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FDA Guidance Limits Flexibility in Social Media Promotional Communications

Three recently issued draft guidance documents (Draft Guidances) from the U.S. Food and Drug Administration (FDA or Agency) are designed to assist manufacturers in product communications via social media and other interactive media platforms. Generally, the Draft Guidances continue to require social media communications by firms to be 1) truthful and not misleading, and 2) balanced in their presentation of risks and benefits. While the Draft Guidances provide helpful clarification on the application of FDA promotional rules to various social media platforms, they leave many questions unanswered and continue the Agency's overly restrictive approach to truthful, nonmisleading commercial speech. Taken as a whole, the Draft Guidances suggest FDA will continue to apply traditional regulatory requirements as much as possible — an approach that firms may find too restrictive when trying to utilize social media to market their products.

Practice Tips

- **FDA believes not all products are appropriate to promote via some social media platforms**: The Draft Guidances suggest that some products — particularly those that carry a high-risk of serious side-effects — are not good candidates for space-constrained advertising platforms like Twitter because of the inability to provide FDA-required risk and safety information.
- **Manufacturers may be responsible for some third-party content**: While firms are not responsible for content of truly independent third parties, they may be responsible for content produced by third parties over which they have some level of control. While the boundaries are not entirely clear, FDA suggests manufacturers may be responsible for content generated by paid experts, affiliated speakers and other peripheral actors.
- **All content must be truthful and not misleading**: FDA continues to emphasize that firms' promotional content must meet these bedrock requirements. Additionally, FDA continues to require firms to present information on products in a balanced way, stating both risks and benefits in each promotional communication.

Background

Following a Congressional directive,[1] FDA has sought to clarify its regulatory authority and enforcement approach to the growing use of social media by manufacturers through guidance documents, enforcement actions,[2] and public pronouncements by Agency

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1 *See* Food and Drug Administration Safety and Innovation Act § 1121, 21 U.S.C. § 379d-5 (2012) ("Not later than 2 years after July 9, 2012, the Secretary of Health and Human Services shall issue guidance that describes Food and Drug Administration policy regarding the promotion, using the Internet (including social media), of medical products that are regulated by such Administration.").

2 *See, e.g.*, FDA Warning Letter to Novartis Pharmaceuticals Corp.. (Aug. 29, 2010) *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM221325.pdf (concluding that a product was misbranded when the manufacturer created allegedly unbalanced and misleading content that it encouraged Facebook users to "share"); FDA Warning Letter to Zarbee's, Inc., (June 27, 2014) *available at* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2014/ucm403255.htm (warning that "liking" consumer Facebook comments about the efficacy of a product could establish evidence of intended, unapproved use).

officials.[3] FDA's three most recent Draft Guidance documents address specific issues for manufacturers' use of social media: (1) postmarketing submissions of interactive promotional media, (2) correcting misinformation on social media platforms and (3) presenting risk benefit information on platforms with character space limitations.

Draft Guidance #1: Guidance on Postmarketing Submission of Interactive Promotional Media Communications[4]

Social media allows drug, biologics and medical device manufacturers to interact with customers in real time, helping customers to receive quick, responsive information about drugs and devices. FDA regulations governing firms' traditional media communications require drug and biologics manufacturers to submit all postmarketing promotional labeling and advertising to FDA's Office of Prescription Drug Promotion prior to dissemination of the materials. This Draft Guidance addresses the application of this requirement to interactive promotional media communications.

FDA's approach to postmarketing interactive promotional communications allows firms some leeway around the requirement that promotional communications be submitted before the communication is initially displayed. This latitude indicates that the Agency appreciates the difficulty of complying with the current regulations in the age of social media, where firms often interact with customers in real time. The Draft Guidance also suggests that FDA supports firms communicating with consumers via interactive media, and may allow firms some discretion around traditional regulatory requirements in settings where it believes customers are benefiting from firms' use of social media.

It is important to note that this Draft Guidance only applies to communications that are interactive in nature. For static communications, firms should follow FDA's traditional submission rules.

Specific questions answered:

When is a drug or biologics manufacturer required to submit interactive postmarketing promotional materials to the FDA?

- Manufacturer's website: A firm must submit all communications on interactive websites that it operates or has influence over, such as the firm's Facebook page.
- Content generated by employees or agents: A firm must submit communications by its agents or employees on interactive third-party websites. This category may include paid medical experts or public speakers who comment about a firm product on a third-party site, even if the firm did not ask these individuals to make these comments.
- Third-party sites: The Draft Guidance suggests that a manufacturer is responsible for submitting to FDA any interactive promotional communications on third-party sites if the firm has "any control or influence on the third-party site, even if that influence is limited in scope." While exercising some editorial, preview or review privilege will render a firm responsible for promotion on the third-party site, however, merely providing financial support to a website will not generate the same obligations.

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3 *See, e.g.*, Martin Kaste, *As Drug Marketers Embrace Social Media, FDA Mulls New Rules*, NPR (Aug. 12, 2010), http://www.npr.org/blogs/health/2010/08/12/129160626/facebook-tasigna-novartis-fda-warning-letter (quoting then DDMAC Associate Director of Operations, Marci Kiester on the issue of manufacturers' use of social media, "If they're presenting efficacy claims, then there should be a balanced presentation of risks that is reasonably comparable to those benefits").

4 Unlike any of the other 2014 Draft Guidance documents discussed in this alert, this January 2014 Draft Guidance applies only to drugs and biologics, not to medical devices. The Draft Guidance is available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM381352.pdf.

If submission is required, when must it occur?

