The US Food and Drug Administration's scrutiny of product promotions online

Cori Goldberg, Chaula Mehta, and Krishna Kavi of Norton Rose Fulbright reflect on the US Food and Drug Administration's ('FDA') enforcement action relating to the promotion of prescription drugs and medical devices online in 2016, reflecting on the draft guidance issued and what 2017 - and a Trump presidency - might hold.

Social media is where it's at. These days, millennials seem to communicate primarily online, and various popular apps have consumers of all ages glued to their screens. It's no surprise, then, that pharma and medical device companies have increasingly been turning to social media and other online platforms to market their products. But with a platform that reaches the hands of so many so instantly, how do companies ensure that their posts are compliant with regulations? In June 2014, after years of issuing individual Warning and Untitled Letters to various manufacturers, packers, and distributors, the FDA published draft guidance[1] regarding the use of social media to promote prescription drugs and medical devices. Throughout 2016, and especially at the end of the year, the FDA's Office of Prescription Drug Promotion ('OPDP') focused its enforcement on such marketing efforts, thus necessitating an organised, thoughtful approach by those drug companies that wish to capitalise on the popularity of social media to inform consumers about their products. While the OPDP focuses on drug promotion, medical device manufacturers should consider these concerns and risks as well as acknowledging that they are not immune to enforcement efforts[2].

Background

Under the authority given to it by the Federal Food, Drug, and Cosmetic Act, the FDA is responsible for regulating the labeling of drugs and medical devices and the advertising of prescription drugs and restricted medical devices. In this capacity, the FDA has issued draft guidance on two key topics involving social media: (1) use of social media on platforms with character limitations (such as Twitter)[3] and (2) correcting misinformation on social media[4].

Use of social media on platforms with character limitations

Generally, when using social media, a company may mention a product's brand name and medical name, on-label benefits/indications, and side effects in a posting. The descriptions of a drug's or device's benefits should be accurate and not misleading, and should also include material facts about indications/use. Further, a discussion of a product's potential risks must accompany any discussion of on-label benefits. At a minimum, the most serious risks should be discussed and a direct link to a more detailed discussion of risks should be provided[5]. The FDA suggests avoiding social media platforms that do not enable adequate mention of the product brand name and medical name, on-label benefits, and side effects (for instance, Twitter may not be the best fit for a product with extensive serious side effects).

Responsibility for social media content

The FDA's oversight extends to both promotional activities that are carried out by a drug or medical device company itself, and promotion conducted on the company's behalf. In other words, a drug or device company is responsible for social media content generated by its employees as well as agents acting on behalf of the company to promote the company's product. The latter instance is further discussed below.

