eugenic. Hence, is a reformed drunkard more eugenic, or less so than a man who has always been a total abstainer?"[17] Once Prohibition became the law of the land, eugenicists and physicians proceeded to divide themselves into both "dry" and "wet" camps to debate the true impact of alcohol on racial degeneracy alongside the relative virtues (or lack thereof) of the Eighteenth Amendment.[18] Yet as Janet Golden has observed, for nineteenth and early twentieth-century social critics, "It was not the method by which alcohol did its damage but the damage it did that captivated their interest. Whether children suffered from poor heredity, poor parenting, poor living conditions…or from their own alcohol habit mattered less than the fact that they were liable to become disorderly and dependent citizens."[19]

The Women's Christian Temperance Union embraced not only the politics of alcohol, but also employed the new science of eugenics as a weapon in their political quest to eliminate alcohol in society. They formed their own "Department of Heredity" and a Bureau of Hereditary Statistics, which served as a research data clearinghouse. They also published their own *Journal of Heredity*, frequently reprinting nearly all of Francis Galton's early essays and addresses on eugenics and setting up the dictates of Galtonian-influenced research programs.[20] Additionally, secondary school temperance literature published by the WCTU's "Department of Scientific Instruction" explained the workings of hereditarian thought to students, and warned of the social consequences of parents' transmittal of liquor-disordered bodies and minds to their children.[21] For the most part, the WCTU's understanding of alcoholism rested on the Lamarckian idea of soft heredity, in which a person's bad environment and bad choices could then be

passed on to their offspring. In other words, as WCTU literature put it, “Sometimes one is sick or suffers very much because of wrong things that his parents or grandparents did.”[22] Heredity was thus understood as an unfixed process, and the popularity of Lamarckian thought ultimately had the effect of bolstering the importance of the WCTU’s efforts at social reform.

By the 1920s, the emergence of the birth control movement would further alter the debates over heredity and its associated connection with the politics of alcohol and Prohibition. Once widely available, birth control devices and literature had been illegal in the United States for decades. Vice-reformer Anthony Comstock, who had established his New York Society for the Suppression of Vice (NYSSV) in 1872, had then successfully persuaded Congress to pass the “Comstock Postal Act” which banned the mailing of “obscene, lewd, lascivious, or filthy” material through the U.S. Postal Service. Over the ensuing decades, judicial interpretations of obscenity were dispensed with wide latitude and covered any publications or materials dealing with sex and birth control.[23]

The Comstock laws alongside Prohibition produced much caustic editorial fodder as some Progressives chafed at both the regulations governing alcohol and Comstockery’s restrictions on free speech. Famed newspaper editor Arthur Brisbane wrote in his syndicated “Today” column of the ironies of unlawful alcohol and illegal birth control.

What about the prohibition law?… A man in the west was accused of having wine in his house. Nobody was drunk, but agents broke in and killed his wife. Is there a different law for Park Avenue, New York? A New York birth control clinic is raided, five women locked up. The law says you mustn’t give information about birth control …Everybody knows that prosperous women get without trouble all the birth control information they want from able, respectable doctors. However, in this land of equality, there is always a difference between the rich and the poor, whether in prohibition or birth control.[24]

In Margaret Sanger’s *Birth Control Review*, she too mocked the double standard of Americans breaking both alcohol and birth control laws “with equal vigor,” but even more importantly, noted there was a gendered price for women seeking reliable medical information on contraception.

When laws are passed that men (or some men) don’t like, they have so many wonderful ways of evading them. Just think of it …Aeroplanes at their service …Hotel proprietors with bureau drawers at their disposal. Automobile makers who will manufacture trucks to hold both gasoline and booze …All at the service of rebellious law breaking men who want to get comfortably drunk. And when women want medical information, safe, sane, decent contraceptive information to protect their health and their homes and their children –they are hounded, vilified, jailed, fined, trapped …They have …no aeroplanes, automobiles …hotels …There you are. A nice clear cut contrast in law breaking.[25]

Other women’s rights advocates also noted the hysteria of purity reformers’ restrictions on both sexual rights and the personal choice to use alcohol. As one editorial put it, “Grandma was a pessimist about human nature. It is pleasant to reflect that her granddaughters today in increasing numbers, have enough respect for the race to believe that prohibition repeal and legalized birth control may be risked without a Saturnalia of promiscuous love making and drunkenness as the inevitable result.”[26]

Yet the overlapping politics of alcohol reform and the birth control movement often resulted in complex divisions. For example, the sympathy exhibited toward “fallen women” by temperance supporters and members of the WCTU did not necessarily extend to supporting Sanger’s movement. The WCTU had its own Department for the Promotion of Purity in Literature and Art, which supported censorship of materials deemed immoral, while the larger organization worked for stricter prostitution reform laws and to raise the age of sexual consent in nearly every state.[27] But their concerns about sex and exploitation did not include openly advocating for legal birth control.[28]

Further, anti-Prohibition supporters often framed their stance not through the rhetoric of civil liberties or personal right, but rather by employing the same arguments of home protectionism and anti-immigrant, anti-criminal sentiments that temperance advocates had used for decades. Opponents of prohibition claimed that the Eighteenth Amendment, far from improving society, had merely provoked a crime wave, created a criminal class, increased prostitution, and decreased young people’s respect for the law. Women, especially those who joined the Women’s Organization for National Prohibition Reform (founded in 1929), used anti-criminal and anti-immigrant rhetoric to argue for the repeal of prohibition but not for the legalization of birth control.[29] Indeed, anti-birth control views fit

neatly into the framework of amendment repeal. As one president of a local chapter of the Hibernian Society declared, Prohibition's increasing crime and lawlessness had "ill effects on our young people" but also that "Birth control will ruin the nation unless the practice is stopped at once."[30]

The movements for temperance, anti-Prohibition, and birth control may have diverged in terms of political framing, but they nonetheless shared a focus on eugenics as a central underpinning. Margaret Sanger and her supporters naturally incorporated the anti-alcohol views present in the philosophy of voluntary motherhood to strengthen their case for the legal distribution of contraceptive literature, and to underscore the link between the need for birth control, the social costs of alcohol, and eugenic improvement.

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Aside from these kinds of emotional appeals long familiar to temperance advocates, Sanger also focused on the problems presented by alcohol as a disseminator of poverty and vice, with the solution being not temperance, but legal contraception. One story reprinted in the *Review* told of a woman who had a "down-at-heel, hungry, out-at-elbow" childhood, growing up with a "swarm of others in a tiny cottage." The woman as an adult then began to "[drift] into daily drinking, a weak-willed, weak-souled, weak-bodied woman creature, easy prey for the first half-drunken, acquisitive male." Her husband was away in the First World War, and "before he had been gone a year, there was another child in the four-roomed cottage and another soldier in France who had 'left a little thing behind him.'" The story concluded with the mother dying and her passel of dirty, hungry children sent to social services. Neatly linking alcoholism, poverty, immorality, and the need for contraception to control the fertility of a woman who could not take care of herself, the tale warned its readers of the consequences of a society rampant with defectives. Sanger explained the need for legalized birth control to prevent people like the woman character of the story from procreating and transmitting indefinitely their insanities and alcoholic predispositions.[33] As the welfare state solidified in this period, Sanger's apocryphal stories about both deserving mothers and those with bad heredity making poor reproductive choices served as important rhetorical tools in urging the legalization of birth control. This rhetoric was part of larger initiatives designed to improve not only general public health, but to lessen the burdens placed on the system by the delinquent and defective —the undeserving poor.[34] Birth control, promised Sanger, could eliminate these problems before they even happened.

Physicians occasionally questioned Sanger's logic. Dr. Aaron J. Rosanoff explained that he doubted whether birth control was "fully capable" of eliminating the problem of "bad heredity," scoffing that birth control "seems to be employed for other than eugenic reasons by those who from a eugenic standpoint would least need to employ it, and it seems to be the most neglected by those from a eugenic standpoint who would most need to practice it." But he conceded that it was entirely possible that freely available birth control information would help eliminate "syphilis, alcoholism and drug addictions."[35] Other doctors insisted that Sanger was right, and that birth control was a crucial prophylactic tool in preventing the births of the feebleminded to drunkard parents.[36] These medical debates aside, by

framing the need for birth control through both the moral and eugenic politics of alcohol use, Sanger was able attract enormous support for her American Birth Control League by the end of the 1920s, and firmly link in the public mind the use of birth control with the prevention of social degeneration, disability, and vice. In other words, by making the link between alcohol and birth control explicit in their propaganda literature, it furthered public support for birth control in a way the deemphasized the radical feminist origins of the movement and instead linked it to broader conceptions of public health.

Examined together, the temperance and birth control movements demonstrate the increasing scientifically-oriented and professionalized nexus of Progressive reform causes. In particular, white, middle-class women reformers stood at the forefront of each of these movements and popularized support for their them by drawing on eugenics, whose doctrines fit neatly into the broader Progressive milieu of social improvement. Moreover, women's central roles in these reform causes were almost certainly a result of eugenics' longstanding emphasis on women's right to choose fit mates and their superior ability to observe and improve familial relationships.[37]

Eugenics thus cemented via the weight of scientific authority the far longer history of American women's reform efforts, whose roots were in antebellum domestic moral reform and the abolitionist movement. Crucially, both anti-alcohol and pro-birth control stances aligned supporters with their causes by emphasizing the preservation of home and family above all. Eugenics provided the scientific and medical backing for much older sentiments about maternal and family affection as the solution for regenerating and improving broader social health. Although temperance had long been part of arguments for moral reform, the birth control movement's ideological pivot toward eugenics and public health was key to incorporating it into the canon of domesticity and Progressive benevolence. The debate over alcohol's effects served as a critical entry point and ultimately altered the nature of concomitant arguments over contraception's role in society.

Yet aligning birth control and anti-alcohol stances would come with a cost for women's rights and the rights of the disabled throughout the remainder of the twentieth century. Women's moral responsibility for their health behavior and the health outcomes of their fetuses and babies would invite medical scrutiny and continued broad policing by the state of their reproductive lives. By stigmatizing alcoholism as a preventable moral disease and prescribing birth control as the solution, women (and not men) were ultimately responsible for the number and health of the children they bore, and for their economic circumstances. Further, as medical understandings of intellectual disability and fetal alcohol syndrome developed later in the twentieth century, the moral panic surrounding women, alcohol, and contraception only intensified.

The making of fetal alcohol syndrome (FAS) reformatted early twentieth-century eugenic concerns about alcohol and babies into a more modern diagnosis. Research on the relationship between alcohol and heredity declined after the lifting of Prohibition laws, and instead focused on alcohol's role in human disease and the science of addiction.[38] At the same time, research on contraceptive drugs and methods ramped up considerably beginning in the early 1940s and can be considered part of the popular twentieth-century scientific interest in population and maternal-child health. Unlike earlier in the century, the two research areas, alcohol and reproductive health, were kept relatively separate, and many experts had come to dismiss the idea that alcohol could affect offspring directly. It was not until the 1970s, when FAS was officially named, that physicians and researchers began to again explore the question of how and why alcohol damages a fetus, and what, if anything, should be done about it. As Janet Golden has noted, FAS came to be understood as both "a description of the spectrum of effects resulting from heavy alcohol exposure in utero and as a way of naming the behavior of pregnant women."[39] The courts, Congress, the FDA, physicians and the public debated the intersections of abortion and disability rights, the rights and obligations of pregnant women, and the right to privacy and choice in women's individual lives, even as teratogens (including alcohol) attracted increasing research scrutiny.

Birth control was part of these debates but served as a less controversial aspect, since by the time FAS emerged as a diagnosis, it was legal for all adult women to obtain contraception regardless of marital status. Medical recommendations for avoiding unwanted pregnancy harmonized with the advice on safe drinking and how to avoid fetal alcohol syndrome. But in 2016, the Centers for Disease Control and Prevention's new guidelines for sexually

active women presented a new angle. Women who did not use birth control should refrain from drinking altogether, as there is no known safe amount of alcohol to drink while pregnant. In response, critics used the words “puritanical” and accused the CDC of promoting the idea that women could not be responsible or trusted. Similar concerns animated the response to the 2021 guidance released by the WHO.

In the story of the long relationship between alcohol use and reproductive health, the WHO and the CDC’s guidelines for alcohol and pregnancy serve as an interesting foil to the rhetoric of the 1920s. Rather than using alcohol as an entry point to further the acceptance or legalization of contraception, instead contraception is now the requirement for women’s alcohol use. And yet, though separated by a century, the exhortations of both campaigns share a similar goal. In both cases, the rhetoric of fetal health places the responsibility on the woman for a healthy pregnancy and the enduring duty to place fetal life above her own, even when that life is nothing more than a future possibility.

The recent guidelines thus reveal an important shift in the thinking on fetal rights. In the 1920s, the literature on temperance, anti-Prohibition programming, and birth control all emphasized the general betterment of the race if each agenda were met. Although women activists also used these individual movements to further their political and social gains, ultimately the strength of the anti-alcohol, anti-Prohibition, and pro-contraception movements rested not on the advancement of individual rights for women or the disabled but rather the broader health of the public.[40] All three campaigns emphasized how social morality would improve, people would be healthier, and the overall strength of the nation would grow.

However, for the past several decades, the emergence of the fetus as an individual subject with equal rights has fundamentally altered medical and public health debates on pregnancy and teratogenic substances like alcohol. Assigning the rights of personhood to fetuses in the womb not only allows the perpetuation of historic arguments about women’s ultimate responsibility for the effects of their moral choices surrounding their unborn children, but also positions arguments for women’s freedom of choice (such as in alcohol use) in competition with abortion rights and the rights of the disabled. As Katha Pollitt phrased it in her famous essay for *The Nation* just as the abortion wars of the 1990s began to escalate, “As the ‘rights’ of the fetus grow and respect for the capacities and rights of women declines, it becomes harder and harder to explain why …a woman can choose an abortion but not vodka.”[41] The recent public health guidelines on birth control, pregnancy, and drinking contribute to these ongoing debates about fetal personhood, as part of a legal and social dilemma that pits women’s rights directly against the rights of other groups.

Further, the historical relationship between alcohol legislation and birth control and abortion politics reveals new insights into contemporary debates about labor force participation, malingering, and the nature of alcohol and drug dependency. Over the last several decades, work requirements under various administrations were tightened for welfare qualification, and the emphasis beginning in the 1990s on transitioning from welfare to work reemphasized recipients’ personal responsibility rather than the structural barriers affecting their employment status, family stability, and health. These policy deliberations also echo far older ideas about gender and motherhood that were present in the late nineteenth and early twentieth century. The emphasis on marriage, sexual abstinence, and women’s responsibility for the family remains central to federal programs like Temporary Assistance for Needy Families (TANF) which has incentives for two-parent families and punishments for parents who abuse drugs or alcohol or who otherwise do not comply with work and child support requirements. In other words, alcohol use, pregnancy, and single motherhood remain hot-button issues in the decisions surrounding who “deserves” welfare.

Examining how these ideas developed in the past and in conversation with each other can be useful indicators for both reproductive and future welfare policy initiatives. Progressive Era reformers, birth control advocates, and pro and anti-Prohibition factions created concrete political strategies and campaigns, often in response to each other, that deliberately exploited deep anxieties about gender, race, and class in America. Although the rhetoric has changed and flattened, the animating core of anxiety remains in the often-confusing modern vocabulary around alcohol, pregnancy, and responsibility. As we seek more effective public health messaging on alcohol and its risks, and a more efficient welfare system that improves peoples’ lives, policymakers’ knowledge of these historic issues is

not just nice to have, but a critical component of improvement in delivery and outcomes.

Note

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DETAIL

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Developing an Innovative Pandemic Treaty to Advance Global Health Security

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ABSTRAK (ENGLISH)

Recognizing marked limitations of global health law in the COVID-19 pandemic, a rising number of states are supporting the development of a new pandemic treaty. This prospective treaty has the potential to clarify state obligations for pandemic preparedness and response and strengthen World Health Organization authorities to promote global health security. Examining the essential scope and content of a pandemic treaty, this column analyzes the policymaking processes and substantive authorities necessary to meet this historic moment.

TEKS LENGKAP

The World Health Assembly will be holding an unprecedented second meeting this year, with only a single item on the agenda for this November 2021 meeting —the development of a new pandemic treaty. This pandemic treaty provides a path to develop international legal obligations through the World Health Organization (WHO). Yet despite strong international political support for such a treaty, there has been little examination of its potential scope, substance, and legal process.

This column explores the legal content of a prospective pandemic treaty, offering guidance on its key provisions. Recognizing stark failures in global governance during the COVID-19 pandemic, this new treaty is intended to clarify state obligations to prevent, detect, and respond to pandemic threats and to strengthen WHO powers. The treaty, therefore, must develop innovative norms, governance, and compliance mechanisms needed to prepare for novel outbreaks with pandemic potential.

Examining the development of global health law reforms, this column opens by reviewing the evolution of international legal agreements governing global health security. However, the COVID-19 pandemic has exposed continuing limitations of international law and weaknesses of WHO authorities. These limitations provide the impetus for a new international legal agreement to strengthen pandemic preparedness and response. This column analyzes potential treaty structures and substantive authorities needed to face future pandemic threats. We end by reflecting on diplomatic challenges that states must confront in bringing the world together to develop a bold new treaty to advance global health security.

WHO Legal Authorities to Develop Global Health Law

States have provided WHO with expansive authorities to develop global health law. Pursuant to these powers, the World Health Assembly has codified evolving regulations to coordinate international action to prevent, detect, and respond to pandemic threats.

WHO Constitution as a Mandate for Global Health Lawmaking

Under the 1946 WHO Constitution, states declared the “highest attainable standard of health” to be a fundamental human right, providing WHO with authority to develop international law on any public health matter through the adoption of:

•Conventions (article 19) —treaties and agreements that set standards to promote public health,

•Regulations (article 21) —legally-binding standards that designate specific actions that must be taken by member states, and

•Recommendations (article 23) —non-binding guidelines that provide member states with standards to promote public health.[1]

Although WHO was created as a normative agency, with a constitutional mandate to develop global health law, the organization has long been reluctant to exercise its legal authority under article 19 to develop conventions, looking instead to article 21 in advancing the International Health Regulations (IHR).[2]

International Law to Prevent, Detect, and Respond to Pandemics

The IHR stand as the leading legal agreement to respond to the globalized threat of infectious diseases. Originating out of the international sanitary agreements that predated WHO, the World Health Assembly has revised the IHR several times to respond to changing health threats.[3] The current IHR, revised comprehensively in 2005 following the SARS-1 epidemic, has broad participation from WHO member states, with 196 states parties adopting the regulations to guide efforts to prevent, detect, and respond to a disease outbreak. In balancing measures to facilitate global health security while maintaining international travel, trade, and human rights, the IHR empower WHO and member states in detecting and responding to public health emergencies of international concern.[4]

Beyond the IHR's binding standards, states have negotiated non-binding "soft law" frameworks to advance health security. The Pandemic Influenza Preparedness (PIP) Framework, while limited to pandemic influenza strains, brings together WHO, member states, and non-state actors (e.g., pharmaceutical companies and academic laboratories) to help coordinate international sharing of novel influenza pathogens, facilitating equitable distribution of the benefits of influenza research in developing vaccines and therapeutics.[5] Outside WHO, states and international organizations have come together to establish the Global Health Security Agenda (GHSA) to enhance country capacities to prevent, detect, and respond to infectious diseases, emphasizing global health security as a national priority and targeting multisectoral gaps in national policy.[6]

Limitations of Global Health Law in the COVID-19 Response

The COVID-19 pandemic has re–vealed deep flaws in this global health law framework for pandemic preparedness and response, as the IHR have faced limitations in shaping national responses, and political controversies have weakened WHO governance and institutional capacities.

