

Getting the FDA and FDA-Regulated Companies Online With Web 2.0

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Introduction

The days of the internet being defined by AOL's "You've Got Mail," dial-up and static worldwide web pages are gone. In particular, Web 1.0 or one-way communications—from content provider to reader—are rapidly becoming obsolete.¹ Today's Web 2.0 no longer restricts web content to company-generated statements and information, and interactivity to email or form-based feedback.² Rather, Web 2.0 is comprised of Facebook, MySpace, Twitter, YouTube, Linked In, FourSquare, Gowalla, Tumblr, Wikipedia, and Sidewikis—fluid, user-generated or reader-modified blogs and microblogs, social networking sites, wikis and multimedia sharing.³ Web 2.0 "enables decentralized and real time communication among small and large audiences of individuals, organizations and businesses."⁴ The speakers are often anonymous, and observers may be active or passive.⁵ In the world of Web 2.0, consumers can independently seek and generate information regarding products, such as FDA-regulated drugs and devices, without fear of reprimand or regulatory oversight. . . thus allowing consumers to fill an information void regarding products or uses with their own information.⁶ Many times this results in lower quality information that lacks the accuracy that would come from a regulated entity, e.g. a pharmaceutical company.⁷ With consumer-formulated and shared information making up the new web landscape, companies are faced with a dilemma of whether to involve themselves in the dialogue and, if so, to what extent to participate.⁸ Particularly where this landscape is very active and broad, e.g., there is an average of 27 million tweets per day on Twitter and 25 million posts of new content (weblinks, news stories, blog posts, notes, photos, etc.) shared each month on Facebook, regulated companies are faced with uncertainty as to whether participation means responsibility for all content and all forums.⁹

The FDA's Role in Web 2.0

In this dynamic environment, FDA's print-based regulation of pharmaceutical, medical device and biologic company advertising, promotion and commercial speech—promulgated in the 1960's—is arcane. While FDA's regulations easily fit to Web 1.0 based

1 CARRIE DOOHER, USING SOCIAL MEDIA IN FDA-REGULATED INDUSTRIES: THE ESSENTIAL GUIDE, p. 5 (2010).

2 *Id.*

3 *Id.*

4 Areta Kupchyk and Kenin Madagan, *Coming Soon! FDA's Current Thinking on Social Media and Product Promotion*, (June 2010), available at <http://www.corporatecomplianceinsights.com/2010/fda-policy-social-media-product-promotion/>.

5 Doohar, *supra* note 1 at p. xii.

6 *Id.* at p. 2.

7 *Id.*

8 *Id.* at p. 11.

9 *What the F**k Is Social Media NOW?*, Espresso, (July 18, 2010), available at <http://www.brandinfiltration.com/dailygrind/2010/07/18/what-the-fk-is-social-media-now/>.

advertisements, the regulations are now unworkable given the malleability of communication in the Web 2.0 medium. In order for the FDA to appropriately regulate communications regarding regulated products and companies in the Web 2.0 domain, the FDA must recognize four key points: 1) control of the forum no longer remains in companies' hands; rather, because "content is user-generated and shared/re-shared...companies are only one participant" of many participants in a discussion; 2) consumers have begun to seek out, "rely on and trust content" from speakers other than companies; 3) neither regulatory agencies (because of lack of authority), nor companies (because of lack of resources and the scope and breadth of Web 2.0) can control all or even a substantial amount of information that is user-generated; and 4) the anonymity of Web 2.0 makes it increasingly difficult for any regulated company or any party to "identify the source (or veracity)" or accuracy of content.¹⁰

FDA Regulatory Background

As a threshold matter, "the Federal Food, Drug, and Cosmetic Act authorizes the FDA to regulate labeling and advertising of therapeutic products, notably stating that a drug or device is deemed "misbranded" if "its labeling is false or misleading in any particular."¹¹ The FDCA applies criminal penalties to companies that are deemed to have misbranded a product because of false or misleading information.¹² The regulatory definition of "labeling" has been expanded so that anything that "supplements or explains a product" constitutes labeling, regardless of whether it is physically distributed with the product.¹³ The FDA has similarly expanded "labeling" to include brochures, booklets, files, cards, films, and slides.¹⁴

