

# ADMINISTRATIVE LAW & REGULATION

## THE REGULATION OF PRESCRIPTION DRUG AND RESTRICTED MEDICAL DEVICE ADVERTISING

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As the Internet's presence in the lives of Americans grows, so does the opportunity for companies to promote their products online. The healthcare industry, in particular, has been influenced by the proliferation of information on the Internet, with over 52 million adults searching the Internet for health information<sup>1</sup> and almost half of all adults turning to the Internet as their first reference point for healthcare information.<sup>2</sup> The Internet's important role in disseminating healthcare information to the public has led inexorably to a proliferation of prescription drug and medical device advertising on the Internet.

Under the Federal Food, Drug and Cosmetic Act (the "FD&C Act"), the U.S. Food and Drug Administration ("FDA" or "Agency") is responsible for regulating the labeling of prescription drugs and medical devices, as well as the advertising of prescription drugs and restricted medical devices.<sup>3</sup> While FDA has issued numerous regulations and Guidance documents<sup>4</sup> on the promotion and advertising of prescription drugs generally, the Agency has not issued any comprehensive regulations or Guidances that give adequate direction to advertising on the Internet.

This Article discusses the current legal framework of FDA regulation of labeling and advertising, how the medium of the Internet confounds the premises upon which current regulations are built, and the steps the FDA currently is taking to understand and regulate prescription drug and restricted medical device advertising on the Internet. The Article then proposes possible approaches to regulation that the FDA may consider.

### I. FDA Regulation of Labeling and Advertising of Prescription Drugs and Restricted Medical Devices

The FDA is responsible not only for regulating the labeling of prescription drugs and medical devices, but also for the advertising of prescription drugs and restricted medical devices. It is important to understand the difference between labeling and advertising in order to consider their possible application to communications on the Internet.

#### A. Prescription Drug and Medical Device Labeling

Under the FD&C Act, a "label" is defined as "a display of written, printed, or graphic matter upon the immediate container of any article."<sup>5</sup> In addition, the Act defines "labeling"

to mean "all labels and other written, printed, or graphic matters (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."<sup>6</sup> In *Kordel v. United States*,<sup>7</sup> the U.S. Supreme Court interpreted the statutory definition of "labeling" broadly, holding that the FDA has the power to regulate both written materials attached to the product (i.e., labels), as well as any written materials that have a "textual relationship" with the product. "One article or thing is accompanied by another when it supplements or explains it . . . . No physical attachment one to the other is necessary."<sup>8</sup> Written materials about a product therefore do not have to be attached to or sent along with a product to be regulated by the FDA as labeling.

Based on *Kordel*, the FDA has issued a regulation defining labeling materials to include

[b]rochures, booklets, mailing pieces, detailing pieces . . . calendars, price lists, catalogs . . . letters, motion picture films . . . sound recordings, exhibits, literature, and reprints and similar pieces of printed, audio, or visual matter descriptive of a drug . . . which are disseminated by or on behalf of its manufacturer, packer, or distributor.<sup>9</sup>

Labeling therefore includes a broad spectrum of written materials. If materials are deemed to be labeling, they must contain "adequate directions for use" of the drug or device, as well as adequate warnings against harmful use<sup>10</sup>—and the materials must not contain any "false or misleading" statements.<sup>11</sup>

#### B. Prescription Drug and Restricted Medical Device Advertising

The FD&C Act does not define "advertising," but the FDA has interpreted the term to include information, besides labeling, that is issued by or on behalf of the "manufacturer, packer, or distributor of the drug" for the intention of drug promotion.<sup>12</sup> FDA regulations list examples of advertising that include "published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems."<sup>13</sup> If material is deemed to be advertising, then it must contain the established name of the drug, the drug's ingredients, and a "brief summary" composed of "side effects, contraindications, and effectiveness."<sup>14</sup>

### II. The Application of FDA Advertising Regulations to the Internet

FDA's regulation of labeling and advertising as set forth in Section I., *supra*, is premised on labeling and advertising that is communicated primarily in print or on television or radio. Court and administrative interpretations have established a body of information about the limits of the law and FDA's regulatory authority and provided regulated industry with some certainty—allowing drug and device companies to label and

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promote their products in magazines and on TV in a lawful manner. Internet search engines, such as Google, that enable consumers to enter keywords and obtain brief summaries of websites potentially relevant to their search, however, have presented unique challenges to drug and device companies who wish to promote their products in compliance with FDA strictures. The so-called “Web 2.0,” which includes interactive social media like YouTube, Facebook, and Twitter, where consumers can create or alter Internet-based communications, also increases the complexity of these challenges. The FDA is likewise challenged to keep up with new technologies and an increasingly technologically savvy public.

