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Social Media and Prescription Drug Promotion: A Survey of Seven Companies' Practices

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The promotion of prescription drugs in recent years has been revolutionized not only by the advent of direct-to-consumer advertising, but also by the proliferation of social media outlets such as Facebook, Twitter, Pinterest, Tumblr, message boards, and chat rooms. Never before have companies had such a direct link to users and potential users of their products, or the ability to interact with them in real time; similarly, consumers now have unparalleled access to information about drugs on the market, whether from other product users, prescribers, or manufacturers themselves. Although the Food and Drug Administration's (FDA) advertising and promotion regulations broadly apply to companies' social media initiatives, the regulations were written at a time when the web did not even exist. As a result, the regulations fail to address a host of issues implicated by these new forms of media, including the anonymous, ''public'' nature of comments; the different characteristics of various platforms; the difficulty of monitoring communication; the sheer volume of outlets and third-party posts; and the global nature of sites and tools.[1]

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Despite FDA promises and industry pleas, the agency has not proposed regulations or guidance to address drug promotion through social media. Instead FDA has chosen to regulate piecemeal, issuing warning and untitled letters to companies it concludes have violated the law by promoting their products through these avenues. The lack of agency guidance has not prevented pharmaceutical and biotechnology companies from utilizing social media, but it has required them to proceed with caution and to develop their own best practices.

This article reports on an informal survey that we conducted to investigate the ways in which companies are addressing the issues presented by social media marketing. To complete the survey, we interviewed legal or regulatory personnel responsible for social media issues at seven multinational pharmaceutical and biotechnology companies, all of which have a presence on social media, whether in the form of, for example, a corporate Twitter feed or Facebook pages for disease states or company products. All participants were asked a core set of open-ended questions, and the resulting conversations explored the use of social media by the companies; identified the most significant issues presented by these new and evolving technology platforms as perceived by the companies; and examined the policies and practices that the companies have adopted to

[1] Indeed, relevant regulations reference ''lantern slides,'' ''film strips,'' ''house organs,'' and other outmoded forms of communication. *See, e.g.*, 21 C.F.R. § 202.1(l)(2).

help ensure compliance with FDA regulations related to product promotion.

The Long Wait for FDA Social Media Guidance

The industry has been waiting for years for FDA regulations or guidance on internet and social media promotion. FDA held its first public meeting on the subject in 1996,[2] where representatives from industry, patient groups, medical societies, and others convened to discuss communication of product information on websites, in chat rooms, and through news groups. Although the technology of the time did not offer the same level of interactivity seen with today's tools, the questions raised at that meeting—such as those relating to the global nature of electronic communications, attribution of third-party posts, and monitoring for and reporting of adverse events—remain unanswered. Thirteen years later, FDA convened its second public meeting dedicated to promotion through these new channels, acknowledging that although ''many issues can be addressed through existing FDA regulations, special characteristics of . . . emerging technologies may require the agency to provide additional guidance to the industry.''[3] At the request of the agency, discussions at the 2009 meeting covered five topics: (1) the online communications for which manufacturers are accountable; (2) how to achieve regulatory requirements (*e.g.*, fair balance, disclosure of indication) when using various platforms; (3) the posting of corrective information on third-party sites; (4) the use of links; and (5) monitoring and reporting of adverse events communicated through social media. FDA has repeatedly stated that guidance on these issues is forthcoming, and with the passage of the Food and Drug Administration Safety and Innovation Act in 2012, Congress has required that FDA release social media guidance by June 2014.[4]

In the absence of clear guidance, companies are left in the meantime to scrutinize FDA warning and untitled letters related to social media in an attempt to glean rules about the use of these new platforms. Those enforcement actions are of limited value, however, largely because they are so fact-specific. It is not certain, for example, that the agency would have cited Novartis for omission of risk information in connection with a Facebook widget had the product at issue not been subject to a Risk Evaluation and Mitigation Strategy and boxed warning.[5] Similarly, when FDA cited Amarc Enterprises[6] for ''liking'' an off-label comment made by a user on a company-sponsored Facebook page, the agency did not clarify whether all user-generated content may be attributed to the manufacturer or whether the company would have been cited for merely allowing the comment to remain on the page rather than ''liking'' it. Even if these letters were subject to only one reasonable interpretation, the vast majority of social media tools and corresponding issues have never been addressed by FDA. Manufacturers are therefore left to operate in a gray area, with the companies themselves deciding how best to achieve consistency with the letter and spirit of FDA regulations related to advertising and promotion.

