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FDA Issues First Guidance on Social Media Policy

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On December 27, 2011, the FDA issued a Draft Guidance for Industry on "Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices."[1] Although much of the document serves as a review of existing FDA policy concerning responses to off-label information requests, it also provides some of the FDA's first thoughts on industry's use of electronic social media. The draft guidance constitutes a very small step, however, toward the FDA's earlier promise to publish comprehensive guidance on the "promotion of prescription drug products using social media tools."

According to a 2010 survey by the Pew Research Center, 80% of American internet users have looked online for health information.[2] 24% have consulted online reviews of particular drugs or medical treatments, and 34% have read the commentary or experiences of patients on blogs, message boards or other social media outlets.[3] Drug and device manufacturers recognize the potential competitive advantage to be had from listening and engaging with patients and consumers through electronic social media. In an uncertain regulatory environment, however, they have been forced to approach the issue with no small amount of trepidation. Companies have long advocated for a clear regulatory framework through which they can more confidently take part in the online conversation, and it appeared that FDA had been listening.

In November, 2009, the FDA received substantial input from industry and consumer groups at a two-day Part 15 Hearing on social media issues.[4] Following that hearing, the FDA Center for Drug Evaluation and Research (CDER) issued its 2010 Guidance Agenda, indicating plans to publish a draft guidance that year on the "Promotion of Prescription Drug Products Using Social Media Tools." Publication was not forthcoming, however, and observers took note when the proposed document was omitted from the 2011 Guidance Agenda. Instead, the 2011 agenda announced plans for a less ambitious document on "Responding to Unsolicited Requests for Prescription Drug and Medical Device Information, Including Those Encountered on the Internet" -- a topic that received relatively little discussion at the 2009 public

hearing.

Far from the comprehensive social media guidance originally planned, the December 2011 publication was further narrowed to address only unsolicited *off-label* information requests. In apparent recognition that the draft guidance addresses social media issues solely within the confines of existing policies regarding off-label communications, FDA dropped the "Internet" language from the publication's title. The document provides little to no guidance on the most pressing issues raised at the 2009 hearing, such as the ability of firms to post corrective information, or complications specific to Internet adverse event reporting.

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Online Responses to Unsolicited Off-Label Information Requests

The draft guidance reiterates existing policy on the distinction between solicited and unsolicited information requests, advising that unsolicited requests can only be initiated "by persons or entities that are completely independent of the relevant firm," and that information requests "prompted in any way by a manufacturer or its representatives" would be deemed solicited. To illustrate the application of this principle in the electronic realm, the document provides several hypothetical scenarios. In one example, the guidance cautions that where a company provides an email address, URL, or other "alpha representation implying the availability of off-label information for its product," any information requests prompted by the offending communication would be deemed solicited. Other examples are more specific; one provides that where a firm "asks or otherwise encourages users to post videos about their own uses of its product on third-party video-sharing sites (e.g., YouTube)," any resulting off-label queries would be considered solicited requests. In March 26, 2012 public comments, marketing firm WCG sought confirmation that solicited requests would not result where a firm specifically asks patients not to submit videos pertaining to off-label use. Other activities that could lead to solicited requests include encouraging bloggers to write about a product's off-label uses; announcing results of a study over microblogging sites such as Twitter "and suggest[ing] that an off-label use...is safe and effective"; or maintaining a website through which consumers can peruse a firm's standard responses concerning off-label use.

The only other advice specific to social media is the draft's discussion of public responses to off-label information requests posted in online forums. While acknowledging that "it can be in the best interest of public health for a firm to respond to unsolicited requests for information...that are made in public forums," such interests appear secondary to the FDA's reservations about making off-label information "available to a broad audience and for an indefinite period of time." Accordingly, the draft guidance directs that substantive responses to publicly posted off-label information requests—if the manufacturer chooses to respond at all—should be provided "*only to the specific individual who*

requested the information as a private, one-on-one communication." (emphasis added). A company may issue a public response on the online forum, but it "should be limited to providing the firm's contact information and should *not* include any off-label information." (emphasis in original). This provision has come under criticism for its potential to negatively impact a firm's reputation. In public comments submitted February 1, 2012, Alphatec Spine, Inc. wrote that "[d]eferring or not answering the question gives the impression that the firm's representative is withholding information or is not knowledgeable about the company's product lines." The draft guidance further provides that any public response should disclose the company's involvement, convey that the question pertains to an unapproved use, and refer to the current FDA labeling. The current guidelines make no distinction among the various forums where prescription drug products might be discussed, whether on a site targeted specifically to health-care professionals or a patient- or consumer-oriented website.

