Do We ‘Like’ FDA’s ‘First Social Media Guidance’ or is it Nothing to ‘Tweet’ About?

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Do We ‘Like’ FDA’s ‘First Social Media Guidance’ or is it Nothing to ‘Tweet’ About?

I. INTRODUCTION

A huge number of Americans, across various populations and demographics, are using the Internet and various social or interactive media platforms to obtain health information, including insights into their diseases, conditions and associated treatment options. In 2012, 72% of Internet users looked online for health information. Drug and device companies are attempting to engage this audience through approximately 200 Twitter feeds, over 150 sponsored or funded YouTube channels, and over 100 Facebook pages. Digital advertising budgets were expected to reach 20% in 2013 out of total marketing budgets, with big increases expected in “social media initiatives for consumers.” Nonetheless, there remain major limitations on manufacturers’ full involvement in social and interactive promotional media due to remaining regulatory uncertainties as to the compliant use of such platforms.

To date, Food and Drug Administration (FDA) regulations and guidance have failed to adequately address the “unique technological features” and “novel presentation and content features” of such media. While FDA has issued several warning and untitled letters regarding online media, such actions have failed to provide the necessary and flexible guidance that industry needs. FDA’s recently issued “Draft Guidance for Industry: Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics” (Guidance), focused on fulfilling post-marketing submission requirements, provides some useful insights into FDA’s current and future approach to interactive promotional media. However, as FDA moves forward on developing additional FDA guidance on the use of links, the correction of third-party misinformation about drugs or devices, space limitations for risk and benefit information, and the reporting of adverse events, it must consider whether the application of its prior policies governing print and broadcast media remain relevant and appropriate for the online world. This Policy Forum provides an overview of the challenges faced by manufacturers, the new FDA Draft Guidance, and some recommendations on key issues for future guidance.
POLICY RECOMMENDATIONS

• Industry and other stakeholders should begin analyzing FDA’s Postmarketing Interactive Promotional Media Guidance and implement any necessary changes or updates to current interactive media policies, procedures or practices, including employee and vendor training.

• The forthcoming additional FDA guidance on the use of links, the correction of third-party misinformation about drugs or devices, and space limitations for risk and benefit information will be critical to the further development of those policies and practices, and hopefully they will allow more realistic industry engagement in online media.

• FDA should not impose any undue burdens on industry regarding either proactive communications or the monitoring, surveillance, correction and reporting of information not controlled or influenced by manufacturers. Recent First Amendment case law must be a central consideration in evaluating policies in this area, and such restrictions may run afoul of protections for industry speech – and constitute unlawful discrimination against such speech – if not framed carefully.

II. BACKGROUND

The United States is one of the only jurisdictions in the world to allow direct-to-consumer (DTC) advertising of pharmaceutical and medical device products. FDA, through its Office of Prescription Drug Promotion (OPDP), has responsibility for regulating the promotion of prescription drugs and biologics directed to both consumers and healthcare professionals (HCPs). Section 201(m) of the Federal Food, Drug, and Cosmetic Act (FDCA) defines labeling as “all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.” In a decision that has long been a source of debate as to the boundaries of FDA’s jurisdiction, particularly with respect to the Internet, the U.S. Supreme Court has held that the language “accompanying such article” includes materials that have a “textual relationship” to the drug or device product article.

FDA generally recognizes two types of labeling for drugs: (1) FDA-required labeling (e.g., the prescribing information or PI); and (2) promotional labeling. According to FDA’s interpretation of the law, promotional labeling is generally any labeling, other than the FDA-required labeling, that is devised and distributed for promotion of a product. Generally, FDA regulations require promotional materials — regardless of medium — to present certain risk information (e.g., warnings, precautions, side effects, contraindications, etc.) in a “fair and balanced” manner. That is, the entire promotional material or advertisement must present a fair and balanced account of all clinically relevant information, and a drug’s risk must be presented prominently so that the promotional
material does not put more emphasis on the drug’s benefits than its risks. Additionally, a drug is misbranded if its advertising is false or misleading, or fails to reveal material facts.

