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EXPERT ANALYSIS

Congress Seeks a Statutory Fix to Stymied Off-Label Discussions

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Without pomp or circumstance, Congressman Morgan Griffith (R-VA) introduced a bill on March 27, 2017, that would expand the communications pharmaceutical and medical device companies can have with doctors about their products. The bill, titled the Medical Product Communications Act of 2017, seeks to clarify the concept of "intended use."

FDA currently regulates communications about off-label uses on the ground that the discussion of an unapproved use creates a new "intended use" for which the company needs specific FDA approval or clearance.

FDA broadly defines the term "intended use" by regulation, and recent attempts to revise these rules have proven controversial.

Representative Griffith represents the Ninth Congressional District of Virginia, which is composed of the counties in the southwest portion of the Commonwealth. Although it is described as a district "slightly larger than the entire state of New Jersey," unlike New Jersey, there are few pharmaceutical and medical device companies located within this district.

According to Griffith, "[d]octors should have the most up-to-date information when caring for their patients and, when done responsibly and in an appropriate context, manufacturers should be able to provide it." Griffith also notes that FDA's regulation of truthful and non-misleading information is "not Constitutional, based on First Amendment principles."

The bill seeks to limit the evidence from which FDA can determine a manufacturer's "intended use," and would permit consideration only of the "objective intent of the manufacturer ... as demonstrated by statements contained in labeling, advertising, or analogous oral statements," and not by reference to communications deemed to be "scientific exchange."

A communication qualifies as "scientific exchange" if it meets the following requirements:

(A) the communication is supported by "scientifically appropriate and statistically sound data, studies, or analyses";

(B) the communication includes a "conspicuous and prominent statement" that the product is not approved or that the information is not contained in the approved product labeling; and

(C) the communication makes no claim that the product or use has been demonstrated to be safe or effective.

The bill proceeds to provide examples of what may constitute "scientific exchange:"

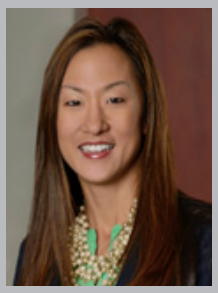
- Dissemination of scientific findings in scientific *or lay media*
- Publication of results of scientific studies

- Letters to the editor in defense of public challenges
- Communications at scientific or medical conferences or meetings
- Dissemination of medical or scientific publications, reference texts, or clinical practice guidelines
- Communication, *both proactive and reactive,* or information regarding a manufacturer's research and development efforts
- Communication, *both proactive and reactive,* of scientific, medical, or technical information
- Communication, *both proactive and reactive,* of health care economic and health outcomes information

Notably the bill would expand the ability of manufacturers to proactively discuss scientific information, which would lift the restriction imposed in this FDA guidance permitting off-label discussions only when responding to unsolicited requests for information.

And while some of these categories of communications already are permissible per FDA guidance documents on distribution of reprints or health care economic information, the bill would codify the "non-binding guidance" from FDA and go further in some instances (e.g., permitting distribution of Letters to Editors or publications in lay media).

We will continue to follow the progress of this bill as it moves through the legislative process.



Anne K. Walsh is a director at **Hyman Phelps & McNamara** in Washington, where she counsels clients on compliance and enforcement issues, including FDA inspections, seizure and injunction actions, warning letters, and recalls. She focuses on defending companies against fraud allegations regarding marketing and promotion, current good manufacturing practices, and FDA quality system regulation. This expert analysis was first published April 10 on the firm's FDA Law Blog. Republished with permission.