Not surprisingly, then, both the FDA and regulated industry are concerned about the lack of clarity surrounding the legal requirements for prescription drug and restricted device advertising on the Internet. On April 3, 2009, the Agency sent 14 Untitled Letters to drug companies that used sponsored links<sup>15</sup> on search engines, such as Google.<sup>16</sup> The Untitled Letters condemned the fact that the brief summaries appearing with the sponsored links did not include all of the risk information required in drug advertising, even though the summaries included links to fully compliant advertising pages.<sup>17</sup>

In light of the dearth of Internet-specific advertising regulatory guidance, the letters frustrated some members of industry.<sup>18</sup> Compounding the frustration was the fact that the brief summaries appearing with the sponsored links are, per search engine standards, only allowed to be of a certain length and cannot, as a result, include all mandatory risk information.<sup>19</sup> Prior to issuance of the Untitled Letters, many in the industry had adhered to a “one-click rule,” believing that if risk information was only a click away, the FDA would determine that the communications were compliant.<sup>20</sup> The FDA apparently did not agree with this assessment.

After the Untitled Letters were issued, an FDA spokesperson confirmed in an interview that “[o]ur laws for how products that are approved by the Agency can be marketed to consumers are the same regardless of the medium, whether they are print ads, radio ads, television ads or Internet ads.”<sup>21</sup> In making these statements, the FDA declared unequivocally that its regulation of prescription drug and restricted medical device advertising extends to the Internet, albeit without addressing the unique complications of applying the Agency’s “earthbound” regulations to that ever-changing medium.

FDA’s failure to address the unique complications of the Agency’s regulation of Internet communications on prescription drugs and restricted devices is problematic. If, for example, FDA continues to enforce the requirement that sponsored links on Internet search engines must contain all of the risk information required of advertising, then drug companies will be forced to change their promotional efforts significantly. These changes may include removing the indication or dosage of a product in order to fall within the regulatory exception from providing safety information for “reminder advertising,”<sup>22</sup> or omitting the name of the product entirely and disseminating only “help-seeking” advertisements.<sup>23</sup>

With nearly half of Internet users employing a search engine,<sup>24</sup> drug and device companies likely will be tempted to employ reminder or help-seeking advertisements on

search engines, rather than miss out on such a large amount of consumer traffic. Industry leaders point out, however, that removing product names and indications might be more confusing and misleading to consumers than the brief summaries associated with Internet search results.<sup>25</sup> For example, Propecia® advertisements currently link to the site, hair-loss-medication.com, which in turn redirects Internet users to Propecia.com. Thus, a consumer might click on hair-loss-medication.com, expecting neutral information about hair loss medication, and instead receive biased advertising materials promoting Propecia®.<sup>26</sup> On the other hand, if drug and device companies do not appear on search engine advertising, it will be more difficult for consumers to locate the official, FDA-regulated company sites regarding the product. Moreover, it will be more likely that consumers are instead unwittingly directed to unregulated, pseudo-medical sites that contain false and misleading information.<sup>27</sup>

In November 2009, the FDA sponsored a public hearing to consider the “special characteristics of Web 2.0 and other emerging technologies” and “issues related to the promotion of FDA-regulated medical products.”<sup>28</sup> In doing so, the Agency acknowledged that the “FDA has not comprehensively addressed when Internet promotion of prescription drugs and medical devices is labeling versus advertising,” but noted that the FDA has jurisdiction over all prescription drug and biologic promotion, device labeling, and restricted device advertising when conducted by a manufacturer, packer, or distributor.<sup>29</sup>

At the hearing, the FDA sought input regarding how the Internet could be used to promote drugs and devices to consumers and healthcare professionals in a truthful, nonmisleading, and balanced manner. The FDA also pointed out several Web 2.0 innovations that challenge the Agency’s current regulatory structure, including blogs, microblogs (i.e., Twitter), podcasts, social networks and online communities, video sharing, widgets, and wikis.<sup>30</sup> In particular, the FDA presented five questions on which it sought public comments:

1. For what online communications are manufacturers accountable?
2. How can manufacturers fulfill regulatory requirements in their Internet and social media promotion, particularly when using tools that have space limitations or allow for real-time communications?
3. What parameters should apply to the posting of corrective information on websites controlled by third parties?
4. When is the use of links appropriate?; and
5. What responsibility do manufacturers have to collect and investigate adverse event information that is posted by Internet users?<sup>31</sup>

The manner in which FDA answers these questions will form the basis of its prospective regulation of promotional communications on the Internet.

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### III. Possible Approaches to Regulation of Prescription Drug and Medical Device Advertising on the Internet

The questions presented by the FDA at the public hearing appropriately frame the most important issues. The first is a line-drawing question: when should Internet communications about a prescription drug or restricted device be attributed to the manufacturer? Official websites which promote a product to consumers or healthcare professionals that are sponsored, paid for, and maintained by a manufacturer unquestionably should be considered advertising and regulated as such. In contrast, truly independent communications made by a third party—communications that are not initiated or solicited by the product's manufacturer—should not be regulated by the FDA. Indeed, regulation of such non-commercial communications could raise significant free speech concerns under the First Amendment.<sup>32</sup> But what of a Web 2.0 interactive scenario where an official, company-sponsored website permits visitors to post their personal thoughts and opinions about a product? Or where a manufacturer “hosts” a blog at which individuals may leave comments? Permitting third parties not connected with the company to provide or alter content on an official, company-sponsored website would likely lead to FDA violations including skewing the “fair balance” presentation of a product's risks and benefits,<sup>33</sup> promoting the product for uses not contained in the FDA's approved label,<sup>34</sup> or posting false or misleading statements about the product.<sup>35</sup>

Inevitably, companies would be obliged to monitor and censor third-party content on company-sponsored sites. In doing so, however, the communications would no longer be fairly characterized as “independent,” and instead would effectively be transformed into communications by the company. Social media thrives on real-time, authentic, person-to-person interaction. Any attempt to influence the content of such communications by a drug or device manufacturer would have to be disclosed to maintain social media credibility.<sup>36</sup> For these reasons, monitoring of such communications by a drug or device manufacturer simply is impractical.

Perhaps this line-drawing problem is best resolved with a bright-line rule: drug and device manufacturers are responsible for Internet-posted content about their products that they created, solicited, or disseminated—including by providing the site on which the content appears. Truly independent third-party communications, by contrast, are not attributable to the manufacturer, and are not prohibited by the FD&C Act.<sup>37</sup> Such a bright-line rule, in addition to being easily understood, would have the salutary benefit of promoting the public health, as consumers would be better able to distinguish between official, FDA-compliant advertising, on the one hand, and communications that are not necessarily accurate, may discuss off-label uses of the product, or may not present a fair balance of risks and benefits associated with using the drug or device, on the other hand.

A second question on which the FDA has solicited comments concerns Internet communications by manufacturers when space is limited. This issue boils down to whether the FDA should adopt the “one-click rule.” Where website space is limited, is a link to the product's risk information sufficient?

The FDA's issuance of 14 Untitled Letters in April of 2009 served to reveal a potential lack of understanding regarding search engines and how they are used by consumers of healthcare information. Search engines are intended to be a gateway to further research and information gathering, to provide many websites relevant to keywords quickly and efficiently. Consumers do not expect all of the information about a topic to appear on the search engine's results page. When a consumer finds the website they believe is most relevant to their search, they click on the link which directs them to another website where they can find substantive information. To require a full and balanced presentation on a search engine results page misses the point. Moreover, because so many consumers of healthcare information begin with the Internet, and because so many Internet users begin with a search engine, prohibiting drug and device companies from providing sponsored links would close consumers out of important relevant health information. In consideration of these circumstances, what makes the most sense is adopting the “one-click rule,” where consumers can easily obtain the FDA-approved label information they decide is relevant to their search.