FDA requires that companies submit promotional materials to FDA at the time of their initial dissemination, and OPDP monitors television ads, magazines, and drug companies’ web sites to ensure compliance with FDA regulations. The Agency also relies on information gleaned from complaints submitted through its “Bad Ad” Program. OPDP’s “high priority” areas of promotional enforcement include: (1) new products; (2) products with significant risks; (3) products cited for violations in past; (4) products cited in complaints; and (5) products with far reaching campaigns.

Between 2008 and 2012, FDA found “290 digital violations,” over half of which were for companies that omitted or minimized risk information, while eighteen percent overstated efficacy. However, of 173 action letters issued in this period, less than 1 percent involved “the nature of the social media mechanism that brought about the violation.” Nevertheless, “omission and minimization of risk information” was one of the “most common violations cited in [OPDP] regulatory letters in 2013,” including “digital” promotional materials.

Proponents of industry promotional communications argue that they: (1) provide useful information to consumers that may result in better health; (2) can advance public health by encouraging more people to talk with their HCPs about problems, particularly under-treated, under-diagnosed conditions; (3) can help remove the stigma associated with certain diseases (e.g., depression); and (4) can remind patients to refill prescriptions and help them adhere to their medication regimens. Critics maintain that such promotion is troublesome because they: (1) may contain false or misleading information; (2) do not provide enough information about the risks and negative effects; (3) may not advance — and may even threaten — public health; (4) encourage overuse of prescription drugs; and (5) encourage the use of costly treatments, instead of generics that may be equivalent, which raises healthcare costs.

FDA recognizes that promotional labeling “can provide useful information for consumers to work with their health care professionals to make wise decisions about treatment.” Moreover, there is significant evidence that unduly limiting DTC promotion could “affect public health” by leaving people who would benefit from a new drug unaware of its availability, causing them not to seek treatment in the absence of such advertising. While FDA has historically regulated promotional materials in magazines, newspapers, and on television, the growing use of the Internet and social media by patients, healthcare practitioners and industry has spurred a new kind of medical product promotion. There are various types of interactive media, including blogs, microblogs, podcasts, video sharing, widgets, wikis, social networking sites, content communities, collaborative projects, and virtual social or game worlds. These constantly changing interactive media platforms have made FDA’s job of reviewing such materials and fitting them into traditional regulatory standards an increasingly difficult task.
III. ISSUES IN DISPUTE

A. The Challenges Posed by Interactive Promotional Media

The use of interactive promotional media creates several challenges for manufacturers. For example, providing fair balance is difficult because Twitter, sponsored links, and share widgets generally do not have enough space for FDA required risk disclosures. In April 2009, FDA issued 14 untitled letters to drug manufacturers who sponsored search-driven ads on Google.\(^{35}\) The letters asserted that information in a sponsored link that includes a website address consisting of the proprietary name for a drug, and that appears on the results page of an Internet search engine when a key word search is conducted, is not a reminder ad but instead is “labeling” and “advertising.”\(^ {36}\) As a result, FDA asserted that all of the mandatory risk information “must likewise appear on the face of the sponsored link and will not be considered in the disclosure analysis even if fully . . . available one click away.”\(^ {37}\)

FDA also sent an untitled letter to Novartis regarding information generated by a “Facebook Share” widget on one of its websites. Clicking on the widget sent Novartis-authored information about the leukemia drug Tasigna® to a user’s Facebook page. FDA alleged that the “shared content [was] misleading because it [made] representations about the efficacy of Tasigna but fail[ed] to communicate any risk information associated with the use of [the] drug.”\(^ {38}\) For promotional materials to be truthful and non-misleading, “they must contain risk information in each part as necessary to qualify any claims made about the drug.”\(^ {39}\) FDA also found a sponsored link misleading, even though it made “no explicit claim about the drug.”\(^ {40}\) This letter illustrates how FDA may find an “implied connection and require risk disclosures in the link text” even if the sponsored link or widget does not explicitly state that the product treats the disease.\(^ {41}\)

Moreover, unlike television, interactive promotional media platforms allow consumers to respond to online promotional materials and communicate their views with others. While the opportunity for patients to share their experiences may have great value, this capability also present risks because erroneous information may deter patients from taking a needed medication.