IHR Limitations

The international response to the COVID-19 pandemic has exposed severe limitations in IHR obligations (and state compliance) to shape an effective coordinated response to global public health emergencies. Despite major IHR reforms in 2005, the national and global response to COVID-19 has seen:

failures to notify WHO promptly of novel outbreaks. The IHR require states parties to report to WHO "timely, accurate and sufficiently detailed public health information." China appeared to violate this norm by failing to promptly report a novel coronavirus circulating in Wuhan. WHO discovered the outbreak from "unofficial" sources, and even then, China downplayed the extent of community transmission. Since that time, China has not fully cooperated with WHO in impartially investigating the origins of SARS-CoV-2. The inability of WHO to assess events independently created delays in detection of, and response to, a novel coronavirus outbreak.

Delays in declaring a Public Health Emergency of International Concern (PHEIC).This inadequate reporting —compounded by a split in expert opinion, misapplication of the legal definition of a PHEIC, and WHO's diplomatic hesitation —prevented a timely WHO PHEIC declaration, by which point a pandemic was already well underway. While the WHO Director General did declare a PHEIC on January 30, 2020, there were confused signals five weeks later when the Director-General declared a "pandemic," as WHO has no formal legal power to declare pandemics under the IHR.

Non-compliance with WHO recommendations in the outbreak res–ponse. It is important to effectively manage an outbreak response at the global level as it spreads internationally. Yet, WHO was unable to influence state measures to contain the pandemic through evidence-based interventions. WHO's public health guidance and temporary recommendations were repeatedly ignored by member states, with WHO lacking compliance mechanisms to monitor, investigate, and remediate harmful state actions.

State health measures disproportionate to public health risks. States rapidly imposed sweeping restrictions on international traffic, economic activity, and individual rights, with many state actions taken without adequate public health justification. Virtually every state would turn to complete, or substantial, bans on entry of international travelers, and while some countries imposed travel restrictions early as a valid public health measure, others acted arbitrarily or with discriminatory intent. With rising human rights violations and democratic backsliding, some heads of state used the crisis as a basis for expanding their powers through autocratic policies and practices.

Lack of global solidarity and equitable allocation of medical resources.Neglecting IHR obligations of international collaboration and assistance, states largely reverted to isolationist policies, geopolitical competition, and global neglect, which served to undermine a coordinated response, threaten WHO support, and lead to vaccine inequities. Even today, as many high-income nations have achieved high vaccination coverage and are returning to some normalcy, most low- and middle-income states face an extreme scarcity of vaccine doses, medical treatments, oxygen supplies, and personal protective equipment.[7]

COVID-19 has highlighted the lack of clarity of state obligations, the failure of political will to follow public health guidance, and the absence of meaningful accountability for IHR violations, weakening WHO governance in the pandemic.

WHO Weaknesses

Global health law further shapes WHO's legal and normative authority to lead the international response to novel outbreaks; however, WHO's leadership has been tested by the pandemic as never before. Although global health law depends on strong governance, WHO has been unable to rally global solidarity throughout the pandemic where it lacks the legal authority and financial resources to effectively coordinate the public health response.[8] Without the ability to independently verify state reports, inspect conditions on the ground, or hold states to account, WHO has at times floundered, drawing on "soft" power and moral pleas to guide the global health response.[9] These weaknesses in WHO governance call into question the continuing effectiveness of global health law and raise an imperative to develop a bold new pandemic treaty, strengthening WHO through political support, ample funding, and legal powers.

Proposals for a Pandemic Treaty

Overcoming limitations in the COVID-19 response, many proponents of a pandemic treaty have looked to WHO's rarely used constitutional authority to develop a binding international convention, providing a legal foundation for proposals to develop a new treaty through the World Health Assembly.

Early Proposals

Early proposals for a pandemic treaty arose out of academic analysis. Recognizing gaps in the scope of the IHR —especially relating to the production of and access to necessary equipment, medicines, and vaccines —scholars began to argue that a new treaty could strengthen WHO authority and generate financial resources for a pandemic response.[10] Given that the IHR focus on outbreak detection rather than disease prevention, scholars pushed for a pandemic treaty to have a "deep prevention" core mandate, including a vital "one health" perspective (especially around zoonotic disease) and a focus on upstream determinants of disease outbreaks.[11] Beyond these substantive provisions, scholars and advocates recognized that key cross-cutting legal principles must serve as a foundation of the treaty, advancing principles of equity, human rights, and accountability.[12] These early contributions would

influence formal evaluations of the pandemic response and recommendations for fundamental reforms.

IPPPR Reports

WHO's Director-General appointed the Independent Panel on Pandemic Preparedness and Response (IPPPR) to examine why COVID-19 became a global health crisis and to ensure that future infectious diseases outbreaks do not lead to another catastrophic pandemic. In preparing its report, the IPPPR commissioned a background paper on international law, with this paper concluding that "a Framework Convention —Protocol approach" to a pandemic treaty could facilitate governance reforms "in coherence with the broader international legal system, including under, or separate to, the auspices of the World Health Organization and with, or without, reforms to existing global health law, such as the International Health Regulations (2005)."[13] Drawing from WHO's past experience in developing an article 19 convention through the Framework Convention on Tobacco Control (FCTC), the final IPPPR report recommended that states:

Adopt a Pandemic Framework Convention within the next 6 months, using the powers under Article 19 of the WHO Constitution, and complementary to the IHR, to be facilitated by WHO and with the clear involvement of the highest levels of government, scientific experts and civil society.[14]

The IPPPR also recommended a broader global pandemic architecture, including a Global Health Threats Council endorsed by the United Nations General Assembly. Supported by the G20 High Level Independent Panel on Financing the Global Commons for Pandemic Preparedness and Response, this Council could ensure high level political leadership and attention to pandemic prevention, preparedness, and response, with the authority, financing, and accountability mechanisms to overcome gaps in national and global capacities.[15]

World Health Assembly Debates

Delegates during the May 2021 World Health Assembly debated the development of a pandemic treaty to strengthen national, regional, and global capacities and guide a coordinated international response to future pandemic threats. Leading up to the World Health Assembly, twenty-five heads of government and international agencies (including WHO Director-General Tedros Adhanom Ghebreyesus) joined in an extraordinary call to develop a new treaty for pandemic preparedness and response, signaling high-level political support to protect the world from future health crises.[16] Director-General Tedros remained steadfast in his support for this pandemic treaty, arguing that such a treaty could promote increased sharing, trust, and accountability, thereby establishing the basis upon which to build other global health security mechanisms.[17]

World Health Assembly debates centered around the nature of international law that should be employed —whether a framework convention, regulations, or recommendations —and whether this legal development should be pioneered under the auspices of WHO.[18] Instead of convening an intergovernmental working group to begin negotiations on the text of a pandemic treaty, the Assembly resolved to hold a "special session" in November to focus on this singular issue. Some states had argued that further discussions about developing a treaty should be delayed until the pandemic is further contained, but others called for a special session to develop the treaty immediately, suggesting that states start negotiations quickly to be prepare for this special session of the World Health Assembly.

Developing a Pandemic Treaty

These processes and proposals will be crucial as states prepare for World Health Assembly debates in November, which will consider "the benefits of developing a WHO convention, agreement, or other international instrument on pandemic preparedness and response with a view towards the establishment of an intergovernmental process to draft and negotiate such convention, agreement, or other international instrument on pandemic preparedness and response."[19]

Policymaking Processes

Wide ranging diplomatic efforts are taking place through WHO, the United Nations, and other international forums that will shape the processes for developing a pandemic treaty. In determining the agenda of the Special Session, the WHO Executive Board will be meeting to decide the intergovernmental processes to draft and negotiate an international instrument. These initial debates will examine the exact legal nature of the proposed instrument and how this new legal authority will relate to the IHR.[20] Leading up to the special session in November, a WHO Working Group on Strengthening WHO Preparedness and Response to Health Emergencies will be meeting to assess the possibility of a WHO convention or other global agreement. This Working Group will submit a report to the World Health Assembly, examining the benefits of a WHO treaty and supporting states as they discuss and negotiate this international instrument. The O'Neill Institute for National and Global Health Law at Georgetown University (a WHO Collaborating Center) is partnering with the Foundation of the National Institutes of Health to support WHO and member states in the pandemic treaty process.

An innovative pandemic treaty could become a transformative model of global solidarity in the face of common threats, but it will require states to overcome nationalist forces to meet this global moment, with leaders embracing diplomacy across nations to prepare for new challenges.

Substantive Authorities

In identifying specific strategies for preventing, detecting, and responding to future pandemics, this prospective global health convention provides a unique opportunity to articulate key state obligations, with strong compliance and accountability mechanisms for:

One Health. Prioritizing prevention through land management, deforestation, and the effective regulation of wild animal markets and intense human-animal interchange —under a comprehensive "one health" approach across sectors —the new treaty could reduce the likelihood of naturally-occurring zoonotic spillovers and other novel threats.[21]

Biosecurity and Biosafety. The treaty should address biosecurity and biosafety to ensure that laboratory conditions do not lead to disease outbreaks, creating mechanisms to reduce the possibility of an inadvertent or intentional release of dangerous pathogens through the regulation of gain-of-function research and laboratory safety protocols.

International Monitoring. In promoting outbreak prevention, detection, and response, strengthened global institutions must overcome obstacles of national sovereignty in order to monitor disease threats. International institutions like WHO must have authority to verify state reports, publish crucial outbreak data without state confirmation, investigate novel pathogens independently, and institute remedial actions.[22]

Research and Data Transparency. Global governance must seek to advance biomedical research to develop therapeutic countermeasures (e.g., diagnostics, vaccines, and treatments). Coordinating research requires sharing of pathogen and genomic sequencing data, with norms of full transparency and scientific cooperation.

This new pandemic treaty must seek not only to construct strong national authorities that reflect good public health practice, but moreover must establish a system of good governance to advance the right to health and human rights principles of equity, transparency, and accountability in the pandemic response:

Good Governance. It is crucial that the new treaty stresses an evidence-based public health response while proscribing and sanctioning iniquitous government actions, including "authoritarian power grabs," continuing monopolies in medical innovations, failure to resource health systems, heightened levels of pandemic-related hate crimes and violence, and an institutional neglect of low-income and marginalized communities.[23]

Right to Health. Following from the WHO Constitution and core international human rights treaties, the pandemic treaty must be grounded in the human right to health, framing efforts to maintain core public health capacities; to

ensure the availability, accessibility, and quality of health services; to provide access to basic needs during lockdowns; and to align global health law with human rights law in framing derogations of human rights to protect public health.[24]

Human Rights Principles. Looking more broadly to human rights as a foundation of the pandemic treaty would provide a cross-cutting lens through which to assess rights-based public health practices, including equity and non-discrimination in the pandemic response, participation that engages affected communities, transparency in government decision-making, and accountability for health outcomes.[25]

In carrying out the aspirations laid out in developing and implementing a pandemic treaty, it will be essential to strengthen global health governance through WHO and other global actors. While Dr. Tedros has become the world's moral conscience in the pandemic response, WHO has lacked the power, funding, and political backing to become the bold leader necessary to respond to this crisis. This unprecedented public health crisis offers a unique opportunity to reform WHO authorities and establish a broader pandemic prevention and response architecture to coordinate pandemic preparedness on a global scale, partner with other international organizations in a pandemic response, and ensure international assistance and cooperation through global health governance:

WHO Authority. In leading the response to pandemic threats, WHO must have a strengthened mandate for building national health system capacities, coordinating international collaboration, and influencing state behavior, with states conferring power to WHO to lead international action against pandemic-level threats and establishing mechanisms to facilitate accountability from non-compliant states.[26]

Institutional Partnerships. It will be crucial for WHO to work with other institutions of global health governance (governments, the private sector, civil society, and other international organizations) to support the global response, ensuring fair intellectual property systems, equitable virus sample (and genomic sequence) sharing, and coordinated research and development systems; and sustaining partnerships developed in the current pandemic to share intellectual property, technology, and data for countering diseases.[27]

International Assistance and Cooperation. As a foundation for responding to pandemic threats, it is imperative that the pandemic treaty recognize the ways in which global inequalities in access to vaccines, medicines, and diagnostics have prolonged the pandemic, providing WHO and the wider global pandemic governance architecture with the authority to work across states to facilitate the equitable distribution of medical resources and establish an International Pandemic Financing Facility to support rapid financing in a pandemic response.[28] This pandemic has revealed deep health inequities that must be rectified, including through new institutions to speed scientific discoveries and make them available globally.

Global Health Security in the Balance

These initiatives will be crucial to developing a pandemic treaty that can overcome many of the limitations of the COVID-19 response. WHO Director-General Tedros has boldly stated that "the world cannot afford to wait until the pandemic is over to start planning for the next one."[29] If there is one overarching lesson from the COVID-19 pandemic, it is that the world is safer when we work together than when we devolve into fierce nationalism and isolated responses. An innovative pandemic treaty could become a transformative model of global solidarity in the face of common threats, but it will require states to overcome nationalist forces to meet this global moment, with leaders embracing diplomacy across nations to prepare for new challenges.

Note

Dame Barbara Stocking is chair and Lawrence O. Gostin is a member of the independent Panel for a Global Health Convention (GPHC). Prof. Gostin is also Director of the WHO Collaborating Center on National and Global Health Law. This column does not necessarily represent the views of either the GPHC or WHO.

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About This Column

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INTRODUCTION: Investigating Malingering and Public Policy Through an Interdisciplinary Working Group

Goldberg, Daniel S

ABSTRAK (ENGLISH)

This Introduction frames the context of the interdisciplinary working group that examined the role of malingering in health and social policy in 2019-2020. The Symposium Issue here is the result of the group's time, energy, and analysis.

TEKS LENGKAP

Anxieties about "fakers" seeking welfare and other social benefits are at least 500 years old in the West and are traceable back to the origins of the modern welfare state. Such concerns are saturated with prejudices and beliefs surrounding race, gender, disability, and class (to name a few). While individual articles analyze malingering and feigned illness, to our knowledge no comprehensive work in the humanities and social sciences studies the persistence of such concerns over time in the West in medicine, health and society. This gap is problematic not simply because concerns over "faking" persist, but because they do so widely across many different public policy arenas, including employment status, public benefits, disability accommodations, access to health care, occupational health, sports participation, child welfare and family policy, and veterans' support. Indeed, historians have noted that concerns about entitlement and just desserts are critical components of the very idea of the modern welfare state. Therefore, there is an urgent need to produce work directly focused on modern anxieties about malingering in the context of health and social policy.

In 2018, two contributors to this Symposium Issue (Casper and Goldberg) began discussing the possibility of

producing a historical anthology that might help fill the gap described above. Several rounds of conversation produced a draft proposal for an anthology and plans to submit to a university press. However, further discussion suggested the merits of slowing down and spending some time in a scholarly workshop that could deepen the scholarship and perspectives on malingering and social policy in historical context. After considering several possibilities for an organization that could serve as the host, serendipity struck in the form of a request for proposals for scholarly working groups extended by the Consortium for the History of Science, Technology, &Medicine ("CHSTM").

Established in 2007, the CHSTM brings under a single umbrella the support and the historical collections available at a considerable number of universities, research libraries, and museums. Directed by physicist-historian Babak Ashrafi, the CHSTM offers a wide variety of programming, including public lectures, an online research hub, a fellowship program, and, of particular interest here, working groups comprised of members from all over the world. CHSTM accepted the "Malingering &Social Welfare Policy" Working Group's proposal for the 2020 calendar year, providing a host of benefits, including secure web space, access to Zoom software for meetings, and expert facilitation and logistical support from environmental historian and CHSTM Manager of Academic Programs Lawrence Kessler (to whom many thanks are owed).

In its late 2019 proposal, the Working Group schedule anticipated 4-6 scholarly meetings during the following year and convened its inaugural meeting in January 2020. Obviously, the world changed dramatically in early 2020. Nevertheless, with considerable assistance from the CHSTM, the Working Group found ways to continue its efforts into early 2021.

Collectively, the six members of the Working Group supplied expertise in health law, public health, epidemiology, history, policy, bioethics, disability studies, sociology, and medicine. All of the contributors to this Symposium issue have spent years thinking, researching, writing, and teaching about these anxieties over faking, feigned illness, and malingering. The remarkable breadth of the Working Group constituents in both approach and substantive expertise produced interdisciplinary work that we hope is fairly represented in the contributions to the Symposium Issue.

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The original ideas that drove the impetus for the Working Group are historical claims and multiple members of the Working Group have professional training in history. Unsurprisingly, the core theme that animates the entire project, and virtually all of the contributions in this issue, are that deeply rooted Western and especially USian anxieties about malingering are central to social welfare policy in the US. The first contribution to this Symposium studies the historical theme in earnest, as physician-historian Lakshmi Krishnan traces how ideas about deception and malingering played a key role in changing the very idea of diagnosis in fin-de-siècle Great Britain.[1] It is no accident that the genre of detective fiction flourished at the same time as the birth of the clinic, with the latter's focus on forensic investigation to discern the "objective" truth of a patient's illness complaint. Krishnan's paper explores these themes in light of two important cases: The real-life case of physician Cornélius Herz's ordeal in light of the collapse of the French Panama Canal Company of 1889, and the fictional 1913 Sherlock Holmes tale "The Adventure of the Dying Detective."

Historian Lauren MacIvor Thompson begins her analysis in late Victorian Gilded Age America, assessing the eugenic politics of birth control and alcohol reform in the US.[2] These politics tracked prevalent ideas about suspicion, doubt, and skepticism of women in particular, thereby reinforcing a key theme in the history of anxieties about malingering: Not all groups are equally likely to be accused of feigning illness. The contributions in this collection show how a variety of historically marginalized groups, including but not limited to women, People of Color, and disabled people have often been targets of skepticism and mistrust in context of illness, welfare benefits, and social policy. Accordingly, the history of concerns about malingering and their connection to the warp and weft of social

policy are also interwoven with histories of structural violence, the consequences of which endure to the present. The 19th c. is especially important in making sense of contemporary connections between malingering and US social policy. Thus, the third contribution to this Symposium Issue, from historian Stephen Casper, also traces important developments in the history of brain injury since the 1800s.[3] There is a tendency among both researchers and policymakers when discussing traumatic brain injury, especially in context of collision sports, to assert an alleged novelty to brain injury science. Casper's manuscript reveals the long history of knowledge and attention to the risks of impact and collisions in causing long-term neuropathology, as well as the myriad ways in which such knowledge was doubted and invalidated in service of various political and economic interests.

Casper is also the principal author and organizer of the fifth piece in the Symposium Issue, which again shows how past and present are connected in the context of malingering and social policy.[4] The paper proposes best ethical and policy standards for international consensus statements that address concussion in sport. At first blush, this might not seem closely connected to accusations of malingering and social policy. However, there is a deep and complex history between disbelief, suspicion, and doubt of illness complaints connected to hazardous products introduced into the stream of commerce by regulated industries. Accusations of deception and malingering are a tried-and-true tactic wielded in service of "the manufacture of doubt," a method by which regulated industries accused of selling dangerous products undermine evidence of a causal connection between the products and health harms. The obvious example here is the tobacco industry, although these techniques have been deployed by numerous other industries, including but not limited to railroad, lead, vinyl, mining, automobile, and pharmaceutical companies. Governing bodies for collision sports including American tackle football, rugby, and ice hockey have all been accused of perpetuating the manufacture of doubt. And, health care professionals and scientists have historically played an important role in this construction of ignorance ("agnotology"), which justifies ethical standards for consensus statements and position papers.