- Manufacturer's website: Before the interactive website or communication is initially displayed, a firm should submit Form FDA 2253 or Form FDA 2301. The firm should include annotations that describe the parts of the website that are interactive, but need not include screenshots or other visual representations of the interactive portion of the site.
- Third-party sites: If participation is limited to interactive or real-time communications, the firm should submit the home page of the third-party site, the interactive page of the third-party site and the firm's first communication on FDA Form 2253 or Form FDA 2301 at the time of initial display. Once per month the firm should submit an updated listing of all non-restricted sites in which it is an active participant. The firm need not submit screenshots or other visual representation of the communication provided the page is not restricted.

Draft Guidance #2: Correcting Independent Third-Party Misinformation on the Internet/Social Media Platforms[5]

Sites that host user-generated content — such as interactive blogs, social media platforms, and live podcasts — may contain misinformation about a manufacturer's drug, biologic or medical device. FDA defines misinformation as "positive or negative incorrect representations or implications about a firm's product" created and/or disseminated by third parties. FDA considers misinformation a potential threat to public health. Accordingly, this Draft Guidance provides steps firms can take if they wish to correct misinformation. In particular, the Draft Guidance requires corrective communications be relevant to the misinformation, limited and tailored, accurate and nonpromotional, consistent with FDA labeling and/or supported by sufficient evidence, and posted in conjunction with the misinformation.

Specific questions answered:

When should a firm correct misinformation?

A firm must correct misinformation on its own websites, websites it has some control over or postings made by its employees or agents on third-party websites. A firm can choose to correct other information on third-party sites, although it is not required to do so.

If a firm chooses to correct misinformation, how should it provide the correct information?

The firm may (1) post the corrective information directly on the forum, (2) provide the corrective information to the forum's author for her to incorporate or (3) request the author and/or site administrator remove the misinformation and/or allow comments to be posted on the forum. The firm is not responsible for the third party's actions after it has provided the third party with the corrective information.

What if a firm only wants to correct one piece of misinformation?

It usually is acceptable for a firm to decide to correct only a portion of the misinformation about its product. A decision to correct misinformation on one forum does not obligate a firm to correct misinformation on another forum. Similarly, a decision to correct misinformation on a forum does not obligate a firm to correct all of the misinformation on that particular forum.

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5 Released in June 2014. Available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM401079.pdf.

A manufacturer must, however, correct all misinformation in the clearly defined portion of the forum it identifies. While it is unclear exactly what constitutes a "clearly defined portion" of a website, this category may be partially defined by a firm's activity. For example, if a firm corrects several pieces of information contained in comments on a blog, the Agency may determine that all of the comments between the corrections fall into the portion of the page that the firm is responsible for correcting. This policy is designed to discourage firms from choosing to selectively correct misinformation in a way that portrays their product positively.

Draft Guidance #3: Presenting Risk and Benefit Information on Internet/Social Media Platforms With Character Space Limitations[6]

While in other respects FDA has sought to give manufacturers some discretion in the use of social media platforms, the Agency appears to have adopted a traditional and restrictive approach to communication of risk and safety information, particularly with respect to space-limited platforms. To this end, the Draft Guidance regarding such platforms requires each individual communication to contain significant information about risks and indicated uses.

Specific questions answered:

What are the current requirements for information disclosure in advertisements and promotional communications?

- Promotional labeling must be truthful and nonmisleading.
- Certain information, such as the indicated uses and the risks associated with the product, must be included on the promotional labeling.
- Required information must be placed prominently on the labeling and be in terms an ordinary individual can understand.
- Advertisements must present a fair balance between information about risks and benefits and risk information must be presented as prominently as benefit information. For prescription drugs, each part of the advertisement must contain risk information that qualifies any representations about potential benefits.
- A drug is considered misbranded if it fails to reveal material facts related to use.

How do these requirements change when firms are utilizing character- and/or space-restricted platforms?

Overall, the application to restricted platforms appears substantially similar to previous FDA requirements. If a firm makes a benefit claim, it must include information about the product's most serious risks within the same communication. The firm also should include a way for customers to access more complete information about the risks associated with a product, such as providing a hyperlink to a page describing only risk information. The hyperlink should be direct, and the landing page should not be promotional in tone or content. Firms also must include both the proprietary name and established name of a product within each communication.

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6 Released June of 2014. Available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM401087.pdf.

Other Recent FDA Guidance About Advertisements

In addition to the three recent Draft Guidances, FDA has revised additional draft guidance documents in 2013 and 2014. These revised guidances, which do not contain significant changes to address issues raised by the use of new or social media, suggest that FDA does not believe best practices vary based upon the type of media used by a firm.

- In particular, in 2013 FDA revised its guidance regarding Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling[7] for drugs and biologics, most recommendations in the revised guidance apply equally to traditional and nontraditional media. The only provision that seems to contemplate the impact of these new technologies is the requirement that the proprietary and established name of a product appear prominently at least once per webpage.
- Similarly FDA's revised guidance regarding Distributing Scientific and Medical Publications on Unapproved New Uses[8] emphasizes that, consistent with its longstanding practice, FDA will not use a manufacturer's distribution of scientific publications that provide information about an unapproved use of a drug, biologic or medical device as evidence that the manufacturer intends the product be used for an unapproved use. This revised guidance does not specifically address the dissemination of such publications through new or social media.

Implications

Taken together, the Draft Guidances and revised guidances issued 2013 and 2014 suggest that while FDA recognizes some of the unique characteristics of social media platforms, the Agency will continue to apply traditional regulatory requirements as much as possible. While aimed at ensuring that promotional communications are balanced in their presentation of risks and benefits and are truthful and not misleading, these requirements may in many respects result in overly restrictive approach that is difficult to square with the realities of new and social media platforms.

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7 Released in November 2013. Available at: http://www.fda.gov/downloads/Drugs/.../Guidances/ucm070076.pdf.

8 Released in February 2014. Available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM387652.pdf.