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@FDA Gives Little Guidance 2 #Pharma re Social Media

By Scott S. Liebman

The way that we communicate has changed. Technology and social media have altered how we keep in touch with friends and family. Whether it is a text message that you will be late for dinner, a Tweet about breaking news, or an Instragram picture of a family vacation, we are all affected. Social media is seamlessly weaving itself into the fabric of our lives. In fact, some are so addicted to social media that a condition called ''FOMO'' or fear of missing out has its own hashtag on Twitter.

The rise in influence of social media is difficult for any marketing department to ignore. Use of social media as a marketing and advertising tool is increasing in the life sciences industry—pharmaceutical, medical device and biotechnology—as well. It is a powerful medium to provide information to a public that spends an enormous amount of time on computers, tablets and smart phones. Forget web pages — almost every major pharmaceutical manufacturer not only has a Facebook page, but an active Twitter account too.

The speed and interactive nature of social media, however, presents challenges to life sciences manufacturers. FDA promotional rules significantly limit how life sciences manufacturers may promote their products. For example, promotional materials, and communications, must be accurate, complete, not misleading and balanced with information related to both benefits and risks. Complying with these federal promotional requirements is difficult enough for television and print advertisements, not to mention real-time interactive media. Sometimes even determining if an interactive communication from a manufacturer rises to the level of promotion and triggers FDA requirements is difficult.

Scott S. Liebman is a partner at Loeb & Loeb LLP, where he heads the firm's FDA Regulatory and Compliance Practice. He specializes in sales and marketing promotion and commercialization for life sciences companies. Liebman can be reached at sliebman@loeb.com.

Against this backdrop, it is no surprise that the industry has longed for formal instruction from the FDA on promoting products on social media. To much excitement, the Food and Drug Administration Safety and Innovation Act requires the issuance of a guidance about ''promotion, using the Internet (including social media), of medical products that are regulated by the FDA,'' by August 2014. Many hoped for a social media manifesto from the FDA.

In January, the FDA released its long-awaited first draft guidance dedicated to ''interactive'' media, officially titled Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics (''Guidance'') (12 PLIR 78, 1/17/14). The Guidance, however, did not exactly meet industry hopes and expectations. After years of FDA delays, many were looking for insight on how to satisfy the complicated federal requirements for promotional communications on social and interactive media. For example, how does a manufacturer adequately provide fair balance of benefit and risk information in 140 characters? After all, the Office of Prescription Drug Promotion (''OPDP'') (formerly Division of Drug Marketing, Advertising and Communication, ''DDMAC'') has been sending Untitled and Warning Letters to pharmaceutical manufacturers since 2009 regarding violations on interactive media from Google sponsored links to Facebook Widgets. Yet, none of these topics are covered in the Guidance. Instead, this Guidance represents the first of many that will inform the use of social media. The Center for Drug Evaluation and Research (''CDER'') recently released its 2014 plan of draft guidances, which includes three regarding social media: (1) character space limitations and presenting the risk and benefit information, (2) correcting independent-third party misinformation, and (3) use of links.

This first Guidance provides the FDA's ''current thinking'' on whether a particular interactive advertisement or promotional piece must be submitted to the FDA at the time of dissemination or publication under the Food, Drug and Cosmetic Act (''FDCA'') and FDA's implementing regulations, also known as Form FDA

2253 submission. For the most part, the Guidance sets forth the procedure of what and when to file with the Agency, and not necessarily how to compliantly promote on interactive social media.

Factors Triggering 2253 Submission

The Guidance evaluates Twitter, Facebook, blogs and other similar sites based on whether they are sponsored by (1) the company, (2) a third-party, or (3) an employee or agent of the company. Although the Guidance document covers each of the different types of content generators, the key factors to triggering 2253 submission requirements are control and influence. Regardless of the generator, if the company has control or influence over the content, then the company is responsible for submitting the promotional communication to the FDA.

The FDA sets a low threshold for control and influence. According to the Guidance, the FDA ''considers whether the firm, or anyone acting on its behalf, is influencing or controlling the promotional activity or communication in whole or part. . .even if the influence is limited in scope.'' The Guidance provides examples of ''limited in scope,'' such as collaboration on or ''editorial, preview, or review privilege over the content provided. . .'' In another section, the FDA expresses that ''any control or influence'' by the company requires 2253 submission.

If, however, the company has no control or influence over the user generated content (''UGC''), then there is no submission requirement. The Guidance continues to explain that financial support alone, without control or influence, does not require submission by the company. The FDA, here, creates a similar paradigm to the continuing medical education model (''CME''). If a company provides an unrestricted grant to an independent CME provider and relinquishes control and influence over a legitimate program, then FDA promotional rules do not apply to the CME event. Similarly, if a company provides financial support for a third-party site and has no control or influence, then the company is not subject to the FDA promotional submission requirements. But, if the company provides financial support and promotional content to a third-party site, yet ''does not direct the placement of the promotion. . .and has no other control or influence on that site,'' the company only has to submit the promotional piece it provided to the third-party site. When a company has some other influence or control over that site, no matter how minimal, not only does the promotional communication require 2253 submission, but so do surrounding pages in order to provide context around the promotional message.