Continuing with the theme of collision sports and the ways in which illness complaints sustained in participation are delegitimized and doubted, public health scholar Kathleen Bachynski's contribution examines how risks of injury were systematically denied by coaches, administrators, and politicians in US college football.[5] Picking up on her authoritative scholarship on these issues, Bachynski further explores how damaging norms of masculinity and everyday racism converged to intensify skepticism and mistrust of brain injury sustained through participation in tackle football in US colleges during the 20th c. Bachynski's article also underscores the extent to which concerns about malingering have contributed to relative neglect of non-fatal outcomes in many contexts. While deaths are more difficult to doubt, chronic illness and impairment (such as degenerative brain disease) are easier to question and delegitimize.

The seventh contribution to the Symposium Issue (Goldberg) offers a broader historical lens in which to consider the role of malingering and its connections to social welfare policy in the West in general and in the US in particular.[6] Beginning especially with the passage of major poor laws in Europe during the 17th century, Western societies connected even older ideas about deservingness to the entitlements of the burgeoning welfare apparatuses. In the modern era, anxieties about malingering took on a forensic quality, and it became increasingly important for scientific, medical, and legal experts to distinguish true from false illness claims. The rise of the modern welfare state during the 19th c. greatly accelerated anxieties over malingering, and the racialized, gendered, and classed nature of these concerns became socially and politically transparent. The essay concludes by connecting modern anxieties over malingering to present policy debates in the US; it argues that the stigma and disbelief so many people who seek public assistance endure is only explicable in context of these deeper historical and social structures.

The final two contributions complete the historical arc of the Symposium Issue by linking past to present. Health law scholar and Medicaid policy expert Nicole Huberfeld addresses the use of Medicaid demonstration waivers to impose eligibility restrictions such as work requirements and draws the connection between modern "able bodied" rhetoric and historical suspicion, blame, and doubt of poor, subordinated, and disabled people.[7] Huberfeld warns that attempts to impose such barriers, which further immiserate some of the most vulnerable populations, accelerated under the Trump administration, but these ideas have a long history in American social programs

traceable to Elizabethan Poor Laws. The forces that give rise to such efforts defy political or ideological affiliation and are likely to ascend again if stronger legal protections do not exist for low-income populations.

Disability law and health law scholar and social scientist Doron Dorfman closes the Symposium with a deep dive into the ways in which the COVID-19 pandemic has intensified the "fear of the disability con."[8] Dorfman has pioneered work into the extent to which people in different contexts are willing to forego social welfare benefits for themselves and for others in their relevant communities because of their fears that disabled people are "conning" society and thereby receiving 'extra' or 'special' benefits. There are obvious connections between the 'fear of the disability con' and anxieties about malingering and feigned illness, which Dorfman explores in the context of the COVID-19 pandemic and how such fears manifest in various legal and policy mechanisms for pandemic response and control.

The original hope for the anthology and the Working Group that resulted was to provide a sustained and synthetic analysis of the connections between malingering and social policy in US history. The contributions to the Symposium Issue offer tantalizing hints for the reasons why state- and national- level fear of dependency have such a powerful effect in shaping social welfare policy, including by restricting it completely for marginalized communities. The argument is essentially that the subject is important enough to merit such attention; the Symposium Issue highlights that a great deal more work remains to be done.

Finally, the contributors to the Working Group[9] and the Symposium Issue are grateful both to the CHSTM and to the *JLME* for creating and for supporting the scholarly space needed to think carefully and deeply about these important issues and supporting this work even during a devastating pandemic.

Note

The author has no conflicts to disclose.

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DETAIL

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Controlled Donation After Circulatory Determination of Death: A Scoping Review of Ethical Issues, Key Concepts, and Arguments

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ABSTRAK (ENGLISH)

Controlled donation after circulatory determination of death (cDCDD) is an important strategy for increasing the pool of eligible organ donors.

TEKS LENGKAP

Introduction

The last three decades have seen a rapid growth in the practice of controlled organ donation after circulatory determination of death (cDCDD).[1] cDCDD is endorsed by the World Health Organization and its increasingly widespread use has offered a welcome expansion of the donor pool.[2] Yet, despite growing acceptance and implementation of cDCDD in many jurisdictions, ethical controversy surrounding aspects of the practice remains present in the medical and bioethical literature.[3] Points of dispute are reflected in variation in protocol worldwide.[4] While authoritative bodies and expert panels endorse cDCDD,[5] these consensus statements often do not engage substantively with prominent debates in the ethical literature.[6] As a result, the myriad nuanced points of ethical contention may fail to penetrate, or be appreciated within, policy and practice. The increasingly vast literature on the ethics of cDCDD makes it difficult for stakeholders, the public, and particularly clinicians to keep up to date on the various conceptual and ethical issues associated with this practice. This may lead to moral distress among clinicians performing cDCDD,[7] the avoidance of practicing cDCDD so as to obviate these controversies, or, potentially, unethical practice. It is critical that stakeholders are sufficiently aware of, and engaged with, the breadth of ethical views and considerations related to the practice, regardless of their currency in the donation and transplant community. For these reasons, this review offers a synthesis of the prominent conceptual and ethical issues surrounding cDCDD. While it is not feasible in a single article to provide a comprehensive accounting of all ethical issues, arguments, and considerations related to cDCDD, let alone to do justice to their many nuances, we believe that this review serves as a vital resource which maps the contours of this ethical terrain, and which signals to those working in this area the prominent locations where further nuance and discussion can be found.

Before proceeding, it is worth noting that the exercise of synthesizing ethical issues, arguments, and considerations can appear to present a phenomenon in a negative light. In other words, by identifying and discussing numerous ethical worries, one may get the sense that a practice is unethical, or that a practice like cDCDD is without ethical merit. This is not our intention. This scoping review is part of *Neurological Physiology After Removal of Therapy* (NeuPaRT), an interdisciplinary project exploring brain function at the end of life that will contribute to a clearer understanding of the physiological process of death in cDCDD. The goal of this review is not to criticize cDCDD, but instead to offer a neutral resource which enables stakeholders to familiarize themselves with its ethical landscape. We outline commonly discussed ethical issues bearing on cDCDD, identify key themes, concepts, and arguments, and provide an overview of notable debates. Importantly, since a number of conceptual ambiguities and empirical uncertainties bear on cDCDD, we seek to furthermore to distinguish between those issues that are resolvable through empirical study, those that are subject to resolution through normative argument, and those that are subject to ongoing disagreement given intractable metaphysical commitments. Progress can be made on the first two sets of issues, but the third will *always* present tensions, no matter how much empirical data or cogent ethical argument we produce. We conclude that while some ethical debates concerning cDCDD may be resolved through further empirical research and ethical dialogue, others will not be. The plurality of viewpoints surrounding some issues is a result of longstanding debates on the metaphysics of death and inherently value-laden judgements concerning the legitimate scope of medical practice. Further dialogue, public engagement, empirical study, and ethical analysis are required as cDCDD continues to advance and grow in complexity.

cDCDD: A Brief Introduction

Controlled organ donation after circulatory determination of death — sometimes referred to as donation after cardiac death, donation after circulatory death, or non-heart-beating organ donation — refers to the recovery of transplantable organs after death is determined based on circulatory criteria (as opposed to death determination based on neurological criteria). Donation after circulatory determination of death is “controlled” when the timing, location and manner of withdrawal of life-sustaining measures are planned and supervised; donation after circulatory determination of death is “uncontrolled” when circulatory arrest is unplanned, typically occurring outside of a hospital setting. cDCDD is therefore generally performed with patients dependent on life-sustaining treatments within an intensive care unit who do not meet criteria for neurological death but who are expected to die within a short period after treatment withdrawal.

Controlled organ donation after circulatory determination of death — sometimes referred to as donation after cardiac death, donation after circulatory death, or non-heart-beating organ donation — refers to the recovery of transplantable organs after death is determined based on circulatory criteria (as opposed to death determination based on neurological criteria). Donation after circulatory determination of death is “controlled” when the timing, location and manner of withdrawal of life-sustaining measures are planned and supervised; donation after circulatory determination of death is “uncontrolled” when circulatory arrest is unplanned, typically occurring outside of a hospital setting.

Protocols mandate that discussion regarding surrogate consent for cDCDD can only occur following consent to withdrawal of life-sustaining measures. After surrogate consent for cDCDD is obtained, life-sustaining measures are continued during donor workup and until such time as suitable recipients are identified and an organ recovery team is assembled. Depending on the protocol, withdrawal of life sustaining measures commonly occurs in either the intensive care unit or the operating room.[8] The process involves protocolized removal of life sustaining treatments combined with the administration of pain and anxiety relieving medications. Antemortem interventions such as the administration of heparin, steroids, antibiotics, and/or cannulation of femoral vessels to facilitate post-mortem mechanical reperfusion of organs are performed in some jurisdictions in order to promote organ viability.[9] A specified number of attending physicians who are not part of the transplant team determine death after a “no-touch” period following asystole. The transplant team commences organ recovery only after the elapse of the no-touch period. In some protocols, in situ post-mortem normothermic regional perfusion is initiated after declaration of death to reverse ischemic organ damage and enable organ graft optimization prior to transplantation.[10]

cDCDD differs markedly from donation after neurological determination of death (DNDD) insofar as time constraints are of paramount concern. In DNDD, determination of death does not require removal of life support, which ensures that organs receive appropriate blood flow and oxygen levels until they are removed for transplantation. In contrast, in cDCDD, withdrawal of life support to enable circulatory arrest and death determination leads to progressive reduction of blood pressure and oxygen levels that contribute to organ injury via ischemia. If this process takes too long, organs can be irreversibly injured and become unsuitable for transplantation. The need to minimize warm ischemic time and the need to ensure the death of the donor before organ recovery commences leads to inevitable tension between these two objectives. [Fig. 1]

Figure 1

Method

Scoping reviews generally aim to map evidence-based literature with a view to examining its extent and range, or to identify existing research gaps.[11] A scoping review of ethics literature — in which study designs, outcome measures, or intervention types are commonly not germane to findings — calls for some modification to protocol. This scoping review was undertaken according to a schema adapted from the methodological framework of Arksey and O'Malley (2005):[12] (i) identification of the research question(s); (ii) determination and implementation of search strategy; (iii) a two stage screening process for article selection; (iv) a grouping of key concepts, concerns and arguments by theme and summarization of findings.

(i) Identifying and Narrowing the Research Questions

The purpose of this review was broad in scope: to identify all important normative issues, concepts and arguments related to the practice of cDCDD. Preparatory background reading and discussion revealed that a number of these issues derive from conceptual ambiguities and empirical uncertainties that bear on cDCDD. The research was thus refined to comprise three questions:

•What are the ethical issues and arguments bearing on cDCDD?

•What debated or ambiguous concepts underlie these ethical arguments?

•What empirical uncertainties underlie these ethical issues?

(ii) Determining and Implementing Search Strategy

Three bibliographic databases were used in the literature search: PubMed, Embase, and SCOPUS. Search strings were developed through an iterative process that evolved as common or recurring themes, concepts and issues became apparent.[Appendix 1] This iterative process was necessary considering the broad scope of the review.[13] To limit the search results to publications that had bearing on substantive ethical and conceptual issues, it was decided that searches of article titles, keywords, and abstracts would be limited to those that included (i) one of the terms currently or previously used to describe cDCDD and (ii) at least one keyword the authors determined was relevant to the review in light of evolving awareness of key issues.[Appendix 2] Search strings were applied to each database in accordance with their specific format requirements using Boolean operators "AND" and "OR" between and within groupings (i) and (ii). No date limits were applied. The initial search was undertaken May 15, 2019 and repeated December 15, 2019 to identify and include recent publications. A hand search of bibliographies was undertaken after article selection to identify publications that did not appear in the database search but which were deemed relevant to the review.

(iii) Screening

The literature search identified 1,726 citations of possible relevance (PubMed *n*= 501; Scopus *n*=514; Embase *n* =711). After screening for duplicates using EndNote X9 functions (*n*=796) a total of 930 remained. Inclusion and exclusion criteria were developed *post hoc* following preparatory background reading.[14] [Appendix 3] Screening for relevance was undertaken in two phases: (a) an initial screening of titles to identify those that were evidently clinical

in focus or clearly did not promise to meet inclusion criteria; (b) a review of abstracts for possible inclusion. In order to provide background on existing practice, a sample of consensus statements and/or protocol guidelines was selected even if these did not engage substantively with ethical or conceptual issues (*n*=8). In phase (b) a total of 106 publications were selected for analysis out of a possible 193 selected during phase (a). A further 61 articles were identified through hand searching of bibliographies of included articles and selected for review because of either reoccurring citation or obvious relevance, bringing the total number of selected publications to 167. [Fig. 2]

Figure 2

(iv) Analysis and Summary

During review of the 167 selected publications key themes corresponding to ethical concerns emerged. These later informed the analytical groupings described in our summary. The themes identified were:

•1. Interpretations of “irreversibility”

•2. Death determination

•3. Dead donor rule

•4. Potential harms versus benefits to donors

•5. Conflicts of interest

•6. Public trust [Fig. 3]

Figure 3

Where there was significant overlap in subject matter it was decided to group arguments, concepts and concerns under the overarching theme considered most relevant. Publications were reviewed, and their substantive comments and arguments recorded under the appropriate theme. In keeping with Arksey and O’Malley’s (2005) methodological approach, we did not attempt to assess the quality of articles reviewed.[15] The information collected was then synthesized into the narrative account below. The flow of our summary of findings reflects an ascending order of more to less foundational concepts and arguments. This bottom-up ordering is reflective of the fact that many of the ethical issues surrounding cDCDD emerge from disagreement on the conceptualization of fundamental terms. Where necessary, key concepts, concerns, and arguments that apply to more than one theme are repeated in the summary to make clear their connection to the overarching theme being discussed.

Results and Discussion

I. Timing of Death: When is Cessation of Circulatory Function “Irreversible”?

The criteria for determination of death in cDCDD require simultaneous and *irreversible* unresponsiveness, apnea, and absent circulation.[16] As Youngner and Arnold (2001) note, “[i]rreversibility remains an essential, but undefined element in the definition and determination of death.”[17] The problem of how to interpret “irreversible” is widely debated in the cDCDD ethical literature. While one might argue that this is primarily a clinical issue, conceptual interpretations of “irreversible” are relevant to the ethics of cDCDD in light of the dead donor rule (DDR) — the ethical imperative that donors be deceased before organ recovery commences. The question of whether cDCDD is in violation of the DDR is perhaps *the* overriding ethical concern attending the practice. Yet, as discussed below, the purported ambiguity of the term “irreversible” drives many of the other controversies that arise in discussions of cDCDD. Two main questions concerning the criterion of irreversibility arise, the answer to the second contingent on the answer to the first. First, how should we interpret the term “irreversible”? Second, what length of no-touch time is

sufficient to ensure irreversibility? Answers to these questions determine whether cDCDD is thought to be in violation of the DDR.[18]

There are several ways that "irreversible" can be interpreted. We group these into four non-mutually exclusive views, each with its own justification. Some authors combine two or more of these views in defense of their understanding of irreversibility.

i) Circulation Cannot be Resumed, Even with Intervention

This is the strictest interpretation of "irreversible." Those who read the term in this way sometimes use it as a premise in an argument that suggests cDCDD often violates the DDR. Perhaps the best exposition of this view comes from Marquis,[19] but it is voiced by many.[20] For these authors, "irreversible" *just means* "cannot be reversed." This accords with a metaphysical view of biological death as the unalterable cessation of bodily function. Therefore, on this view, cDCDD may violate the dead donor rule when circulation has not irreversibly stopped at the point of organ recovery. In many instances, it *could* be resumed with medical intervention. Conceptual concerns stemming from this reading of irreversibility are exacerbated by the increasing use of recovered donor hearts: the restoration of heart function in recipients appears to confound the requirement that circulation cease irreversibly.[21] However, this worry is circumvented by emphasizing cessation of circulation *in the donor* as opposed to heart function, or by emphasizing the importance of cessation of circulation to the donor's brain.[22]

ii) Circulation Will Not Resume Spontaneously

Advocates of this reading argue that our understanding of "irreversible" should at minimum preclude the possibility of the spontaneous resumption of circulation, referred to as autoresuscitation. This in mind, many argue that the only ethically relevant concern regarding understandings of "irreversible" is whether autoresuscitation is possible after a required no-touch period.[23] While suggestions for this period have run as low as 75 seconds,[24] most consensus statements endorse a specific no-touch period within the range of 2-5 minutes in order to preclude autoresuscitation.[25] However, some authors have worried that these guidelines are based on insufficient data and therefore we cannot exclude the possibility.[26] Additionally, some suggest that autoresuscitation may be underreported and thus assessment of its probability is not properly informed.[27] The likelihood of autoresuscitation appears to be an unresolved empirical question.[28] Previous investigations on the incidence of autoresuscitation in the context of donation have found little evidence that it occurs outside of the context of uncontrolled donation after circulatory determination of death and concomitant attempts at cardio-pulmonary resuscitation.[29] That said, skeptics may note that these findings do not *prove* that autoresuscitation cannot occur beyond the 5 minute benchmark espoused in many jurisdictions. Thus, advocates of this understanding of "irreversible" seek to exclude the possibility of autoresuscitation while continuing to debate the appropriate length of no-touch time. Further empirical study will help to resolve debate surrounding this reading of irreversible.[30]

iii) Circulation Could be Resumed but Will Not Be - Based on a Morally Justified Decision

This understanding of "irreversible" is sometimes called a "decisional"[31] view or an "appeal to a norm."[32] Under this view, determinations of death should not be divorced from context. If a no-cardiopulmonary resuscitation or "do not resuscitate" order has been signed, and if patients or surrogates have consented to WLSM and donation, then the mere possibility of resuscitation with medical intervention is of little or no moral importance. Restoration of function would be ethically inappropriate. This means that the view is partly, and explicitly, normative.[33] In this sense, "'irreversible' […] is best understood not as an ontological or epistemic term, but as an ethical one."[34] Or, we might add, a legal one. Thus, as Shemie argues, "… the issue is not whether the body or brain circulation and function can be resumed (because it can), but rather, whether it will be."[35] The outcome of this view is similar to that of (ii) because it does not necessitate a no-touch period beyond that required to preclude autoresuscitation.

iv) "Irreversible" Just Means "Permanent"

This view is almost indistinguishable from (iii) but merits its own category insofar as its defense sometimes relies on a standard of medical practice.[36] Advocates of this view hold "permanence" has always been the medical standard for declaration of death in clinical settings. As such, its application in the context of cDCDD is warranted. Like (iii), this reading holds that there is a meaningful distinction between "irreversible" ("cannot be restored") and "permanent" ("will not be restored").[37] Since cDCDD donors or their surrogates have determined that resuscitative efforts will not be undertaken, the permanence criterion allows for declaration of death before "irreversibility" in its strictest sense obtains.[38] Since permanence inevitably leads to strict irreversibility, the former is a plausible proxy for the latter.[39]

Discussion

The problem with these varied understandings, note Aulisio, Devita, and Luebke, is that the "[s]atisfaction conditions for each of these notions of irreversibility are not co-extensive."[40] That is, a single set of clinical criteria will not satisfy all interpretations. Nonetheless, the prevailing view in the donation community holds that "permanent" is a reasonable interpretation of "irreversible," and as such a 5-minute no-touch period is a reasonable safeguard against the possibility of autoresuscitation.[41] Consensus statements from professional and regulatory bodies endorse these conclusions.[42] That said, the issue of how to interpret "irreversible" is far from resolved in the ethics literature. We contend that disagreement in this domain is explained by metaphysical disagreements about the definition of death and, hence, appropriate criteria for its determination. The crux of the matter is when the term "deceased" can be used to denote a body. As will be seen below, given that there is no consensus on the definition of death, prospects for a universally endorsed resolution to the debate on the interpretation of irreversibility appear dim. However, increasing consensus regarding its interpretation in the medical community suggests that this issue is primarily of concern to bioethicists.

