How FDA's Restriction on Free Speech Hurts Doctors and Patients

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Last week's Super Bowl ads were some of the most-hyped commercials of the year. A thirty-second spot easily cost companies millions of dollars and was almost by necessity subject to layers of approval from the networks, the NFL, and others. Regulation of commercial speech in this sense is common. On a federal level, laws ensure that commercial speech is truthful in nature and is not intended to harm others. In the medical realm, it becomes more complicated. Many medications and devices are used by doctors for purposes other than what they have been explicitly tested for. However, medical device companies are prohibited from advertising these uses of their products or even informing doctors of available data. The impacts of the FDA's restriction on speech, which also has the potential to prevent patients from accessing needed treatment, was the subject of a discussion hosted by the Cato Institute on Wednesday.

"If you ask most Americans, they would say that the First Amendment to the Constitution protects freedom of speech so that if someone is engaged in truthful, non-misleading speech there is nothing the government can do to prevent you from speaking," said Michael F. Cannon, the director of Health Policy Studies at the Cato Institute. He quickly explained that, when it comes to medicine, that is not necessarily the case.

In the medical device and drug industries, this is not necessarily the case. Under the FDA's restriction, companies are banned from marketing drugs that have not yet met FDA standards for safety and efficacy. Additionally, they are prohibited from telling doctors about untested uses of their products, such as different doses or the use of a device to treat a related condition, even if the information is truthful and non-misleading.

This distinction had severe consequences for Howard Root, the former CEO of Vascular Solutions, a Minnesota-based medical device company. Root spent five years under investigation and later prosecution of claims that his sales representatives had told doctors about a non-FDA approved use of a device. Root notes that there were no reports of any patient injuries as a result of this device, which was intended to treat a different type of varicose vein.

Ironically, nothing under federal law prohibits doctors from using medical devices for conditions not explicitly listed on the FDA label. The sale of devices for unlisted uses and their later use is all legal. It is only illegal for a representative of the company to approach doctors to explain these uses. Supporters of a change to the FDA's restriction argue that this means doctors lack access to information about treatment options that are in development.

"Prohibitions of off label promotion are a sort of censorship," says Jessica Flannigan, a professor whose research focuses on ethics in public health. "It is censorship because it is government restriction on speech that advocates in favor of lawful conduct."

Underlying the FDA's restriction is a philosophical difference in how commercial rather than political speech is treated. In practice, this distinction is difficult to draw in many instances. For example, a newspaper may endorse a political candidate, which is protected political speech. At the same time, that newspaper is a commercial operation and is trying to sell copies. Regulation of commercial speech would not be seen as justification for government censorship of a paper, Flannigan says.

Ethicists argue that free speech is founded in addition upon a recognition of both the rights of the speaker and those of the audience, who are prevented from accessing certain information when speech is restricted. Beyond restricting the rights of a speaker or company, restrictions on commercial speech in the medical industry create a barrier to doctors continuing their education about new treatments.

From a medical perspective, these FDA decisions can have significant impacts on patient outcomes. Insurance may not cover a non-FDA approved treatment even when recommended by a doctor. This reality is exacerbated by laws that prevent manufacturers from sharing with doctors and insurance companies their own research about the effectiveness of a treatment or device.

"The oddity in the law [is] that while the treatment is legal and perscribing for off-label use is legal, federal law prohibits the truthful, non-misleading information from going from the manufacturer to the doctor, to the patient, or to the insurance company," says Christian Sandefur, executive vice president of the Goldwater Institute, who litigates cases involving healthcare freedom. "It's bizarre because oftentimes the manufacturer is the one who has the most information about their product."

Sandefur summed up the situation as an instance where conduct was allowed even while speech was prohibited. This is a key difference from how speech is generally treated under American law. Frequently, the underlying principle of speech regulation is that more information is beneficial to the audience and so speech should be allowed as long as it is not explicitly harmful.

In the case of medical uses, this situation has been inverted. Instead of speech being potentially harmful, Sandefur and Flannigan argue that the lack of access to information caused by the FDA's restriction on speech hurts patients.

"The people that we are purporting to help are actually the ones who are harmed most by these types of prohibits," says Sandefur.

“The speaker is harmed…but it is the individuals who are no longer empowered to make their own decisions. They don’t have the information they need to be able to decide and weigh the costs and benefits of taking a treatment and so it is society we are ultimately harming in the name of helping society,” she continued.

On a practical level many of the distinctions that government regulators attempt to draw between types of speech are difficult to sustain. Continuing to attempt to enforce them, though, has significant negative effects on patients, doctors and businesses.