ROPES & GRAY ALERT

FDA Regulatory ▪ Government Enforcement / White Collar Crime

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FDA Announces Public Hearing on Manufacturer Communications Regarding Off-Label Uses

On August 31, 2016, FDA announced that it will hold a two-day public hearing on November 9 and 10, 2016 to obtain input on issues related to manufacturer communications regarding drugs and medical devices, particularly communications regarding unapproved uses of approved or cleared products (*i.e.*, "off-label" uses). FDA's notice is published in the Federal Register here.

This notice comes more than five years after the Medical Information Working Group ("MIWG"), an *ad hoc* coalition of drug and device manufacturers co-represented by Ropes & Gray, submitted its first Citizen Petition seeking clarity on FDA regulation of manufacturer communications, and nearly three years after the MIWG submitted a second Citizen Petition requesting that FDA review and modify its regulatory scheme in light of important developments in First and Fifth Amendment case law. FDA granted both Citizen Petitions in 2014 and initially promised to release guidance on discrete issues involving manufacturer communications within the year, but, so far, has not made good on its promise.[1] The scheduling of this hearing, with the comment period open through January 9, 2017, suggests that these vital constitutional and public health issues will remain unresolved well into the next presidential administration.

This Alert summarizes the key aspects of FDA's announcement and the significance for regulated industry.

Framing the Discussion

FDA's Federal Register notice requests stakeholder comments addressing manufacturers' communications about medical products, with a particular focus on communications about unapproved uses of approved or cleared medical products, and reflects a careful framing by FDA of the discussion around its regulation of manufacturers' speech. Consistent with past agency statements, the notice emphasizes the importance of premarket review and cites a few examples, all of which are decades old, to illustrate the public health risks potentially associated with off-label communications. Furthermore, while courts have held that truthful, non-misleading off-label promotion is fully protected by the First Amendment,[2] and that the Fifth Amendment requires government agencies such as FDA to issue clear and narrowly tailored rules when regulating speech,[3] FDA largely fails to acknowledge the impact of these critical constitutional developments on its regulatory regime. In fact, there is only a single mention of constitutional considerations in the entire Federal Register notice, where FDA states that the purpose of FDA's review of its off-label policies is to "help ensure that our implementation of the FDA Authorities . . . best protects and promotes the public health in view of ongoing developments in science and technology, medicine, health care delivery, and constitutional law" (emphasis added).

Moreover, while FDA pays lip service to the practice-of-medicine doctrine—stating that "FDA generally does not seek to interfere with the exercise of the professional judgment of health care providers in prescribing, for

[1] *See* June 2014 Citizen Petition Response, FDA-2011-P-0512 and FDA-2013-P-1079. *See also* July 2011 Citizen Petition, FDA-2011-P-0512; September 2013 Citizen Petition, FDA-2013-P- 1079.
[2] *See United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012); *Amarin Pharma, Inc. v. FDA*, 119 F. Supp. 3d 196 (S.D.N.Y. 2015).
[3] *See FCC v. Fox Television Stations*, 132 S. Ct. 2307 (2012).

unapproved uses for individual patients, most legally marketed medical products"—FDA does not appear to believe this doctrine should impact its regulation of off-label communications. Indeed, by emphasizing the necessity of FDA premarket review of all potential uses for a product, the agency would appear to be suggesting that health care professionals lack the judgment to analyze the risks and benefits of a product for a particular patient without FDA weighing in.

Purpose and Scope of the Public Hearing

The Federal Register notice poses more than two dozen questions about off-label communications for consideration by a broad group of stakeholders, including, but not limited to, health care professionals, payers, industry representatives, patients and patient advocates, and public interest groups. Of note, FDA's request does not appear to cover communications about pipeline products (*i.e.*, products not yet marketed for any use), but only unapproved uses of products that have already been approved or cleared by the agency. Nevertheless, there may be some room for stakeholder comment on this point, as FDA has requested comment on areas where it could clarify regulations that touch on issues broader than the communication of off-label information. Specifically, FDA poses an open-ended question on "what additional changes, if any . . . FDA [should] consider in its regulations related to firms' communications about medical products, such as the regulations related to what is false or misleading, adequate directions for use, the definition of labeling, or other relevant provisions[.]"

Other notable questions posed by the agency include:

- How could increased communications from manufacturers about unapproved uses impact the public health, and would the impact differ across different categories of medical products?
- What criteria should FDA consider in determining whether a study or analysis that is the basis of a manufacturer's communication is scientifically appropriate to support the presentations or conclusions in the communication?
- What factors should FDA consider in evaluating whether manufacturers' communications about unapproved uses of approved/cleared medical products are truthful and non-misleading, and what information should manufacturers disclose in these communications to help ensure audiences are not misled?
- What kinds of surveillance and monitoring could be undertaken to measure the public health impacts of communications about unapproved uses?
- To what extent is it appropriate for manufacturers to communicate information about unapproved uses of their approved/cleared medical products to patient and consumer audiences?

Implications of the Announcement

While FDA does acknowledge the need to reform and clarify its regulation of manufacturers' off-label communications, the hearing will likely delay agency action even further. Moreover, while it may be a valuable exercise to solicit public feedback on off-label communications, absent FDA action, the hearing will not provide regulated industry with the clarity it has repeatedly requested or do anything to bring FDA's regulatory framework into conformance with the First and Fifth Amendments.

Nevertheless, it will be important for stakeholders to weigh in on the questions posed by the agency for consideration, if and when FDA ultimately issues guidance or a proposed rule addressing off-label communications. Persons seeking to attend or present at the public hearing on November 9-10, 2016 must register by October 19, 2016. Comments on the Federal Register notice may be submitted to the agency until January 9, 2017.

If you would like to discuss the foregoing or any other related matter, please contact any member of Ropes & Gray's FDA regulatory or government enforcement practices or your usual Ropes & Gray advisor.