II. Understandings of "Death" and Criteria for its Determination

This theme in the literature underscores how the practice of cDCDD is plagued by ambiguities in the concept of "death," ambiguities which parallel and inform debates around irreversibility. Unless there is greater clarity on both the definition of death and criteria for its determination, concern will remain that cDCDD violates the DDR.[43] In this context, there are three areas of disagreement.

(A) How Should "Death" be Understood?

Although this question points to an enormous body of philosophical literature that is beyond the scope of this review, it bears on criteria for determinations of death and thus merits brief discussion. Youngner notes that any understanding of death must have three components: "a concept or definition of what it means to die, operational criteria for determining that death has occurred, and specific medical tests showing whether or not the criteria have been fulfilled."[44] Considerable confusion surrounds the conceptual side of this triangle.[45] This is problematic, because the criteria for the determination of death will vary according to our conception of death. That is, the architecture of the conceptualization is hierarchical. A given *concept* suggests certain *criteria* which entail specific *medical tests.* Most conceptions of death focus on the loss of the integrative unity of bodily functions rather than the loss of function in its constituent parts.[46] Beyond this, scholars who discuss criteria for determinations of death can be categorized as falling (very generally) into two camps, each of which understands death somewhat differently:

(i) Those who hold that death is strictly an ontological category. This is the "classical"[47] conception of death, sometimes called "biological death."[48] This understanding corresponds to the common-sense view of death as the unalterable cessation of bodily functions. This view is consonant with a strict interpretation of "irreversible."

(ii) Those who hold that death is admittedly a distinguishable ontological category, but "nonetheless, philosophy,

religion, psychology, politics and even economics play major roles in how individuals and groups interpret the biological facts."[49] In this way, "death" is both a biological and social phenomenon insofar as factors external to biology have some bearing on what "death" is thought to be, or at least when it can be declared.[50] There are compelling social and cultural reasons for why it can be declared before "biological death" obtains.[51] This view is consonant with less restrictive interpretations of "irreversible."

The view of death adopted in a given jurisdiction has important social ramifications. For example, it is important to know when to sign a death certificate, when the rights of a person cease to be, and when to enact the provisions of a will. Yet, because of time constraints inherent in cDCDD, the need for specificity with regard to the concept-dependent criteria for determination of death is acute. Minimizing ischemia time while ensuring accurate death determination is paramount.

Despite disagreement over how death should be conceptualized there is general agreement in the literature that death is a process, not a singular event occurring at a determinable moment in time.[52] This observation of indeterminacy features in arguments which conclude that determinations of death, proclaimed at a point in time, have always been discretionary.[53] If determinations of death have always been the result of social consensus, it seems that no amount of scientific evidence will resolve the debates:

For all medical diagnoses except death, we believe that greater scientific knowledge will bring increasing clarity about how to make the diagnoses with ever higher levels of precision. In the case of death, however, our uncertainty is not related to the state of our scientific knowledge, but rather to different and incompatible understandings about the meaning of death.[54]

Since unequivocal criteria for determinations of biological death are difficult to apply in the time-sensitive cDCDD context, some argue that we should be satisfied with social consensus and clinical practice standards for determining death.[55] With that said, the various "incompatible understandings of the meaning of death" employed in the context of organ donation raise worries that "death" — long thought to be a strictly ontological category — has been manipulated for utilitarian reasons with a view to increasing the organ donor pool.[56]

(B) What Criteria are Sufficient for Determinations of Death in cDCDD?

Answering this question requires that one first decide how we should understand "death." Given disagreement on how to define death in this context, it is no surprise that there is also disagreement on how criteria for determinations of death in cDCDD should be constructed. It is at the level of criteria that most debates around death occur.[57] Here again the controversy surrounding the legitimacy of circulatory criteria for determination of death centers around the above-mentioned "irreversibility" debate and its attendant problems (sec. I). While there are strict (though somewhat variable) criteria for brain death, inconstancy in cDCDD protocols suggests that there is no comparable consensus on interpretations of the criteria for circulatory death.[58]

The main concern over the determination of death based on circulatory criteria is that the required no-touch period may be insufficient to ensure "death" or irreversibility. As noted (sec. I), many authors worry that the 2-5 minute wait period is arbitrary or based on insufficient data.[59] For some, this means that circulatory death criteria do not actually describe death.[60] While others argue that somewhere within 2-5 minutes is sufficient,[61] the (remote) possibility of autoresuscitation, as well as the potential for resuscitation with medical intervention, suggests that these authors are operating with a different conception of death (clinical death relying on "permanence") than those who worry that the no-touch period is insufficient (biological death relying on a strict interpretation of "irreversible").

In some jurisdictions, another concern relating to circulatory death criteria is that "[t]he post-mortem use of [normothermic regional perfusion] may retroactively invalidate the preceding death declaration by negating the necessary condition of permanent cessation of circulation."[62] In other words, the use of medical technologies such

as normothermic regional perfusion can retroactively negate the *justification* for the determination of death by restoring circulation to the body.[63] Of perhaps greater concern is the risk of reperfusion to the brain and the consequent possibility of reanimation.[64] In this way, the introduction of new technologies can confound death determination.[65] Given these issues, there are three options: admit that criteria for circulatory death are flawed and revise them to accommodate objections; relax or abandon the DDR so as to avoid these objections; or circumscribe the use of normothermic regional perfusion in this context. As discussed below, given an apparent reluctance to abandon established criteria for death and the arguably inviolate tenets of the DDR, the permissibility of normothermic regional perfusion is a controversial issue in cDCDD.

(C) What is the Relationship Between Circulatory Death and Brain Death?

The relationship between the two established standards for declaration of death — neurological criteria and circulatory criteria — is unclear. While some argue that the two corresponding sets of criteria point to a co-extensive concept of death, this conclusion is not obvious. According to Youngner, Arnold, and DeVita,[66] there are two ways that the relationship between circulatory and brain death can be understood:

i) Circulatory and brain functions are jointly necessary and interdependent; each is equally essential for life, so the loss of just one will mean the loss of life. There are simply two ways to establish the same phenomenon: death. Death is the loss of integrated functioning of bodily systems. The loss of either brain or circulatory function therefore leads to death.[67]

ii) Circulatory death is a proxy for brain death, which is what really matters. Circulatory death is just the usual way of determining brain death.[68] Since the brain cannot survive without circulation, it is reasonable to assume that circulatory death leads rapidly to brain death.[69] The necessary and sufficient condition for life is brain function.

Both of these views lead to conceptual and ethical worries. Opponents of (i) argue that the two established sets of criteria for determining death point to different *kinds* of death, something that should not be possible for a univocal phenomenon.[70] While expert bodies and the oft-cited American *Uniform Declaration of Death Act* maintain that the criteria point to the same phenomenon, many are not convinced that they do. For example, a minority of critics hold that “brain death is incoherent in that it fails to correspond to any biological or philosophical understanding of death.” [71] This is because the body often retains some integrative unity after brain death, albeit with mechanical intervention. [72] More germane to cDCDD, the brain may retain some function after circulatory death for an unknown period of time.[73] Perhaps more to the point, cessation of brain function following circulatory arrest may not be *irreversible*.[74] There is growing consensus that (ii) is correct.[75] As Dalle Ave and Bernat argue, “[t]hrough the pathway of circulatory cessation, the fundamental criterion of death is also the brain criterion.”[76] Cessation of circulation is thus a proxy for brain death. This raises problems on two fronts. First, since the temporal relationship between cessation of circulation and brain death is uncertain,[77] some scholars worry that circulatory death criteria do not, in fact, ensure brain death in the context of cDCDD (at least not within the 2-5 minute no-touch period).[78] If circulatory death is a proxy for brain death, and if brain death is what really matters, then a donor is not *known* to be dead at the point of organ recovery without confirming brain death, and nor is it certain that brain function has been irreversibly lost. Second, with the growing use of thoracic normothermic regional perfusion in some jurisdictions, fears that reperfusion of the brain could reanimate the donor and negate the justification for determination of death threaten to render impracticable the use of circulatory criteria as a proxy for brain death.[79] These observations lead to suggestions that both sets of criteria need to be met in declarations of death in cDCDD.[80]

Discussion

There is some agreement in the literature that understandings of death are justifiably based on biology, culture, medical practice, and social norms, and therefore criteria for its determination are not restrictively tied to the

ontological category of death. This observation helps to explain the consensus that has emerged around the interpretation of “irreversible” as “permanent.” Yet it also demonstrates how incompatible understandings of death may result in morally and metaphysically defensible yet contrary viewpoints concerning when exactly death can be declared. For this reason, disagreements about definitions of death are likely to remain unresolved. Because of the hierarchical relationship between concepts and criteria, universal consensus on interpretation of the criteria for determinations of death is similarly, and consequently, unlikely. However, the physiological (and temporal) relationship between circulatory death and brain death can be clarified with further empirical research. This may go some way towards illuminating socio-cultural understandings of when it is justifiable to declare death. We contend that much of the disagreement surrounding cDCDD is at root a debate about the definition of death. This has implications for the question of whether cDCDD can be said to violate the DDR.

There is some agreement in the literature that understandings of death are justifiably based on biology, culture, medical practice, and social norms, and therefore criteria for its determination are not restrictively tied to the ontological category of death. This observation helps to explain the consensus that has emerged around the interpretation of “irreversible” as “permanent.”

III. The Dead Donor Rule (DDR) and cDCDD

At minimum, the DDR holds that (a) no patient should be killed by organ recovery and (b) patients must be dead before organs are recovered.[81] This is consistent with the injunction that physicians do no harm to their patients. Although most authors do not discuss the foundations of the DDR explicitly, there are several that can be identified in the literature.

Most agree that the primary reason for the DDR is to protect patients from harm and exploitation.[82] This motivation is therefore deontological: using patients as a mere means would demonstrate disrespect for persons. As Robertson states, “[t]he dead donor rule is a centerpiece of the social order’s commitment to respect for persons and human life.”[83] Other authors add that there is also a consequentialist motivation for the DDR insofar as it protects physicians from criminal charges and preserves public trust in organ donation schemes and physicians.[84] Although different motivations are emphasized by different authors, it is arguable that respect for persons is the fundamental principle underlying the DDR. However, disagreements discussed in the foregoing sections opens the door to debates concerning whether cDCDD sometimes violates the DDR. Given controversies over interpretations of “irreversible,” criteria for determination of death, as well as debates on the need for the DDR in light of evolving societal norms, two important questions arise regarding the DDR and its bearing on cDCDD.

(A) Is cDCDD in Violation of the DDR?

This question highlights how the debates discussed thus far are not disparate themes; they are ineluctably intertwined. Whether or not the DDR is thought to be violated in cDCDD depends on one’s positions with respect to understandings of “death” and the interpretation of “irreversibility.” As Truog and Robinson argue, the DDR “depends on a coherent definition of death, yet this definition has proven elusive.”[85]

A vocal minority of authors assert that the DDR is violated in cDCDD.[86] The main reason for this worry stems from the way that death is declared. This is because, once again, it is not clear that a 2-5 minute no-touch period is sufficient to preclude the possibility of auto-resuscitation, and, second, it is not certain that donors meet the irreversibility criterion at the time that organs are recovered (when interpreted in the strict sense of *cannot be reversed*) (see sec. I). If donors are not certainly dead, it is arguable that organ recovery is sometimes the cause of death.[87] Similarly, if one holds that criteria for circulatory determination of death do not actually describe death, then the DDR is potentially violated in cDCDD.[88] For example, uncertainties regarding the physiological and temporal relationship between circulatory cessation and cessation of brain activity casts doubt on the vital state of donors, at

least for those who worry that the bifurcation between brain and circulatory death is confused.[89] Furthermore, when thoracic normothermic regional perfusion is used in cDCDD protocols, the possibility of restoration of circulation to the brain means that criteria used to determine death could be invalidated.[90] Therefore, patients cannot reliably be declared dead. If they are not dead, then the DDR is violated during recovery. If this is so, since the DDR is inviolable, cDCDD is unethical.

(B) Should the DDR be Relaxed or Abandoned?

It is important to note that while most authors consider any violation of the DDR unethical, others suggest that violation of the DDR is not inherently so, and may be justifiable given informed consent.[91] Intractable debates concerning the DDR in this context have led some to propose that it should be relaxed or abandoned altogether. Critics argue that blind adherence to the DDR has led to insupportable revisions to the concept of death and that we must face the fact that, since medical practice may already violate the DDR, it could be time to do away with it in circumscribed areas.[92] Adherence to the DDR obscures what is really at issue: how can we maintain respect for persons while respecting the wishes of patients to donate?[93] Or, for those who contend that cDCDD donors are not dead, when is it permissible to retrieve organs from the dying?[94] Some suggest that the DDR can — and should — be supplanted by other ethical principles that could govern cDCDD, such as non-maleficence and respect for autonomy.[95] After all, they argue, denial of a patient's desire to donate based on an arbitrary rule amounts to an act of disrespect. Waiting until donors are dead may impact the chances of organ graft, and surely a patient desiring to donate would prefer not only to preserve the donation opportunity, but also to bequeath organs that have suffered minimal ischemic damage.[96]

Defenders of the DDR muster consequentialist arguments in its support. These authors worry that cDCDD without the DDR would: erode public trust in organ donation schemes and physicians;[97] distort the therapeutic doctor-patient relationship;[98] cause dignitary harms to donors;[99] lead to a slippery slope whereby patients are routinely killed for organs;[100] or erode widely endorsed societal values.[101]

Discussion

Ultimately, universal consensus on whether the DDR is respected in cDCDD is lacking, though the widespread practice of cDCDD suggests that this is not a reflection of the views of the donation and transplant community. Those who argue that the DDR is not violated generally rely on the permanence criterion for irreversibility. Those who argue that it is violated generally interpret the irreversibility criterion strictly. This lack of consensus is once again best explained by the reasonable moral and metaphysical disagreement concerning death and criteria for its determination. However, the debate concerning the relaxation of the DDR is less fractured. Despite occasional calls for doing away with the DDR in the context of cDCDD, it seems that most authors are not ready to countenance this option. Ultimately, "[…]the symbolic costs of relaxing the dead donor rule appear to be too great to be tolerated."[102]

IV. Tensions Between Potential Harms and the Benefits of cDCDD

Discussion of the DDR draws attention to the potential harms to which, some argue, donors are susceptible in cDCDD. Since the principle of non-maleficence guides medical practice, the possibility of harm needs attention when assessing the ethical propriety of cDCDD. In this context, the root issue concerning purported harm to donors is to what extent donor care can or should be altered in the interest of promoting both donors' autonomous wishes to donate and the interests of organ recipients. In this area there are three main areas of concern. Since cDCDD protocols vary widely, not all of these concerns apply to every form.

(A) The Potential for Deontological Harms to Donors vs. Promotion of Autonomous Wishes

To cause a deontological harm is to fail to treat a person with the respect they deserve, whether or not that person perceives it. The deontological foundation of the DDR leads some to argue that the DDR is not just a prohibition

against killing. It has two components: “a prohibition on killing and a prohibition on using living patients solely as a means to an end.”[103] The latter injunction expands the purview of the DDR to include issues that arise prior to a donor’s death.

A minority of authors suggest that the practice of cDCDD could express disrespect for persons. The worry is that patients may be instrumentalized or considered as a mere means to an end — organ procurement.[104] To treat someone as a mere means rather than an end is to cause them a deontological harm through instrumentalization. The use of antemortem interventions and the prolongation of life sustaining measures during workup and until such time as an organ recovery team has been readied is presented as putative evidence that patients are instrumentalized. The overarching concern is that practices that are not in the *medical* interest of the donor suggest that the patient is being treated as a mere means to organ procurement.[105] Seen this way, note Gardiner and Sparrow, “the DDR is breached whenever procedures to harvest vital organs are initiated while the patient is still alive.”[106] This arguably results in a loss of dignity in the dying process.

Despite this concern, many respond to the above worries by noting that the deontological basis of the DDR does not require that donors can *never* be used as a means, but rather that they never be used *solely* as a means. Since respect for human dignity and autonomy underlie the deontological aspect of the DDR, if a patient has an expressed wish to donate then antemortem interventions and the prolongation of life sustaining therapies serve in reality to promote the interests of donors: “[t]o fulfill someone’s wishes, and most especially those pertaining to personal core values, is to properly give respect to that individual’s (prior) autonomy.”[107] Supporters of cDCDD argue that dissenters mischaracterize the attitudes of clinicians and interpret “best interests” too narrowly.[108] In fact, they argue, to deny the opportunity to donate is to deny concrete benefits to donors.[109] This response echoes debates concerning the DDR. While it may not be in the donor’s best *medical* interest to be subject to antemortem interventions and prolongation of life-sustaining measures, “[s]uch acts may be justified through their promotion of the donor’s legitimate interests in what becomes of their bodies after death.”[110] Donors have concrete interests in the success of transplant and may wish to leave a legacy. Benefits to donors, their families and recipients should not be discounted. To deny an autonomous wish to donate on the grounds that it causes a dignitary harm is, paradoxically, to deny that the donor has the dignity that attends personal autonomy.