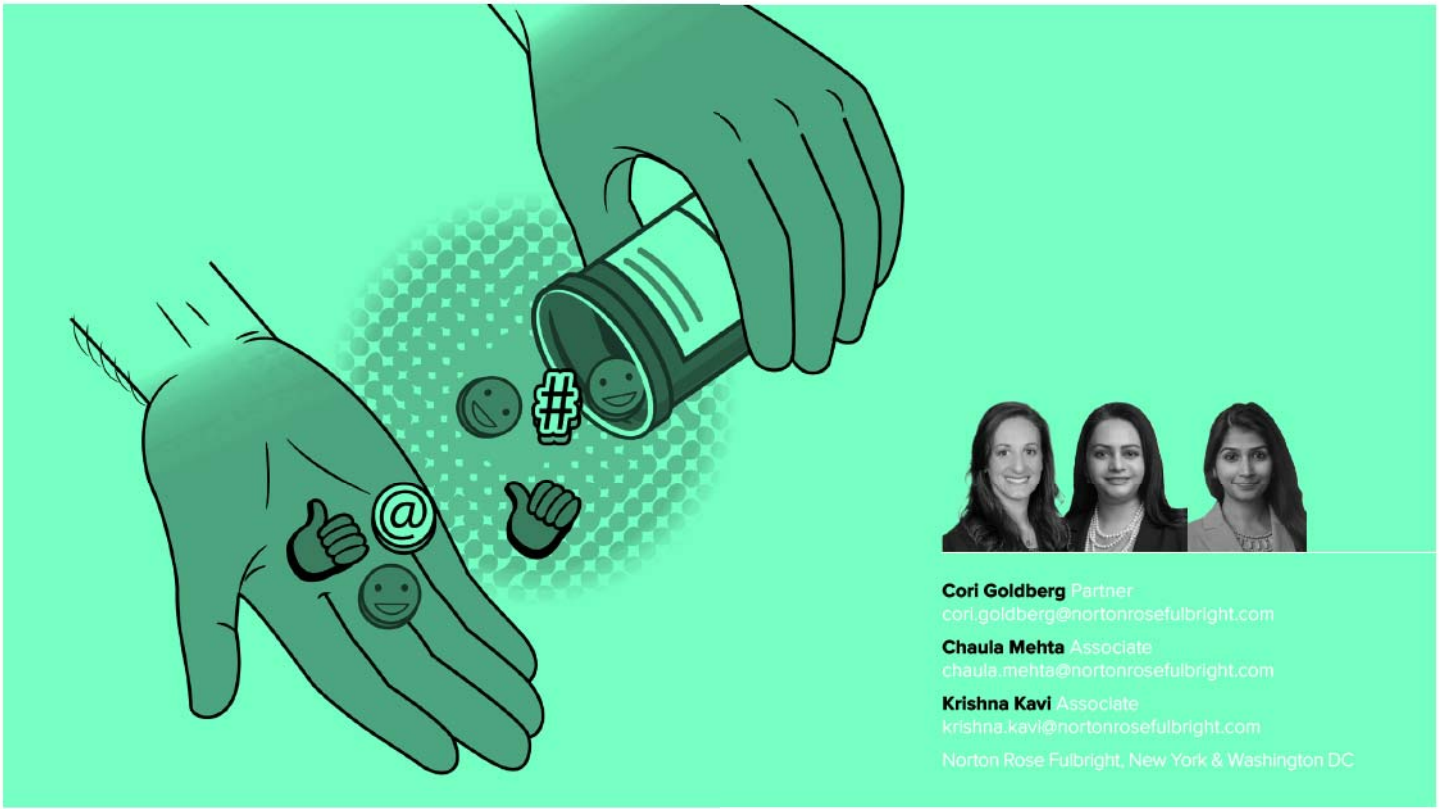
Correcting third party misinformation on social media

According to the FDA, a company is not responsible for user generated content on social media platforms as long as (1) the user is not affiliated with the company and (2) the company had no influence over the user. If misinformation about a company's products is created or disseminated by third parties unaffiliated with the company, the company is not required to correct it, but may voluntarily do so. If a company voluntarily corrects misinformation, the FDA does not need to be notified, but it recommends maintaining internal records of the correction.

The FDA has indicated that if a company attempts to make corrections in a truthful and non-misleading manner pursuant to FDA guidance, the FDA does not intend to object if the company's voluntary corrections do not satisfy otherwise applicable regulatory requirements regarding labeling or advertising. Companies must therefore consider whether to have personnel devoted to searching for company ads and a legal or compliance team ready to analyse the implications of correcting or not correcting such user generated content.

FDA and OPDP enforcement

It has been commonplace for the OPDP to issue Warning and Untitled



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letters to pharmaceutical companies for their promotion of drugs on traditional media such as television and print advertisements[6]. In recent years, the OPDP has increased its focus on online and social media drug promotion, even going beyond typical social media sites such as Instagram to platforms such as YouTube, company websites, and email communications.

The OPDP has recently increased its enforcement efforts, issuing nine enforcement letters in 2015 and even more - 11 - in 2016. Notably, the OPDP issued in December 2016 six of its 11 total enforcement letters for the year. Further, six of the 2016 enforcement letters were for videos on YouTube or the applicable company website, webpage advertisements, and emails. For example, one of the OPDP's Untitled Letters was to a foreign drug manufacturer that targeted the manufacturer's YouTube video, which the OPDP claimed was intended to show or at least implied that the drug was approved worldwide. Specifically, among other violations, the OPDP stated that language in the video, such as "world's first," with no other clarification statements about the drug's actual approved use in the United States or in other countries was misleading, especially since the drug is still under investigational status in the United States[7]. The letter called for the manufacturer to cease its use of the misleading language in the video and to submit a response letter to the FDA with a plan outlined for the discontinuation of such language.

