Bloomberg BNA

Social Media Law & Policy Report™

A Social Experiment: 2015 Outlook for FDA's Social Media Policy

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Industry has awaited meaningful social media guidance for years, dating back to 2009, when the U.S. Food and Drug Administration (FDA) announced its intention to regulate social media and the Internet.[1] As social media began to evolve, the pharmaceutical industry continued to wait for the FDA to establish clear guidelines for acceptable marketing strategies before allocating significant resources to promotional activities using social media campaigns. In 2014, the FDA finally delivered on its promise with the release of three new Draft Guidances that, in addition to a Draft Guidance released in 2011, collectively make up the FDA's current thinking on social media. The four Draft Guidances (collectively, the Social Media Guidances) are:

- **December 2011**: Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices (the Unsolicited Requests Draft Guidance)[2];
- **January 2014**: Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics (the Postmarketing Submission Draft Guidance)[3];
- **June 2014**: Internet/Social Media Platforms with Character Space Limitations—Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices (the Space Limitations Draft Guidance)[4];
- **June 2014**: Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices (the ''Correcting Misinformation Draft Guidance'')[5].

These Social Media Guidances address many of the important topics that the FDA's Division of Drug Marketing, Advertising and Communications, now the Office of Prescription Drug Promotion, had raised back in 2009, including responding to unsolicited requests for off-label information; fulfilling regulatory requirements for postmarketing submissions; accountability of manufacturers, packers and distributors; social media tools with space limitations; the use of links on the Internet;

[1] *See* Public Hearing on the Promotion of FDA-Regulated Medical Products Using the Internet and Social Media Tools (Nov. 12-13, 2009), *available at* http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm184250.htm.

[2] *See* FDA, Draft Guidance for Industry: Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices (December 2011), *available* at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM285145.pdf.

[3] FDA, Draft Guidance for Industry: Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics (January 2014), *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM381352.pdf.

[4] FDA, Draft Guidance for Industry: Internet/Social Media Platforms with Character Space Limitations—Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices (June 2014), *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM401087.pdf.

[5] FDA, Draft Guidance for Industry: Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices (June 2014), *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM401079.pdf.

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and the correction of misinformation.[6] The Space Limitations Draft Guidance, for example, describes the FDA's current thinking regarding the presentation of balanced risk and benefit information in advertising and promotional materials on social media platforms with character space limitations. The Correcting Misinformation Draft Guidance, meanwhile, addresses how companies may voluntarily correct inaccurate information about their products that appear on social media platforms. Together, the Social Media Guidances are intended to provide a road map to industry for the use of social media platforms.

For many industries, social media is no longer a trend, but a business necessity, yet the pharmaceutical industry has generally been an exception to the rule. Although industry is now equipped with a road map, it remains to be seen in 2015 whether firms will seek to expand their presence on social media platforms. On the one hand, firms may remain reluctant to adopt social media because the lure of greater brand recognition through the use of social media may still not outweigh the risks of regulatory and enforcement action by the FDA. On the other hand, with blueprint in hand, companies may be willing to experiment with social media and even test the boundaries of the FDA's new Social Media Guidances, knowing how expansive the Internet has become and how difficult it would be for the agency to police this sphere. Although the future of social media in the pharmaceutical realm remains uncertain, trends have begun to emerge that provide some insight into 2015 and beyond.

I. Finalizing Social Media Guidances

After the final two Social Media Guidances were released in June 2014, the FDA encouraged stakeholders to submit comments within 90 days to ensure that those comments would be considered as the FDA developed final guidances. The next logical step is for the FDA to finalize each guidance after review and consideration of the comments. Although most stakeholders expect these Social Media Guidances to be finalized in 2015, the FDA declined to provide a date during its Social Media Draft Guidance Webinar in July 2014.[7] Perhaps more important than when the guidances will be finalized is what the FDA's current thinking will be in the guidance documents. Often, the FDA makes minor modifications to a Draft Guidance document after review of stakeholder comments, unless scores of comments highlight the need for more significant changes.[8]The FDA often declines to deviate significantly from its Draft Guidance because new language in any Final Guidance represents information that has not been publicly vetted prior to issuance of the Final Rule.