While the foregoing argument has many proponents, doubt remains over whether donors’ autonomous interest in donation really can justify antemortem interventions which were never anticipated by the donor. A prominent source of worry is how prior consent to organ donation may not entail consent to the interventions associated with cDCDD. The public’s lack of awareness of cDCDD protocol, and the lack of detailed information relayed through generic donation consent processes, suggests that potential donors are not always fully informed about what they are consenting to.[111] Donors may object to procedures that have the potential to instrumentalize them or cause psychological distress to their loved ones. As Gardiner and Sparrow note, “there is a certain amount of intellectual strain involved in thinking of premortem interventions in the care of a patient designed to facilitate [cDCDD] as motivated by a concern for the best interests of the *donor*.”[112] While antemortem interventions may promote an autonomous wish to donate organs, critics worry that this may come at the cost of causing deontological harm. This stimulates proposals for specific informed surrogate consent to each antemortem procedure employed in a given cDCDD protocol.[113]

(B) The Possible Negative Impacts on Care Towards End of Life in cDCDD vs. the Option of cDCDD as a Component of High-Quality End of Life Care

While cDCDD may not cause deontological harms, there is a distinct concern that, since care towards end of life in some jurisdictions proceeds differently in cDCDD than it does in non-donation scenarios, cDCDD protocols may

worsen the experience for donors, if they retain conscious awareness, or their families.[114] Differences in care may include the performance of antemortem investigations and interventions intended to improve organ graft and function,[115] the necessity of withdrawing life sustaining measures in the operating room,[116] or the prolongation of these measures during donor workup.[117] Some critics describe cDCDD as "an antithesis of quality end-of-life care, when health care teams await at the bedside for death and then rapidly procure organs in a race against ischemic time."[118] For others, cDCDD is "a stage-managed affair, lacking in all human dignity."[119] There is, then, a real concern in some quarters that donor and family experience towards end of life in cDCDD may be negatively impacted.[120]

cDCDD, say some, risks a deterioration in care prior to withdrawal of life-sustaining measures (WLSM).[121] In addition to the view that the use of some antemortem interventions could conceivably cause physical harm to donors (see below), a minority of authors have speculated that care may suffer if health care providers consider a patient primarily as a means to donation.[122] More notably, there remains a distinct worry that physicians may be reluctant to provide sufficient comfort care *after* WLSM to avoid accusations of violating the DDR.[123] Furthermore, since time pressures are inherent in cDCDD, there is speculation that the manner of WLSM — which may be chosen to expedite death — can cause greater discomfort than in non-cDCDD (e.g., rapid extubation).[124]

The view that cDCDD risks a deterioration in end of life care is counterbalanced by the widespread sentiment that the option of organ donation is an important component of high-quality end-of-life care.[125] The prevailing view is that cDCDD protocols do not result in a deterioration in care prior to and after WLSM. Indeed, most established guidelines emphasize that care should be altered as little as possible when facilitating organ donation.[126]

In addition to discussion of potential harms to donors, some authors note that cDCDD protocols may harm families insofar as their experience of the dying process could be negatively impacted.[127] Of particular concern are those cDCDD protocols which require death in the operating room, where families are separated from dying donors.[128] This is arguably not a component of high-quality end-of-life care. While some respond by asking why death in the intensive care unit is any better,[129] separation of families from loved ones may cause unavoidable distress. The fact that donors are sometimes returned to the intensive care unit if death does not occur in the proscribed time frame (usually 60-120 minutes) means that an already traumatic experience for families could be exacerbated. Predicting time to death is very difficult, and there is evidence that unsuccessful donation can harm families.[130] At the root of many worries surrounding care in cDCDD is the fact that families sometimes do not understand the (emotionally painful) trade-offs required for cDCDD.[131]

In general, responses to concerns about the potential deterioration of care towards end-of-life and harms to families in cDCDD contend that these worries are overblown, out of touch with the realities of clinical practice, or even cavalier towards the wishes of both donors and families. Families and donors often derive comfort from the knowledge that a death was given meaning through organ donation.[132] In this sense, organ donation is an important aspect of end-of-life care for many. Furthermore, denying a patient's expressed wish to donate on the basis of worries like the above can be described as paternalistic.[133] As Gardiner and Riley concede, "[t]o watch as a wish to donate goes unfulfilled is a strong argument against all [of these] concerns."[134] Given appropriate training, resources and guiding moral principles, end of life in cDCDD can be just as dignified as in non-donation scenarios.[135] One way to overcome the above worries is to ensure that end of life in cDCDD adheres as closely as possible to a standard end of life protocol,[136] and that palliation proceeds as it would in any other case.[137] This imperative is widely accepted and endorsed in the donation and transplant community. Quality of care, it is thought, should not be affected by the exigencies of cDCDD.[138]

(C) The Ethical Permissibility of Antemortem and Postmortem Interventions

The most prominent debate surrounding the potential for harms in cDCDD concerns the ethical permissibility of antemortem and postmortem interventions designed to improve organ graft and function in recipients. The ethical literature is split on the question of whether antemortem interventions should be allowed, especially antemortem cannulation in anticipation of post-mortem normothermic regional perfusion.[139] There is no consensus in the broader literature,[140] although consensus statements from expert panels in a number of jurisdictions endorse some or all of these procedures.[141] Many consider postmortem mechanical reperfusion to be impermissible because of the danger of brain reperfusion and the consequent potential for reanimation, but again, there is at present no consensus.[142]

Those who argue that we should be wary of antemortem interventions muster three main arguments. First, (i), these interventions provide no medical benefit to donors and can be highly invasive; thus, they are arguably not in the patient's best interest.[143] This concern is exacerbated by the fact that consent to organ donation may not entail informed consent to invasive antemortem interventions.[144] Second, (ii), certain invasive interventions can conceivably cause physical (and deontological) harm to donors.[145] Since these practices arguably transgress the principle of non-maleficence, vocal critics argue that "[p]rocedures that can only cause harm to a patient without providing any benefit are unethical and the person performing them is no longer practicing medicine."[146] Third, (iii), some worry that antemortem interventions (such as the use of heparin) can actually hasten death, which, if true, can evidently be construed as a harm.[147]

In response, those who advocate for the permissibility of antemortem interventions argue correspondingly that (i) we can construe best interests broadly such that antemortem interventions are, in fact, of benefit to donors insofar as they serve to promote their autonomous decision to donate organs.[148] (ii) Building on the response to (i), while it is possible that these interventions can cause harm, there is in fact little evidence that they do.[149] Furthermore, informed consent and the doctrine of double-effect can justify their use,[150] though the applicability of this latter doctrine is highly contested.[151] Finally, (iii) the possibility that antemortem interventions can hasten death is remote, and thus not of great concern.[152]

Some authors regard postmortem mechanical reperfusion to be impermissible. The main concern with reperfusion is that it risks restoring brain function.[153] The use of aortic occlusion balloons or clamps on the aorta and great vessels arising from the aortic arch to restrict blood flow to the brain promises to minimize chances of such occurrences,[154] yet some argue that it does so at the risk of conceptually undermining the justification for the determination of death. That is, employing aortic clamps or occlusion balloons "demonstrates that the loss of all brain functions in these protocols cannot be considered irreversible, and that permanent loss is not a valid surrogate for irreversible loss."[155] Further empirical research can help to establish the risks associated with this practice, though its conceptual ramifications will continue to be debated.

Discussion

Inherent in cDCDD protocols are several important objectives: care for a dying donor and the promotion of their interest in donation on one hand, and the recovery of viable organs for transplantation into a waiting recipient on the other. Sometimes these objectives are thought to be at odds. More often, they are thought to converge.[156] Greater clarity on the risks associated with antemortem interventions will inform debates on their ethical permissibility. That said, the tension inherent in this debate raises an important ethical question: when is it permissible to alter care for the donor in the interests of donation? Or, how can interventions that are not in the best medical interests of a dying patient be undertaken in an ethical way? Conflicting views on these issues betray deeper disagreements about the legitimate scope of medical practice and the interpretation of the moral principles which guide it. While some argue that potentially harmful interventions should be prohibited, others plausibly respond that their prohibition would unjustifiably encroach on individuals' autonomous interests in seeing their organs successfully transplanted. Since

these are value-laden assessments, moral debate is likely to continue.

V. Potential Conflicts of Interest in cDCDD

The tension between the duty of care to the donor and the desire to procure viable organs for waiting recipients is at the root of putative conflicts of interest that some argue can arise in cDCDD. Conflicts of interest, both personal and institutional, are a pressing issue in cDCDD in part because "[t]he ambit of interests extends beyond the donor, to the donor's family, the recipient, transplant professionals, institutions, and society generally; and they involve issues such as priority setting, resource allocation, and so on."[157] Real or perceived conflicts of interest in cDCDD could result in unethical practices or an erosion of public trust in organ donation schemes. The need to identify and address conflicts of interest is widely discussed in the literature on cDCDD. There is widespread agreement that conflicts of interest could arise in cDCDD, but whether these conflicts of interest do arise, or whether they undermine the practice, continues to be debated.

Conflicts of interest can arise at both the personal and institutional level.[158] Personal conflicts of interest involve decision-making at the level of the bedside; institutional conflicts of interest may impact wider policies and protocols.[159] It is argued that conflicts of interest can arise at every step of the cDCDD process.[160] We list these concerns below before considering generic responses and mitigation strategies.

(A) Determinations of Futility and WLSM

With respect to identifying candidates for donation, notes Doig, "there is an inherent conflict of interest for physicians caring for these and other individuals in the ICU who might also be candidates for [cDCDD]: attempts to preserve the life of a patient might limit or preclude these same individuals from being organ donors."[161] Some worry that early or erroneous determinations of treatment futility could occur if health care providers are (consciously or unconsciously) motivated by the desire to procure organs from critically ill patients.[162] While others respond that the risk of premature or biased determinations of futility can be overcome with robust guidelines that are already largely in place,[163] detractors point out that determinations of futility are never certain, and that unconscious bias is possible.[164] Furthermore, in the unlikely event of physicians seeking primarily to secure organs to reduce shortages rather than ensuring the best possible care for patients, it is conceivable that not all treatments options will be explored prior to determinations of futility or WLSM.[165]

(B) Care Towards End of life and WLSM

As noted above (sec. IV), a minority of authors worry that care towards end of life may suffer if patients are considered mere means to organ donation. As Rady, Verheijde, and McGregor argue, "the care of the dying patient [may be] guided by a team whose primary interest is the preservation of organs until procurement has been accomplished."[166] This could affect the type and quality of care towards end of life.[167] The use of antemortem interventions (with the goal of improved organ graft and function) that are not in the patient's best medical interest (and may also expedite death) raise worries that care towards end of life may be compromised by conflicts of interest.[168] For instance, say some, antemortem interventions are in the interest of recipients, not the medical interests of dying patients. For those who take this narrow view of "best interests," this tension epitomizes the conflicts of interest attendant on cDCDD. Additionally, some argue that the timing, location and manner of WLSM may be affected by conflicts of interest in cDCDD, thus undermining the quality of end of life care.[169] In the past, variability in end of life ICU practice raised worries that conflicts of interest were of more than theoretical concern.[170] Standardized protocol and emerging consensus surrounding guidelines seem to have alleviated these apprehensions.

(C) Securing Consent

There is wide variation in procedures for consent among organ donation organizations, transplant centers, and

hospitals.[171] Some critics worry that "[t]he conflict of interest and self-serving bias of [organ procurement organizations] can limit the exchange of information with surrogates and violate the standards for true informed consent."[172] Likelihood of consent may be higher when both the putative trade-offs in end of life care and the nature of antemortem interventions required for cDCDD are not fully understood by donors or surrogates, and this may be one motivation for a lack of transparency.[173] As noted above, some authors emphasize that, given the public's limited understanding of cDCDD, prior consent to organ donation does not entail consent to antemortem interventions.[174] Donors and surrogates may not be fully informed of the putative risks of these interventions when consenting to donation.[175] In addition, there are legal concerns in some jurisdictions surrounding the legitimacy of surrogate decision-makers consenting to antemortem interventions.[176] Furthermore, it is likely that surrogates and donors are not aware of the controversies surrounding determinations of death, the possibility of reanimation through reperfusion, and the practice of cDCDD more generally while consenting to donation.[177] Again, this may violate the requirements for valid informed consent.

(D) Determination of Death

Although conflicts of interest in the determination of death are rarely explicitly spelled out in the literature, it is reasonable to assume that they can occur given the time pressures that are inherent in cDCDD.[178] For example, from an institutional perspective it is expedient to adopt a weak construal of irreversibility and a shorter no-touch period in the interest of recovering viable organs. Institutions may be motivated by utilitarian rationales to adopt perspectives on these debates that are amenable to their organ procurement goals.

Discussion

Despite the many potential conflicts of interest in cDCDD, the vast majority of authors argue that these can be mitigated or eliminated.[179] Indeed, this is one area where there seems to be uncharacteristically strong consensus. The primary objective of clinical medicine is the care of patients. As such, the mitigation of conflicts that may undermine this objective is of paramount importance. This will help to ensure that medical practice does not stray beyond its morally sacrosanct boundaries.

Conflict of interest mitigation strategies are noted in all reviewed consensus statements on cDCDD.[180] The most commonly proposed is the separation of care and organ recovery teams. Since unseparated teams may be influenced by conflicts of interest, those that care for dying patients and those that secure consent or recover organs for transplantation must be strictly separated. Separation of teams will address both real and perceived conflicts of interest in cDCDD.[181] Guidelines emphasize that decisions regarding withdrawal of life sustaining measures must precede any discussion of organ donation. In addition, clear protocols for cDCDD will lessen the chances of conflicted decision-making.[182] Potential conflicts of interest should be disclosed in order that surrogates can make informed decisions on donation.[183] Finally, fully informed consent requires transparency. Surrogates must consent to each aspect of cDCDD: withdrawal of life sustaining measures, donation, and antemortem interventions.[184]

A few dissenters take issue with the view that a mandated separation of teams will effectively eliminate all conflicts of interest. While possible in theory, they argue, such separation is difficult in practice.[185] These objections notwithstanding, the prevailing view is that conflicts of interest are manageable.

VI. cDCDD and the Preservation of Public Trust

Public trust in physicians is essential for the practice of medicine. Trust is especially important in the context of organ donation and cDCDD. Patients and their surrogates need to be confident that physicians will always put patient interests first, that donors will not be killed for their organs, and that cDCDD rests on firm empirical and ethical foundations.[186] This is in the interest of donors, recipients, families, health care providers, and the public. Preserving public trust in organ donation schemes is also essential to promoting recruitment in these schemes. As

Gallagher, Skaro, and Abecassis argue, "[u]ltimately, defining what is ethically acceptable must be balanced with maintaining the public trust, which is sacrosanct in the field of transplantation."[187] Some have argued that the practice of cDCDD might inflame public anxieties about medicine insofar as it tests societal boundaries of ethically acceptable practices in health care to such a degree that it could erode trust in both physicians and organ donation schemes.[188] This is why some consider public trust to be the "major issue" in cDCDD.[189] We outline these concerns before considering responses.

In this context, many worries relating to public trust arise. It is arguable that all of the controversies surrounding cDCDD raised in the foregoing could undermine public trust. Indeed, many arguments have the following form: "*the concern we have raised regarding* X *is worrisome; disclosure of the uncertainty and debate around* X *will thus erode public trust*." These arguments involve speculation on empirical consequences that may obtain in the future. Since the suggested consequences are empirical in nature, disagreement in this area could be informed by further study of public attitudes towards the various aspects of cDCDD.

(A) Does the Practice of cDCDD Test (or Transgress) Society's Ethical Boundaries?

Answers to this question draw on more focused debates in the literature on cDCDD. The question's answer is contingent on one's position with respect to these narrower debates, as well as one's views on how the ethical principles guiding medical practice should be interpreted. Most arguments concluding "yes" take the following form: "*concern* X *is a problem;* X *means that we are transgressing ethical principle* Y*; once made aware of* X*, the public will lose trust in physicians and organ donation schemes because it espouses* Y." As such, a few examples will suffice. If one thinks that the risk of hastening death by way of antemortem interventions is non-negligible, one might contend that doctors are sometimes killing patients — something that could stoke public fears of patients being killed for organs.[190] Killing patients distorts the nature of the doctor-patient relationship and thus runs the risk of eroding public trust.[191] A similar argument can be made if one thinks that cDCDD donors are not actually dead when organs are retrieved. The public may react negatively if it believed that organs were being taken from the living, for doing so would represent a violation of the DDR. Similarly, suggestions that "irreversible" loss of brain function *could* be restored after circulatory determination of death could lead to "public uncertainty and the possibility … of derailing the transplant programme in general."[192] Finally, if one contends that cDCDD causes deontological harms to donors [193] then public trust could be impacted insofar as the practice may be perceived to undermine society's commitment to the inherent worth of all persons.

(B) Will Real or Perceived Conflicts of Interest Erode Public Trust?

Some authors suggest that public perception of conflicted decision-making at any stage of cDCDD would erode trust in organ donation schemes and physicians. Here again the arguments take a similar form: "*because of the conflict of interest we have identified, public trust may be eroded*." For example, "[…a]ny doubt over decisions to withdraw life-sustaining treatment would be a potential disaster for any [DCDD] programme."[194]

Responses to these concerns piggy-back on those that respond to the worry that conflicts of interest jeopardize the ethical permissibility of cDCDD. First, perceptions of impropriety will be alleviated by separation of teams.[195] Second, clear protocols for cDCDD will mitigate the chances of conflicted decision-making.[196] Finally, all potential conflicts of interest must be transparently voiced to promote confidence in the medical profession.[197]

(C) Is the Public Being Deceived When it Comes to cDCDD?

A minority of critical authors worry that the public is being misled about the practice of cDCDD. There is a concern that a weakening of public trust may result from wider awareness of this purported deception. This debate focuses on the contentious criteria for determination of death employed in cDCDD. Death, say some, is a concept that is being gerrymandered in order to increase the pool of eligible organ donors.[198] Physicians, institutions and organ

procurement organizations are practicing “deception” when it comes to cDCDD: donors are not dead.[199] Falsely claiming that sound science underlies criteria for determination of death is dishonest.[200] The arguably misleading language used to describe the vital states of cDCDD donors leads the public to falsely believe that donation only ever takes place after death has been unequivocally determined.[201]

(D) Will the Proposed Relaxation of the DDR Erode Public Trust?

Perhaps the most prominent debate surrounding public trust concerns the possible impacts resulting from something that has not even happened: the relaxation of the DDR. This debate is stimulated by proposals to abandon the DDR in order to facilitate cDCDD and avoid conceptual turmoil.[202] As previously noted, these proposals stem from the belief that the DDR is already violated,[203] that blind allegiance to the rule obscures what is really at issue,[204] and that this allegiance requires indefensible revisions of the concept of death.[205] Despite these arguments, the vast majority of authors suggest that relaxing DDR will lead to an erosion of public trust in cDCDD.[206] Maintaining the DDR is essential to reassure the public of the primacy of patient interests.[207] Proponents of jettisoning the rule argue that such slippery-slope rejoinders are not based on any firm evidence; in fact, available evidence suggests that the public will not be unduly concerned with a loosening of the DDR.[208] Yet despite proposals for relaxing the DDR,[209] the prevailing view is that it should not be abandoned.

Discussion

Given the concerns regarding the possible impact of cDCDD practice on public trust, there is consensus that full transparency and consultation with the public are essential for determining the ethical appropriateness of the various elements of cDCDD protocol.[210] All controversies in the literature must be presented to the public. As Vincent and Brimioulle argue, “[w]ith the sensitive nature of all organ donations, [DCDD] must be considered and discussed openly and honestly to avert raising unnecessary concern or suspicion among the public.”[211] Feedback from the public must be considered when designing cDCDD protocols.[212] Clear, standardized protocols help to preserve public trust in organ donation schemes.[213] It is only through public education, debate, feedback, and endorsement that public trust in cDCDD can be ensured. This strategy respects our contention that many of the most important controversies in cDCDD arise from inherently debatable conceptions of death and similarly arguable moral positions on the legitimate scope of medical practice and the principles which guide it. Socially acceptable answers to these debates are one way to ensure that cDCDD rests on firm ethical foundations. However, the consensus on the need for transparency and public feedback evident in academic literature seems not to have translated into robust and effective public education and engagement on the part of transplant organizations.[214] This dissonance is surprising, leading some to worry that a failure to engage robustly with the public is part of a utilitarian-informed “masking strategy” which serves to promote cDCDD at the cost of transparency and a fully informed public.[215]

Conclusion

Our overview of the ethical controversies surrounding cDCDD identified emerging agreement in the donation and transplant community on suitable interpretations of the criteria for determinations of death in the context of cDCDD,[216] as well as on the measures necessary to mitigate conflicts of interest in practice.[217] Other issues, especially among bioethicists, remain fractured. There is concern from small but vocal camps which argue that donors can be harmed in cDCDD, that the practice violates the DDR, and that cDCDD will lead to an erosion of public trust in organ donation schemes. That said, the increasingly widespread use of cDCDD suggests that the donation and transplant community considers these issues resolvable through iterative analysis and dialogue. Perhaps the most interesting finding of this review concerns the apparent bifurcation between two categories of issues: the normative/philosophical and the empirical. Our discussion suggests that this cleavage is somewhat artificial, for it illustrates how cDCDD operates at the intersection of science, medicine, law, social science, and philosophy in such

a way that insights from each field are required for its ongoing development.

Some of the debates highlighted above are eminently suitable for resolution through empirical research. For example, further data will inform debates on the incidence of autoresuscitation and, consequently, the appropriate no-touch period required following asystole. The uncertain relationship between brain activity and circulatory death will likewise be informed through empirical research. Our prospective study, *Neurological Physiology After Removal of Therapy* (NeuPART), promises to illuminate the physiological and temporal relationship between neurological and circulatory activity during and after end of life by measuring cortical function using electroencephalogram, cerebral blood flow using transcranial Doppler, and brainstem function using evoked potentials.[218] Other areas amenable to empirical resolution include the risk of harm from antemortem interventions, the likelihood of reanimation through postmortem reperfusion in conjunction with procedures to prevent blood flow to the brain, and the potential impacts of cDCDD on both donor families and public trust.