Other enforcement letters touched on similar problems where drug manufacturers had promoted their products as being safe and effective when the drug was not yet approved by the FDA. Further, even in promotions where drug companies acknowledged their products' investigational status, the OPDP letters focused on how the drug companies did this very quickly or minimally compared to the entirety of the advertisement.

The OPDP also issued enforcement letters on email promotions. One manufacturer received a Warning Letter because the OPDP claimed that the company's promotional emails minimised the product's risks, as the email contained no mention of the drug's risks, yet included all of the drug's benefits. Markedly, the email did include a link to more information about the drug, but the FDA found that the link was insufficient to inform readers about the drug's risks, as the actual email text did not mention these risks. The Warning Letter called for the manufacturer to discontinue the misleading emails and any other similar promotions, as well as issue a corrective action plan to the FDA.

Considerations for using social media and other online platforms

The correction actions stated in the enforcement letters may not seem very extreme, but having to change promotional materials is costly and time consuming for many companies, especially when these mistakes can be easily identified and prevented on the front end. Further, the enforcement actions lead to bad press, which may result in consumer distrust. The bottom line: Warning Letters are generally bad for business. Based on the draft guidance and enforcement letters, industry may want to consider a few key items to help them navigate the complex, yet lucrative, area of online and social media promotions.

We recommend, prior to relying on social media or other online platforms to publicise drug or device products, that a company first and foremost has a fulsome social media or online promotion policy in place. Employees should be well versed in the policy, which should also be reviewed by legal counsel.

Moreover, and this should be clearly delineated in the policy, companies should delegate the role of social media or online promotions to certain individuals or departments, and permit only these individuals to create and post online advertisements on their behalf. This will help the company streamline the process of reviewing and monitoring promotional materials, and also ensure that comprehensive training on online promotions is provided to these key individuals. All social media or online posts should be monitored for accuracy and consistency with FDA guidance.

Companies, in addition, should limit the content of online posts to only a product's approved or cleared

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indications/uses. While some recent cases have allowed truthful, non-misleading off-label promotion, the holdings of those cases were very fact-specific and based on unique circumstances[8]. In contrast, as seen in the enforcement letters, the FDA is very clear on its stance in prohibiting safety and efficacy promotions and claims for investigational drugs. As the nature of online promotional materials make it so that they can be accessed all over the world, it is important that these materials clarify the countries where the drugs are approved and available for commercial distribution, or explicitly mention the drug's approval status in each country. Further, manufacturers should avoid language that implies that their drug is approved in the United States when it is not, such as 'leading global diabetes medicine,' which suggests that the drug is approved worldwide.

Companies should make efforts to present an accurate picture of the risks associated with their products on any online medium. For example, instead of including only a link to the product's risks, companies should consider presenting the risks in the actual promotional material itself and with more detail. A product's risks should also be highlighted and detailed to the same degree as its benefits. This does not necessarily mean that for every benefit discussed, there must be a risk discussed; rather, instead of discussing the risks, for example, in a rushed manner for eight seconds of a three minute video, consider allotting additional time to an explanation of the risks and side effects of the drug. Ultimately, the FDA expects a balanced portrayal of a drug's risks and benefits in these materials to ensure consumer safety. On certain character-limited social media platforms, it may be difficult to present the risks of a product in an adequate manner and therefore, in these instances, as the FDA suggested in its guidance, it may be best for the manufacturer to use other online platforms.

While paying attention to the ways that drug and device promotions need to change and adapt to social media platforms may seem challenging, manufacturers should not lose sight of the fact that the basic requirements of drug and device promotions still need to be followed on these new platforms. For example, the enforcement letters targeted promotional materials where manufacturers made unsubstantiated 'superior product' claims without any basis, such as reference materials or citations. Some of these enforcement letters for online promotions may have been avoided if manufacturers treated their online and social media advertisements similarly to their traditional advertisements.

As discussed above, in addition to being responsible for its own social media, in certain situations a drug company will also be responsible for social media on third party sites (for instance if it has contracted with an 'influencer' to promote its product). An example of this involves a drug company's use of Kim Kardashian, whom the company paid to promote its morning sickness product on Instagram. The FDA determined that Ms Kardashian's original Instagram post did not adequately mention the product's side effects and resulted in the FDA sending a Warning Letter to the drug company. Ms Kardashian ultimately published a corrected Instagram post[9].

