On the WLF Legal Pulse

Timely commentary from WLF's blog

Washington Legal Foundation
Advocate for Freedom and Justice®
2009 Massachusetts Avenue, NW
Washington, DC 20036
202.588.0302 wlf.org

February 5, 2020

FDA's Laudable "CURE ID" Program Fatally Undermines Agency's Censorship of Off-Label Speech

by Richard A. Samp

The Food and Drug Administration announced in December its launch of CURE ID, an Internet repository for information about off-label uses of FDA-approved medical products. FDA asserts that "crowdsourcing" off-label information will assist healthcare providers by offering guidance on treating difficult-to-treat diseases. But FDA's active promotion of off-label speech fatally undermines what was left of its already shaky claim that it is entitled to suppress truthful speech by drug manufacturers.

The Supreme Court has long recognized that the First Amendment, subject only to narrow and well-understood exceptions, bars the government from imposing content-based controls on speech. FDA has nonetheless asserted authority to severely restrict what drug manufacturers can say about their products, even speech that is neither false nor misleading. In general, FDA limits manufacturer speech to information contained on a product's FDA-approved labeling. Courts have been highly skeptical of FDA's various rationales for its restrictions on truthful manufacturer speech. Those rationales have been rendered unintelligible by FDA's decision to facilitate the very same off-label speech by others.

CURE ID Serves Important Health Care Functions

FDA deserves praise for its decision to launch CURE ID. As FDA acknowledges, many patients would receive sub-optimal care if their doctors were limited to prescribing drugs only for FDA-approved uses. Over the course of their medical practices, doctors routinely discover that a patient who does not respond to treatment with a drug labeled as safe and effective for his condition will nonetheless respond to other drugs not so labeled (generally referred to as "off-label" uses). In some fields such as oncology, the great majority of medically accepted treatments involves off-label uses of FDA-approved drugs and medical devices.

Doctors' ability to effectively employ off-label uses of FDA-approved products is predicated on their access to reliable information about the effectiveness of new off-label treatments. FDA's launch of CURE ID advances that educational process; it will provide doctors with invaluable information in deciding how to treat patients who have not responded to FDA-approved treatments. The program encourages doctors to share clinical outcomes whenever they prescribe FDA-approved drugs for off-label uses. FDA's press release announcing the launch of CURE ID asserted, "The systematic collection of real-world experience in the app will help identify drug candidates for additional study, encourage further drug development, and may serve as a resource for practitioners making individual patient treatment decisions in the absence of established safe and effective options."

Richard A. Samp retired on December 31, 2019 after a three-decade career as Washington Legal Foundation's Chief Counsel.

FDA's First Amendment Defenses

So now that FDA is in the business of promoting widespread dissemination of off-label information, how does it justify its continuing efforts to bar drug manufacturers from doing likewise? In defending its ban over the past 25 years, FDA has relied on three principal arguments: (1) the First Amendment is inapplicable because it is regulating manufacturer conduct (*i.e.*, the marketing of a drug for an unapproved new use), not manufacturer speech; (2) the ban prevents the dissemination of false or misleading information; and (3) the ban encourages manufacturers to undertake the "well-controlled" (*i.e.*, massively expensive) clinical studies necessary to obtain FDA approval to add the new use to its product label.

Federal courts have universally rejected FDA's First-Amendment-is-inapplicable defense. Courts have held that FDA is, in fact, regulating speech when it relies on a manufacturer's off-label speech as its basis for concluding that the manufacturer is marketing a drug for an unapproved new use.

Court have also been wary of FDA's claim that the ban is necessary to prevent the dissemination of false or misleading information. Of course, the Constitution doesn't prevent FDA from suppressing commercial claims unsupported by any reliable clinical data. But the First Amendment does not permit FDA to put a hold on manufacturers' speech until after the agency has reviewed and has blessed the data supporting the claims. A federal judge flatly rejected that FDA argument in *Washington Legal Foundation v. Friedman*, explaining, "[I]n asserting that any and all scientific claims about the safety, effectiveness, contraindications, side effects, and the like regarding prescription drugs are presumptively untruthful or misleading until FDA has had the opportunity to evaluate them, FDA exaggerates its overall place in the universe." 13 F. Supp. 2d 51, 67 (D.D.C. 1998). That argument is even less tenable now that FDA, by launching CURE ID, is actively promoting crowd-sourced clinical data that it has not sought to verify.

What About Manufacturer Participation in CURE ID?

Conspicuously absent from those invited to contribute clinical data to CURE ID are drug manufacturers. Only "health care providers" are invited to supply off-label information to the Internet-based repository. In other words, in launching CURE ID, FDA is not signaling an intent to loosen its ban on manufacturer off-label speech.

As a scientific question, that policy makes little sense. The manufacturer of an FDA-approved product is very likely to be very familiar with all available data regarding off-label uses of its product. It is the entity best positioned to distinguish scientifically validated off-label information from off-label information that lacks solid scientific support. Thus, by preventing manufacturers from being part of the conversation, FDA is likely causing medical professionals to make worse decisions on whether to make off-label use of FDA-approved products when treating their patients.

As to the constitutional question, FDA's launch of CURE ID undermines its remaining First Amendment defenses. FDA argues that suppressing truthful off-label speech encourages manufacturers to seek new labeling authority as a means of garnering increased sales revenue. There is little evidence that FDA's policy has ever had that desired effect. But even if the policy once had that effect, it is far less likely to have that effect now that FDA has launched CURE ID. By facilitating the dissemination of off-label information (and thereby encouraging increased prescriptions for off-label uses), FDA greatly reduces manufacturer incentive to invest in the well-controlled studies necessary to obtain labeling authority for those uses. And in the absence of evidence that commercial speech suppression directly and substantially advances an important government interest, the First Amendment prohibits speech suppression.