However, it is clear from our overview of ethical concerns surrounding cDCDD that most debates cannot be resolved through empirical research alone. Prominent issues discussed above point to ongoing disagreement around fundamental moral and metaphysical questions. What is death? What are its indicators? How should we construe "harm"? When can care be altered in the interest of donation? And just what exactly does the DDR prohibit? Since work in a number of fields is required to resolve these issues, progress will only be made with advances in each. Ultimately, the plurality of viewpoints found in the literature is a natural result of not only empirical uncertainties, but also complex debates concerning the metaphysics of death and value-laden judgements concerning the legitimate scope of medical practice. Since moral and metaphysical positions are inherently debatable, we do not foresee the imminent emergence of universal agreement on the propriety of all aspects of cDCDD. Given the dilemmas attending moral and metaphysical debate, it is possible that variation in cDCDD protocol and practice is not just to be expected, but also embraced. If this important and promising form of organ donation is to continue to develop and expand, protocols may have to be adapted to local moral, social and cultural perspectives. While some of the issues discussed in this review are empirically tractable, some of the most contentious are not. This means that any socially acceptable form of cDCDD must emerge from public engagement if it is to reflect societal perspectives on death and the boundaries of medical practice. Further dialogue, public feedback, and analysis are required as cDCDD advances and becomes even more widely used as a means to expand the donor pool.

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Appendix 1

PubMED

((“DCD” OR “donation after circulatory death” OR “non-heart-beating organ donation” OR “donation after cardiac death” OR “donation after cardiocirculatory death”) AND (trust OR ethic* OR harm* OR irreversible OR irreversibility OR permanence OR permanent OR “dead donor rule” OR “conflict? of interest” OR consent))

SCOPUS

(TITLE-ABS-KEY (“DCD” OR “donation after circulatory death” OR “non-heart-beating organ donation” OR “donation after cardiac death” OR “donation after cardiocirculatory death”) AND TITLE-ABS-KEY (ethic*) OR TITLE-ABS-KEY

(harm*) OR TITLE-ABS-KEY (trust) OR TITLE-ABS-KEY (irreversibility) OR TITLE-ABS-KEY (irreversible) OR TITLE-ABS-KEY (permanence) OR TITLE-ABS-KEY (permanent) OR TITLE-ABS-KEY (“dead donor rule”) OR TITLE-ABS-KEY (“conflict* of interest”) OR TITLE-ABS-KEY (consent)) AND PUBYEAR <2020

Embase

(“DCD” OR “donation after circulatory death” OR “non-heart-beating organ donation” OR “donation after cardiac death” OR “donation after cardiocirculatory death”) AND (trust OR ethic* OR harm* OR irreversible OR irreversibility OR permanence OR permanent OR “dead donor rule” OR “conflict? of interest” OR consent)

Appendix 2

Donation after circulatory death; non-heart-beating organ donation; donation after cardiac death; donation after cardiocirculatory death

Trust; ethic*; harm*; irreversible; irreversibility; permanence; permanent; dead donor rule; conflict* of interest; consent

Appendix 3

Inclusion criteria. The article, editorial or commentary was included if: the abstract and/or article was accessible through Western University library catalogue/subscribed databases; published in English; explicitly engaged in an analysis or description of at least one issue, concept or argument bearing on the ethics of cDCDD.

Exclusion criteria. Articles were excluded if they were: primarily clinical in focus; primarily legal in focus; primarily religious in focus; a case report; focused only on uDCDD; reported findings on surveys of attitudes towards cDCDD; reported findings on animal studies; discussed issues around cDCDD specific to one country; focused on pediatric cDCDD; focused on cDCDD in the context of specific underlying illnesses. Exceptions were made for articles which were discussed or cited extensively in numerous publications.

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218. Personal communication with M. Slessarev and T. Gofton, June 22, 2020.

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Doubt &Social Policy: The Long History of Malingering in Modern Welfare States

Goldberg, Daniel S

ABSTRAK (ENGLISH)

This essay explores the long Western history of anxieties about feigned illness connected specifically to social policy. There is a remarkable consistency of such anxieties across time, as they appear in almost every major historical period in the West since the Middle Ages.

TEKS LENGKAP

Introduction

While it is dangerous to speak of historical constants, Western anxieties about feigned illness occur repeatedly in a variety of historical contexts. In *The Odyssey*, Odysseus feigns madness by sowing salt in a field. In the Hebrew Bible, when David fled from King Saul, Bathsheba reported that he was sick in bed and could therefore not attend. 13th century physician, alchemist, and astrologer Arnau de Vilanova was anxious about "patients intending deception through faked illness or supplying wrong or outdated urine."[1] In part, Arnau's anxiety arose because patients sometimes sought to test the expertise of physicians by sending
an intermediary with 'their' urine in their stead, making it impossible for the doctor to see and assess the patient directly through other visible symptoms. Presented with a flask of mysterious liquid and the poker face of a healthy comrade of the ill, the physician was at risk of discrediting himself spectacularly.[2]

In his writings on uroscopy, Arnau therefore prescribed at least nineteen pieces of advice by which the keen physician could separate the truly ill from the tricksters. For example, he suggested that physicians "ask leading questions in the hope the uneducated client would accidentally reveal the real source of the liquid."[3]

In Chaucer's *Troilus and Criseyde* (c. 1380s) Troilus feigns a fever to take to his bed and therein hide his love for Criseyde from the public world.[4] In 15th century Valencia, court records regarding disputes between buyers and sellers of slaves show that slaves were routinely accused of feigning illness. Slaveowners did so "in order to sabotage their resale, thereby preventing their transfer to an unknown, and potentially worse, master."[5] Four centuries later, slaves in the 19th c. US were also often accused of "malingering" or feigning illness.[6]

In the early modern context, feigned illness is an important motif in Shakespeare's works, including in the character of Hamlet himself, Prince Edgar (*King Lear*), and the Earl of Northumberland (*2 Henry IV*).[7] While the reasons for anxieties about feigned illness vary, astonishingly often they have centered on pain. In Papal physician Paolo Zacchia's early modern medico-legal text *Quaestiones* (1661), evidence of pain is often the central bone of contention.[8] In examining the case of a painful malady involving Spanish priest Christophorus Gomez, Zacchia paid special attention to the problem of malingering or feigned illness. He devoted an entire section of the text
to the simulation of diseases and was here reporting the received view that fear, shame or greed were the main causes of this phenomenon …Malingering had traditionally been associated with avoiding tasks and assignments, but reasons to simulate illnesses or unusual alterations of the body were allegedly on the increase in early modern society.[9]

Thus, Zacchia documented a variety of social contexts in which fears of malingering might arise, including

- The "armies of undeserving poor who would routinely fake fits to stir the charities of passers-by;"
- "impudent women simulating ecstasy to gain status in their communities;" and
- "defendants who would pretend to suffer from all sorts of illnesses to avoid the torture that was routinely administered in Continental tribunals."[10]

Surely, Zacchia observed, it is conceivable that a timorous priest might exaggerate a “minor ailment to make his workload lighter.”[11] But the patient himself was deemed untrustworthy, and so “his testimony had to be corroborated by other evidence.”[12]

There are two takeaway points here. First, anxieties about malingering or feigned illness are at least a thousand years old in the West. Second, doubt is a core aspect of how pain in particular has been socialized in the West for roughly the same length of time. This astonishing persistence of doubt has rarely been distributed equally, however. Women, slaves, soldiers, and, especially since the early modern era, Black and Brown peoples in particular seem more likely to excite doubt and accusations of feigned illness.

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These anxieties about malingering have not escaped contemporary scholarly attention. However, there exists no single synthetic historiography explicating the persistence of doubts and anxieties about feigned illness in the West. This gap is especially significant given the primary claim of this essay: concerns of malingering or feigned illness are fundamental to USian social welfare policy. It is thus not simply that accusations of malingering are important in health care encounters; rather, what passes for a contemporary welfare and social policy regime in the US is deeply linked with concerns about people feigning illness.

Admittedly, there is a sense in which this too is not novel. Distinguishing between the deserving and undeserving poor has been a core feature of welfare policy in the West since at least as far back as the Elizabethan poor laws of the early 17th c.[13] As noted above, di Renzi demonstrates that by the 1660s the perceived need to make such a distinction was firmly entrenched. Despite these general connections between concerns of deservingness and social welfare policy in the West, few sustained studies have explored potential links between accusations of malingering in particular and the specific scope and contours of USian social policy. This essay suggests some reasons for thinking that these links exist and merit scholarly attention and resources.

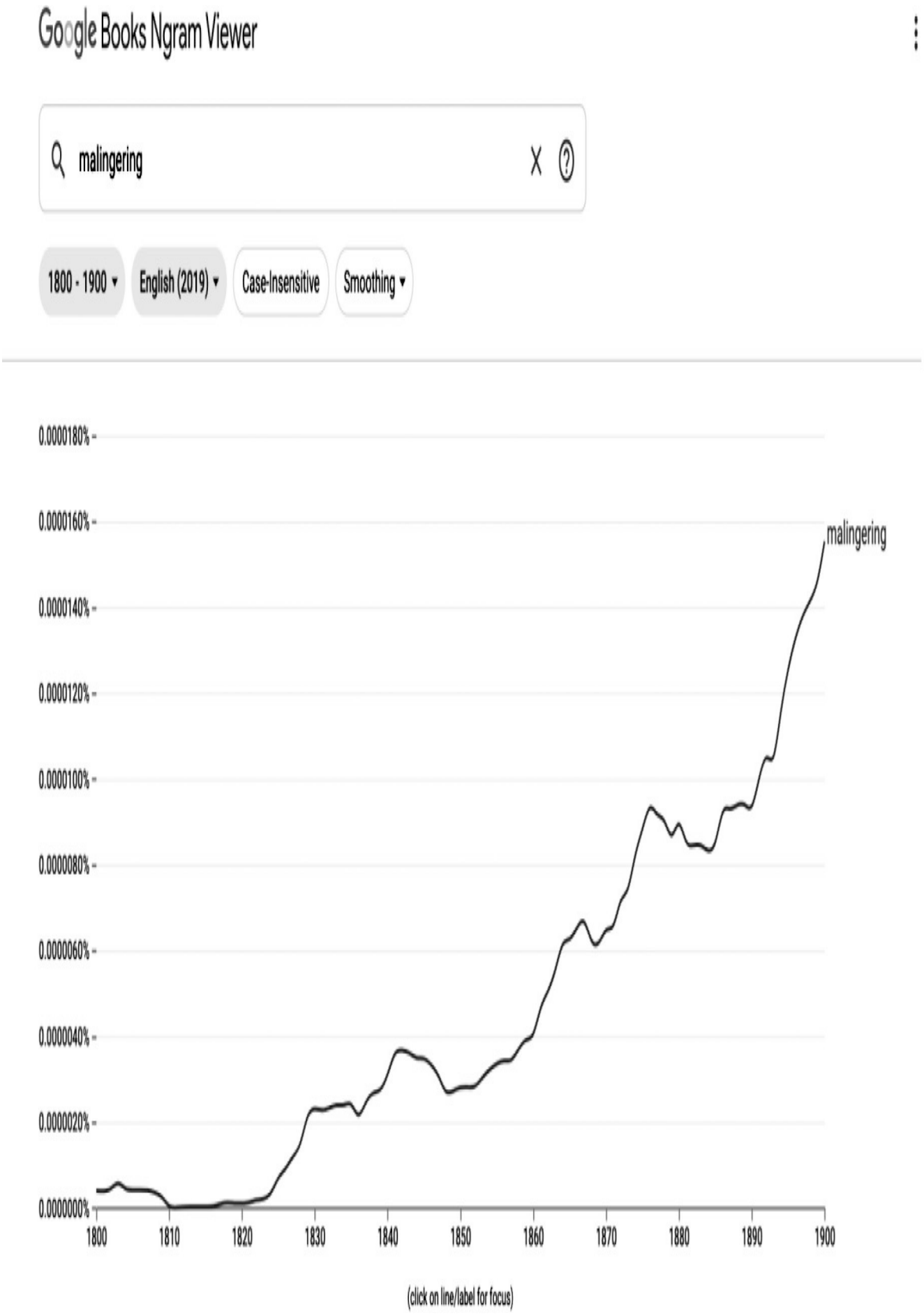
Malingering, Soldiers, and Pensions

In a 1998 essay on malingering in the modern era (roughly post-1800), historian of medicine Roger Cooter explained that accusations of feigned illness took on particular force in martial contexts.[14] There is no question that this observation holds for US history, as we can locate anxieties about what Doron Dorfman analyzes as “the disability con”[15] as far back as pensions go in the US. For example, in prefacing William Henry Glasson’s 1918 history of federal military pensions, his editor, David Kinley, lamented that “[a]s is usual under all governments when money is to be paid out to numerous individuals in the community, a class of people fastened themselves as parasites on the beneficiaries.”[16] An 1818 act of Congress established new pensions for veterans from both the War of Independence and from the War of 1812, and led to “flagrant abuses …made the subject of severe comment in the newspapers of the time. Men of means were charged with having made themselves out to be paupers in order to receive the benefits of the law …The country at large was indignant …”[17]

Both Confederate and Union sources voiced considerable concern over malingering as the US Civil War dragged on, with medical men on both sides writing treatises and manuals addressing malingering and how to detect it. Confederate surgeon J. Julian Chisholm’s 1864 *A Manual of Military Surgery* devoted an entire section to malingering, noting that it “has ever been, and will continue to be, popular with soldiers, irrespective of the material of which an army is composed.”[18] Like Zacchia, Chisholm saw pain as a particular problem, numbering it first among

“the diseases most readily and easily feigned ….”[19] “When pain is feigned, as this may really exist as a disease without external manifestation, it is the most difficult of all symptoms to detect.”[20] And like Arnau de Vilanova, he expounded on a variety of creative methods for outing the malingerer.

On the Union side, physicians William W. Keen and Silas Weir Mitchell joined George Morehouse to pen an influential 1864 article in the *American Journal of Medical Sciences* entitled “On Malingering, Especially In Regard to Simulation of Disease in the Nervous System.”[21] (Keen and Mitchell would go on to help found the specialty of neurology in the US). Union surgeon Roberts Bartholow matched his Confederate counterpart Chisholm’s interest in malingering with the publication of his own 1863 treatise, this one specifically focused on malingering: *A Manual of Instructions for Enlisting and Discharging Soldiers: With Special Reference to the Medical Examination of Recruits, and the Detection of Disqualifying and Feigned Diseases.*[22] And like Chisholm, Bartholow perseverates on the problem of pain, noting that “[p]ain of all descriptions, existing often without evident external sign, is peculiarly liable to be simulated, because difficult of recognition.”[23] He also goes through several different techniques for testing the pain sufferer in an effort to detect malingering.



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Ultimately, there is little question that anxieties about malingering rise in the US over the long 19th century. N-grams

show a consistent rise in the use of the term beginning in the early 1820s. Not only does the absolute concern with malingering increase, but its relative distribution also begins to shift from soldiers to Black communities, and especially slaves.[24]

Yet, as the 19th century lengthens, concerns over malingering also track to bourgeoisie white bodies.[25] In sum, there is a general expansion in fears of malingering from the martial contexts where it was most active, to Black bodies, and subsequently to civilian white bodies as well. Concerns over malingering in context of US veterans' pensions antedate the US Civil War by at least a half-century, but take on a new intensity in the postbellum pension context. This is true both for the much larger and more enduring federal pension scheme for Union veterans as well as the incipient pension programs for Confederate veterans. These latter programs emphasized deservingness and merit as part of the Lost Cause mythos, with a particular emphasis on Confederate veterans who could demonstrate visible marks of their sacrifice via amputations or other highly noticeable injuries and wounds.[26] (In the absence of these kinds of somatic testimonies, complaints of pain tended to fare less well in justifying pension entitlements).[27] While visible injuries and disfigurements marked the Civil War veteran as authentically ill or injured and therefore deserving of public assistance, the insufficiency of welfare policy in the latter half of the 19th c. introduced a visible blemish onto the USian cityscape: Impoverished, injured, and disabled Civil War veterans begging on urban streets. Municipalities all over the US introduced so-called "ugly laws" intended to reduce the visibility of these veterans and essentially erase them from public view.[28] Ironically, the structural deficiencies of US social welfare policy rendered the very markers of these veterans' merit unacceptable for public consumption and thereby transformed the markers into stigmata.

The resonance of concerns about feigned illness, and about separating deserving from undeserving veterans in pension contexts is incredibly important because these pension schemes form the core of the modern welfare state in the U.S. Theda Skocpol's pioneering work demonstrates how a "maternalist" welfare state began to form as both the federal government and over forty states enacted a variety of pension and welfare programs to assist spouses and children of Civil War veterans.[29] While these policies did not ultimately generate a robust social welfare program for all residents and citizens, the fact remains that what passes for social welfare policy at all in the US is historically grounded in concerns and specific programs for veterans. Therefore, inasmuch as anxieties about deservingness form a core part of the pension schemes for US veterans, it would be surprising if anxieties about feigned illness were not integrated into social policy in the US in general.[30]

Lost limbs, amputations, and traumatic injuries play a significant role in shaping discourse on social policy and deservingness in the 19th century. Curiously, these conditions do not simply apply to pensions, but to a different social context that is also crucial for exploring the links between malingering and social policy: railways.

Railways, Injury, and Malingering

The significance of the railroads in the history of USian medicine and public health can barely be overstated. For example, with the important exception of professional sports leagues (see Stephen Casper and Kathleen Bachynski's contributions to this Symposium), while much private health insurance in the US is obtained through employment, large employers as a rule do not directly employ health care workers to provide care for their employees. Instead, employers typically contract out with third-party administrators to arrange and manage the health care needs of their employees. This arrangement is traceable to the railway industry, which helped originate the provision of health care services for employees through a model of direct care that its employees almost universally loathed.[31] Employees hated the direct care model so much —largely for the conflicts of interest it structured among company physicians —that large employers distanced themselves from such a model in the first quarter of the 20th c.

The point is that important features of USian health and social policy are connected to the railway industry. And the railway industry was supremely concerned with malingering and feigned illness. Trains are mighty machines, moving immense weight at incredible speeds. Railways were —and remain —hazardous, both to workers and to passengers. The spate of railway injuries contributed to a sharp rise in tort litigation in the late 19th-early 20th centuries, which had an increasing impact on industrial revenues.[32] Partly as a way of managing these liabilities, railway companies began to hire physicians both to provide care for injured employees and passengers and to prepare expert defenses against any ensuing tort litigation. The rise of railway medicine and railway surgery as distinct specialties in allopathic medicine are therefore marked by special care and attention to malingering.

To give just a few choice examples, railway surgeon Shobal Vail Clevenger remarked in an 1889 treatise that "rheumatism, fright, old age, and phthisis are frequently suggested as the real causes of death, and recovery was good ground to suspect malingering. Fraud abounded in most of the claims made. It would be interesting to be able to examine the records of the plaintiffs' lawyers in these cases."[33]

Railway physicians and specialists in nervous injury and disease wrote of so-called "litigation" or "traumatic" neuroses, which conveniently disappeared once a legal settlement was reached or the litigation completed. Railway physicians also took special interest in spinal or other "nervous" injuries that attended the violent and relatively frequent collisions. Like their US Civil War predecessors, they deemed such injuries particularly susceptible to dissimulation; railway surgeon Webb Kelly famously remarked in the pages of *JAMA* in 1895 that "[r]ailway surgery without the spinal malinger would be like a ship in mid-ocean bereft of her sails and rudder."[34]

I have discussed elsewhere some of the social, political, and intellectual contexts for the 19th and early 20th century rise in anxieties about malingering.[35] The focus here is on the primary role such anxieties played in the formation of modern social welfare policy in the US. Five centuries of Western social policy have centered the question of desert, of distinguishing who deserves the aid of the state and who does not. And finding those who "deserve" welfare has been central to US social policy in pension schemes and in public health litigation involving railway injuries.