Finally, if a company is engaging an outside party to post content, the company should have final control over the content of the postings. As noted above, a company should also either monitor comments made by third party users on its social media platforms, or for simplicity, disable third parties' ability to post comments at all.

Looking ahead to 2017 and beyond

The FDA guidance and OPDP enforcement actions discussed above show that the FDA is increasing its scrutiny of online promotion efforts. As drug and device companies increase their use of online platforms and social media to promote their products and reach broader audiences and customers, there are bound to be more FDA enforcement actions and clarification guidance and notices in 2017 and beyond. While President Trump has not published any plans specifically on pharmaceutical and medical device promotion on social media and online, he has, however, taken a strong stance against pharmaceutical companies when it comes to their drug pricing[10]. If President Trump's stance on reigning in pharmaceutical companies and their drug prices is any indication of how his Administration will view the drug and device industry in 2017, then these companies may want to make all efforts possible to comply with current guidance and rigorously monitor their online promotions. On the flip side, Trump has criticised the FDA's approach to food safety, discussing it as unnecessary enforcement, so it could also be that he applies the same approach to the FDA oversight described here.

Until the new Administration's objectives in this space become clearer, companies have recent history upon which to rely in order to predict the future. The FDA has foreshadowed increased enforcement and has told companies how to correct mistakes in online promotion through its guidance and enforcement letters. Drug companies should heed these warnings. So, too, should medical device manufacturers.

image: Evgeniy Yatskov / Shutterstock.com

1. 'Draft guidance' means that although the guidance is not mandatory to follow, it outlines what the FDA considers important and appropriate in the use of social media by drug companies, and indicates where the FDA may take enforcement action.
2. The medical device industry should be just as concerned as pharma companies when it comes to online promotions. The Center for Devices and Radiological Health ('CDRH') issues Warning Letters for medical device promotions and marketing. For example, the CDRH recently found, among other violations, that a certain medical device manufacturer's website ad promoted its devices for intended uses beyond the scope of the devices' legal classifications and premarket approval exemptions. The CDRH found that the promotion and its marketing of additional intended uses of the devices voided the devices' exemptions from premarket approval and thus, the devices were adulterated. Further, the CDRH stated that it would refuse entry of the devices into the United States until the devices were no longer adulterated and the violations were corrected. The US Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health Warning Letters (Jan 2017), available at: http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm
3. U.S. Department of Health and Human Services, Food and Drug Administration, 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
4. U.S. Department of Health and Human Services, Food and Drug Administration, 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
5. On 7 November 2016, the FDA requested comments on proposed research into 'Character-Space-Limited Online Prescription Drug Communications.' The FDA expressed the purpose of this proposed research is to "test whether a link to prescription drug risk information can effectively convey the risks associated with a drug when benefit claims about that drug are made" on communication forums with character limitations. The FDA's request is available at https://www.federalregister.gov/documents/2016/11/07/2016-26793/agency-information-collection-activities-proposed-collection-comment-request-character-space-limited
6. U.S. Department of Health and Human Services, Food and Drug Administration, Office of Prescription Drug Promotion Letters (Jan 2017), available at: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm482462.htm#OPDP
7. Further, the OPDP noted these claims violated the Federal Food, Drug and Cosmetic Act since the drug was not even proven to be safe and effective in the United States. Additionally, the video made claims about the superior quality of the drug compared to competitor products and minimised the drug's risks.
8. The FDA has published draft guidance dated December 2011 regarding how a company may respond to unsolicited requests, including on social media platforms, for off-label information about drugs and medical devices, available at: http://www.fda.gov/downloads/drugs/guidances/ucm285145.pdf. It has, in addition, issued a memo in a question-and-answer format dated January 2017 discussing drug and device companies' use of medical product communications, including promotional materials, where the agency makes clear that it still plans to go after off-label promotion, whether truthful or not, available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM537130.pdf
9. http://www.thehealthlawpulse.com/2015/09/kim-kardashian-posts-corrective-ad-on-instagram/
10. http://www.thehealthlawpulse.com/2017/01/how-pharma-cos-can-shape-the-drug-pricing-landscape/