Various stakeholders are concerned that manufacturers may be influencing or controlling content on web-based social media by supporting “third-party bloggers, posters, and Twitter users who make flattering claims and discredit negative claims about products in online discussions.”\(^ {42}\) Conversely, it may no longer be technically possible for companies to clearly distinguish a company-generated online activity from third-party content because applications such as Google’s “Sidewiki” can “layer a social network of commentary onto any existing static Web site, with or without the site owner’s consent.”\(^ {43}\)

Without further FDA guidance, the difficulties posed by interactive promotional media will continue. For example, FDA sent a Warning Letter to AMARC Enterprises regarding its (non-FDA approved) dietary supplement Poly MVA®. The letter – the first of its kind – cited, among a broad range of more serious alleged violations, a March 10, 2011 post on AMRAC’s Poly MVA Facebook page, in which a consumer noted how Poly MVA had “done wonders for me;”\(^ {44}\) FDA also cited a Facebook
post that provided “a link to [a] blog post.” FDA took issue with the fact that AMRAC “liked” this favorable consumer testimonial.\textsuperscript{45} It remains unclear whether ‘liking’ is akin to ‘favoriting’ a Twitter user, ‘retweeting’ a post, “sharing” or “re-posting” content from other uses, or “+1” a post on Google+.\textsuperscript{46}

Despite these challenges, the current state of regulatory ambiguity, which has resulted in an artificial absence of a true industry voice in many interactive media, is counterproductive. Indeed, great value can be achieved by encouraging manufacturers to participate in these online interactions. Although DTC ads are often the subject of criticism, the actual experience is instructive: a recent survey showed that almost 50\% of physicians agreed that DTC ads inform, educate and empower patients; 68\% agreed that DTC ads encourage patients to contact a physician; 64\% agreed that DTC ads promote patient dialogue with healthcare providers; and over 50\% agreed that DTC ads removed stigma associated with certain diseases.\textsuperscript{47} Such findings should encourage FDA to develop policies that encourage industry to increase its presence and investment in interactive media platforms.\textsuperscript{48}

Continuing to delay full pharmaceutical and medical device industry social media involvement may only harm patients further because companies will be unable to fight the continued rise of “lousy information.”\textsuperscript{49} Understanding the regulatory landscape of interactive promotional media will also be critical for companies to realize the promise of mobile medical applications (“apps”) in delivering effective patient educational information through general health and wellness apps, as well as those designed for medication adherence and drug-interaction warnings. Until FDA finalizes guidance on the use of links and character space limitations on such apps, however, this area remains uncertain.

B. FDA’s Recent Draft Guidance

As noted, FDA issued its first true draft social media-focused guidance in January 2014, entitled “Draft Guidance for Industry: Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics.” The Draft Guidance acknowledges the “unique technological features” and “novel presentation and content features” of “interactive promotional media,” which FDA defines to include “modern tools and technologies that often allow for real-time communications and interactions (e.g., blogs, microblogs, social networking sites, online communities, and live podcasts) that firms use to promote their drugs.”\textsuperscript{50} The Draft Guidance: (1) describes FDA’s current thinking on what the Agency considers to be interactive promotional media; (2) outlines the considerations taken into account in determining if product communications using interactive technologies are subject to FDA’s postmarketing submission requirements; and (3) makes recommendations for how firms can fulfill the regulatory requirement to submit postmarketing promotional materials to the FDA in a practical manner to address the potential volume of real-time information that is continuously posted and shared through various interactive promotional media platforms.

