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Was It Worth the Wait? - FDA Releases Two Social Media Guidance Documents for Drug/Device Industry

Written by Colleen T. Davies, Celeste A. Letourneau, Kevin M. Madagan, and Jennifer L. Pike

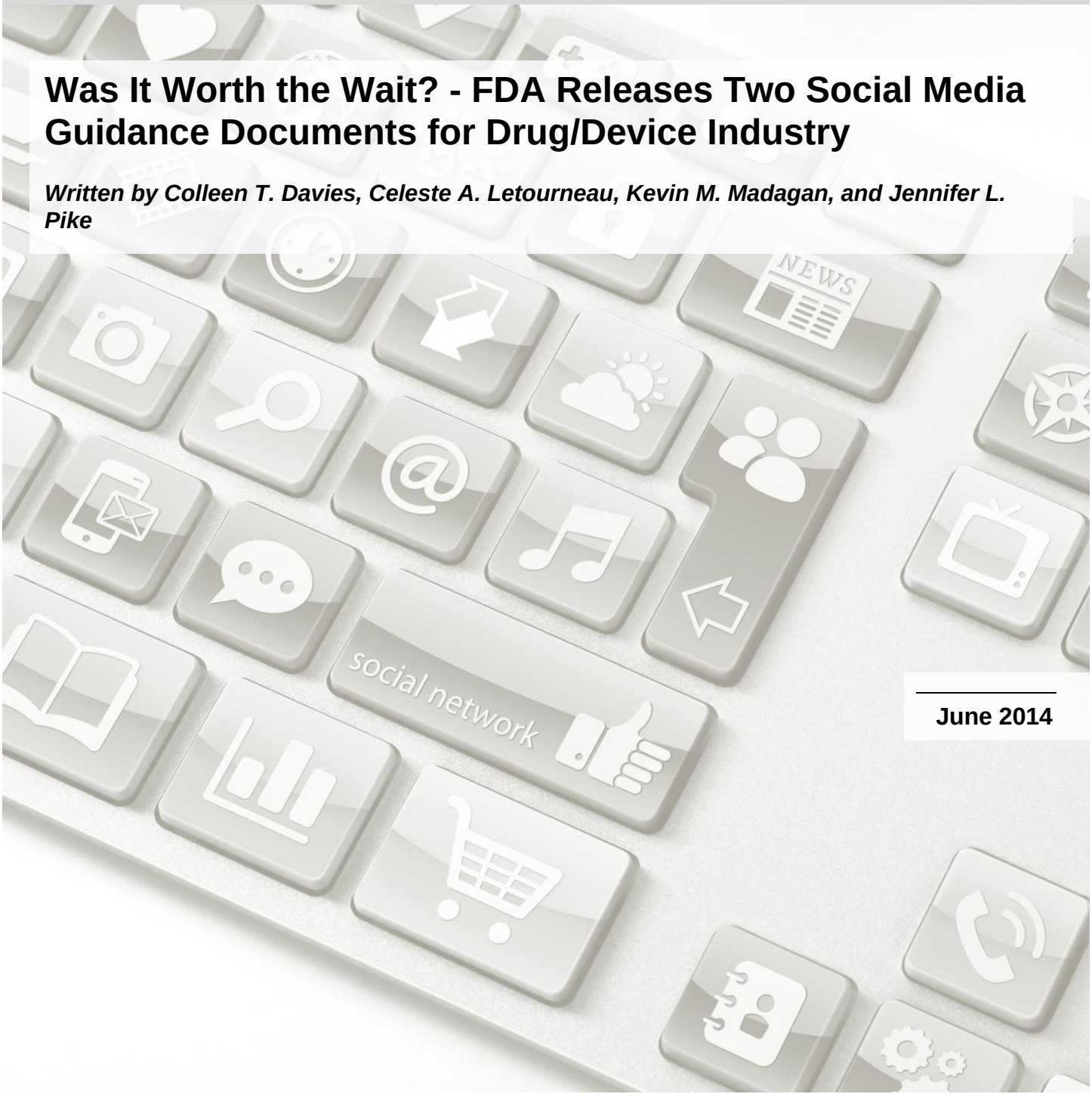

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Table of Contents

Page

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Written by Colleen T. Davies, Celeste A. Letourneau, Kevin M. Madagan, and Jennifer L. Pike

On June 17, 2014, the Food and Drug Administration ("FDA") released two draft social media guidance documents. These documents describe FDA's current thinking about how manufacturers, packers and distributors ("firms") of prescription drugs and medical devices may: (1) communicate both benefit and risk information on Internet/social media platforms with character space limitations, and (2) correct independent third-party misinformation about a firm's products.