Whether a manufacturer has the right or obligation to respond to inaccurate or misleading content published on the Internet by third parties presents a difficult question for both the regulated industry and the FDA. Sophisticated consumers know that not all information found on the Internet is truthful, and no company could respond to every inaccurate statement made about its product in cyberspace. Although the FDA has long been concerned about unsophisticated consumers,<sup>38</sup> it cannot compel companies to respond to independent communications made by third parties about drugs or devices<sup>39</sup>—it can only require that the company's own communications about FDA-regulated products are appropriate.<sup>40</sup>

The question therefore becomes whether companies should be allowed to respond to incorrect information at all and, if so, how much information on the independent website should the company become responsible for? For example, if a website claims that Product X marketed by Company Y produces birth defects, and a spokesperson for Company Y posts a comment on the site stating that birth defects have never been reported in connection with Product X, is the spokesperson's statement advertising? If it is, must all of the requirements imposed on advertising be followed? One possible bright-line rule is to permit companies to respond to inaccurate or misleading third-party communications on the Internet, but only with a reference to the company's official, FDA-compliant website.

Just as it is problematic for drug or device companies to have an influence over what is said on independent websites, it is also concerning if a drug or device company allows a link on its official product page that re-directs to a non-FDA regulated website. Consumers should be able to rely on a company-sponsored website as being fair, balanced, truthful, and compliant with all FDA advertising regulations. Similarly, consumers should be able to rely on the websites to which a company-sponsored website links. The argument behind the industry-favored “one click” rule for sponsored links is that the entire purpose of displaying a link is to encourage consumers to click on it for more information. Therefore, drug and device

companies on their official product page should not encourage consumers to redirect to unregulated pages. A company-sponsored site should be a safe haven of regulated material, and links to sites which are not so regulated is confusing and misleading for consumers.

Finally, the FDA has sought input on the extent to which manufacturers should be required to collect and investigate adverse event reporting on the Internet. In March of 2001, the FDA issued a draft Guidance in which it differentiated between a company's obligation to monitor websites that the company itself sponsors for adverse event reports, and its obligation to monitor websites of third parties not connected to the company for adverse event reports. In sum, the draft Guidance provides that companies are not responsible for monitoring third-party sites; however, if a company becomes aware of an adverse event on a third-party site, then the company must investigate the adverse event and determine whether it should be reported to the FDA.<sup>41</sup> If it were otherwise, and companies were expected to monitor the entirety of the Internet and investigate every reported adverse event, the magnitude of the obligation would be enormous and the resources required to address it and collect all required information would be staggering, if not impossible. Moreover, the draft Guidance is in harmony with the possible approaches we have suggested, which recommend that the FDA establish a bright line of demarcation between company-sponsored Internet sites and content, on the one hand, and independent, third-party sites and content, on the other.

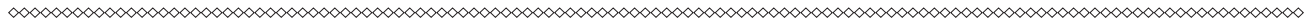
### Conclusion

The FDA appears to be moving to address the important issues relating to regulation of prescription drug and restricted device advertising on the Internet. Providing certainty to the industries it regulates, as well as to consumers, should be a primary objective of its actions in the future. Adopting bright-line rules and policies on Internet-based communications about drugs and devices will go far to meet this objective.

### Endnotes

- 1 See Ben S. Gerber & Arnold R. Eiser, *The Patient-Physician Relationship in the Internet Age: Future Prospects and the Research Agenda*, 3(2) J. MED. INTERNET RES. e15 (2001).
- 2 See generally B.W. Hesse et al., *Trust and Sources of Health Information: The Impact of the Internet and Its Implications for Health Care Providers: Findings from the First Health Information National Trends Survey*, 165(22) ARCH. INTERN. MED. 2618 (2005).
- 3 I.e., devices requiring a prescription or pre-market approval from the FDA. See FDA, GUIDANCE FOR INDUSTRY: PRESENTING RISK INFORMATION IN PRESCRIPTION DRUG AND MEDICAL DEVICE PROMOTION (May 2009), available at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm064956.htm>.
- 4 Guidance documents provide the Agency's "latest thinking" on a topic. See FDA, Guidances, available at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> (last visited Feb. 6, 2010).
- 5 21 U.S.C. § 321(k).
- 6 *Id.* § 321(m).
- 7 335 U.S. 345 (1948).