Survey of Social Media Practices

To better understand how companies are grappling with regulatory uncertainty and the challenges of social media, we surveyed seven attorneys and regulatory affairs personnel, each of whom is involved with social media policy development or promotional initiatives at a major pharmaceutical or biotechnology company. Our conversations focused on the companies' use of social media tools; their practices related to the surveillance and reporting of adverse events communicated through social media; the extent to which they manage misinformation about products posted on company-sponsored and third-party sites; and the best practices that have emerged in the absence of FDA guidance. We discuss our findings below.

Proactive Use of Social Media

Facebook

Although all the companies participate in social media, the platforms they use and the information they share varies. Facebook is used most extensively by the seven companies, with most sponsoring corporate profiles, as well as unbranded pages dedicated to disease awareness. A few companies also host branded pages dedicated to specific products, designed for groups of patients with particular diseases or conditions, or developed to promote product-focused events (*e.g.*, consumer education programs). Pharmaceutical and biotechnology companies' presence on Facebook largely predates an important change that Facebook made to its policy in 2011. Previously, companies could disable the commenting function on their pages. Drug companies could thereby ensure that users could not post information related to an adverse event or information that was inaccurate, off-label, or otherwise inappropriate. This practice, known as ''whitelisting,'' made Face-

[2] *See* Promotion of FDA-Regulated Medical Products on the Internet; Notice of Public Meeting, 61 Fed. Reg. 48707 (Sept. 16, 1996), *available at* http://www.gpo.gov/fdsys/pkg/FR-1996-09-16/pdf/96-23616.pdf. A transcript of the meeting is available at http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm175775.htm.

[3] *See* Promotion of Food and Drug Administration-Regulated Medical Products Using the Internet and Social Media Tools; Notice of Public Hearing, 74 Fed. Reg. 48083 (Sept. 21, 2009), *available at* http://www.gpo.gov/fdsys/pkg/FR-2009-09-21/html/E9-22618.htm. A transcript of the meeting is available at http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm184250.htm.

[4] Pub. L. No. 112-144, § 1121, *available at* http://www.gpo.gov/fdsys/pkg/PLAW-112publ144/pdf/PLAW-112publ144.pdf.

[5] Letter from Karen Rulli, Division of Drug Marketing, Advertising, and Communications (DDMAC), to Lisa Drucker, Novartis Pharmaceuticals Corp., Jun. 29, 2010, *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM221325.pdf.

[6] Letter from Alonza E. Cruse, FDA, to Albert Sanchez, Amarc Enterprises, Dec. 11, 2012, *available at* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm340266.htm.

ISSN

book a relatively low-risk option from a regulatory perspective, because it obviated the need for constant monitoring of Facebook pages, and given the lack of space constraints on the site, allowed pharmaceutical and biotechnology companies to share meaningful information about their products without compromising their ability to comply with FDA requirements. Subsequent to the policy change, which Facebook said it thought was necessary to encourage an ''authentic, engaging two-way dialog,'' companies may request the removal of comment functionality only for pages solely dedicated to prescription drugs, which Facebook evaluates on a case-by-case basis.

In conducting our survey, it was clear that many companies terminated or overhauled their branded Facebook profiles after the 2011 policy change; the companies have largely refrained from launching new branded pages since then, as well. The individuals we spoke with noted that their companies lacked the resources to engage in real-time monitoring, and that given FDA's silence on the extent to which manufacturers are obligated to manage user comments, the companies said they think two-way Facebook communication is high risk. Some companies are even questioning whether there is enough ''bang for the buck'' to justify the resources necessary to maintain a branded Facebook page. In addition, a few companies noted that Facebook's tendency to announce and implement changes to the terms with no notice whatsoever makes Facebook a less attractive marketing spend because there is uncertainty as to when and how the rules of that tool will change.