This may not be the case if the FDA carefully considers comments from industry stakeholders. While industry has expressed its gratitude to the FDA for the release of the Social Media Guidances, many stakeholders raised concerns that the Social Media Guidances continue to discourage pharmaceutical companies from engaging in social media and interacting with consumers.[9] Although it is clear that the FDA has taken the position that social media promotion is not suitable for many drugs, particularly those with complex indications or serious risks,[10] many of the comments submitted by stakeholders in response to the Space Limitations Draft Guidance encourage the FDA to soften this stance for a number of reasons.

a. Requesting Clearer Scope

Some comments addressed the broad application of the Social Media Guidances to all medical devices, even though the FDA maintains legal authority only over advertising for restricted devices.[11] Although the FDA cites its legal authority over advertising for restricted devices, the agency merely mentions in a footnote that its advertising authority does not cover nonrestricted devices, which represent the vast majority of devices available in the U.S.[12] The Advanced Medical Technology Association (AdvaMed) requested that the FDA clarify the scope of the Space Limitations Draft Guidance, citing the FDA's specific authorities for medical devices, which is limited to restricted device advertising and device labeling. AdvaMed objected to the FDA's collective treatment of medical devices under the guidance and highlighted an important distinction that devices are not legally required to include a ''brief statement'' in their advertising unless they are restricted devices. These requests for clarification from industry demonstrate that stakeholders are still unclear about the requirements set forth in the Social Media Guidances and are unlikely to move forward without clearer guidance from the agency.

b. Raising Constitutional Concerns

Some commenters cited First Amendment concerns regarding the Space Limitation Draft Guidance's recommended disclosures, given the complexity and sheer

[6] *See supra* note 2.

[7] *See* Social Media Draft Guidance Webinar Q&A (July 10, 2014), *available at* http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM404784.pdf.

[8] *See, e.g.*, FDA, Final Guidance for Industry, Mobile Medical Applications (Sept. 25, 2013), *available at* http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf (containing sweeping changes from the Draft Guidance document issued on July 21, 2011).

[9] *See* Comments from Medical Information Working Group, Draft Guidance for Industry on Internet/Social Media Platforms with Character Space Limitations—Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices (''Instead of enabling the appropriate use of these channels of communication, however, the Draft Guidance effectively precludes such use.'').

[10] *See, e.g.*, the Space Limitations Guidance at 5 (''For some products, particularly those with complex indications or extensive serious risks, character space limitations imposed by platform providers may not enable meaningful presentations of both benefit and risk (although they may be sufficient for ''reminder'' promotions—see footnote 10 [in the Space Limitations Guidance]). 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 (other than for permitted reminder promotion.'').

[11] *See generally* Comments from Advanced Medical Technology Association, Draft Guidance for Industry on Internet/Social Media Platforms with Character Space Limitations—Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices (asking the FDA to better clarify the scope of the Guidance).

[12] *See, e.g.*, the Space Limitations Guidance, *supra* note 4, at 4 n.9.

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length of the corresponding information in approved labeling, which are not viable for space-limited platforms in the manner described in the Draft Guidance for the vast majority of products.[13] According to these comments, the burden the Draft Guidance would impose on speech based on its specific content and the identity of the speaker is in conflict with basic First Amendment principles. As the Washington Legal Foundation highlighted, the Draft Guidance ''compel[s] a drug or device manufacturer to include detailed risk and benefit information in connection with virtually any information it disseminates regarding one of its drugs or medical devices.''[14] Although the government has greater leeway to regulate commercial speech, and an interest in doing so to prevent consumers from being misled, the constraints cannot go so far as to chill protected commercial speech. The Washington Legal Foundation's comments may foreshadow litigation to come if the FDA seeks to enforce the requirements that some might argue would effectively compel speech.[15]