- 8 *Id.* at 350.
- 9 21 C.F.R. § 202.1(l)(2).
- 10 21 U.S.C. § 352(f).
- 11 *Id.* § 352(g).
- 12 21 C.F.R. § 202.1(k).
- 13 *Id.* § 202.1(l)(1).
- 14 21 U.S.C. 352(n).
- 15 Sponsored links are advertisements that appear on other websites, such as search engines, that solicit consumers, with a brief description, to click on a link that will lead them to the product's website for more information. The host website gets paid every time someone clicks on the sponsored link.
- 16 The FDA issues Untitled Letters to regulated industry for violations of legal requirements. The FDA issues Warning Letters for violations that are of "regulatory significance." Warning Letters state that the Agency may take enforcement action if the violation is not corrected.
- 17 See FDA, 2009 Warning Letters and Untitled Letters to Pharmaceutical Companies, available at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm055773.htm> (last visited Jan. 31, 2010).
- 18 See Rich Thomaselli, *FDA to Hold Public Hearings on Big Pharma's Social-Media Use*, ADVERTISINGAGE, Sept. 23, 2009.
- 19 See Arnold I. Friede & Robert B. Nicholas, *Yes, We Can: Time for an FDA Internet Drug Advertising Policy*, FDLI UPDATE, July/Aug. 2009, at 22.
- 20 See Posting of Mark Senak to eye on FDA, 14 Warning Letters in a Day! What's that About?, [http://www.eyeonfda.com/eye\\_on\\_fda/2009/04/14-warning-letters-in-a-day.html](http://www.eyeonfda.com/eye_on_fda/2009/04/14-warning-letters-in-a-day.html) (Apr. 6, 2009).
- 21 Stephanie Clifford, *F.D.A. Rules on Drug Ads Sow Confusion as Applied to Web*, N.Y. TIMES, Apr. 16, 2009.
- 22 21 C.F.R. § 202.1(e)(2)(i).
- 23 FDA, HELP-SEEKING AND OTHER DISEASE AWARENESS COMMUNICATIONS BY OR ON BEHALF OF DRUG AND DEVICE FIRMS (Jan. 2004), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070068.pdf>.
- 24 See DEBORAH FALLOWS, PEW INTERNET AND AMERICAN LIFE PROJECT DATA MEMO RE: SEARCH ENGINE USE, available at <http://pewinternet.org/Reports/2008/Search-Engine-Use.aspx> (last visited Feb. 1, 2010).
- 25 See Clifford, *supra* note 21.
- 26 See *id.*
- 27 See Friede & Nicholas, *supra* note 19.
- 28 FDA, Notice of Public Hearing: Promotion of Food and Drug Administration-Regulated Medical Products Using the Internet and Social Media Tools, 74 Fed. Reg. 48,083 (Sept. 21, 2009).
- 29 *Id.*
- 30 See *id.*
- 31 See *id.*
- 32 See Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y., 447 U.S. 557, 562-64 (1980) (discussing the "commonsense" distinction between commercial speech and "other varieties" of speech).
- 33 21 C.F.R. § 202.1(e)(5)(ii).
- 34 See *id.* § 202.1(e)(4)(i)(a).
- 35 See *id.* § 202.1(e)(5)(ii).
- 36 See Pharma Companies Should Have Public Social Media Disclosure Policies, Survey Results Show, <http://pharmamktng.blogspot.com/2009/10/pharma-companies-should-have-public.html> (Oct. 8, 2009).
- 37 21 U.S.C. 331.
- 38 See FDA, GUIDANCE FOR INDUSTRY: PRESENTING RISK INFORMATION IN PRESCRIPTION DRUG AND MEDICAL DEVICE PROMOTION (May 2009), available



at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm064956.htm>.

39 See generally *Pacific Gas & Elec. Co. v. Public Util. Comm'n of Cal.*, 475 U.S. 1 (1986) (expanding the limitations of compelling speech to corporations as well as individuals).

40 See 21 C.F.R. § 202.1(e)(5)(ii).

41 See FDA, DRAFT GUIDANCE FOR INDUSTRY: POSTMARKETING SAFETY REPORTING FOR HUMAN DRUG AND BIOLOGICAL PRODUCTS INCLUDING VACCINES (Mar. 2001), available at <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Vaccines/ucm074850.htm>.