The Guidance applies the same control and influence standards to employees and agents of the company, including medical science liaisons, key opinion leaders and bloggers. The company must submit any UGC by an employee or agent of the company. The Guidance further calls for transparency and disclosure for content generated by an employee or third party. Again, however, a company is ''not responsible for UGC that is truly independent.'' The FDA further indicates that it ''will not ordinarily view UGC on firm-owned or firm-controlled venues such as blogs, message boards, and chat rooms as promotional content on behalf of the firm as long as the user has no affiliation with the firm and the firm has no influence on the UGC.''

FDA's Recommendations

After acknowledging the difficulties of submitting material that contains real-time information, the FDA enumerates a number of recommendations or approaches to submitting interactive promotional media. Some recommendations are obvious and already best practices in the industry and others are more burdensome and less widely used.

Generally, the FDA recommends that companies submit entire sites for which they are responsible at the time of initial display. For third-party sites that have real-time or interactive content, the FDA recommends submission of the home page and the first communication on the interactive page at the time of initial display. The FDA also recommends submission of content on restricted sites that the FDA might not be able to access.

The most burdensome recommendation may be the monthly submission of all active sites with interactive or real-time promotional communications. This recommendation may require some internal processes and procedures to ensure accuracy and completeness of submission. Not many organizations have policies in place to satisfy the recommended monthly submissions. As the use of social media increases, this recommendation becomes more laborious and requires additional company resources.

Finally, the Guidance discusses format of submissions. Since context is critically important, the FDA asks that submissions ''enable the Agency to view the communications as a whole,'' and view the ''submissions in the same way as the end user.'' The FDA recognizes the difficulty of formatting these submissions and recommends screens shots as an alternative to provide context.

What's Missing

The Guidance focuses on when FDA 2253 submission is necessary and how to submit, but provides no clarity on how to satisfy the FDCA and FDA regulations on promotional material. A review of OPDP Warning and Untitled Letters over the past five years clearly demonstrates the challenges that manufacturers have in meeting the regulatory requirements.

A survey of OPDP violation letters shows that the most difficult FDA requirement to meet on social media is adequate disclosure of risk and other information about a drug. As a Warning Letter states, ''[p]romotional material, other than reminder pieces, which include the name of the drug product but do not include indications or other representations or suggestions relative to the drug product. . .are required to disclose risk and other information about the drug.'' Failure to provide such risk information, in these cases, violates the federal promotional rules.

Providing risk and other drug information require space. Anyone that has seen an advertisement for a drug in a magazine or newspaper understands how much space is needed to satisfactorily meet FDA regulations. Herein lies the problem. For the most part, space in social and other interactive media is limited. Sponsored links on internet search engines, like Google, and micro blogs, like Twitter, only permit 140 characters. It is nearly impossible to provide adequate risk information with such a strict character limitation. Currently, manufacturers include statements like

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''Click to see full safety and prescribing information, including boxed warning. More info.'' But, a 2011 Warning Letter regarding a manufacturer's website stated that providing a ''Click to Continue'' link to the product website and package insert is ''insufficient to mitigate the misleading omission of risk information.'' The FDA's position on the ''one-click'' rule appears to be clear for websites, but is unknown for more limiting social and interactive media.

A firm ''no one-click rule'' limits manufacturers' ability to use such mediums. Sponsored ads and micro blogs would be effectively limited to reminder pieces that cannot discuss the drug's use, the condition treated or the effectiveness. According to the FDA, a reminder ad states the drug's name and assumes that the audience does not need to be told for the drug's indication. Additionally, reminder ads are not permitted for products with boxed warnings, which increases the complexity for social media.

Yet, based on the Guidance, reminder ads present significant risks as well. The Guidance document makes clear that the FDA will review promotional communications, including reminder ads, in its entire context. Therefore, if a company has control or influence on *when* or *where* the reminder ad appears, then the context will be considered. If the context indicates or implies the drug's use or effectiveness and there is insufficient risk information, the reminder ad violates FDA regulations.

Much of the power and influence that social and interactive media present is severely limited for the life sciences industry. Reminder ads are not the most effective marketing tool for a manufacturer, particularly for lesser known or new products. For the most part, social media has only been effectively used for disease awareness campaigns.

Conclusion

The key points of this Guidance surround the control and influence that companies extend over interactive promotional media. To simply summarize, any control or influence triggers 2253 submission requirements.

Some insights regarding FDA enforcements can be gleaned as well. The FDA acknowledged that it will not ''ordinarily'' view UGC on forums like message boards and chat rooms even when the company owns the venue as long as there is no influence over the UGC. Perhaps more importantly, remarks in the Guidance regarding context suggest that the FDA will view interactive social media in its entirety and with a wide lens.

Unfortunately, the Guidance document is most remarkable for what it did not say. The FDA's silence on advice on how to meet risk information requirements leaves the industry still questioning and struggling. To some degree this Guidance puts the proverbial cart before the horse. It gives clarity on *when* to submit interactive promotional media before it tells *how* to create compliant interactive promotional media. Hopefully, the guidances planned for 2014 will provide more clarity and instruction on some of the specific challenges facing the industry.

Comments on the draft Guidance are due April 14 (Docket No. FDA-2013-N-1430).