c. Understanding Technological Capabilities

The FDA finally addressed many of the issues that it emphasized in its 2009 Public Hearing on the Promotion of FDA-Regulated Medical Products Using the Internet and Social Media Tools, but some stakeholders highlighted what they believed to be the FDA's incomplete understanding of the technological capabilities of certain platforms. For example, the Space Limitations Guidance states that messages on Twitter (tweets) are limited to 140 characters per message. Although this was the case when Twitter launched in 2006, many commenters keenly noted that the platform has evolved and tweets now can also include photos, videos and links.[16] These features may provide additional opportunities to present risk and benefit information to the public in a manner that is consistent with FDA requirements, but remain largely ignored in the FDA's Draft Guidance. For example, a feature known as Twitter Cards allows for rich media to supplement text-based tweets with additional content and context.[17]

d. Recognizing Technological Limitations

Other commenters noted that the FDA further demonstrated a lack of understanding of the capabilities of certain social media platforms by its discussions regarding Google sitelinks. For example, the Space Limitations Draft Guidance states that if a firm concludes that adequate benefit and risk information, as well as other required information, cannot all be communicated within the same sponsored link format, then the firm should reconsider using Google's sitelinks for the intended promotional message.[18] Under Google's policies, however, sitelinks are not always guaranteed to appear, meaning that risk information may or may not display alongside product benefit claims.[19] Google explicitly disclaims that advertisements will not always display sitelinks and also that formats may vary. For instance, anywhere from two to six sitelinks may appear on desktop ads. This significant technical limitation is not addressed by the Draft Guidance.

Although numerous stakeholders raised these issues in their comments to the Social Media Guidances, there is no guarantee that the FDA will incorporate any or all of these considerations into the Final Guidances. When it comes to technology, however, the FDA has shown a willingness to understand the technological capabilities and limitations of certain platforms and amend its guidance accordingly. For example, the FDA's Mobile Medical Apps Final Guidance featured several significant changes from the Draft Guidance, which narrowed the scope of mobile apps that the FDA intended to regulate and greatly expanded the categories of apps that would be subject to enforcement discretion.[20]

The FDA should carefully consider the important technological capabilities and limitations that have been challenged by industry in its Draft Guidances in order to provide meaningful recommendations that industry can implement. If the FDA were to incorrectly describe the functionalities of certain platforms in its Final Guidances, it would create confusion in the marketplace regarding existing platforms and would lead to even more uncertainty as new platforms are rolled out. The FDA has rightfully focused on the capabilities of Twitter and Facebook, the two largest social media websites in the U.S., with 284 million[21] and 1.35 billion users[22], respectively, but some of the guidances appear to reflect a lack of comprehensive understanding of the technological capabilities of these platforms. The problem is that technological advances continue to outpace the ability of regulators to monitor these developments.

In 2015, we are unlikely to witness a large-scale movement by pharmaceutical companies to the social media sphere. Although the Social Media Guidances provide some clarity regarding the FDA's expectations about the use of different social media platforms, the requirements set forth in these Social Media Guidances are rigid enough that they may discourage companies

[13] *See id.*; *see generally* Comments from Washington Legal Foundation, Draft Guidance for Industry on Internet/Social Media Platforms with Character Space Limitations—Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices.

[14] *See* Comments from Washington Legal Foundation, *supra* note 13, at 4.

[15] *See id*. Note that the tobacco industry prevailed in its suit against the FDA when the FDA tried to compel speech by requiring color graphics and warning statements under the Family Smoking Prevention and Tobacco Control Act of 2009. *See R.J. Reynolds v. FDA*, 845 F. Supp. 2d 266 (D.D.C. 2012). However, in that case, the court found that the graphic images were crafted to evoke a strong emotional response calculated to provoke the reviewer to quit or never start smoking, but the required warning statements were *not* struck down. Although the First Amendment provides robust protections against compelled speech, the government may require disclosure of purely factual and noncontroversial information.

[16] *See, e.g.*, Comments from the Internet Association, Draft Guidance for Industry on Internet/Social Media Platforms with Character Space Limitations—Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices.