Character-Space-Limited Communications

The first draft guidance – *Internet/Social Media Platform with Character Space Limitations – Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices* – provides recommendations as to how firms should communicate both benefit and risk information about their FDA-covered products on Internet/social media platforms that have character space limitations, such as Twitter, and online paid search mechanisms, such as "sponsored links" on Google. The scope of the guidance is limited; it does *not* apply to promotion via product websites, webpages on social media networking platforms (e.g., individual product pages on websites such as Facebook, Twitter, YouTube), and online web banners, as FDA believes that these specific types of Internet/social media platforms do not impose the same character space constraints as online microblog messaging and online paid search.

The primary message of the draft guidance is that firms that choose to make product claims on Internet/social media platforms containing character space limitations should incorporate comparable risk information within the same communication, and allow for easy access to additional product risk information. Fair balance – and inclusion of risk information – is not a new concept. As highlighted in the draft guidance, firms must remember that even where they follow FDA's recommendations for presenting risk information where character limits are an issue, the general requirements for promotional labeling of FDA still apply – information should be accurate and non-misleading, and should reveal materials facts within each communication (i.e., paid search result or tweet).

Using a hypothetical tweet for a fictional product called "NoFocus" and a hypothetical sponsored link for the fictional product "Headhurtz," the draft guidance illustrates how a "concise disclosure" of specific risk information might be presented together with benefit information within the confines of character-space-limited platforms. The rules are basic. FDA recommends the following:

- **Always link product brand/establishment names and at least one form of dosage.** Communicate both the proprietary (trade or brand) name and established (generic) name within the character-space-limited

communication, and link to full risk with brand/ generic name and at least one form of dosage. Within the character-space-limited communication, the generic name should be located directly to the right of, or directly below, the brand name.

- **Include "the most serious" product risks.** For prescription drugs, this would include the boxed warning information, all fatal or life-threatening and contraindication information. If the prescription drug does not have a boxed warning, fatal or life-threatening risks or contraindications, the most significant warnings or precautions about the product should be communicated. For medical devices, this would require information on whether a particular risk is associated with a particular identifiable use or population.

- **Use formatting (e.g., bolding), where possible, to emphasize and highlight significant risk information.**

- **Use hyperlinks to send users directly to risk information.** The risk statement should include a mechanism, such as a direct hyperlink, to a destination (e.g., to a landing page) that is devoted exclusively to a more complete discussion of risk information about the product.

- **Supplemental links are permitted.** Firms may include supplemental hyperlinks (e.g., to a product home page) either within the character-space-limited communication or the landing page, of risk information, but FDA recommends that a direct hyperlink to a destination devoted exclusively to comprehensive risk information about the product be initially included within the original character-space-limited communication.

- **URL shortening services are permitted.** FDA does not object to using URL shortening services; however, when possible, the Agency would like URLs or web addresses to denote to the user that the landing page consists of risk information (e.g., www.product.com/risk).

- **Use punctuation marks, commonly understood or known abbreviations, and symbols whenever possible.** Common abbreviations (including scientific and medical abbreviations), punctuation marks, and other symbols may, in many cases, reasonably be used to help address character space constraints. The draft guidance states clearly that "commonly recognized linguistic symbols may be substituted for words" (e.g., ampersand symbol, "&"); punctuation marks "may be used to help separate benefit and risk information (e.g., dashes, "-"); and a scientific abbreviation may be used to denote a chemical ingredient name (e.g., "HBr" for hydrobromide).

Not surprisingly, the draft guidance notes that some products may be "too complex" to advertise on platforms with character space limitations, and warns that "if an accurate and balanced presentation of both risks and benefits of a specific product is not possible within the constraints of the platform, then the firm should *reconsider* using that platform for the intended promotional message." (emphasis added)

This is an important caveat. The vast majority of prescription drugs are not as uncomplicated as FDA's fictional drugs "Headhurtz" or "NoFocus." The vast majority of prescription drugs have risk profiles that are far too complex to fall within FDA's new draft guidance. (Perhaps there are some, but not many.)

For those of you who do manufacture non-complex prescription drugs, this new draft guidance has arguably equipped you with sufficient information to develop a scripted guide for disclosing benefit and risk information in social media. Before moving forward, however, it would be worthwhile to review and update any relevant internal policies to include FDA's new specific recommendations for space-limited communications.

Correcting Misinformation

The second draft guidance – *Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices* – describes FDA's current thinking about how firms should respond (if they choose to respond) to misinformation related to the firm's own FDA-approved or -cleared products when that information is created or disseminated by independent third parties on the Internet, or through social media or other technological venues, regardless of whether that misinformation appears on a firm's own forum or on an independent third-party forum or website.

Notably, the draft guidance applies only when a firm is *not* responsible for the product communication containing the misinformation.

Through a series of 15 examples, the draft guidance describes what types of communications qualify as "misinformation" that could be corrected, and sets forth multiple approaches for voluntarily correcting such misinformation. Specifically, FDA recommends the following:

- **Firms have multiple options for voluntarily correcting misinformation.** A firm may correct misinformation by posting "appropriate corrective information" to the social-media forum. Alternatively, a firm may provide a "reputable source" from which to obtain the correct information, such as the contact information for the firm's Medical Affairs Department.