Companies that are using branded Facebook pages have taken steps to mitigate the risks associated with user-generated content. Some companies, for example, routinely monitor and delete some or all user comments. Others use application software that stores user comments in a queue and allows an administrator to approve, revise, or decline the comments for posting. The resources required to engage in this type of monitoring and evaluation of comments are significant, which is why some individuals think that their companies do not maintain branded Facebook pages. Regardless of the monitoring method employed, many Facebook profiles also contain detailed ''Terms of Use'' statements providing general posting guidelines (*e.g.*, related to spam or abusive language), instructing users to refrain from providing medical advice or other information about the product and its uses, clarifying that the page is intended for U.S. audiences only, and directing users to report potential adverse events in a certain manner.

Twitter

Although not as extensive as Facebook use, each of the seven companies has developed an active presence on Twitter, which limits user messages to 140 characters. Each company must operate within the space constraints without sacrificing adherence to FDA requirements, such as fair balance. The *type* of information communicated with Twitter, however, differs significantly from company to company. All of the companies maintain a feed dedicated to company news and investor information, but although some companies circumvent character limitations by linking to press releases about product approvals and study results, which maintain fair balance and satisfy other FDA regulatory requirements, other companies avoid altogether product mentions on their corporate Twitter feeds. A few of the companies we spoke with currently sponsor or are planning to host Twitter feeds that are unbranded and focus on disease awareness, but none of the companies has launched branded Twitter feeds at this time. When asked, the interviewees generally explained that the space constraints of Twitter may undermine its utility as a brand-specific marketing tool. Because safety and risk information typically cannot be communicated in 140 characters, the use of Twitter is effectively limited to reminder advertisements (*i.e.*, those that identify the brand and generic name of the drug but do not reference the indication or make dosage recommendations).[7] This approach is not permitted for drugs containing a boxed warning,[8] however, and although reminder information about other products can be shared in a compliant manner, many interviewees questioned the ultimate value of a Twitter feed that does not provide any claims about a product. Nevertheless, we heard consistently that commercial and marketing personnel consider Twitter to be the next frontier for drug promotion, meaning that attorneys and regulatory affairs personnel will likely be working with their digital media colleagues to develop a more robust presence on this platform.

Other Forms of Media

In addition to Facebook and Twitter, most of the company representatives we spoke to use other forms of social media, such as Flickr, Pinterest, SlideShare, Tumblr, or YouTube. The companies make decisions to utilize these platforms on a case-by-case basis, implicitly acknowledging the unique characteristics inherent to each (*e.g.*, space constraints, sharing features). A few of the companies also use or are currently exploring the use of controlled-access platforms, such as speaker communities or medical information chat rooms, where licensed health care professionals would obtain a password for access and the companies could strictly manage the format and content of communication. From what we heard, it seems there is a general presumption *against* the use of a new social media tool, and that advocates within the company must fully vet an initiative with members of a product review committee and other stakeholders before launch.

Monitoring and Reporting Adverse Events

FDA regulations require companies to submit reports of postmarketing ''adverse drug experiences'' to the agency in certain circumstances and within certain periods of time. In connection with these requirements, the agency expects that ''entities responsible for reporting will promptly review all adverse event information received or otherwise obtained, which potentially includes information from the Internet and social media tools.''[9] FDA draft guidance from 2001 recommends

[7] *See* FDA, *Reminder Advertisements*, *at* http://www.fda.gov/Drugs/ResourcesForYou/Consumers/PrescriptionDrugAdvertising/ucm083573.htm.

[8] *Id.*

[9] *See* FDA, *Promotion of Food and Drug Administration-Regulated Medical Products Using the Internet and Social Media Tools; Notice of Public Hearing*, 74 Fed. Reg. 48083 (Sept.

that companies should report adverse event information received on the internet, so long as the company can discern (1) an identifiable patient; (2) an identifiable reporter; (3) a suspect drug or biological product; and (4) an adverse experience or fatal outcome suspected to be due to the suspect drug or biological product.[10] The draft guidance also states that

''[a]pplicants 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. However, if an applicant becomes aware of an adverse experience on an Internet site that it does not sponsor, the applicant should review the adverse experience and determine if it should be reported to the FDA.''[11]

Although the agency's position makes clear that companies are not obligated to scour the internet for adverse events, the certainty stops there.[12] The draft guidance, issued more than a decade ago, did not contemplate the proliferation of social media and the real-time, interactive experience that these new platforms would provide. The extent to which, if any, companies should monitor for adverse events on platforms that they use (*e.g.*, by performing global keyword searches on Twitter), and the lengths to which companies should go in following up with potential adverse event reporters to obtain additional information, remain unclear.[13] In any event, because any social media platform that allows for user-generated content implicates issues relating to the monitoring and reporting of adverse events, we asked company representatives to share their relevant practices with us.