Specifically, the Draft Guidance states that firms are responsible for submitting postmarketing information if they “own, control, create, influence, or operate” the interactive promotional media platform.\textsuperscript{51} In fact, FDA emphasizes that a firm is responsible for promotion both on sites that it owns or controls and third-party sites if the firm “exerts influence over a site in any particular, even
if the influence is limited in scope," such as “collaborat[ing] on or ha[ving] editorial, preview, or review privilege over the content provided.”

FDA also explained that firms are responsible for content generated by an employee or agent who is acting on behalf of the firm to promote the firm's product. This position is consistent with a 2011 FDA Untitled Letter that cited a YouTube video, posted by a Warner Chilcott sales rep, for being misleading, failing to disclose the drug indication, failing to present risk information, and omitting material facts.

However, in an important acknowledgement by FDA, the Draft Guidance states that firms are "generally not responsible for [user generated content] (UGC) that is truly independent of the firm (i.e., is not produced by, or on behalf of, or prompted by the firm in any particular)." The remainder of the Guidance explains the frequency with which firms must submit promotional materials generated on these platforms to comply with the "initial dissemination" requirements.

For example, at the time of "initial display," FDA explained that firms should submit in "its entirety all sites for which it is responsible," including the "comprehensive static product website with the addition of the interactive or real-time components." FDA asked that firms "include annotations to describe the parts that are interactive and allow for real-time communications" and to annotate and resubmit any subsequent changes to their interactive platforms at the time of initial display (e.g., resubmission). For third-party sites on which the firm's participation is limited to interactive or real-time communications, FDA asked that firms submit the home page, interactive page, and the firm's first communication on the third-party site at the time of initial display. If the firm-owned or third-party site is non-restricted (e.g., publicly accessible without a password or subscription), FDA will allow firms to submit a monthly updated listing of such sites; firms do not need to submit screenshots or other visual representations of the actual interactive or real-time communications. For firm-owned or third-party sites with restricted access, FDA asked that firms submit on a monthly basis "all [UGC] related to the discussion . . . to adequately provide context to facilitate the review," including screenshots and interactive or real-time communications. Interestingly, FDA stated that these principles for submission "apply . . . regardless of the target audience" of the interactive promotional media. This position may explain the Agency's recent and highly controversial Warning Letter to Aegerion Pharmaceuticals, Inc., focusing on certain oral statements the company's CEO made on CNBC's television show "Fast Money," which is directed to investors. This letter also demonstrates the risk firms may face when corporate executives use interactive promotional media.

While the recent Draft Guidance provides some limited insights into FDA's general approach to pharmaceutical companies' responsibilities with respect to their interactions with interactive promotional media, many questions remain open. FDA has already announced plans to publish three additional Guidance documents on interactive promotional media this year that may address some of those issues.

IV. RECOMMENDATIONS

In moving forward in this area, FDA should consider whether a more fundamental change in its approach to promotion is warranted in the interactive promotional media context. Some of the new policies FDA should consider include the following.
A. Correcting Independent-Third Party Misinformation

FDA should consider allowing companies to have broad latitude in taking a proactive approach – wholly at their discretion – to correcting misinformation about their products that appears in interactive media, including with respect to third-party interactive media that they do not control or influence. FDA’s revised and future guidance, therefore, should include recommendations for industry and stakeholders on how to correct such misinformation in a compliant manner, with realistic requirements for disclosures and balance appropriate for the space and other limitations of such media.

In such guidance, FDA should also explain acceptable ways, using examples, that manufacturers can correct misinformation without triggering full requirements applicable to promotional materials. For example, an exemption from promotional labeling requirements could be established if language used to correct third-party misinformation remains consistent with the product’s PI, addresses the specific misinformation only, provides a link to the approved labeling if possible, and is reviewed by an appropriate internal compliance process before posting. FDA could request additional information if necessary and monitor corrective statements through general surveillance or recordkeeping requirements. Alternatively, FDA could ask companies to certify annually that they are correcting third-party misinformation in compliance with FDA’s future guidance.