[17] *See* Twitter Cards, https://dev.twitter.com/docs/cards.

[18] Space Limitations Draft Guidance at 8.

[19] *See* Comments from Medical Information Working Group, Draft Guidance for Industry on Internet/Social Media Platforms with Character Space Limitations—Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices.

[20] *See supra* note 8.

[21] Number of Monthly Active Twitter Users Worldwide, The Statistics Portal, http://www.statista.com/statistics/282087/number-of-monthly-active-twitter-users/.

[22] Number of Monthly Active Facebook Users Worldwide, The Statistics Portal, *available at* http://www.statista.com/statistics/264810/number-of-monthly-active-facebook-users-worldwide/.

from increasing their level of participation in social media. Without this flexibility, it has been common industry practice to avoid social media, and the status quo may remain unchanged in 2015 and beyond for more conservative companies. There remains the possibility, however, that bolder companies will experiment with the new parameters established by the FDA for use of these media. It is clear that industry understanding of certain technologies far exceeds the FDA's ability to keep pace with rapid changes through guidance documents, and certain companies may opt to explore new ways to use social media while remaining cognizant of the requirements imposed by the FDA in its Social Media Guidances. Firms must tread carefully, however, because there are several ways to overstep the bounds of the Social Media Guidances and risk FDA enforcement action. However, social media is rapidly developing and constantly evolving and is likely to remain beyond the comprehensive grasp of the FDA for the foreseeable future.

II. New Trends in Enforcement Action

Although the Social Media Guidances seem to clarify how and when firms can use social media and provide clearer direction for their use, the parameters that have been set are stringent, and there appears to be little room for error. Even with a clear road map for firms to follow if they are seeking to expand their social media presence, the specter of an FDA Warning Letter or other enforcement action looms large for stakeholders that misstep. Although FDA Warning Letters citing Facebook or Twitter violations were rare in 2013, there has been a huge uptick in the number of Warning Letters issued by the FDA that cite violations on social media platforms. These Warning Letters have become even more prevalent since the June 2014 release of the final two parts of the FDA's Social Media Guidances. Although these Warning Letters have not yet addressed violations of the specific requirements and/or recommendations set forth in the Social Media Guidances, the sheer number of letters citing social media provides insight into the FDA's focus on noncompliance in the social media arena and demonstrates that the agency clearly reviews and considers the content of social media in the same way that it does more traditional company websites.

Industry should expect this upward trend to continue in 2015 as the FDA's own understanding of social media evolves. In December 2012, the FDA made headlines when it issued a Warning Letter to AMARC Enterprises for ''liking'' a post by a consumer.[23] More than two years later, it is easy to understand why this happened because one of the FDA's bedrock principles is that manufacturers are generally responsible and accountable for any website or social media content that is under their direct control or influence. Once the FDA finalizes its Social Media Guidances, however, these issues will become far more nuanced. Companies that push the envelope and attempt to obtain a competitive advantage may be the test cases for the FDA's enforcement of the Social Media Guidances. The fact that the FDA has repeatedly cited companies for violations on social media clearly indicates that this can be risky behavior. This year will provide more clarity on how stringent the FDA will be in enforcing these requirements and how much flexibility it is willing to afford industry. Firms must tread carefully, however, because a ''social experiment'' could easily turn into a Warning Letter.

III. Conclusion

Although industry has a sense about where the FDA is going with its Social Media Guidances, it remains unclear what the agency's position will be and whether the agency will keep pace with technology. The FDA has finally provided industry with the road map it needs to move forward, but that movement may be glacial in 2015. Conservative companies are likely to continue to proceed with caution when using social media platforms due to the tight parameters for social media use established in the Social Media Guidances and the concern of FDA enforcement action. Whether this outlook changes over time will depend on how the ''social experiment'' turns out, and whether the FDA makes any changes to its social media policy to enable the appropriate use of these channels of communication.

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[23] FDA Warning Letter to AMARC Enterprises (Dec. 11, 2012), *available at* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm340266.htm.