As an initial matter, all seven companies involve safety or pharmacovigilance personnel in their social media initiatives and seek their guidance on how to identify and report adverse events obtained through these channels. Consistent with the 2001 FDA draft guidance, companies focus most of their adverse event monitoring efforts on sites they own or pages they host. Given the lack of social-media-specific guidance from the agency, several company representatives we spoke with indicated that they struggle with whether and how they should engage in ''listening activities'' for adverse events reported on third-party sites. In particular, they expressed uncertainty with where to draw the line once monitoring begins and concern that active surveillance of social media in the absence of a legal obligation could create a *de facto* duty to continue. Additionally, because FDA reporting requirements cover adverse events that are ''unexpected,'' companies are unable to develop search terms or design other monitoring tools to capture all potentially reportable events given the volume of social media sites and users. When monitoring their own pages, most companies encounter potential adverse events infrequently, largely because they have disabled user comments or have attempted to redirect users to report adverse events to company hotlines or directly to FDA. If adverse event information does appear on a company-hosted page, the companies all stated that they evaluate and report it to FDA provided that the four elements are satisfied.

Approaches to follow-up vary significantly, though, when any of these elements are missing. A few of the companies have policies or practices that encourage reaching out to the user for more information where feasible, such as where the user has provided an email address or may be contacted with a private message through the social media site. Most of the companies, however, handle follow-up on a case-by-case basis, depending on the initial information provided. Under those circumstances, safety or pharmacovigilance colleagues typically review the posted information and make a determination of whether, on the face of the post, follow-up is warranted. Where, for example, the user comment suggests that a competitor product is at issue, or that the adverse event was experienced by someone other than the commenter, a company may decide not to seek additional information. More so than for other topics we discussed, the companies emphasized the difficulty of operating in the social media space without FDA guidance on the monitoring and reporting of adverse events. Without clarity regarding how to handle user-generated content, the disparity in practices among companies will likely persist.

Correcting False, Misleading, or Off-Label Information

FDA regulates product promotion by or on behalf of a manufacturer, and the agency has indicated that it will assess a manufacturer's control or influence over a third-party message to determine who is ultimately accountable for it. In the context of social media, FDA has acknowledged that some tools permit companies to ''prompt'' communications and that company decisions related to the posting and moderation of user comments may influence their weight or reach.[14] The agency has also drawn a distinction between messages posted on company pages and those conveyed on pages beyond a company's control.[15] Although obligations to correct

21, 2009), at http://www.gpo.gov/fdsys/pkg/FR-2009-09-21/html/E9-22618.htm.

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

[11] *Id.*

[12] For a comprehensive discussion of adverse event reporting and social media, *see* Stuart L. Friedel and Joseph A. Sena, Jr., *Pharma Challenges: Adverse Event Reporting and Social Media*, BLOOMBERG BNA: SOCIAL MEDIA LAW & POLICY REPORT, Oct. 23, 2012.

[13] Moreover, although the ''identifiable patient'' reporting element was subject to interpretation when the draft guidance was released, it is even more complicated now, because some social media users share detailed personal information on their publicly accessible profiles, while others prefer to remain anonymous, and still others create ''dummy'' or ''sock'' accounts.

[14] *See* FDA, *Promotion of Food and Drug Administration-Regulated Medical Products Using the Internet and Social Media Tools; Notice of Public Hearing*, 74 Fed. Reg. 48083 (Sept. 21, 2009), *at* http://www.gpo.gov/fdsys/pkg/FR-2009-09-21/html/E9-22618.htm.

[15] *See id.* (discussing third-party sites as distinct from company-owned sites); *see also* FDA, *Draft Guidance for Industry: Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines*, (Mar. 2001), at 21, *available at* http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/

  ISSN

false, misleading, or off-label information are surely more substantial when dealing with company-hosted pages, FDA has neither outlined those responsibilities in detail nor explained when correcting such information on a third-party page may be appropriate.[16]

In general, the seven companies' approaches to correcting false, misleading, or off-label information on sites and pages that they host are consistent with their Facebook practices. In other words, the companies use a variety of methods to manage user-generated content, such as moderating or removing comments, or establishing Terms of Use that prohibit certain types of messaging. Notably, the companies rarely attempt to ''correct'' information by replying to user comments, because they want to avoid such a resource-intensive practice, as well as the creation of a ''slippery slope,'' whereby any inaccuracy, no matter how insignificant, is expected to be corrected by the company.