B. Disclosure

Manufacturers that post promotional content or corrective information on interactive promotional media should be transparent about the relationship of the author to the company, but the rules for such disclosure should be reasonable and appropriate in light of the nature of the media. FDA has stated that such disclosure could be achieved by including a firm’s identifier (e.g., name or logo) as part of the communication. However, on Facebook, Twitter, LinkedIn, or other platforms, users have profiles that may indicate their place of employment (e.g., “Social Media Manager, Company XYZ”). Thus, FDA should make clear when such profiles are sufficient to satisfy disclosure requirements. Similarly, in blogs, chat rooms, or other forums where users may not have profiles or are anonymous, FDA should clarify whether the use of a disclaimer (e.g., “I am an employee at Company X . . .”) in posts is sufficient.

FDA should also make clear that manufacturers are not responsible for statements in interactive media made by investigators, consultants, and other contractors when such statements are not within the ambit of their duties or contractual relationship. For example, a physician may receive funds for research or education from a manufacturer, but absent a contractual limitation they should be free to comment about disease states and products as independent individuals without their interactive activities being attributed to one or more of the companies with which they maintain a relationship. Given the increased transparency stemming from the Physician Payments Sunshine Act, anyone concerned about the potential conflicts of interest of such parties will soon have ample information available to make their own judgments about the potential influence of such relationships on interactive media participation.
C. The Use of Links to Provide Risk Information

FDA should formally permit manufacturers to use the “one-click away” rule. The one-click away rule is consistent with FDA’s approach with DTC TV ads, which direct viewers to look for full prescribing and risk information either on the Internet or in a print ad due to the lack of space in the broadcast context. Adopting this rule would satisfy FDA concerns because the nature and use of hyperlinks on the Internet make it more likely that consumers would click to receive the risk information. In drafting this guidance, FDA should consider the FTC’s recently released guidance on “.com Disclosures.” For example, FDA should consider allowing the use of hyperlinks when disclosure in a space-constrained ad is not possible. Under these circumstances, FDA could recommend: (1) making the link obvious; (2) labeling the hyperlink appropriately to convey the importance, nature, and relevance of the information it leads to; (3) using consistent hyperlink styles; (4) placing the hyperlink as close as possible to the relevant information it qualifies and make it noticeable; (5) taking consumers directly to the disclosure on the click-through page; and (6) assessing the effectiveness of the hyperlink by monitoring click-through rates. Moreover, FDA could explicitly allow companies to use abbreviated “mouse-overs” to display required disclosures such as key risk information, as long as the mouse-overs otherwise complied with FDA’s guidance on displaying risk information.

V. CONCLUSION

Given the overwhelming reliance on interactive media to share and obtain information about drugs, devices and treatments, FDA should finalize broader, flexible guidance on the use of these platforms so that manufacturers can advance public health by disseminating reliable and accurate information about their products and associated disease states. Such guidance should move sharply away from the agency’s prior formalistic mode of regulating print and broadcast communications so that manufacturers can be full partners in ensuring that patients and consumers can receive reliable online information about specific treatments instead of being unnecessarily hampered relative to other stakeholders. The result may be something that everyone can “Like,” “Share,” “Tweet,” and “ReTweet” about.

ENDNOTES


6. Id. at 1 (noting that interactive promotional media includes “modern tools and technologies that often allow for real-time communications and interactions (e.g., blogs, microblogs, social networking sites, online communities, and live podcasts) that firms use to promote their drugs”).

7. FDA, Keeping Watch Over DTC Ads (New Zealand is the only other nation) (May 2010), available at http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm107170.htm.

8. This office was previously the Division of Drug Marketing and Communications (DDMAC).


12. See 21 C.F.R. §§ 202.1(1)(2), which define labeling to include “[b]rochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion picture films, film strips, lantern slides, sound recordings, exhibits, literature, and reprints and similar pieces of printed, audio, or visual matter descriptive of a drug and references published (for example, the Physicians’ Desk Reference) for use by medical practitioners, pharmacists, or nurses, containing drug information supplied by the manufacturer, packer, or distributor of the drug and which are disseminated by or on behalf of its manufacturer, packer, or distributor.”

