

# ONE CLICK AWAY FROM UNTANGLING THE WEB: THE UNITED STATES FOOD AND DRUG ADMINISTRATION & INTERACTIVE PROMOTIONAL MEDIA

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## I. INTRODUCTION

The United States is one of the only countries in the world that allows direct-to-consumer (DTC) advertisement of pharmaceuticals and medical devices.<sup>1</sup> The United States Food and Drug Administration (FDA) regulates all prescription drug advertising—to medical professionals and consumers—and promotional labeling.<sup>2</sup> DTC advertisements are directed to consumers rather than healthcare providers, and include, broadcast (e.g., television), print (e.g., newspaper), and internet (e.g., website) advertisements. In contrast, promotional labeling includes brochures or pamphlets that medical professionals provide to consumers or other non-healthcare providers.

DTC advertising has become an increasingly important topic because a growing number of Americans, across various populations and demographics, are looking online for health information,<sup>3</sup> and they are looking primarily to “learn more about” their disease or condition.<sup>4</sup> In 2010, eighty-nine million adults in the United States tapped into social media resources for health-related purposes, compared with sixty-three million in 2008 and thirty-eight million in 2007.<sup>5</sup> Moreover, fifty-nine percent of non-physician healthcare professionals who work directly with and on behalf of patients indicated that

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<sup>1</sup> U.S. FOOD AND DRUG ADMIN., *Keeping Watch Over Direct-To-Consumer Ads*, FDA.GOV (Aug. 19, 2013), <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm107170.htm> [hereinafter *Watch Over DTC Ads*]. New Zealand is the only other developed nation that permits DTC advertising of drugs and medical devices. *Id.*

<sup>2</sup> U.S. FOOD AND DRUG ADMIN., *Drug Advertising: A Glossary of Terms*, FDA.GOV (Sept. 13, 2012), [http://www.fda.gov/Drugs/ResourcesForYou/Consumers/PrescriptionDrugAdvertising/ucm072025.htm#promotional\\_labeling](http://www.fda.gov/Drugs/ResourcesForYou/Consumers/PrescriptionDrugAdvertising/ucm072025.htm#promotional_labeling) [hereinafter *FDA Glossary*] (defining promotional labeling as having the same purpose as advertising to sell prescription drugs but as being effectuated through different mediums).

<sup>3</sup> Richard Meyer, *Is ROIA Roadblock to New DTC Marketing Initiatives?*, WORLDOFDTCMARKETING.COM (Oct. 12, 2012), <http://worldofdtcmarketing.com/is-roi-a-roadblock-to-new-dtc-marketing-initiatives/business-of-the-drug-industry/> (noting that 72% of 18–29 year-olds; 71% of 30–49 year-olds; and 46% of 50 individuals and older use the internet to research health questions).

<sup>4</sup> *Engaging E-Patients In Dialogue*, WORLDOFDTCMARKETING.COM (last visited Mar. 24, 2014), <http://worldofdtcmarketing.com/wp-content/uploads/2012/10/Engaging-epatients-in-dialogue.jpg> (explaining that 36% of patients visit online health communities to learn more about their disease)

<sup>5</sup> Richard Meyer, *Sanofi-Aventis Blazes Social Media Trails*, WORLDOFDTCMARKETING.COM (Aug. 21, 2012), <http://worldofdtcmarketing.com/sanofi-aventis-blazes-social-media-trails/social-media-and-healthcare/> (noting that consumers turn to each other on social media due to distrust of advertisers); see also NAT'L RESEARCH CORP., *1 In 5 Americans Use Social Media for Health Care Information*, NATIONALRESEARCHCORPORATION.COM (Feb. 28, 2011), <http://hcmg.nationalresearch.com/public/News.aspx?ID=9> (discussing the increasing influence of social media on Americans seeking healthcare information).