The FDA has also promulgated regulations broadening advertising to not only include ads in journals, magazines, and newspapers, but also to include ads placed through broadcast media, including television, radio, and telephone communication systems.¹⁵ Further, in order to avoid presenting false or misleading information, regulations require that companies disclose risk information associated with their therapeutic products "ads must present a *fair balance* between information relating to risks and benefits, which is achieved when the treatment of risk and benefit information in a promotional piece is comparably thorough and complete throughout the piece."¹⁶ Companies must also disclose (and report to the FDA) adverse events associated with their products provided the manufacturer has "knowledge of four data elements: 1) an identifiable patient; 2) an identifiable reporter; 3) a suspect product and 4) an adverse or fatal outcome."¹⁷ Additionally, "companies are permitted to market

10 Doohar, *supra* note 1, at p. 5.

11 21 U.S.C. § 352.

12 21 U.S.C. § 333(a)(1)-(2).

13 *Kordel v. United States*, 335 U.S. 345, 347-348, 350 (1948).

14 21 C.F.R. § 202.1 (1)(2).

15 21 C.F.R. § 202.1 (1)(1).

16 U.S. Food & Drug Adm'n, *Draft Guidance for Industry: Presenting Risk Information in Prescription Drug and Medical Device Promotion*, 23 (May 2009) (citing 21 C.F.R. s 202.1(e)(5)(ii)).

17 U.S. Food & Drug Adm'n, *Draft Guidance for Industry: Postmarketing Adverse Experience Reporting for Human Drug and Licensed Biological Products: Clarification of What to Report*, 2-3 (Aug. 1997) (citing 21 C.F.R. §§ 301.305, 314.80, 314.98, 600.80).

products only for those indications for which FDA has granted approval or clearance.”¹⁸ Promoting a drug or device for an unapproved use is a violation of the FDCA § 505 and requires a new drug/device application.¹⁹ Finally, “companies must submit their drug/biologic promotional materials and ads to the FDA on a Form FDA-2253 for review at the time of initial publication or dissemination.”²⁰ This includes website text, videos, etc. as well as text-based documents.²¹

The Current Paradigm

Trying to adapt the current FDA regulatory framework to company communications in the Web 2.0 forum is nearly impossible. With respect to fair balance, Web 2.0 social media websites and mobile phones format of content distribution makes presentation of risk information very difficult. Mediums such as microblogs like Twitter, for instance, cannot comply with traditional FDA requirements for labeling and advertising because of the character limitations of tweets, sponsored links and banner ads.²² Yet, the FDA’s recent rejection of the Federal Trade Commission’s “one click rule” for internet advertising (allowing ads where the reader could access risk info with one click) appeared to be an irrational rejection of a reasonable middle ground.²³ With respect to the issue of correcting misleading or false information, in the Internet context, it is equally unreasonable to expect companies to be able to track all information that is user-generated or modified. A company simply cannot and should not be held responsible for independent third-party tweets, posts, blogs, videos, etc. Yet again, at recent FDA stakeholder meetings, FDA indicated companies might be liable.²⁴ Likewise, with Web 2.0, many reports of “adverse events” are “reported” by anonymous persons on third-party websites or blogs. Because current FDA regulations require that there be an identifiable patient and an identifiable reporter, arguably such “reports” of adverse events do not trigger reporting to the FDA. However, if the company can contact the poster, e.g. a doctor using a social networking site for physicians, should the company be required to monitor all of the millions of sites on the web? How can this be expected? While a company may reasonably be required to monitor forums where it has control of the outlet, such as a Facebook fan page or its own website/chat room, it is too much to require companies to expend resources on fact-checking all web material. Aren’t these companies’ resources better spent on areas such as research and product development? On the issue of off-label promotion, social media and Web 2.0 generates content that goes

18 21 U.S.C. § 355.

