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FDA to Conduct Public Hearing on Manufacturer Communications for Unapproved Uses of Approved or Cleared Medical Products

The Food and Drug Administration (FDA) announced[1] that it will hold a public hearing on November 9 and 10, 2016, for input from stakeholders to inform FDA's policy development in the area of manufacturer communications for unapproved (off-label) uses of approved or cleared medical products. Since the recent court cases regarding off-label pharmaceutical advertising, FDA is performing a comprehensive review of its regulatory framework related to manufacturer communications of off-label uses for approved or cleared medical products. In this review, FDA seeks to find a new balance between communications about the known, safe and off-label uses for medical products and protecting the public health. FDA seeks both verbal and written comments during and after this hearing.

Background on Manufacturer Communications

FDA currently reviews the labeling and promotional information for medical products as part of its premarket review, a practice born from various public health tragedies. Generally, manufacturers may only promote their products according to the FDA-approved labeling information, including the indications for use and the product claims. However, a doctor's ability to prescribe products for off-label purposes creates a need for relevant, truthful and non-misleading scientific or medical information to help doctors treat their patients. Current FDA regulations restrict manufacturers from communicating to doctors about these off-label uses except in tightly controlled cases and usually only through the manufacturer's own medical staff. While these controls are in place to prevent public health tragedies, FDA is interested in examining whether, and in what form, less restricted off-label communications may provide unique benefits compared to other sources.

Scope of the Public Hearing

FDA will hold the hearing to receive comments on its regulation of manufacturers' communications about off-label uses of their approved or cleared medical products. To facilitate these comments, FDA published a series of discussion points to gather information on the impact that manufacturers' communications have on industry and the public health:

- How increased communications from manufacturers about off-label uses could impact the public health and whether this impact would differ across different categories or medical products.
- For changes in the healthcare system that are outside FDA's jurisdiction, the extent to which these changes provide incentives for manufacturers to seek FDA approval or clearance on new uses, or to generate the data necessary to demonstrate safety and effectiveness for new uses.
- How the increasing availability of information on off-label uses of approved or cleared medical products incentivizes (or not) manufacturers' to communicate information about these off-label uses.
- The standards that should be applied to off-label use communications to minimize the potential of these types of communications to be misleading or otherwise cause harm.
- The factors that FDA should consider in evaluating whether manufacturers' communications about off-label uses of approved or cleared medical products are truthful and non-misleading.
- How the growing transparency, including the growing expectation that data from human studies will be made available for public review, affects manufacturers' communications.
- How FDA should monitor manufacturers' communications about off-label uses of their medical products, and what actions FDA should take with respect to manufacturers' communications that are determined to be false or misleading, or otherwise raise public health issues.
- How FDA should revise, if at all, its regulations regarding communications about off-label uses.[2]

How to Comment

Stakeholders that wish to comment may attend the hearing to submit verbal comments, or may submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. Written comments must include Docket No. FDA-2016-N-1149.

Our lawyers have significant experience advising clients on FDA issues relating to advertising and promotion of their products. For more information about this hearing, and how to take part, please contact your principal Squire Patton Boggs lawyer or any of the lawyers listed in this alert.

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[1] 81 Feg. Reg. 60299 (Sept. 1, 2016).

[2] 81 Fed. Reg. 60299, 60302-60304 (Sept. 1, 2016).