Op-Ed

Public Health and the First Amendment

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TWENTY-SEVEN YEARS AGO, THE INSTITUTE OF MEDICINE (IOM) defined public health as “what we, as a society, do collectively to assure the conditions for people to be healthy.”¹ By this definition, court decisions in recent years involving the First Amendment have been undermining the health and well-being of the American people. These decisions are the consequence of an emerging ideology that gives tremendous weight to commercial speech but little deference to the speech of health professionals or to evidence of public health consequences.

Foundational to keeping people healthy is integrity in the doctor-patient relationship.

Yet in the 2011 case *Sorrell v IMS Health*, the US Supreme Court struck down a Vermont law intended to protect the doctor-patient relationship by prohibiting the sale to pharmaceutical companies of data that identify which specific doctors wrote prescriptions for which drugs. The Court applied a legal standard that treats the sharing of prescription data for the purpose of marketing to physicians as among the most protected speech in our nation.

The courts have not accorded similar reverence to the advice offered by health professionals. In 2012, the 8th Circuit Court of Appeals upheld a South Dakota law requiring physicians to tell patients that abortion is related to a risk of suicide. The editors of the *New England Journal of Medicine* called this conclusion “false and misleading.” The editors wrote, “Patients should not accept, and our profession should not allow, physicians to become a mouthpiece of state sponsored ideology.”²

In 2014, the 11th Circuit Court of Appeals upheld a Florida law making physicians subject to discipline for asking patients about gun ownership, even in cases when professional guidance recommends that they do so.

Another condition for people to be healthy is an effective regulatory framework for drugs, devices, and biologics.

Throughout most of the 20th century, companies selling “patent” remedies hid ingredient lists and made outlandish claims. There was little incentive for research on safety or effectiveness. After legislation requiring evidence of effectiveness passed Congress in 1962, the National Academy of Sciences found insufficient evidence for many marketed products, which were then removed from the market.³

Companies recently have been gaining traction by arguing that their commercial speech rights are violated when the Food and Drug Administration (FDA) requires evidence before permitting new uses of their medications. Most recently, in May 2015, the pharmaceutical manufacturer Amarin sued the agency, arguing that it should be able to inform doctors about a cardiovascular medication’s effect that the FDA had determined, based on evidence, to be of no clear value to patients.

Such lawsuits threaten to turn back the clock on the oversight of efficacy claims and in the process to undermine a key incentive for companies to produce basic data to inform clinical care.

A third condition for people to be healthy is an effective tobacco policy. The history of the 20th century illustrates the danger of inadequate limits on the world’s leading cause of preventable death. At one time, cigarette manufacturers marketed “light” and “low tar” brands as alternatives to quitting, in what some have called the largest fraud ever perpetrated on US consumers.

Fifty years after the US Surgeon General linked cigarettes to lung cancer, Congress passed, and President Barack Obama signed, legislation that would provide significant restrictions on and oversight of the tobacco industry. But in 2012, the DC Court of Appeals, under the First Amendment, hamstrung the FDA’s effort to enforce the law by placing graphic warning labels on cigarettes, finding insufficient evidence to justify impositions on commercial speech.⁴

Moreover, the Court combined deference to commercial speech with outright hostility to the role of public health. A footnote in its decision stated: “We are skeptical that the government can assert a substantial interest in discouraging consumers from purchasing a lawful product, even one that has been conclusively linked to adverse health consequences.”

The FDA has since struggled to find a path that the courts will find acceptable. Even if the agency is eventually successful, the delay will result in many more people starting or continuing to smoke.

The First Amendment looms over other possible tobacco control measures, including plain packaging, additional marketing restrictions to

protect youth, and even the FDA's ability to stop companies from claiming without persuasive evidence that new products may be less addictive or pose less of a health risk. The courts could even establish the legal right to advertise novel products using the same sort of messaging that for decades deceived the nation regarding "light" and "low tar" cigarettes.

It is not only in the case of tobacco that the distance between First Amendment legal decisions and their public health ramifications is separated by years.

In 2002, for example, the Supreme Court blocked an effort by the FDA intended to control the dangers of compounded medications. The agency sought to stop small compounders from advertising their wares nationally, in order to prevent them from developing a large manufacturing capacity without adequate oversight. Instead, the Court found that the companies had a right under the First Amendment to tell the world about their products.

We now know how that turned out. The New England Compounding Center advertised widely, grew to an enormous scale, and was responsible for an outbreak of fungal disease in which more than 750 people across the nation developed serious infections and 64 died. Many factors contributed to the outbreak, including failures of oversight. Nonetheless, if the FDA's approach had been allowed to stand, the scale of human suffering would certainly have been less.

Courts are failing to acknowledge the trade-off between the emerging ideological view of commercial speech and health.

For example, the *Sorrell* decision ignored evidence of the impact of data-driven pharmaceutical marketing on patient care. The 8th Circuit developed its own medical judgments on abortion and suicide. In its decision on graphic warning labels, the DC Circuit conducted a "scientific analysis" whose conclusion was the opposite of that of the world's leading health authorities. In the compounding case, the Supreme Court called it a "questionable assumption" that "doctors would prescribe unnecessary medications" and so saw little risk to the public.⁵

By failing to admit these consequences, the courts are not just undermining the "conditions for people to be healthy." They are obscuring and undermining the collective process that "we, as a society" use to make decisions on health.

The courts should instead respect that saving lives with evidence-based policy is a substantial governmental interest that can justify limiting commercial speech. We should reestablish the wide berth

that existed in previous decades for courts to recognize the value of evidence and professional judgment on important questions of medicine and public health.

It has been said in the context of national security that the Fourth Amendment, which pertains to preventing unreasonable search and seizure, is not a suicide pact.

Nor is the First Amendment, in the context of public health.

References

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