13. 21 C.F.R. §§ 202.1(e)(5)-(7). For example, the risks should not appear in much smaller type than the benefits and be placed in a corner of the ad far from the benefits because they are likely to be overlooked.


15. 21 C.F.R. § 314.81(b)(3)(i). This is to be transmitted on an FDA Form 2253.

16. FDA, Truthful Prescription Drug Advertising and Promotion, available at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/DrugMarketingAdvertisingandCommunications/ucm209384.htm. The Bad Ad program is “an outreach program designed to educate healthcare providers about the role they can play in helping the agency make sure that prescription drug advertising and promotion is truthful and not misleading.” OPDP offers HCPs training, including accredited continuing education (CME/CE), to help HCPs identify allegedly improper promotional materials or activities, and to report such instances to OPDP through “complaints.” OPDP has already issued several regulatory letters to firms in response to complaints submitted through the Bad Ad Program.

17. Mark Senak, Comparing Types of Violations Between Digital and Non-Digital, eyeonFDA (Apr. 11, 2013) (noting that these represented only 43% of the total violations). See also Kassity Liu, FDA and Social Media: The Impact of Social Media on Prescription Drug Advertising, (Apr. 17, 2012) (noting that in 2010, FDA issued 13 regulatory letters related to online media including “emails, websites, website videos,
social media, and/or webcasts); Jacqueline West, National Marketing Gone Unintentionally Global: Direct-to-Consumer Advertising of Pharmaceutical Products and the Internet, 11 J. Int’l Bus. & L. 405, 414 (2012) (noting that in 2011, FDA issued seven warning letters related to misleading online promotion, most involving “the placement and/or lack of prominence of risk information”).


21. Branded Pharmaceutical Websites Continue to Generate Highest Lifts in Rx Conversion and Adherence, comScore (noting that existing patients of a drug brand who visited the brand site increased their refill rate by 14.7% and also saw an 8.9% increase in beginning treatment compared to those with no exposure to the site) (Apr. 5, 2012).

22. FDA, Draft Guidance for Industry: “Help-Seeking” and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms (Jan. 2004) (also noting depression, hyperlipidemia, hypertension, and diabetes) [hereinafter FDA Help-Seeking Guidance].

23. Keeping Watch Over Direct-to-Consumer Ads, supra n. 9.

24. Id.

25. Id.


27. Promotion of FDA-Regulated Medical Products Using the Internet and Social Medial Tools; Notice of Public Hearing, 74 Fed. Reg. 48083-01 (Sept. 21, 2009) [hereinafter 2009 FDA Social Media Hearing Notice]. Web logs, or “blogs,” are generally informal journal-type updates that encourage dialog about a subject. Id. at 48085.

28. Id. A “microblog” is similar to a blog but much shorter. Twitter is a microblog service.

29. Id. Podcasts are video or audio clips that users can listen to or watch from a remote location.

30. Id. Video sharing allows the public to upload video clips to the internet (e.g., YouTube).

31. Id. Widgets are a graphic control on a Web page that allows the user to interact with it. Widgets can be posted on multiple sites, host ‘live’ content, and are often on-screen tools.

32. Id. Wikis are web pages that anyone with access can modify (e.g., Wikipedia).
33. *Id.* Social networks allow users to connect with others (e.g., Facebook and LinkedIn).


37. *Id.* FDA was especially concerned because one drug had a boxed warning, and another a bolded warning.


39. *Id.*


41. *Id.* (noting that FDA has issued over a dozen such untitled letters on sponsored links or share widgets).