19 *Id.*

20 21 C.F.R. § 314.81(b)(3)(i).

21 *Id.*

22 Dooher, *supra* note 1, at p. 7.

23 Fed. Trade Comm’n, *DotCom Disclosures: Information About Online Advertising*, FTC Staff Working Paper (May 2000), available at www.ftc.gov/bcp/edu/pubs/business/e-commerce/bus41.pdf; In March 2009, the FDA issued 14 untitled letters re: pharma’s use of Google-sponsored links. Because the Google ads failed to present risk information on the banners, the FDA alleged that they lacked fair balance. FDA basically said that naming a drug and an indication for use triggered the fair balance requirements. Similarly, in July 2010, FDA issued an untitled letter to Novartis for its use of the “share” widget on Facebook which allowed users to transmit material from the Novartis website to their Facebook feed. FDA said that the absence of risk info (because a widget could capture only the first few lines of the website material) constituted a violation of labeling/advertising regulations. See Dooher, *supra* note 1, at p. 8.

24 Dooher, *supra* note 1, at p. 9.

beyond a company's control, thereby allowing third-parties to promote off-label uses for FDA regulated products. For example, Sidewiki allows consumers to post comments that appear alongside a company's website.²⁵ The companies have no control over what is posted and by whom.²⁶ Thus, a compliant company website can display user-generated, off-label promotion via Sidewiki. Interestingly, the companies are most empowered with correct information, yet these companies are reasonably afraid to enter a forum because they may be drawn into a non-compliant discussion and be rewarded with an untitled letter²⁷ for not correcting each and every user-generated piece of information in that third-party forum. Finally, Form FDA 2253 submission requirements typically have applied only to static content on company websites.²⁸ If social media were similarly classified, this would be very burdensome and would likely result in no social media use by regulated companies.

Conclusion

The lack of FDA Guidance and recent issuance of untitled letters has resulted in a chilling effect, where companies have simply avoided Web 2.0's interactive tools and user discussions. The downside is that there is an emergence of online discussions about FDA regulated products that are not controlled by the companies that produce such products. Therefore, these forums can, and often do, contain false, misleading or harmful information.

While companies should be regulated in controlled forums, extending responsibility and potential criminal liability for fluid and easily-modified forums is unreasonable. Industry has recognized that there is a need for "safe-spaces" marked with a seal or symbol, where the consumer/reader can distinguish between company communications and third-party communications.²⁹ In this arena, regulation of speech is fair game. However, in other forums, the FDA must recognize the public health interest in allowing companies to correct misinformation or participate in third-party discussions without *obligating* them to correct *all* misinformation or be held responsible for all content from other parties. Likewise, the adverse reporting requirement should only apply in the web context where it is clear on its face that the company has become aware of the complaint and the requisite information exists. Finally, social media speech should neither be held to rigid requirements of risk information being presented up front, as opposed to through a link to a website nor classified as advertising requiring Form FDA 2253 submissions. Such regulation would only stifle and stunt truthful commercial speech while letting unregulated parties (including foreign online pharmacy companies) taint the pool of information.

The FDA is expected to issue draft guidance by the end of this year and finalize guidance by the end of 2011. In formulating regulatory requirements for regulated companies' speech and liability for speech in the Web 2.0 context, the FDA should be cognizant of both the

²⁵ *Id.* at 10.

²⁶ *Id.*

²⁷ An untitled letter is "initial correspondence . . . that cites violations that do not meet the threshold" for issuing a more serious "warning letter." See FDA Regulatory Procedures Manual, Ch. 4, Advisory Actions 4-27 (2006)(available at <http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/default.htm>).*Id.*

²⁸ Dooher, *supra* note 1, at 12.

²⁹ Kupchyk and Madagan, *supra* note 4.

economic reasonableness of demands and the effect onerous requirements will have on speech from the key players—in this case the regulated companies—the party that has the best ability to disseminate truthful and useful speech in furtherance of a strong public health interest.

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