Although neither of these policy interventions initiated a robust set of welfare entitlements for USians of all races, classes, and genders, the focus on deservingness and merit is not difficult to see in other arenas of social policy. US almshouses, for example, took their cue from analogous programs in 19th c. Great Britain.[36] "The poor would receive care if they agreed to reform their characters. Euro-American benevolence aimed to socialize the 'deviant' …as part of a moral obligation of 'doing good.'"[37] Distinguishing between the deserving poor and the undeserving "morally deviant" was critical.[38] In US and British contexts, the objective was to render living or sheltering in an almshouse so terrible that only a person or family with literally no other options would choose to do so. Only the truly desperate and optionless merited an entitlement to this most meager of benefits. Thus, David Wagner explains that US poorhouses were meant to provide poor people with "a bare minimum existence …such that they would not starve …but the subsistence was to be 'minimal' and harsh enough to deter the 'indolent and vicious,' 'lazy,' and 'intemperate."[39] The fear that if almshouses were made too attractive, "undeserving" people might dissemble and/or feign penury, illness, and injury was so powerful that it led politicians, philanthropists, and communities to intentionally immiserate the least well-off as a means of ensuring their deservingness for public assistance.

The notion that is better to intensify the suffering of the least well-off then to facilitate access to social services and benefits that in theory could invite "fakers" is so common as to be virtually emblematic of USian approaches to social welfare policy in the modern era. How else can we explain the "fear of the disability con"[40] despite the overwhelming empirical evidence showing that disability and benefit fraud perpetuated by a claimant in the US is vanishingly rare?[41] While such fraud and especially health care fraud does occur, in virtually every case the malfeasant is a health care worker or health care organization defrauding government assistance programs or payors.[42] In other words, the

specter of hordes of “fakers” crashing social welfare regimes has no connection to the reality of benefit fraud in the US.[43]

Yet the fears of deception and malingering are so powerful that they shape the very structure of USian social policy. The remainder of this essay is therefore devoted to canvassing several prominent contemporary examples that link past to present in illustrating how anxieties about malingering and feigned illness continue to animate social policy in the US.

Linking Past to Present in Connecting Malingering and US Social Policy

During the Trump Administration, 12 states sought and received permission from the US government to impose Medicaid work requirements as a condition of eligibility. Center for Medicare &Medicaid Services (“CMS”) Administrator Seema Verma justified the requirements by arguing that (1) employment has a beneficial effect on health and (2) “dependency” on safety net programs is problematic.[44] Yet, the policy case for Medicaid work requirements is paper-thin.

First, the vast majority of Medicaid recipients who are able to work, work. A left-leaning think tank argues that at least 60% of the people who could be subject to such work requirements already work.[45] Whatever the exact percentage, there is no serious dispute that a significant majority of those impacted by these requirements already work. Even states which tried to implement work requirements noted as much: “According to one study in Michigan, CMS said, “Nearly everyone who was targeted by the community engagement requirement in Michigan already met the requirement or was exempt from it, so there was little margin for the program to increase work or community engagement among beneficiaries.”[46]

Second, as several courts noted in enjoining such requirements, the principal effect of the policy change is Medicaid disenrollment. A federal district court, for example, concluded that DHHS’s granting of the waiver to impose Medicaid work requirements was arbitrary and capricious because it “entirely failed to consider Kentucky’s estimate that 95,000 persons would leave its Medicaid rolls during the 5-year project.”[47] The District Court was unimpressed with DHHS’s suggestion that alternative criteria could be used to justify the waiver because, it noted, a central purpose of Medicaid is to furnish medical assistance. Striking 95,000 citizens from the Medicaid rolls contravenes this objective. Moreover, given that most Medicaid enrollees are either ill, disabled, in school, informal caregivers, and/or poor, interrupting critical coverage has the general effect of immiserating some of the least well-off.

Third, there is no good evidence that work requirements actually increase employment rates or reduce poverty. Several studies have documented transient impacts on employment and poverty that fade to null over a five-year period.[48] A brand-new NBER paper released in June 2021 found that work requirements for a different safety net program, Supplemental Nutrition Assistance Program (“SNAP”), increased “program exits by 23 percentage points (64 percent)” and produced a “53 percent overall reduction in program participation.”[49] In fact, the effects on participation were so pronounced the investigators concluded that eliminating work requirements would “transfer more resources to low-income adults” per dollar of public expenditure than alternative policy interventions.

Ultimately, the policy case justifying the imposition of Medicaid and/or other safety net work requirements is so weak that very few policy organizations or think-tanks, including ideologically conservative or laissez-faire groups, publicly endorsed any of the proposals. Yet numerous politicians on both state and federal levels pursued them.

Why? How can we account for the eagerness to impose policy changes that have as their only probable effect the immiseration of the least well-off? Former CMS Administrator Verma supplies part of the answer: the need to make sure that only those who are “truly” unable to work receive public benefits. This answer of course rests again on the idea of deservingness, of ensuring that only those who are genuinely sick, injured, and/or destitute merit assistance. Ability to work has been the central feature of virtually all pension entitlements in US history, showing again how

past connects to present in illuminating key features of health and social policy in the US.

The argument, thus, is that whatever explanations we generate for the eagerness to impose Medicaid work requirements in spite of at-best tepid policy rationales is incomplete if it does not include anxieties about deception, malingering, and feigned illness. The “fear of the disability con” is not simply a curious quirk of US social policy; it is rather a deus ex machina for the entire apparatus itself.

Another example are regulations governing access to Social Security for disabled people. As I have previously written, “C.F.R. §[416.929 (2017] provides that proof of disability must come by medically acceptable clinical and laboratory diagnostic techniques. A physical or mental impairment must be established by medical evidence consisting of signs, symptoms, and laboratory findings, not only by your statement of symptoms.”

This provision has particular implications for the class of people seeking disability benefits by virtue of chronic pain. Because many forms of chronic pain defy the objective armamentarium of Western medicine and health care, the population of claimants with chronic pain will likely have a much more difficult time drawing up the needed proof. This state of affairs is all the more problematic given that virtually every health professional modality charged with providing care for people in pain prioritize the patient’s subjective self-report.[50]

This regulation also promotes epistemic injustice against people in pain[51] inasmuch as it “mandate[s] a prejudicial credibility deficit for chronic pain sufferers —their testimony about their own experiences of illness is, as a matter of law, regarded as insufficient to justify an entitlement to disability benefits.”[52]

Finally, as Dara Purvis has noted, claimants seeking Social Security benefits for disability flowing from a chronic pain condition like fibromyalgia are, as a class, much more likely to fail to satisfy the regulations because of the difficulty of producing so-called “objective” evidence of impairment. Because women are much more likely to experience fibromyalgia, the regulations themselves are gendered and intensify chronic pain stigma along gender lines.[53]

This regulation demonstrates several historical threads connecting anxieties about malingering and deception to social policy. The policy evinces particular mistrust of people in pain. Only people who are “truly” disabled by pain “deserve” public assistance. And unless the cause of the disability can be shown via the objective armamentarium of Western health care and medicine, the truth of the claimant’s disability remains questionable. Thus the fear of dissimulation is deemed sufficient to obstruct or bar altogether access to welfare benefits for an entire class of people. Moreover, the regulation may have disproportionate impact on women, thereby reinforcing that some social groups (i.e., women, slaves, Black and Brown peoples, the poor, etc.) in the West seem particularly likely to be accused of feigning illness across time and space.

As a third example, consider state and federal resistance to extending or increasing unemployment benefits during the COVID-19 pandemic. In initial debates, several US senators urged that the proposed $600 weekly payments were simply too generous.[54] Their concern was that the amount would encourage people to stay unemployed. Indeed, by June 2021, 22 states had voluntarily withdrawn from the federal government’s pandemic unemployment benefits program. Many officials in these states offered similar reasons for ending such benefits. Although the COVID-19 program supports benefits regardless of the reason for employment, concerns of “overgenerous” employment benefits have historically been intimately connected to anxieties about malingering.[55] The modern argument simply launders historical tropes through the contemporary “wonkspeak” of social choice theory:

When social scientists use the term choice to discuss withdrawal from work in the face of chronic disease, they give a nice name to behavior which as easily may be called malingering. When they argue that social policy encourages the exercise of that choice to exchange labor for leisure, the response in Washington is to the image of malingering, not choice. The response is to try to get the malingerers off the disability rolls, or at least, to reduce the size of their

benefits.[56]

Ultimately, the policy case justifying the imposition of Medicaid and/or other safety net work requirements is so weak that very few policy organizations or think-tanks, including ideologically conservative or laissez-faire groups, publicly endorsed any of the proposals. Yet numerous politicians on both state and federal levels pursued them.

There is, of course, little evidence that during times of economic and social extremis in particular increasing unemployment benefits depresses willingness to work. Yelin's detailed 1986 study found exactly the contrary: Increased unemployment benefits and physician-provided diagnoses had extremely weak effects on labor-force participation. The strongest effects on such participation came from variables like job autonomy ("discretion over the pace and activities of the job"), and the level of psychological demand on the worker: "The combination of low discretion and high demands reduces the probability of working by a half."[57]

Yelin also draws the critical point regarding the reach of ideas about malingering. Mostly chimerical anxieties about malingering and the implications on deservingness for public assistance are so powerful in the US they are sufficient to convince stakeholders to immiserate the least well-off: "[I]f the intent is to remove the undeserving from the rolls, all beneficiaries suffer."[58]

Conclusion

One of the most fundamental and important axioms of intellectual history is that ideas are social actors.[59] It is common to think of ideas as gossamer in contrast to the realities of the material world. But this is a grave mistake. Ideas can move mountains. To do so, ideas have to be embedded in social matrices of power, politics, and material conditions. But properly nested, ideas can and do catalyze enormous social and political change.

The point of this essay is to suggest the significant hold that fears of malingering and feigned illness have on Western societies across time and space. These ideas are powerful enough to influence social welfare policy in different societies and in different places. In the modern US, fears of malingering are, in concert with other important ideas of deservingness, merit, and responsibility, sufficient to shape the very core of what social policy does exist in the U.S. In other words, the social safety net in the US on both federal and state levels looks and functions the way that it does because of the power of fears of deception, malingering, and feigned illness.

Admittedly, the claims contained herein are merely meant to be suggestive. A great deal more scholarly work is needed to shore up the argument. While ideas of deservingness at the core of social policy across the West are connected to fears of malingering, they are not identical and the former is almost certainly broader than the latter. Explicating the precise connections between these two sets of ideas is complex and important. Moreover, this essay has not even mentioned the powerful role of religious ideas, institutions, and actors in shaping notions of merit and deservingness of public assistance in the West.

Nevertheless, while anxieties about malingering cannot fully account for the peculiar and meager scope of social welfare policy in the US, the argument here is simply that no explanation of the structure and function of US social and health policy is complete without accounting for the critical role such anxieties play.

Note

The author has no conflicts to disclose.

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DETAIL

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Shared Decision-Making and Prevention Recommendations: Evolution, Implications, and Challenges for Public Health

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ABSTRAK (ENGLISH)

Recent guidelines and recommen dations from government prevention advisory groups endorsing shared clinical decision-making reflect an emerging trend among public health bodies.

TEKS LENGKAP

In June 2019, revised recommendations for human papillomavirus (HPV) vaccination for adults 27 years and older and for the pneumococcal conjugate vaccine (PCV13) for adults 65 years and older were approved by the Advisory Committee on Immunization Practices (ACIP) to the U.S. Centers for Disease Control and Prevention (CDC). The committee declined in both cases to make a “routine” recommendation for the use of these vaccines in those age groups, instead advising that decisions be made on an individual basis through shared clinical decision-making between patients and health care providers.[1]

These actions reflect an emerging trend among public health bodies to incorporate shared clinical decision-making (SCDM or SDM) into their guidelines and recommendations. But they also raise unique considerations and complexities, particularly for vaccination, where tensions can exist between individual decision-making prerogatives and the population-level consequences of high vaccination rates in communities. SCDM recommendations reframe traditional approaches to evidence-based prevention, affect insurance coverage and patient access to preventive services, and influence patient-provider discussions and subsequent patient decision-making. Understanding the opportunities, challenges, and implications of SCDM recommendations as produced by public health advisory groups is particularly important as their use expands.

Shared Decision-Making: Origins and Expansion

Since its emergence in the 1980s, shared decision-making —defined by the Department of Health &Human Services (HHS) Agency for Healthcare Research and Quality as “a model of patient-centered care that enables and encourages people to play a role in the medical decisions that affect their health” —has gained broad support in clinical settings due to its dual embrace of patient-centeredness and evidence-based medicine.[2] By facilitating open communication through which health care providers offer information on the benefits and harms of options and patients identify their preferences, both parties are thought to gain a better understanding of patient priorities and values which shape decision-making.[3] Based on the ethical principles of relational autonomy and self-determination, shared decision-making is intended to individualize medical care based on patients’ priorities through physician-patient partnership.[4]

In clinical contexts, shared decision-making has been associated with greater patient participation and satisfaction, improved medication adherence, and decreased healthcare utilization.[5] It has been found to be particularly useful in preference-sensitive conditions, where multiple evidence-based treatment options exist but have different benefits and side-effect profiles, such as multiple sclerosis or type 2 diabetes mellitus.[6]

Reflecting its widening appeal, in 2010, the Affordable Care Act (ACA) called for the HHS to encourage shared decision-making and develop related decision aids.[7] The Centers for Medicare &Medicaid Services in 2015 mandated shared decision-making as a condition of coverage for lung cancer screening with low-dose computed tomography, and similar requirements have since been applied to other conditions.[8]

Shared clinical decision-making (SCDM) recommendations reframe traditional approaches to evidence-based prevention, affect insurance coverage and patient access to preventive services, and influence patient-provider discussions and subsequent patient decision-making. Understanding the opportunities, challenges, and implications of SCDM recommendations as produced by public health advisory groups is particularly important as their use

expands.

Endorsements of shared decision-making as part of prevention and public health have also gained support and recognition among governmental bodies, advisory committees, and professional organizations. In 2017, the American College of Obstetricians and Gynecologists (ACOG) recommended shared decision-making for patients and providers interpreting the at-times conflicting screening guidelines related to clinical breast exams and screening mammography published by the US Preventive Services Task Force (USPSTF), American Cancer Society, and National Comprehensive Cancer Network.[9] In its guidelines, ACOG highlighted shared decision-making as a mechanism to help patients make informed decisions consistent with their values and preferences.

Similarly, the USPSTF updated its guidelines for prostate-specific antigen (PSA) testing in 2018, recommending that decisions be made on an individual basis by patients in conjunction with their providers, thereby modifying its 2012 recommendation against PSA screening.[10] In its recommendation statement, the USPSTF stated that patients "should have an opportunity to discuss the potential benefits and harms of screening with their clinician and to incorporate their values and preferences in the decision."[11] Another 2018 USPSTF guideline emphasized shared decision-making in recommendations on screening for cervical cancer, encouraging women to make an informed choice among three specified approaches to screening.[12]

Prevention and public health guidelines endorsing SCDM, such as those published by the USPSTF and ACIP, have broad implications for patients, health care providers, payers, and health systems alike. Recommendations based on SCDM aim to embrace the ideals of shared decision-making at the population level, but endorsements of SCDM over traditional prevention recommendations introduce many challenges and complexities. Recent SCDM recommendations regarding vaccination provide a particularly illustrative setting through which to analyze the implications, opportunities, and difficulties posed by SCDM-based prevention recommendations and to identify actions that could improve their contribution to evidence-based disease prevention policy.

Vaccination Recommendations and the Advisory Committee on Immunization Practices

The ACIP was established in 1964 to assist the CDC in developing guidance for the control of vaccine-preventable communicable diseases.[13] ACIP recommendations become official following approval by the CDC director, typically a pro forma step, and subsequent publication in *Morbidity and Mortality Weekly Report (MMWR).*[14] ACIP recommendations profoundly impact public health nationwide, functioning as the "gold standard" for evidence-based vaccination practices, shaping patient and provider decision-making, and determining the vaccines covered by private health insurers and government vaccination programs, as discussed below.

In 2010, the ACIP adopted the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) framework to systematize its development of evidence-based recommendations.[15] Under this approach, vaccines most often receive a routine recommendation (previously "Category A" or "universal") by which a vaccine is advised for everyone in a specified age- or risk-based population group without a defined contraindication.

In recent years, a growing number of vaccines have instead received a non-routine recommendation in which the committee notes that a vaccine may be administered based on SCDM. (Earlier iterations of this class of recommendation were called "Category B" or "permissive" recommendations.) These SCDM recommendations avoid a general endorsement, instead encouraging shared decision-making between individual patients and health care providers regarding the use of a given vaccine. Several vaccines have both routine and SCDM recommendations for different populations, stratified by age or risk factors.