43. West, *supra* n. 19 (the app left no control over the content of the Sidewiki to the site owner).

44. FDA, Warning Letter to Mr. Albert Sanchez, CEO, AMARC Enterprises, Inc. (Dec. 11, 2012), which states: “We also note claims made on your Facebook account.” “The following are examples of the claims: In a March 10, 2011 post which was “liked” by “Poly Mva”:

“PolyMVA has done wonders for me. I take it intravenously 2x a week and it has helped me tremendously. It enabled me to keep cancer at bay without the use of chemo and radiation… Thank you AMARC”


46. *Id.*


48. Clark Herman, *Companies Trim Social Media Spending, While Platform Priorities Shift*, PharmExec.com (Dec. 4, 2012) (noting that while social media use among pharma employees shot up, “29% of companies spent less than 5% of their budgets on social media in 2011 and 50% have spent only that much in 2012; spend in the 5-10% range increased by a mere one percent and declined in the 10% and beyond range by an average of 4.5%.”

FDA Postmarketing Interactive Promotional Media Guidance at 1.

Id. at 3-4. This would include product websites, discussion boards, chat rooms, or other public electronic forums that a firm uses to promote its products, which the firm maintains, and over which it has full control. FDA further explained that firms would be responsible for product promotional communications if the firm exert influence over a site in "any particular, even if the influence is limited in scope," such as content collaboration, "preview, or review privilege over the content." Id.

Id.

Id. at 4.


Id. at 5 (citing 47 U.S.C. 230(c)(1) ("no provider or user of an interactive computer service shall be treated as the publisher or speaker of any information provided by another information content provider"). The Communications Decency Act further defines "information content provider" as someone "responsible, in whole or in part, for the creation or development of information provided through the Internet or any other interactive computer service." 47 U.S.C. 230(f)(3).

21 C.F.R. § 314.81(b)(3)(i) .

FDA Postmarketing Interactive Promotional Media Guidance at 6. FDA explained that submissions could include "interactive or real-time communications in an archivable format that allows FDA to view and interact with the submission in the same way as the end user (e.g., working links) or firms can submit "screen shots or other visual representations." Id., n. 7. FDA also recommended that firms "take formatting factors (e.g., appearance, layout, visual impression) into consideration" when compiling submissions. Firms should consider how screenshots or other materials will be sized on an 8 x 11 inch piece of paper or similarly sized computer monitor.


FDA, Guidance Agenda: New & Revised Draft Guidances CDER is Planning to Publish During Calendar Year 2014 (Jan. 31, 2014). available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM314767.pdf. These include: (1) Internet/Social Media Platforms with Character Space Limitations: Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices; (2) Internet/Social Media Platforms: Correcting Independent-Third Party Misinformation About Prescription Drugs and Medical Devices; and (3) Internet/Social Media Advertising and Promotional Labeling of Prescription Drugs and Medical Devices – Use of Links

2009 FDA Internet and Social Media Hearing, supra n. 82 (Nov. 12, 2009) (See e.g., Rohit Bhargava, Senior Vice President, Ogilvy 360 Digital Influence, at 64; John Mack, Publisher, Pharma Marketing News, at 90; Maureen Miller, Account Supervisor & Social Media Lead, Compass Healthcare Communications, at 407).
61. Medicare, Medicaid, Children’s Health Insurance Programs; Transparency Reports and Reporting the Physician Ownership or Investment Interests. 78 Fed. Reg. 9458, 9518 (Feb. 8, 2013). In general, the Sunshine Act requires applicable manufacturers to report certain payments they make to physicians to CMS, which in turn will post these payments on a public, searchable database with certain identifying and contextual information.

62. FTC, .com Disclosures: How to Make Effective Disclosures in Digital Advertising, at pp. 11-2 (Mar. 2013) (noting that hyperlinks that say “disclaimer,’ ‘more information,’ ‘details,’ ‘terms and conditions,’ or ‘fine print’ do not convey the importance, nature, and relevance of the information to which they lead and are likely to be inadequate.” FTC added that labels such as “important information” or limitations may also be inadequate. While FTC said there is “no one-size-fits-all word or phrase to use in a hyperlink label, “more specificity” is better), available at http://www.ftc.gov/os/2013/03/130312dotcomdisclosures.pdf [hereinafter FTC Online Guidance].

63. Id. at ii (emphasis added).

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