

The First Amendment vs. the FDA

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One of the Food and Drug Administration's (FDA) highest priorities over the past two years has been battling the opioid crisis, which resulted from a combination of over-prescription (and ever higher dosing) of opioid medication, "pill mill" prescribers who provided little therapeutic value, misinformation from the scientific community, propagated by Purdue Pharmaceuticals and the easy availability of black market Schedule II prescribed opioids and cheap, illegal substitutes like black tar heroin.

Pacira Pharmaceuticals recognized the need to treat post-surgical pain with non-opioid medications, and that's the company's current therapeutic focus. In 2012, Pacira launched EXPAREL®, after FDA approval. And, yet, despite the opioid crisis facing the FDA, one of the few OPDP Warning letters (sent by the office regulating drug promotion) issued in 2014 was directed at Pacira Pharmaceuticals.

Pacira's drug EXPAREL was indicated for "single-dose infiltration into the surgical site to produce postsurgical analgesia in adult patients 18 years of age or older." And yet FDA was concerned that Pacira's promotion implied the drug could be safe and effective in "various other surgical procedures" when Pacira truthfully communicated to healthcare professionals that EXPAREL had been used in surgical settings such as laparoscopic cholecystectomy and an open colectomy.

The Pacira letter is one of many letters indicating the degree of control that the agency expects to have over promotional materials, whether or not the claims are truthful and non-misleading. (The agency also broadly interprets "misleading" material.) Pacira filed a lawsuit, stating its belief that the information provided was truthful, supported by data and was not misleading, and that this communication was protected under the First Amendment.

The landscape for truthful and non-misleading communication by pharmaceutical and medical device makers has been rapidly changing over the past few years. FDA promotional enforcement actions [hit a record low in 2015](#), with only nine letters issued by the Office of Prescription Drug Promotion (OPDP) in 2015 (down from 52 letters in 2010). One of the letters regarding off-label marketing from 2014, previously discussed, was issued against Pacira Pharmaceuticals and then eventually disappeared from the OPDP website in September 2015 after Pacira filed suit. In [December 2015](#), OPDP confirmed that it formally withdrew the letter against the company. This occurred on the heels of [Amarin's August 2015 proactive challenge](#) of FDA's enforcement authority rooted in free speech claims. In a recent criminal case, [Vascular Solutions' CEO was found not guilty of charges](#) related to off-label promotion; the jury instructions in the case hearkened back to *Caronia's* First Amendment findings. Judge Lambeth (W.D. Tex.) instructed that it is not a crime "for a device company or its representative to give doctors wholly truthful and non-misleading information about the unapproved use of a device."

These successful challenges have resulted in a transitional period of uncertainty. Noting that this

uncertainty “has led to an unsatisfactory and unsustainable patchwork of regulations, guidance documents, and agency practices related to off-label communication, product labeling, and scientific exchange of information,” the [Duke-Margolis Center for Health Policy](#) recently submitted [proposals to the FDA](#) regarding how to improve this status quo.” The Center’s white paper introduces policy changes that it hopes will encourage evidence development and appropriate scientific communication by pharmaceutical companies. The proposals include issuing new FDA guidance, consolidating rules clearly on its website, piloting labeling process change ideas (including a tiered evidence label, with the strongest data at the top and lesser quality evidence lower down), and some members of the committee suggested a third-party data-review organization similar to Canada’s Pharmaceutical Advertising Advisory Board (PAAB).

“Targeted, surgical” changes by the FDA are necessary, [PhRMA argued last year](#), to avoid the regulatory uncertainty that would come from “blowing up entire swaths of federal regulation without building in something new.” PhRMA’s General Counsel Mit Spears stated, “We do believe that the FDA’s existing regulations are vulnerable to constitutional attack, and we believe that the FDA could avoid the possibility of a sweeping court ruling by adjusting its approach to regulating communications between pharmaceutical companies and health care professionals.”

The FDA previously stated that it planned to address the issue in light of the challenges, but no guidance was issued, despite third party calls for action to resolve the First Amendment question. Finally, the [FDA issued 11th hour guidance this year](#) addressing off-label promotion as the Trump administration took office.

On January 18, the FDA issued the Draft Guidance “Medical Product Communications That Are Consistent With the FDA-Required Labeling.” The guidance does limit “consistent” communications to uses that are approved or cleared, the information must be truthful and non-misleading, and a three-factor test will now be applied. The first factor is whether the indication or patient population are the same as the FDA-approved label and whether the limitations, directions for handling and use, and dosage/administration conflict with the approved label for the product. The second factor is whether the representations in the communication increase the potential for harm to health. The third factor is “whether the directions for use in the FDA-required labeling enable the product to be safely and effectively used under the conditions represented/suggested in the communication.”

It is clear that the latest Draft Guidance does not resolve the continuing tension between the FDA’s stance that it may strictly regulate truthful and non-misleading communications and the First Amendment. But it does provide evidence of evolution within the FDA as to communicating accurate information to healthcare professionals in promotional settings. How it will be implemented—and whether that will be sufficient for all companies and all products—remains to be seen.

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