ROPES & GRAY

ALERT

FDA Regulatory ▪ Government Enforcement/White Collar Crime

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FDA Holds Public Hearing on Manufacturer Communication of Scientific and Medical Information

On November 9 and 10, 2016, FDA held a public hearing to obtain input on manufacturer communications involving unapproved uses of approved or cleared medical products (*i.e.*, "off-label" uses). The hearing was moderated by Leslie Kux (Associate Commissioner for Policy, Office of the Commissioner) and included numerous high-ranking FDA officials as panelists, including Commissioner Robert Califf.[1] Nearly sixty speakers, including members of the biopharmaceutical and medical device industries, health care professionals, patient and public health advocates, payers, and academics, testified at the hearing.

Ropes & Gray partner **Kellie Combs** (Washington, D.C.) spoke on behalf of the Medical Information Working Group ("MIWG"), urging the FDA to establish clear, constitutionally appropriate policies that permit biopharmaceutical and medical device manufacturers to share truthful and non-misleading scientific and medical information about their products with health care professionals and payers.

This Alert summarizes several key aspects of the hearing and describes its potential significance for regulated industry.

Overview of the Public Hearing

As discussed in a previous Ropes & Gray alert, FDA's Federal Register notice requested stakeholder comments about off-label communications and asked more than two dozen questions about whether and in what way FDA should change its regulations. Notably, while courts have held that truthful, non-misleading off-label speech is protected by the First Amendment, and that the Fifth Amendment requires government agencies such as FDA to issue clear and narrowly tailored rules when regulating speech, the Federal Register notice made only a single, passing reference to constitutional developments.

In his opening remarks, Dr. Califf spoke about the rationale for the agency's speech restrictions, emphasizing the importance of premarket review of new uses of approved products and describing several commonly cited examples of the potential harms that may result from off-label communications (*e.g.*, the thalidomide case). He also acknowledged that FDA-approved or-cleared labeling does not contain all clinically relevant information, and he asked whether health care professionals currently faced challenges in accessing off-label information.

More than half of the speakers advocated for broader allowances for manufacturer communications, arguing that the provision of clear pathways for manufacturers to communicate truthful, non-misleading, clinically relevant off-label information is critical to the public health and consistent with constitutional requirements. Many of the speakers,

[1] The full panel included Rachel E. Sherman (Deputy Commissioner for Medical Products and Tobacco), Kristin Davis (Senior Policy Advisor, Office of Policy, Office of the Commissioner), Karen E. Schifter (Senior Counsel, Office of the Chief Counsel, Office of the Commissioner), Diane Maloney (Associate Director for Policy, Center for Biologics Evaluation Research), Thomas Abrams (Director, Office of Prescription Drug Promotion, Center for Drug Evaluation and Research), Lauren Silvis (Deputy Director for Policy, Center for Devices and Radiological Health), and Dorothy McAdams (Supervisory Veterinary Medical Officer, Office of Surveillance and Compliance, Center for Veterinary Medicine).

however, favored tighter FDA restrictions on manufacturer speech, though they generally grounded their arguments in the potential dangers associated with lawful off-label use rather than off-label communications by manufacturers.

Presentations in Favor of Greater Flexibility and Clarity in FDA's Regulatory Scheme

Speakers in favor of broader dissemination of truthful and non-misleading scientific and medical information asserted that manufacturers are often able to provide valuable and unique insights to both payers and healthcare professionals, and that FDA's current framework sharply limits manufacturers from sharing information even when consistent with the approved or cleared indication. Speakers also explained that, in addition to the public health benefits associated with greater flexibility to engage in off-label communications, the First and Fifth Amendments prohibit the government from restricting truthful and non-misleading speech unless the rules are clear and are narrowly drawn to advance a compelling government interest. Health care professionals argued that they benefit from receiving up-to-date information that, in many cases, only manufacturers are able to provide, and payers explained the significant advantages early pipeline communications with manufacturers would have on formulary planning and insurance rates. Numerous patient groups contended that off-label communications are necessary in the context of rare diseases such as lupus and pediatric cancer, where on-label treatments are either ineffective or unavailable.

Presentations in Favor of the Status Quo or Enhanced FDA Regulation

Several speakers, including academics and physicians, also advocated on behalf of FDA's current regulatory regime, and some argued that FDA should impose broader restrictions, limiting all forms of manufacturer communication about unapproved uses. These speakers asserted that off-label communications are invariably detrimental to the public health, expressing concerns that modifications to FDA's regulatory framework would increase off-label prescribing and that manufacturers would share low-quality data or misleading information. Speakers also contested the impact of the recent constitutional case law, arguing that FDA's public health mission should take precedence over speech arguments raised by industry or other advocates for greater flexibility in the agency's regulatory regime.

FDA will accept written comments from interested stakeholders until January 9, 2017.

Implications of the Public Hearing

The FDA panelists were noticeably engaged during the public hearing, and most speakers received multiple questions. It was evident from the questions that the agency is cognizant of the public health value of off-label information, particularly with respect to serious or life-threatening conditions and in therapeutic areas where on-label treatments are limited. However, it was also clear that FDA remains uncomfortable with significantly relaxing long-standing agency rules and is grappling with the potential impact that constitutional case law has on its highly restrictive regulatory framework.

The ultimate impact of the public hearing is difficult to predict. When FDA granted two citizen petitions submitted by the members of the MIWG in 2014, it stated that it was engaged in a comprehensive review of its regulations and policies governing manufacturer speech and promised to issue four relevant guidance documents by the end of that year. FDA has still not issued those guidance documents or otherwise taken any meaningful action to clarify or modify its regulatory scheme.

Listen to the Podcast

In this podcast, **Doug Hallward-Driemeier**, chair of Ropes & Gray's appellate and supreme court practice, moderates a discussion with partner **Kellie Combs** and senior counsel **Alan Bennett** about the FDA's open hearings regarding off-label communications. Click here for transcript.

Ropes & Gray will continue to monitor developments. In the meantime, 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.