REGULATORY FOCUS

Applying FDA's Rules in the new World of Online Marketing and Crowdfunding

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This article provides an overview of US Food and Drug Administration (FDA) authority, regulations and policies regarding promotion of medical devices through websites and social media. The principles discussed generally apply to promotion of pharmaceutical products also. The author discusses internet and social media marketing and online preapproval communications, specifically addressing "crowdfunding" and where FDA may focus its enforcement activity in this newer context. This article was adapted from a RAPS Convergence presentation held in Philadelphia 21-24 September 2019.

General Rules of Marketing and Promotion

What are claims?

Under the *Federal Food, Drug, and Cosmetic Act* (*FD&C Act*),[1] FDA has jurisdiction over medical device labeling, as well as over advertising of prescription drugs and restricted devices. Importantly, FDA and the courts have broadly interpreted "labeling" to encompass essentially any material that is used to facilitate the sale of a product; it may, but need not be, physically affixed to the product package.[2] Examples include:

- letters/e-mails to customers

- brochures/flyers
- price lists/catalogues
- trade show exhibits
- literature
- website materials
- social media posts and interactions
- testimonials by health care professionals or patients

Advertising can include information in published journals, magazines or other periodicals, and broadcasts through media such as radio and television. Promotion refers to any activity meant to facilitate the sale of a medical device and includes all oral and written statements by a manufacturer or its representative, regardless of medium, whether in person (e.g., presenting product capabilities at public forums), in print (e.g., distributed collateral) or online.

Unless exempted by regulation, a medical device requires either 510(k) clearance, premarket approval (PMA) or *de novo* down-classification prior to commercial distribution. In the US, commercial distribution refers to displaying, promoting or otherwise offering for sale for a specific intended purpose, taking orders or entering into distribution agreements and discussing when the product will be available. Company labeling/advertising may promote a device only for cleared/approved intended uses. Advertising, promoting or labeling a product for a new intended use that requires premarket clearance or approval, may be deemed adulteration and/or misbranding in violation of the *FD&C Act*.

Medical device claims are tied to the device's intended use and the company's intent in selling it. These may be express or implied. As a general rule, claims must be adequately substantiated by scientifically valid data (e.g., statistically valid sample size, peer-reviewed publication) at the time the claim is disseminated in order not to be considered false or misleading (and thereby in violation of the *FD&C Act*). Relevant facts about underlying studies should be disclosed. For cleared devices, data to support certain claims may sometimes be kept in the sponsor's regulatory files without requiring submission of data or a [new] 510(k) notice. However, FDA increasingly seeks to review the support for a claim prior to its being made. Significant performance claims must be submitted for review. Clinical outcome claims must generally be supported by clinical data. For PMA-approved (Class III) devices, approval of a PMA supplement is generally required to support new claims, even if there has been no change to intended use.

FDA also may find a claim false/misleading if it reflects misstatement or omission of material fact,[3] lack of fair balance, lack of adequate directions for use or misleading representation with respect to another device. Risk information should not be minimized (e.g., tiny font at the very end) and should be presented in a manner that is balanced and consistent with the presentation of benefits.[4] FDA considers comparative/superiority claims

inherently misleading unless based on appropriate head-to-head testing.[5] In addition, the agency is sensitive to claims about FDA regulatory status, as it does not want to impart an erroneous impression of official endorsement of a product.[6]

Marketing, Advertising and Promotion in the Online World

The emergence of the internet and social media, such as blogs, Facebook and Twitter, have opened new channels of communication and opportunities for advertising, marking and promotion of pharmaceuticals and medical devices. These avenues have raised questions because they are not always immediately comparable to traditional marketing as historically regulated by FDA. The key message is that regardless of the medium used by the product manufacturer, the fundamental advertising, marketing and promotion "rules of the road" remain the same. In other words, FDA holds companies responsible for their websites and online activities just as they do for other promotional material. Use of newer channels does not change the agency's expectation that devices be promoted in a manner consistent with the cleared/approved labeling and that marketing include all information as required by existing regulations and policies.

However, when compared to traditional print marketing, marketing through the internet/social media does create new challenges because of the differences in format, audience and accessibility. Many companies have internal Standard Operating Procedures (SOPs) to ensure consistent activities in this space, particularly with respect to controlling employee statements on today's social media platforms. FDA has issued Warning Letters for misuse of the internet and social media for a number of issues which are not unique to online marketing but do manifest there somewhat differently.