ACIP recommendations are based on an evaluation of potential benefits and savings in relation to potential harms and costs, considerations which are evaluated through the Evidence to Recommendations (EtR) framework. This analysis integrates critical outcomes, including anticipated benefits and harms of a vaccine as identified through the GRADE framework, as well as disease burden, patient values, acceptability, cost-effectiveness, and feasibility.[16] Routine recommendations for vaccination are issued when the anticipated desirable effects of a vaccine clearly outweigh the predicted undesirable effects for the specified population. Recommendations based on SCDM are adopted for various reasons, including when vaccination of a group is thought to be unlikely to produce substantial population-level impacts, but when some individuals in that group may nonetheless benefit.[17] Additional factors

leading to a vaccine receiving a recommendation based on SCDM include lower confidence regarding the effect of vaccination on health outcomes, smaller anticipated net benefit, and lower or uncertain cost-effectiveness.[18]

Recent Vaccine Recommendations Endorsing Shared Clinical Decision-Making

Prior to implementing the GRADE framework, the ACIP at times adopted "permissive" recommendations (which included language such as "may be vaccinated,") instead of routine "universal" recommendations (with "should be vaccinated" language).[19] The terminology of Category A and Category B recommendations were implemented in 2010 alongside the GRADE framework; under this structure, Category B recommendations advised decision-making based on "individual clinical decision making," intending to allow providers and patients to jointly determine whether to pursue vaccination as opposed to making sweeping guidelines for populations.[20] The Category B recommendation was renamed in 2019 to the current "shared clinical decision-making" recommendation, functionally identical but including amended language intended to emphasize physician-patient partnership in decision-making rather than individual responsibility, according to the ACIP.[21]

Initially, recommendations endorsing SCDM (and its "Category B" or "permissive" predecessors) were used by ACIP principally for populations with specific risk factors. For example, the approach was employed in 2011 to recommend that adults 60 years of age and older with diabetes discuss the hepatitis B vaccine with their physicians, in tandem with a traditional recommendation that adults with diabetes less than 60 years of age be vaccinated against hepatitis B at diagnosis. ACIP cited less robust data on the risk for hepatitis B for this older age group as the impetus for these different recommendations.[22]

The SCDM approach to recommendations was also applied in the early years of human papillomavirus (HPV) vaccination. HPV vaccine was initially recommended for routine use only in females. Following Food and Drug Administration (FDA) approval of an indication for its use in males, the ACIP approved in 2009 a permissive recommendation for the quadrivalent HPV vaccine for males aged 9-26 years.[23] The recommendation noted high efficacy of the vaccine in preventing genital warts in males, good immunogenicity, and minimal adverse reactions, but lower anticipated cost-effectiveness than policies that prioritized vaccination of females.[24]

Recommendations based on SCDM were first applied to a large population group in 2015 when ACIP approved an SCDM recommendation for people aged 16-23 for vaccination against serogroup B meningococcus (MenB), a rare but potentially life-threatening bacterial infection. In its recommendation report, the committee cited a lack of information about the vaccine's long-term effectiveness, the low burden of MenB disease, minimal documented effects of vaccination on MenB carriage, and unfavorable cost-effectiveness modeling as justifications for its narrower recommendation.[25]

The ACIP has continued to adopt SCDM recommendations, most recently at its June 2019 meeting. Updating its previous guidelines on HPV vaccination, the committee recommended routine vaccination of all persons aged 11-26 years, thereby harmonizing recommendations for males and females; it additionally recommended SCDM for HPV vaccination in adults aged 27-45 years.[26] In the associated GRADE report, ACIP concluded that although the population benefit of vaccination in the 27-45 year age group would be minimal, potential benefits existed for some adults at risk for HPV infections due to waning immunity, inadequate vaccination, or lifestyle-related risk factors.[27]

Also in 2019, ACIP updated guidelines for the pneumococcal conjugate vaccine (PCV13) vaccine against pneumococcus, a major cause of bacterial pneumonia and bloodstream infections, calling for SCDM for people 65 years and older without specified risk factors; this recommendation coexists with a routine recommendations for vaccination of those aged 6 weeks-71 months.[28] For PCV13, ACIP cited an unclear need for vaccination in the general 65+ age group due to the success of childhood vaccination efforts, yet noted that the vaccine may still be beneficial to some members of this older population.[29]

Effects of SCDM Recommendations for Insurance Coverage and Patient Access

ACIP recommendations shape public and private insurance coverage of vaccines, directly affecting patient access and affordability. As part of the ACA, private health insurance plans are required to cover all ACIP-recommended vaccines without patient cost-sharing, including coinsurance, copayments, or deductibles. This requirement includes vaccines recommended based on SCDM in addition to those with a traditional, routine recommendation.[30] New ACIP

recommendations are also reflected in coverage updates for the Medicare program for older Americans, most commonly through Medicare Part D, though some are covered by Medicare Part B with no cost-sharing for patients.[31] This coverage requirement for both routine and SCDM recommendations stands in contrast to the coverage implications of narrower recommendations of the USPSTF. Recommendations from that group endorsing shared clinical decision-making ("Grade C") for a specific preventive service do not qualify for first-dollar coverage under the ACA and private insurance coverage is not mandated.[32]

ACIP recommendations additionally have implications for the Vaccines for Children (VFC) program. That federal program purchases all ACIP-recommended vaccines and distributes them via state and local health departments to health care providers at no cost for children through 18 years of age who are eligible for Medicaid, uninsured, underinsured, or American Indian or Alaska Native, representing approximately half of all childhood vaccine doses.[33] The ACIP is empowered to add vaccines to the VFC program and does so immediately following the approval of new recommendations. As with the ACA coverage requirement, the VFC program includes vaccines that are routinely recommended and those recommended based on SCDM.

ACIP recommendations also inform adult vaccine coverage through Medicaid, although the precise mechanisms through which adoption occurs vary among states. Some expressly follow ACIP recommendations, while others include an evaluation of ACIP guidance alongside state health agency recommendations, recommendations from medical professional societies, or the determinations of Medicaid managed care organizations.[34] Recommendations based on SCDM can adversely affect vaccine access for adult Medicaid beneficiaries, unlike those for whom coverage for vaccines comes from other programs. For example, serogroup B meningococcal vaccines are covered by fewer state Medicaid programs than is the meningitis ACWY vaccine, which protects against other types of meningococcal bacteria and is recommended for routine use by the ACIP.[35]

Implications of SCDM-Based Recommendations

By adopting recommendations that endorse SCDM as opposed to more familiar and broader "routine" recommendations, public health agencies and their expert advisory committees aim to acknowledge limited available data or inconclusive findings regarding key considerations such as long-term effectiveness, risk-benefit ratios, or safety; recognize scenarios in which population-level anticipated benefits are modest because of the low prevalence of a condition or other factors; respond to unfavorable economic analyses; and yet preserve financial access through recommendations that facilitate insurance coverage for those interventions.[36]

For the vaccines discussed above, the principal justifications for SCDM-based recommendations varied, yet each case reflects the challenge of generating clear public health guidance in the context of limited evidence of benefit for a low-risk intervention among a specific population. Pending the emergence of additional data regarding vaccine efficacy, immunogenicity, disease burden, or cost-effectiveness, SCDM recommendations present the current evidence but effectively affirm the status quo, since any vaccine approved by the FDA —as all ACIP-recommended vaccines are —is already available for providers to use at their discretion and in discussion with their patients. Recommendations based on SCDM nonetheless promote patients' active participation in discussions of their values and priorities in the context of an evaluation of the benefits, risks, and uncertainty associated with specific preventive interventions. By encouraging dialogue between patients and providers, these recommendations —if implemented in a manner consistent with their design and intent—work toward the original goals of the shared decision-making movement: patient-centeredness coupled with evidence-based medicine.

However, surveys of health care providers report a general lack of familiarity with SCDM recommendations and difficulty communicating these recommendations to patients. A 2018 survey of pediatric primary care providers found that only 24% could correctly define the Category B vaccination recommendation (prior to its recent renaming).[37] Clear provider recommendations have been found to be highly influential in patient or parental vaccination decisions, and missed opportunities for vaccination are more likely when providers have difficulty communicating relevant recommendations or correctly conveying the implications of a government recommendation for insurance coverage.[38]

Many providers who offer vaccines recommended based on SCDM are not aware of insurance coverage

requirements that facilitate access and affordability. In the same survey, 55% of providers did not know that private insurance would pay for vaccines recommended based on SCDM, and 51% did not know that these vaccines were covered by VFC.[39] Because of this knowledge gap, vaccination opportunities may be missed due to unfounded affordability concerns.

Perhaps as a result of these knowledge deficits, recent studies have found that SCDM recommendations are not being implemented as intended. In one survey of providers, only 7% reported using individual clinical decision-making to decide whether to administer vaccines against MenB; instead, most providers simply chose to recommend or not recommend the vaccine to all of their patients or to recommend it only to patients with certain risk factors.[40] Less than half of providers indicated that they “almost always” provided educational materials or discussed that vaccine with their patients.[41]

SCDM recommendations are associated with lower vaccination rates than comparable vaccines or population groups for which traditional, routine recommendations are in place. For example, among individuals with diabetes, hepatitis B vaccination coverage (r3 doses) is 26.3% for individuals aged 19–59 years, the group for whom there is a routine recommendation. For individuals with diabetes aged ≥60 years —for whom the vaccine is recommended based on SCDM —hepatitis B vaccination rates is 13.9%.[42] Similarly, while 88.9% of adolescents have received 1 or more doses of the routinely-recommended meningococcal serogroups A, C, W, and Y vaccine, which has a routine recommendation, 21.8% of adolescents have received 1 or more doses of the serogroup B meningococcal vaccine, which has a SCDM-based recommendation.[43]

Potential Consequences for Health Disparities and Health Equity

Although vaccination rates in the United States generally remain high, disparities have been observed by race, ethnicity, sociodemographic status, and insurance status for many vaccines among adults and children alike.[44] These findings are consistent with health disparities and health equity concerns identified throughout health care in the United States.[45] Although the VFC program has improved vaccination rates and immunization equity among children, disparities persist, and some, such as those related to income, have increased for certain vaccines.[46] These disparities are thought to be associated with a number of factors including structural inequality, likelihood of seeking or accepting vaccination, disparate attitudes towards immunization and prevention, variations in provider recommendations, and quality of primary care.[47] Ethnic and racial minorities are also more likely to be uninsured or underinsured, adding to financial barriers to vaccination, particularly among adults.[48]

ACIP recommendations are directed toward populations on the basis of age, risk factors, or, in select cases, sex, rather than sociodemographic factors such as race or insurance status. Exceptions to this approach are exceedingly rare, such as the 2019 recommendation for hepatitis A vaccination for individuals experiencing homelessness.[49] However, the real-world implementation of traditional, routine recommendations compared to those prioritizing SCDM may inadvertently affect how prevention is framed and delivered to underserved populations or those with substantial barriers to care. There are well documented associations between such groups and economic status, race, and ethnicity. Understanding the potential effects of SCDM-based recommendations is therefore all the more important as its use increases for vaccination and other preventive services.

Opting against routine recommendations in favor of the flexibility, provider discretion, and meaningful patient-provider dialogues envisioned by SCDM-based recommendation leaves open the possibility of differences in vaccination practices among health care providers that may increase already-present disparities in vaccination rates. The substantive discussions of evidence, values, and preferences envisioned by SCDM recommendations are increasingly difficult to perform in today’s primary care settings, where time constraints and multiple competing health concerns are among the many factors that may limit opportunities for such dialogues. This risk is particularly acute among low-income, Medicaid-eligible, and minority populations that already face numerous obstacles to the delivery of recommended care, preventive or otherwise.[50] A recent study found an association between patient ethnicity and the likelihood of receiving a meningitis B vaccination, for example, with Hispanic and African-American patients less likely to receive the vaccine.[51]

Provider knowledge regarding financial coverage for vaccines with an SCDM recommendation could also

disproportionately affect patients who are underinsured or uninsured, potentially exacerbating existing vaccination disparities among those with public, private, or no insurance.[52] Patient insurance type has also been associated with the probability of adolescents receiving a meningitis B vaccine, despite the provisions common to public and private insurance programs that facilitate patient affordability among its target age group.[53]

Strengthening the Effectiveness of Shared Decision-Making Recommendations in Prevention

Shared clinical decision-making recommendations aim to offer balanced, evidence-based guidance and to apply the ideals of shared decision-making to public health and prevention. However, additional efforts are required for these recommendations to achieve the goals of their proponents and to support public health and prevention efforts most effectively.

Formally Reassess SCDM-Based Guidelines on a Regular Basis

The work of advisory bodies such as ACIP and USPSTF in developing rigorous, accurate, evidence-based guidelines is complicated by uncertainty and limited or evolving evidence. Periodically and formally revisiting guidelines in light of new evidence is therefore essential to ensuring that recommendations reflect current evidence and best practices. However, there is currently no regular timeline or cycle for individual recommendations to be reviewed or revisited by the ACIP. While the committee on occasion commits to revisiting a recommendation in select cases, as occurred for the PCV13 vaccine at its 2014 committee meeting, it generally reviews existing recommendations periodically on an as-needed basis and as its workload permits.[54]

Timely reassessment is especially important for vaccines recommended based on SCDM, as uncertainty or limited evidence regarding the effects of vaccination on health outcomes, duration of protection, or cost-effectiveness may contribute to the initial adoption of such a recommendation.[55] Implementing a formal schedule for revisiting SCDM recommendations (such as every 5 years) would ensure that guidelines reflect the most up-to-date evidence on vaccine effectiveness, disease burden, vaccination-related effects on disease incidence, and uptake, permitting the ACIP to determine whether the SCDM recommendation is still appropriate. Additionally, formal reassessment cycles would provide an opportunity to synthesize recent research and to explicitly articulate specific factors —such as patient characteristics, exposures, and comorbidities —that providers should note with their patients as part of shared decision-making conversations.

Support Research Examining Potential Associations Between SCDM Recommendations and Disparities in Vaccination Coverage

To ensure that recommendations endorsing SCDM are promoting health equity, government public health agencies whose advisory bodies are responsible for these guidelines should support and facilitate research examining the potential effects of SCDM recommendations on disparities in access to vaccines and other interventions. Evaluating the administration of vaccines and other interventions recommended for SCDM stratified by sociodemographic factors such as race, ethnicity, and insurance status would enhance the evidence base regarding potential differences in delivery, insurance coverage effects, and disparate provider practices associated with these recommendations. Such research would enable the CDC, ACIP, USPSTF, and other public health bodies to better understand effects of their recommendations in specific groups and to amend or clarify them, as needed.

By providing a more comprehensive and nuanced understanding of current vaccination disparities specifically associated with SCDM-based recommendations, such research findings could support targeted investments of additional resources —financial, educational, or otherwise —to communities most impacted by disparate vaccination uptake.

Enhance Provider Education Through Updated and Expanded Continuing Medical Education Offerings

In order for guidelines based on SCDM to achieve their intended objectives, providers must be informed about this class of recommendations, their translation to practice, and their implications for patient access and affordability through public and private insurance or inclusion in government-supported programs. Public health bodies like the CDC, with support from medical and public health professional societies, should offer and expand continuing medical education (CME) activities that discuss SCDM-recommendations and their relevance for patients and providers. Such educational programs should be updated regularly to reflect current evidence and provide

information regarding consequences of these recommendations for patient coverage through health insurance or federal programs.

These CME offerings should additionally include state-specific information related to Medicaid coverage to provide more tailored information about access for adults. Improving provider education would address the knowledge gaps and divergent interpretations of SCDM recommendations identified in recent research.

Develop Shared Decision-Making Aids to Better Inform Discussions Between Patients and Health Care Providers

CDC should collaborate with medical professional societies to develop shared decision-making tools that facilitate informed conversations between patients and providers for any vaccine with an SCDM recommendation. Similar resources should be produced or supported by other entities issuing comparable recommendations, including the USPSTF. Assisting providers with approaches to meaningful shared decision-making is essential to such recommendations functioning as intended and minimizing associated disparities.[56]

Potential shared decision-making tools include accessible, interactive decision aids describing risks and benefits of specific vaccines or other preventive interventions. In other contexts, decision aids have been shown to improve patient knowledge, encourage patient engagement, and decrease distress related to medical decision-making.[57] Additional resources could include in-office decision aid handouts for patients, patient education materials, and short videos or informational brochures guiding health care providers on facilitating shared decision-making conversations with patients for SCDM-recommended interventions.

Through these materials, patients would be better positioned to have productive conversations with health care providers regarding SCDM-recommended interventions, and providers would have additional resources available to them to facilitate those discussions. Materials developed to support shared clinical decision-making for vaccines and other types of prevention should be systematically studied to assess their effects on patient understanding and decision-making.

Conclusion

Prevention recommendations that endorse shared clinical decision-making seek to extend to areas of public health the enthusiasm and possibilities of shared decision-making initially found in the context of clinical care. When applied to national guidelines and recommendations for vaccines and other preventive interventions, they allow for greater flexibility and accommodation, particularly when evidence is limited or benefits are likely only for portions of a recommended population.

However, calls for shared decision-making instead of more familiar, routine recommendations for the use of vaccines or other preventive interventions present unique challenges and complexities, including decreased provider familiarity and understanding, potential access barriers, and the potential to exacerbate existing health disparities. As the prominence of shared decision-making in prevention and public health guidelines grows, additional efforts would be valuable in strengthening the effectiveness of these recommendations for public health policy-makers, expert advisory committees, health care providers, and patients alike.

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DETAIL

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Parmet, W. E. (2021). From the shadows: The public health implications of the supreme Court's COVID-free exercise cases. The Journal of Law, Medicine & Ethics, 49(4), 564-579. doi:https://doi.org/10.1017/jme.2021.80

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.

Opel, D. J., & Larson, H. J. (2021). Vaccine confidence and the importance of an interdisciplinary approach. The Journal of Law, Medicine & Ethics, 49(4), 596-598. doi:https://doi.org/10.1017/jme.2021.82

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.

Benbow, D. I. (2021). The dizziness of freedom: Understanding and responding to vaccine anxieties. The Journal of Law, Medicine & Ethics, 49(4), 580-595. doi:https://doi.org/10.1017/jme.2021.81

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.

Haupt, C. E. (2021). Assuming access to professional advice. The Journal of Law, Medicine & Ethics, 49(4), 531-541. doi:https://doi.org/10.1017/jme.2021.77

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.

Rattani, A., & Hyder, A. A. (2021). Letter to the editor. The Journal of Law, Medicine & Ethics, 49(4), 692-693. doi:https://doi.org/10.1017/jme.2021.95

Rothstein, M. A. (2021). Big data, surveillance capitalism, and precision medicine: Challenges for privacy. The Journal of Law, Medicine & Ethics, 49(4), 666-676. doi:https://doi.org/10.1017/jme.2021.91

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.

Leiter, R. E., & Tulsky, J. A. (2021). Say no to this: Unilateral do-not-resuscitate orders for patients with COVID-19. The Journal of Law, Medicine & Ethics, 49(4), 641-643. doi:https://doi.org/10.1017/jme.2021.88

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.

Wilson, L. A., Rogers Van Katwyk, S., Weldon, I., & Hoffman, S. J. (2021). A global pandemic treaty must address antimicrobial resistance. The Journal of Law, Medicine & Ethics, 49(4), 688-691. doi:https://doi.org/10.1017/jme.2021.94

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.

Suter, S. M. (2021). Reproductive technologies and free speech. The Journal of Law, Medicine & Ethics, 49(4), 514-530. doi:https://doi.org/10.1017/jme.2021.76

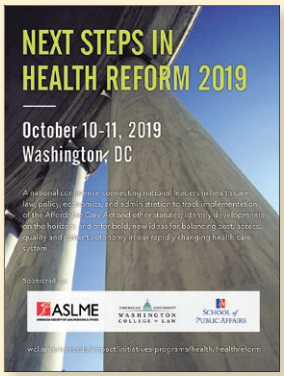
The Supreme Court and lower courts have not articulated a clear or consistent framework for First Amendment analysis of speech restrictions in health care and with respect to abortion. After offering a coherent doctrine for analysis of speech restrictions in the doctor-patient relationship, this piece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

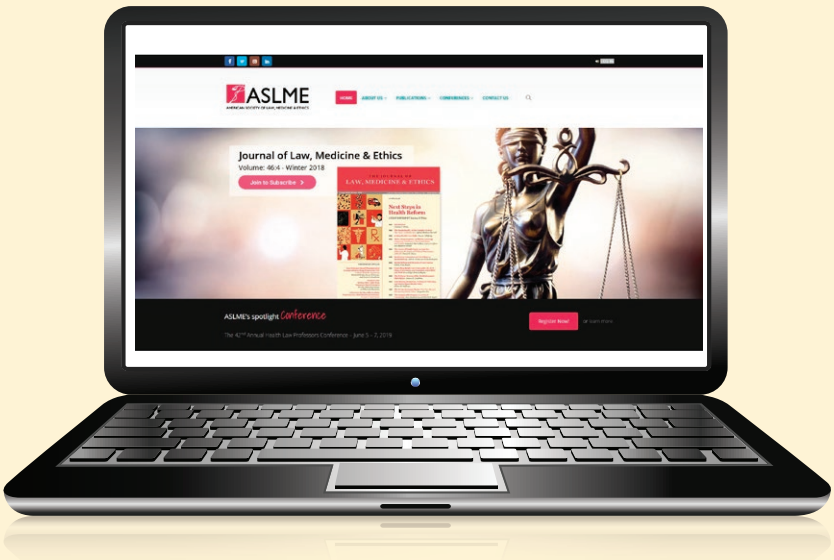
Kramer, D. B. (2021). Mandates for shared decisions: Means to which ends? The Journal of Law, Medicine & Ethics, 49(4), 630-632. doi:https://doi.org/10.1017/jme.2021.86

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.3In 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

Nagar, S., & Kesselheim, A. S. (2021). Promoting competition in drug pricing: A review of recent congressional legislation. The Journal of Law, Medicine & Ethics, 49(4), 683-687. doi:https://doi.org/10.1017/jme.2021.93

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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