- **Provide "appropriate corrective information" only.** To be considered "appropriate corrective information" under the draft guidance, a firm's communication should:

    - Be relevant and responsive to the misinformation

    - Be limited and tailored to the misinformation. If a product has multiple approved indications, a firm should limit its correction to the indication being discussed.

    - Be non-promotional in nature, tone, and presentation

- Be accurate
- Be consistent with the FDA-required labeling for the product
- Be supported by sufficient evidence, including substantial evidence, when appropriate, for prescription drugs
- Either be posted in conjunction with the misinformation in the same area or forum (if posted directly to the forum by the firm), or reference the misinformation and be intended to be posted in conjunction with the misinformation (if provided to the forum operator or author)
- Disclose that the person providing the corrective information is affiliated with the firm that manufactures, packs, or distributes the product. (All corrective communications must be non-promotional in "nature, tone, and presentation." Thus, a prudent approach would be to ensure that only Medical Affairs or some other non-marketing department is authorized to provide corrective information.)

- **Include a link to FDA-required labeling.** Because risk and other information about a product are not necessarily part of corrective information, FDA-required labeling should be included or provided in any corrective communication (e.g., a link that goes directly to the FDA-required labeling or a link that opens a new window to a PDF file). A corrective communication should *not* include a promotional URL or a link to a promotional website, even if the product's full risk information is available through the link or on the promotional website.

- **Clearly define the portion of the forum being corrected.** Because it may be difficult for a firm to correct all misinformation about its products included in one forum (because of the nature of the forum, the quantity of information, and the length of time the forum encompasses), FDA recommends that a firm: (1) identify the misinformation it is correcting in a forum, define the portion of the forum it is correcting, and correct *all* the misinformation (including positive incorrect representations or implications about a product) that appears in that clearly defined portion; and (2) describe the location or the nature of the misinformation that was corrected, and provide a date the correction is made to ensure that parties reading the information do not assume the firm has responded to the entire forum.

- **Direct correction of misinformation on a forum is not required.** Although a firm may choose to correct misinformation directly on the forum in which it appears, a firm may also: (1) provide the corrective information to the independent author for the author to incorporate, (2) request that the author remove the misinformation or all comments to be posted, or (3) request that the site administrator remove the misinformation or allow comments to be posted. Firms are *not* accountable for an author's or site administrator's refusal to comply with its requests.

- **Continued monitoring is not required.** Once a firm corrects misinformation, or attempts to do so, FDA does *not* expect the firm to continue to monitor the website or communication that previously included the misinformation.

- **Keep records of efforts to correct misinformation.** Although firms are not expected to submit corrections to FDA, firms should keep records to assist in responding to questions that may come from the Agency. Such records should include, for example, the content of the misinformation, where it appeared, the date it appeared or was located, the corrective information that was provided, and the date the corrective information was provided.

Unanswered Questions Suggest Need for Additional Guidance

So was it worth the wait?

In some respects, yes. Even though they are not perfect, these two draft guidance documents represent a significant step forward in what has been (and will continue to be) a very long process within the Agency to establish a framework for regulating social media, provide guidance to the industry, and find a way to adapt to emerging technologies. This is the first time FDA has attempted to provide formal guidance about *promotional* activity on social media. Moreover, the draft guidance about correcting misinformation not only provides a roadmap to approaching misinformation, but it is also helpful from a product liability standpoint, making clear, for example, that firms have *no* duty to correct misinformation or to monitor websites or communications that previously included misinformation.

The two draft guidance documents, however, leave much unanswered. For instance:

- How should a firm determine which risks to include when a product does not have a boxed warning, fatal or life-threatening risks, or contraindication?

- Should a firm be concerned about how narrowly it defines a “forum” for purposes of correcting misinformation? How does a firm decide what misinformation it should correct? Who should correct it? Should a firm create a formal strategy and protocol dedicated to correcting misinformation?

- What are the implications for adverse event reporting?

- What does FDA mean when it says that it “recommends” that firms keep records to “assist in responding to questions” that may come from the Agency? Why would FDA want this information? How might the FDA use it? Is FDA going to begin requesting these records during inspections? Might other agencies begin requesting these records?

We applaud FDA's attempt to resolve a problem that has confounded FDA (and the drug and device industry) since the Agency held its first hearing in 1996 about the Internet and social media.

We also appreciate how Thomas Abrams, the director of FDA's Office of Prescription Drug Promotion, described the two draft guidance documents. According to Abrams, they are the latest in a series of documents representing specific aspects of the Agency's "evolving consideration" of social media and other Internet-related matters.

Importantly, FDA is "very interested" in receiving comments from stakeholders. We hope this is true. If the response FDA received from its last social media guidance (a technical document discussing the 2253 submission process) is any indication of the level of interest in this issue, then Abrams and FDA will have plenty to read once the latest comment period ends September 16, 2014.

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