A Bit of Reprieve

FDA draft guidance[7,8] issued in 2014 provides some assistance in understanding the agency's interpretation of how existing rules should be applied in the context of the newer internet promotional vehicles. This guidance also provides a bit of leeway for manufacturers to navigate limited-character settings (e.g., Twitter) by deferring complete instructions for use to another site and providing a mechanism (e.g., hyperlink) to allow direct access to a more complete discussion of risks. Nevertheless, each post or webpage is required to provide a balanced presentation of both risks and benefits, and must include at a minimum the most serious risks and the risks associated with any discussed particular use or population. Importantly, just because a platform exists does not mean it is appropriate for a particular product—if it cannot adequately convey the key information in a non-misleading manner, it should not be used.

Separately, in June 2018, FDA finalized two guidance documents which providing manufacturers some additional leeway in communications about their drugs/devices. While FDA has, through these guidance documents,

defined a broader category of claims as "on label," it stops short of permitting claims regarding unapproved uses, patient populations, doses and situations that might shift the risk/benefit balance. The types of information covered by both still constitute promotion, so corresponding requirements still apply (not false/misleading, balanced, etc.)

In its guidance "*Medical Product Communications That are Consistent With the FDA-Required Labeling*,"[9] the agency concedes that FDA-required labeling is not meant to encompass all information about a drug/device and its approved uses. This is important, as cleared or approved indications for use range from one sentence to a few paragraphs. If a company can only use that text to promote the product, it would be challenging from a business perspective. To that end, the guidance permits manufacturer communications to include claims that are not contained in, but "consistent with," FDA-required labeling as long as they consist of truthful, non-misleading data/information about cleared/approved use(s), and clarifies what that entails. Information/data supporting a "consistent" claim that is not misleading must be "scientifically appropriate and statistically sound." The "consistent with labeling" framework is more notable for PMA-approved devices, as for cleared (and exempt) devices, the guidance directs manufacturers to the pre-existing framework for assessing 510(k) modifications.

FDA's guidance, "*Drug and Device Manufacturer Communications with Payors, Formulary Committees and Similar Entities*,"[10] defines a specific audience with appropriate knowledge/expertise ("payors") and related entities—to whom firms may disseminate Health Care Economic Information (HCEI) that is "related to" a prescription product's cleared or approved indication. Importantly, while this guidance also allows some claims which are not directly encompassed by the product's clearance or approval, the audiences with whom they may be shared explicitly exclude patients and health care professional users.

Internet and Social Media Promotion and Enforcement

FDA considers website materials as "labeling." This includes information to which a company links on its website. Portal pages should direct visitor to sections of the site if clearance/approval is not universal. Disclaimers regarding US regulatory status are not enough. Regarding press releases, FDA permits more information than otherwise typically allowed in labeling, but restrictions still apply and the material should be in a distinct, clearly identified section of the website.

Social media platforms using the internet and social media tools, such as blogs, YouTube, Instagram and Facebook have raised unique challenges as compared to traditional print marketing. In terms of social media marketing, a company is responsible for any site/content that it owns, controls, creates, influences or operates, content generated by an employee or agent acting on behalf of the firm, and promotion on third-party sites where it has any control

or influence (e.g., editorial, preview or review privilege). This includes marketing communication carried by someone else but on behalf of the firm. However, a company is not considered responsible for content that is truly independent from it (e.g., user-generated) and not prompted by the company, even if it is on a company-owned or -controlled medium, message board or chat room. It is unclear exactly where FDA draws the line on what constitutes "prompting" in this context, so many companies prefer a cautious approach to third-party marketing of their products.

More specifically, companies are responsible for the following:

- providing fair balance and required context on platforms with space restrictions and functionality limitations
- monitoring user-generated content for Adverse Event (AE) reporting requirements
- responding to "misinformation" posted by users on webpages owned, operated or influenced by the company (includes potential off-label information and false, misleading or biased materials)
- controlling employees' comments and responses

The fundamental requirements for promoting via social media are the same as for any other forum, such as accuracy, being non-misleading, including key risk information and fair balance. The key violations cited in internet and social media marketing are the same as in other promotional platforms and center around promotion outside the scope of clearance/approval, promotion without any clearance/approval and misleading presentations (e.g., unbalanced presentation of risks/benefits). The difference is that the violations are carried out via links on company websites, search engines and meta-tagging as opposed to other, more "traditional" means. FDA is now looking to such "tech-savvy" applications as a basis for construing evidence of company intent or inappropriate promotion.

A new Type of Preapproval Communication: Crowdfunding Medical Devices

A key concern with any preapproval communication is that it may lead potential users to forgo cleared/approved therapies based on the promise of a pipeline product that has not been and may never be found safe and effective. FDA does not want a false impression to be given; its primary mission is to protect the public health.

