The FDA’s Social Media Guidelines Are Here … Were They Worth the Wait?

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After two years of promises, and a few disappointing postponements along the way, on December 27, 2011, the FDA finally delivered its highly anticipated guidelines on the use of social media by the pharmaceutical industry. And they couldn’t have come soon enough. For years, while other businesses have jumped full force into Facebook, blogs, and other online venues, drug manufacturers have been treading lightly in cyberspace amid strict regulatory restrictions and requirements. So, has their patience paid off?

For those who were expecting a comprehensive set of rules for engaging in social media, the answer is probably no. The title of the 15-page draft document, Guidance for Industry: Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices, makes it clear that the content addresses exclusively off-label usage of pharmaceuticals—a narrow, albeit critical, issue—and does not even focus solely on social media. It seems, at least at first glance, that the guidance is a bit underwhelming after such a long wait and falls short of what the pharmaceutical industry so urgently needs.

With that said, the development of these guidelines does represent a step forward by the FDA, which began the process with a two-day public hearing in 2009 to gather input from the pharmaceutical and medical device industries on Internet marketing. The agency solicited written comments from all interested parties, including consumers, patients, caregivers, health care professionals, patient groups, Internet vendors, advertising agencies, and the regulated industry.

The guidance also takes into account a citizen petition filed with the FDA in July of 2011 by seven of the nation’s largest drug companies, which urged the agency to come up with “comprehensive, clear, and binding regulations” for the industry concerning communicating off-label drug information to physicians and payers.

According to the FDA, this is the first of multiple guidances that the agency plans to issue in response to the suggestions and comments. Following are some of the document’s key highlights:

1. The guidance clarifies the difference between unsolicited and solicited requests in the social media realm. For example, a question about off-label use posted on a pharmaceutical company’s Web site, whether directed to the drug maker or others visiting the site, is an unsolicited request. On the other hand, if a drug manufacturer encourages people to post videos on YouTube about using one of its products and the content prompts questions about off-label use, this would be a solicited request. The FDA may consider solicited requests evidence of a firm’s intent that a drug be used for off-label purposes.

2. The guidance also distinguishes between non-public and public unsolicited requests and recommends appropriate responses. For example, a telephone call to a company’s medical affairs department is a non-public (private) request, and the response should be provided only to the individual who made the request in a one-on-one communication. A question about off-label use that is posted on an Internet discussion board is considered a public request, and if a company chooses to respond, it should give contact information only; anything else could be misinterpreted by others in the forum as off-label promotion. The FDA is also concerned about publicly posted drug information, such as product risks, that might reside on the Internet indefinitely even after the information becomes outdated.

3. The guidance encourages drug companies to respond to unsolicited requests that are made in a public forum because other forum participants might not provide or have access to the most accurate, up-to-date information.

4. Companies should respond to unsolicited requests only if they pertain to that company’s own named product.

5. Responses to unsolicited requests should not be promotional in nature or tone, and they should not provide links to promotional content.

Notably, according to the guidance, if a company responds to an unsolicited request for off-label information as per the FDA’s recommendations, the company’s response will not be used as evidence of its intent to support the product for an unapproved use. Conversely, responses to unsolicited requests that are not in accordance with the guidance may be considered evidence of a new intended use of the product.

Initially caught off guard by the release of the guidance, the blogs instantly became abuzz with reaction to the FDA’s first-ever attempt at forming social media policy. Reviews were mixed, with some bloggers expressing disappointment that the document does not cover more ground and others giving kudos to the agency for starting to incorporate social media into its thinking. Many commented that the FDA’s mention of YouTube and Twitter in one of its guidances was groundbreaking in and of itself, given the agency’s image of not being up to speed on issues regarding social media marketing. Still others remain skeptical that the FDA will be able to keep pace with these constantly evolving platforms and technologies.

Pharmaceutical companies seem to have maintained a more reserved, wait-and-see response. On its corporate blog, AstraZeneca “applaud[s] the FDA for providing guidance and...”

The author is a medical writer living near Philadelphia, Pennsylvania.
look[s] forward to the evolution of health care conversation in
digital media.”

A spokesperson for Boehringer Ingelheim Pharmaceuticals, Inc., which has been using its own internal social media
guidelines, says the company is examining the impact the
guidance has on its current business practices and online ac-
tivity but welcomes the idea.

“Industry guidelines, including the latest guidance from
FDA, offer Boehringer Ingelheim additional considerations on
how to provide a responsible, educational service to patients,
physicians and the community to enable them to make
informed decisions about their health through increased
knowledge of diseases and treatment options.”

Novartis, one of the companies that filed a citizen petition
asking for clarity on off-label use, thinks that the guidance “is
a step in the right direction in that regard.” According to a
spokesperson for Novartis, the companies are currently eval-
uating the content of the guidance, “but the larger question of
FDA’s policies regarding social media must await further com-
munications from the agency.” The six other petitioners are
Allergan, Eli Lilly, Johnson & Johnson, Pfizer, Novo Nordisk,
and Sanofi-Aventis.

Comments on the draft guidance must be submitted to the
FDA by March 29, 2012, in order to be considered in the
preparation of the final version. In the meantime, drug manu-
facturers will probably have to start looking more closely at the
way they currently respond to requests for off-label informa-
tion, particularly through social media.

REFERENCES

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