No Safe Harbor for Correction of Misinformation

The December draft guidance does not address the need for parameters governing public correction of online misinformation, an issue that for years has created uncertainty for manufacturers. According to the FDA, some companies "have stated that they have not corrected what they believe is misinformation" on third-party websites, for fear that they could then be viewed "as being responsible for all the information" on the site.[5] At the 2009 hearing and in written comments, industry sought formal confirmation that corrections by manufacturers in response to inaccurate postings, whether on company-run or third-party websites, will not be considered promotional labeling. "Recognition that companies should not be responsible for [user-generated content] merely because they have participated in the online discussion would be consistent with Congressional policy regarding Internet content generally, as reflected in Section 230 of the Communications Decency Act, which provides online publishers broad immunity from content they do not create," wrote Johnson & Johnson in a February 2010 submission.

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The issue becomes more fraught when online misinformation concerns off-label use. The draft guidance contemplates responses only to "requests" or "questions," not affirmative statements. Despite the potentially greater danger posed by inaccurate information about unapproved uses, a company considering a public response faces the additional disincentive of potential liability for off-label promotion.

Clarity Still Needed on Adverse Event Reporting

With respect to potential adverse events encountered on the Internet, a March, 2001 draft guidance provides that companies "should review any Internet sites sponsored by them for adverse experience

information, but are not responsible for reviewing any Internet sites that are not sponsored by them."[6] If a company does become aware of such information on a site it does not sponsor, it "should review the adverse experience and determine if it should be reported to the FDA." At the 2009 hearing, the FDA was urged to clarify its definition of "sponsorship" and confirm that the placement of advertising on third-party websites would not impose an obligation to monitor such sites for adverse events. This suggestion would be in keeping with International Conference on Harmonization (ICH) guidelines, which state more clearly that companies "are not expected to screen *external* websites for [adverse event] information."[7] (emphasis added).

Also unclear is the extent to which online posts should be investigated to determine if submission of an adverse event report is warranted. In an analysis of 500 messages across various online healthcare forums, Nielsen Online found that only one message contained information sufficient to meet all four of the FDA's adverse event reporting criteria.[8] In most cases, following up to obtain the required information would appear impractical. Nielsen found that 11% of the messages contained identifying information that could be used to reach out to an individual for follow-up, but these messages were confined only to Yahoo! or Google groups, which use email addresses for online identification. Most online discussion forums--particularly those dedicated to healthcare--discourage the use of personally identifiable information.

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The uncertainty is having a tangible effect on industry behavior. At the 2009 hearing, a representative from the Pharmaceutical Research and Manufacturers of America (PhRMA) explained that under the current regime, pharmaceutical companies don't know "how far you have to go to find" a reportable adverse event online. Currently, "the safest thing to do is to not pay attention to anything online and to not listen to anything[,] because if you find any sort of mention of your product" that could potentially be considered an adverse event, it could lead to a significant outlay of resources.[9] Separately, Peter Pitts of the Center for Medicine in the Public Interest told the panel of "one company whose policy is not to monitor social media sites, because they don't want to unearth adverse events."[10] As it continues to ponder the issue, the FDA should be mindful that excessive requirements for follow-up of online reports may exacerbate such sentiment.

The FDA has stated that the development of guidelines for social media "are among our highest priorities" and that multiple draft guidances will be issued on topics including the correction of misinformation and adverse event reporting. The considerable uncertainty around these issues, however, is unlikely to abate any time soon; CDER's 2012 Guidance Agenda discloses no planned publications on social media this year.[11] The period for public comment on the December draft guidance ended on March 29, 2012. Comments can be viewed at http://www.regulations.gov under docket FDA–2011–D–0868.

[1] *Available at*
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM285145.pdf

[2] Susannah Fox, Pew Internet & American Life Project, The Social Life of Health Information, 2011, at 2, *available at*
http://pewinternet.org/~/media//Files/Reports/2011/PIP_Social_Life_of_Health_Info.pdf

[3] *Id*.

[4] *Transcripts available at*
http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm184250.htm

[5] Notice of Public Hearing, 74 Fed. Reg. 48,083, 48,087 (Sept. 21, 2009), *available at*
http://www.gpo.gov/fdsys/pkg/FR-2009-09-21/pdf/E9-22618.pdf

[6] Guidance for Industry: Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines, 21 (March 2001), *available at*
http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Vaccines/ucm092257.pdf

[7] ICH Harmonised Tripartite Guideline: Post-Approval Safety Data Management: Definitions and Standards for Expedited Reporting E2D, 3-4 (2003), *available at*
http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E2D/Step4/E2D_Guideline.pdf

[8] Melissa Davies, Listening to Consumers in a Highly Regulated Environment: How Pharmaceutical Manufacturers Can Leverage Consumer-Generated Media, Nielsen Online (2008), *available at*
http://blog.nielsen.com/nielsenwire/wp-content/uploads/2009/11/Nielsen-Online-Healthcare-Practice_Social-Media-Adverse-Event-Reporting_nov09.pdf

[9] Nov. 13, 2009 Transcript at 59

[10] Nov. 12, 2009 Transcript at 55

[11] Guidance Agenda: New & Revised Draft Guidances CDER is Planning to Publish During Calendar Year 2012, *available at*
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM079647.pdf