Correcting false, misleading, or inaccurate information on third-party pages is also uncommon. Although a few companies we surveyed engage in limited monitoring of social media for market research purposes, these efforts are not designed to uncover this type of information and are not typically staffed by individuals qualified to correct it. Company representatives emphasized the impossibility of capturing all misinformation on social media and again noted the slippery slope problem associated with monitoring and correcting inappropriate messages. User-generated entries on Wikipedia appear to be a notable exception to the general position against correcting misinformation; there, three of the companies we spoke with have become aware of inaccuracies on their product's pages and have worked with Wikipedia staff to revise the content.

Mitigating the Risk: Best Practices for Social Media Marketing

During our conversations, as well as in our practice, there have emerged a number of best practices to guide companies that want to engage in social media promotion in the absence of clear guidance from FDA.

■ *Internal guidance development*: It is essential that companies develop internal guidance related to the promotion of products through social media, whether in the form of detailed policies or Standard Operating Procedures (SOPs), or informal guidelines, checklists, playbooks, or similar materials. The internal guidance should make clear that FDA laws and regulations related to advertising and promotion apply to social media efforts and should either be (1) broad enough to encompass new and evolving technologies; or (2) subject to frequent revision if needed to keep up with changes in platforms and the ways in which they are used. In addition to addressing promotional requirements, such as fair balance and communication of safety and risk information, guidance should also outline considerations for the surveillance and reporting of adverse events and establish criteria for determining when and how false, misleading, or off-label information on company-hosted and third-party sites should be addressed.

■ *Social media working group*: Even if a company has robust social media policies in place, it would be well-advised to establish a cross-functional team responsible for keeping abreast of social media developments; bringing consistency and structure to social media initiatives within the company; and addressing thorny issues not covered by internal guidance. Many of the company representatives we spoke with described a committee composed of attorneys, marketers, digital media experts, and safety and pharmacovigilance colleagues that meets on an *ad hoc* basis to discuss relevant events (*e.g.*, FDA enforcement actions); steer company responses where appropriate; and advise on unique issues or initiatives outside the scope of internal guidance.

■ *Familiarity with sites and tools*: A nuanced understanding of social media is critical to ensure that product promotion occurs in a manner that is both compliant and effective. For product review committee members to advise on and accurately assess the risk of a particular social media initiative, they should know about the platform's characteristics, relevant limitations, and how information will be accessed and shared by users. Similarly, companies should stay up-to-date on the ''Terms of Use'' and other policies governing use of social media applications and reevaluate their promotional initiatives in connection with relevant revisions to ensure that company messaging remains in compliance with FDA regulatory requirements. Finally, companies should avoid adopting a ''one-size-fits-all'' approach for social media platforms and the products they are promoting. Although Twitter may be a poor vehicle for advertising a product with a boxed warning, for example, a video-sharing site may be appropriate.

Conclusion

Our survey of social media practices at large pharmaceutical and biotechnology companies indicates that although manufacturers are frustrated by the lack of FDA guidance, they are cognizant of the regulatory issues implicated by new media platforms and careful in how they approach them. Indeed, we heard repeatedly that company stakeholders tend to be risk-averse when it comes to social media initiatives, making sure to vet them adequately before launch and reevaluate them periodically and in response to new developments. The long-awaited FDA guidance promises to clear up uncertainty related to the monitoring and reporting of adverse events and the need to address false, misleading, or off-label information on company-hosted or third-party pages. Until then, the best practices described above may help companies enhance their social media acumen and establish an active presence without sacrificing regulatory compliance.

Vaccines/ucm092257.pdf (relieving manufacturers of the responsibility to monitor third-party sites for adverse event information).

[16] FDA has offered guidance on how companies should respond to off-label questions received through social media. *See, e.g.*, FDA, *Draft Guidance for Industry: Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices* (Dec. 2011), at 10-11, *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM285145.pdf. That guidance is beyond the scope of this article, as this section focuses on false, misleading, or off-label statements posted by a third party, as opposed to questions.