Against this background, newer avenues for preapproval communications raise some unique questions not explicitly covered by FDA's existing policies. One area for consideration is "crowdfunding."[11] Crowdfunding websites enable companies to showcase uncleared/unapproved devices and to promise or provide them to consumers. One of the draws is that it enables capital to be raised from a larger pool of people than was historically possible through standard funding avenues; it also rapidly raises awareness of (and interest in) the product. Questions that apply to all preapproval communications

including crowdfunding, but which manifest a bit differently in this context, include: when does soliciting for funding of a developmental product become preapproval commercialization or "priming the market?" Are companies "priming the market" when social media is involved? At what point does funding become a "purchase?" Other important issues include:

- the potential inappropriate display/promotion of an investigational device for a specific intended purpose
- the perception of taking orders or [preparing for] selling an uncleared device through its delivery or promising to deliver it upon FDA clearance
- the promotion to a non-specific/layperson audience may encourage

FDA to scrutinize communications more closely as "direct to consumer" (DTC) marketing, because the audience is less educated in assessing risks/benefits than health care professionals.

There is a notable lack of direct FDA guidance on what a company should or should not do in terms of crowdfunding marketing/promotion. An article in the *Boston Globe* a few years ago (2015) reported FDA as stating that companies must follow marketing and advertising regulations regardless of how funds are being raised and noted the agency did not respond to questions on the legality of specific crowdfunding practices, saying it will tailor its regulatory approach as appropriate.[12] This emphasizes that the fundamental rules in this context are the same, but does not give companies any practical advice on how to move forward as the marketing mediums shift and evolve.

With a dearth of targeted FDA guidelines addressing crowdfunding, regulatory professionals are left striving to apply existing rules and guidance and hope they are doing it right. In this situation, consideration of existing legal frameworks, current agency policies where there may be parallels, and any cases of FDA enforcement action or intervention in a similar campaign provides useful insights for evaluating the likelihood of FDA attention to a particular campaign. Companies set to engage in crowdfunding should assess the proposed campaign and its website per FDA's general framework, and provide only truthful, accurate and non-misleading information. They also should not imply a product's safety or effectiveness where this has not yet demonstrated to FDA. A key concern (not specific to crowdfunding, but important to look out for) are videos, images or statements on the website that may violate FDA rules/policies around preapproval commercialization. Additional nuances more unique to this context include:

- stage of product development
- higher-risk devices are more likely to garner FDA concern
- content of campaign, e.g., explicit clinical outcome claims or superiority to alternatives versus "general wellness" type claims

- whether the device's FDA regulatory status is conspicuously stated
- if product is 510(k)-pending, whether campaign is consistent with FDA's Compliance Policy Guide (CPG)[13]
- consistency with FDA's laws and policies for investigational devices[14]
- structure of investment

Factual statements limited to technical characteristics or statements regarding the company's mission, are less likely to garner attention than significant claims related to a product's safety or effectiveness. If a 510(k) is pending, all statements should be limited to and consistent with what was submitted to FDA. In terms of the campaign's structure, providing or promising to provide the device might be seen as tantamount to taking orders for it or generating a list of future customers, both of which practices would be a violation of FDA requirements. Specifically, a "promise" of a device in exchange for a donation is more likely to generate FDA concern as a 'pre-order,' or purchase, as opposed to more limited "rewards." Along the same lines, if there is no promise of a coming device and/or the company is only fundraising for early R&D or to support a planned regulatory filing, that is both less controversial and less likely to raise concern from an FDA regulatory standpoint. Therefore, it is important for statements to make clear exactly in what manner contributors' money will be used.

Precedent also sheds some light on FDA's priorities in this space. A number of recent medical device crowdfunding campaigns have been cut short without clarity as to whether this was motivated by an FDA communication.[15,16] In other cases, products that appear to warrant FDA regulation as a medical device have been funded in this manner without evidence of any FDA objection to their lack of clearance or the claims being made.[17] Based on available precedent, FDA is more likely to step in where the crowdfunding platform is used to conduct DTC marketing for a type of device it finds particularly concerning. For example, FDA has long scrutinized promotion/sale of genetic testing without FDA review or physician oversight (recall, for instance, the Warning Letter issued to 23andMe expressing concerns over clinical/analytical validity). When Tute Genomics offered to sequence the entire genome and exome of contributors to its Kickstarter campaign, and to provide them with a report containing information on actionable variants in their DNA and the risks of developing various diseases, FDA took notice. The company suspended the campaign only two days after it began, informing backers that the agency had expressed concern.[18]

Takeaways

Newer avenues for internet marketing, including in the sphere of preapproval communications, raise unique questions not explicitly covered by existing regulations and FDA policies. Crowdfunding is an interesting new way to raise money for new inventions from a broader population base, and one which may be more representative of the full audience that would use a device; but it also has potential pitfalls. Similarly, social media and other internet

marketing presents great opportunities but also notable risks. With very limited public instructions on how to proceed with specific types of such newer communications, companies must interpret the available guidance and precedent and determine how much risk they are willing to incur in the gray areas. Signs indicate that FDA will continue to apply its governing risk-based framework in deciding where to focus its attention; by and large, "triggers" for FDA scrutiny appear when statements or practices are inconsistent with past policy/enforcement and/or raise notable risks for consumers. Ultimately, to successfully balance business needs with regulatory compliance in selecting a path forward, companies will need to take into consideration existing regulations/policies, past actions by FDA and common sense. The "rules of the road" remain the same; how they are applied in practice in these newer contexts just takes a bit more thinking.

