Delivering expert knowledge to global counsel

International Law Office®

Product Regulation & Liability - USA

Drugs and the Internet: draft guidance on social media platforms and prescription drugs

Contributed by **Morrison & Foerster LLP**

July 17 2014

Authors

Erin M Bosman

Joanna Simon

The Food and Drug Administration (FDA) recently promulgated two much-anticipated draft guidance documents on the use of social media to present information about prescription drugs and medical devices. The draft guidance documents, which were originally promised by the FDA in 2010, represent its latest attempt to provide direction for drug and device manufacturers concerning how and when they may use social media.

Background

Drug and device labelling and promotion are highly regulated activities, subject to onerous approval requirements enforced by the FDA under the Federal Food, Drug and Cosmetic Act . Under the act, 'labelling' includes "all labels and other written, printed, or graphic matter" that "accompany" a drug or device.(1) This definition has been broadly interpreted by the courts to include materials that supplement or explain a drug or device, even when there is no physical attachment to the drug.(2)

Rapidly growing internet-based technologies have made it quicker and easier for both manufacturers and independent third parties to disseminate information about drugs and devices. This has led to a host of issues, including what drug companies can:

- say online about their drugs without violating misbranding regulations; and
- do with what third parties have said online about their drugs.

The guidance documents attempt to answer both of these questions.

The Twitter Guidance

The Twitter Guidance lays out the FDA's position concerning manufacturers presenting 'benefit information' for regulated drugs on electronic platforms with character space limitations. This guidance instructs companies on the steps to take to avoid inadvertently misbranding a drug by providing information about the drug's benefits without disclosing accompanying risks. With that in mind, the Twitter Guidance provides the following directions for drug companies that seek to use space-limited social media platforms:

- Include the brand and established name, dosage form and ingredient information;
- Ensure that benefit information is accurate;
- Accompany benefit information with risk information;
- Provide direct access to a more complete discussion of the risks associated with the drug or device. Notably, the Twitter Guidance says that the link should lead to a page devoted exclusively to risk information; and
- If both benefit and risk information cannot be communicated within the space limit, consider using a different platform.

To prove that it is not impossible to provide the required information within Twitter's 140 character limit, the Twitter Guidance provides the following example of a fictional acceptable tweet:

> "*NoFocus (rememberine HC1) for mild to moderate memory loss-May cause seizures in patients with a seizure disorder www.nofocus.com/risk [134/140]*"

This example from the FDA may prove unhelpful in reality, especially considering that many drugs would be required to list more than one risk.

The main take-away from the Twitter Guidance is not new: to avoid enforcement, provide "truthful, accurate, non-misleading, and balanced product promotion". If a company cannot achieve this delicate balance within Twitter's space limitations, it should "reconsider using that platform for the intended promotional message".

The Misinformation Guidance

The Misinformation Guidance describes the FDA's current thinking about how manufacturers and distributors "should respond, if they choose to respond, to misinformation" related to FDA-approved products, specifically when the misinformation is disseminated by third parties over the Internet. The guidance defines 'misinformation' as "positive or negative incorrect representations or implications" about a company's drug or device that is created by someone who "is not under the firm's control or influence". Thus, the guidance does not apply when misinformation is created or disseminated by the firm itself.

The Misinformation Guidance makes it clear, however, that companies have no independent obligation to correct third-party posted misinformation. This may obviate the need for companies to continuously monitor and mine massive amounts of internet data related to their products.

Nonetheless, the FDA recognises that it may "benefit the public health" for companies to be able to correct misinformation about their products. With the public health benefit in mind, the Misinformation Guidance sets forth the following guidelines for companies that seek to correct misinformation voluntarily:

- Post the correction in the same area or forum where the misinformation is found. If that is not possible, reference the area where the misinformation can be found;
- Disclose that the person making the correction is a company employee;
- Include the package insert via PDF or link to the approved labelling;
- Limit the correction to the scope of the misinformation;
- Do not use the misinformation as a catalyst for promotional messaging; and
- Record misinformation corrections in case the FDA has questions or concerns.

The Misinformation Guidance's bottom line is that "if a firm voluntarily corrects misinformation in a truthful and non-misleading manner", then the "FDA does not intend to object if the corrective information . . . does not satisfy otherwise applicable regulatory requirements regarding labeling or advertising".

Comment

Although the draft guidance documents provide some clarification on the FDA's positions, it is unclear whether they provide a noticeable benefit to the industry. The strict requirements related to providing risk information, including linking to a page dedicated exclusively to risks, may sway companies away from using popular social media platforms at all. Indeed, the guidance may have the unintended consequence of limiting, as opposed to expanding, the information available to the public about a given drug.

Companies have 90 days from publication to comment on the draft guidance documents.

For further information on this topic please contact Erin M Bosman or Joanna L Simon at Morrison & Foerster LLP by telephone (+1 858 720 5100), fax (+1 858 720 5125) or email (ebosman@mofo.com or joannasimon@mofo.com). The Morrison & Foerster website can be accessed at www.mofo.com.

Endnotes

(1) 21 USC Section 321(m); 21 CFR Section 1.3(a).

(2) *See Kordel v United States*, 335 US 345, 350 (1948).

Online Media Partners