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## Daily News

# Off-Label Guide Could Prompt Re-Evaluation Of Public Presentation Policies

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Drug firms will likely reconsider internal policies surrounding public presentations in light of recent FDA guidance on unsolicited requests for off-label information that sources say limits companies' ability to respond to questions publicly, such as during presentations to doctors or in online posts. The agency's call for companies to respond to such off-label questions through a private response could raise practicality issues, and has prompted some in industry to suggest that online questions should be addressed differently from public responses to oral questions, drug industry attorneys said.

A recent guidance addressing unsolicited requests for off-label information tackles website postings and other public forums, telling companies to refer questions raised publicly to medical affairs staff within the company. Some industry sources agreed that limiting online responses was reasonable given that they could come up in web searches and have a more permanent effect. But they predicted the agency would likely face pushback on the restrictions' application to public oral presentations because it could devalue the use of credentialed speakers who have experience with a product's clinical data and could make it difficult for medical professionals to get information.

**"Although the agency's goal might be laudable, in practice it might create more problems than it solves," said Meredith Manning, an attorney at Hogan Lovells.** She noted that allowing responses to unsolicited off-label questions during public presentations is a "better policy alternative" because it would assure that the questioner receives an answer, as opposed to pursuing the information through a company contact and reading through the provided response. The company could provide a scientifically rigorous and unbiased oral response, she said.

"A private response allows you to meet that standard but it creates so many practicality hurdles that it's not clear the response will actually be provided," she said.

Another industry attorney said the new stance reduces the value of credentialed speakers who have the most experience with clinical data.

"What this is basically saying is you need to stay on script and all things that deviate form the script need to be referred to medical affairs," the attorney said.

**The FDA guidance directs companies to respond privately to all public questions and not mention any off-label information in the forum.** If a question is raised, the responder should specify that it is an off-label use and refer the person inquiring to a specified person within the company, the guidance says.

The private response should be tailored to address the specific question with unbiased information, including: publications that reach contrary conclusions; complete scientific information, as opposed to summaries; and rely as much as possible on peer-reviewed sources of information, according to the guidance. The response should also include a copy of any FDA-required labeling, a statement that FDA has not cleared the product for that use, any approved indications, safety information and a list of references for information presented in the response.

"[A]ny substantive communication about off-label uses for the product, in response to the original unsolicited off-label question, should occur solely between the firm and the individual who made the request," according to the guidance. "Regardless of the fact that the original, unsolicited off-label question may have been available to a very broad audience, the firm should not make its detailed response with off-label information publicly available within the same forum."

Further, the agency grouped oral public responses with those written and posted online, raising concerns about the lasting nature of comments, their availability to people who did not solicit the information and the possibility that risk information could change.

"Concerns about the online scenario…are probably more valid than responding in a meeting where you have a meeting with a bunch of doctors," the attorney said, noting that a more nuanced approach between the two types of public forums is preferred, but unlikely.

**The guidance also provided an initial glance into FDA views on social media policies, although it was not the focus of the document** (see *FDA Week*, Jan. 6). Industry attorneys said it shows that the agency so far is taking a restrictive approach to the new medium, and that companies should be applying current standards to online media tools as they await guidance from the agency.

Off-label promotion policies are likely to be a major source of debate in 2012, as the agency is also posing questions to stakeholders regarding the scientific exchange of information prior to a product's approval (see *FDA Week*, Jan. 6). The question and unsolicited request guidance were addressed in an industry-backed citizen petition. Further pending cases, including a criminal case that is being re-evaluated in light of a recent First Amendment ruling, could result in more clarity from the courts. -- *Alaina Busch* (*abusch@iwpnews.com* )