References

1. *Federal Food, Drug, and Cosmetic Act* (*FD&C Act*). FDA website. https://www.fda.gov/regulatory-information/laws-enforced-fda/federal-food-drug-and-cosmetic-act-fdc-act. Accessed 6 January 2020.
2. 21 CFR § 1.3(b)], Kordel v. US, U.S. Supreme Court, 1948.
3. "Material facts" refer to relevant warnings and risk information, qualifying requirements for use, potential consequences from use of a product as suggested in the piece and adequate directions for use (prescription and over-the-counter devices have slightly different requirements in this last respect, but the fundamental categories of information that must be included are the same).
4. FDA's 2009 Draft Guidance, Presenting Risk Information in Prescription Drug and Medical Device Promotion. FDA website. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/presenting-risk-information-prescription-drug-and-medical-device-promotion. Accessed 7 January 2020.
5. 21 CFR Part 801: Labeling. Subpart A: General Labeling Provisions. Sec. 801.6 Medical Devices; Misleading Statements. "Among representations in the labeling of a device which render such device misbranded is a false or misleading representation with respect to another device or a drug or food or cosmetic." Even where a company is comparing to a prior version of its own device, head-to-head supportive testing should be provided. Typically, such testing must be reviewed by FDA prior to serving as a basis for claims. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=801.6. Accessed 7 January 2020.
6. 21 CFR Part 807: Establishment Registration and Device Listing for Manufacturers and Initial Importers of Devices. Subpart B: Procedures for Device Establishments. Sec. 807.39 Misbranding by Reference to Establishment Registration or to Registration Number. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=807.39. Accessed 7 January 2020.
7. *Guidance for Industry. Internet/Social Media Platforms with Character Space Limitations: Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices. Draft Guidance*. FDA website. https://www.fda.gov/media/88551/download. Accessed 6 January 2020.

8. *Guidance for Industry. Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices. Draft Guidance.* FDA website. https://www.fda.gov/media/88545/download. Accessed 6 January 2020.
9. *Medical Product Communications That Are Consistent With the FDA-Required Labeling: Questions and Answers. Guidance for Industry.* June 2018. FDA website. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-product-communications-are-consistent-fda-required-labeling-questions-and-answers. Accessed 6 January 2020.
10. *Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities: Questions and Answers. Guidance for Industry and Review Staff.* June 2018. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/drug-and-device-manufacturer-communications-payors-formulary-committees-and-similar-entities. Accessed 6 January 2020.
11. There are two types of crowdfunding. The first, on which this article focuses, is rewards-based: individuals donate to a cause or pre-purchase products without getting shares or a stake in the recipient of the funds. The second is equity/investment, where funding is tied to an equity interest granted to the payor.
12. "Crowdfunding of Medical Devices Raises Money and Questions." *Boston Globe.* 8 September 2015.
13. *Compliance Policy Guide*. CPG Sec. 300.600. Commercial Distribution with Regard to Premarket Notification (Section 510(k)). September 1987. FDA website. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-300600-commercial-distribution-regard-premarket-notification-section-510k. Accessed 6 January 2020.
14. 21 CFR Part 812 Investigational Device Exemptions and related FDA guidance documents.
15. "Cur is Crowdfunding a Medical Device That Isn't Cleared by the FDA and That's a Problem." *The Verge*. 14 May 2015.
16. Buhr S. "Scanadu to Shut Down Support for its Scout Device per FDA Regulation and Customers are mad." TechCrunch.com. 13 December 2016.
17. For instance, Upright Technologies promoted its wearable biofeedback device intended to correct posture by vibrating to remind the user to sit straighter. The website had offers of sale comparable to other crowdfunding campaigns and explicit efficacy/clinical outcome claims. The company appeared to have data supporting its assertions, but the device was not, and still is not, FDA-cleared. https://www.kickstarter.com/projects/upright-go/upright-go-fix-your-screen-slouch-correct-your-pos. Accessed 6 January 2020.
18. "Tute Genomics Suspends Kickstarter Campaign Following FDA Letter." SciPol. Duke University. 3 October 2016. http://scipol.duke.edu/content/tute-genomics-suspends-kickstarter-campaign-following-fda-letter. Accessed 6 January 2020.

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