patients “often or sometimes bring information from the internet to discuss.”<sup>6</sup> While pharmaceutical and medical device manufacturers<sup>7</sup> have decreased spending on DTC television advertisements in recent years,<sup>8</sup> digital advertising budgets were expected to reach fifteen percent in 2012 and twenty percent in 2013 out of total marketing budget, with big increases expected in “social media initiatives for consumers.”<sup>9</sup> While declines in internet DTC spending were actually seen in 2013 by almost fifteen percent, this can be attributed to the lack of FDA guidance and manufacturers “well-known anxiety around all things ‘e,’ media.”<sup>10</sup>

There are both proponents and opponents of the use of DTC advertising by drug and device companies. Proponents of DTC advertisements argue that they (1) provide useful information to consumers that may result in better health;<sup>11</sup> (2) advance public health by encouraging more people to talk with healthcare professionals about problems, particularly under-treated, under-diagnosed conditions, such as high blood pressure;<sup>12</sup> (3) help remove the stigma associated with certain diseases (e.g., depression); and (4) remind patients to refill prescriptions and help them adhere to their medication regimens.<sup>13</sup> Critics maintain that such advertisements are troublesome because they (1) may contain false or misleading information; (2) do not provide enough information

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<sup>6</sup> *Patient Ed: How Patients Learn In the Digital Age*, WORLDOFDTCMARKETING.COM (last visited Mar. 24, 2014), <http://worldofdtcmktg.com/wp-content/uploads/2013/02/HealthEd-Academy-How-Patients-Learn.jpg> (finding that non-MDs who work with and on behalf of patients use online videos like YouTube to educate their patients (44%), as well as blogs (18%), and patients themselves print out online materials to use patient visits (55%)).

<sup>7</sup> Pharmaceutical and medical device manufacturers, manufacturers, or companies may be used interchangeably throughout this paper to signify entities that manufacture or produce FDA regulated pharmaceuticals, biologics, medical devices, or medical supplies.

<sup>8</sup> Bruce Japsen, *Drug Makers Dial Down TV Advertising*, NYTIMES.COM, Feb. 2, 2012, [http://prescriptions.blogs.nytimes.com/2012/02/02/drug-makers-dial-down-tv-advertising/?\\_php=true&\\_type=blogs&\\_r=0](http://prescriptions.blogs.nytimes.com/2012/02/02/drug-makers-dial-down-tv-advertising/?_php=true&_type=blogs&_r=0).

<sup>9</sup> Richard Meyer, *Digital Budget for Pharma Expected To Be 20% for 2013*, WORLDOFDTCMARKETING.COM (Oct. 30, 2012), <http://worldofdtcmktg.com/digital-budget-for-pharma-expected-to-be-20-for-pharma/business-of-the-drug-industry/>. See also Matt Kapko, *Pharma and Healthcare Drive Biggest Online Ad Spending Gains*, CLICKZ.COM (Oct. 11, 2012), <http://www.clickz.com/clickz/news/2216594/pharma-and-healthcare-drive-biggest-online-ad-spending-gains>.

<sup>10</sup> Larry Dobrow, *DTC Report: DTC Gets Smart*, Medical Marketing & Media (Apr. 1, 2014) available at <http://www.mmm-online.com/dtc-report-dtc-gets-smart/article/339357/>.

<sup>11</sup> *Branded Pharmaceutical Websites Continue to Generate Highest Lifts in Rx Conversion and Adherence*, COMSCORE.COM (Apr. 5, 2012), [http://www.comscore.com/esl/Insights/Press\\_Releases/2012/4/Branded\\_Pharmaceutical\\_Websites\\_Continue\\_to\\_Generate\\_Highest\\_Lifts](http://www.comscore.com/esl/Insights/Press_Releases/2012/4/Branded_Pharmaceutical_Websites_Continue_to_Generate_Highest_Lifts) (determining 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).

<sup>12</sup> U.S. FOOD AND DRUG ADMIN., *Guidance for Industry: “Help-Seeking” and Other Disease Awareness Communications By or On Behalf Of Drug and Device Firms: Draft Guidance*, FDA.GOV (Jan. 23, 2004), <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070068.pdf> [hereinafter FDA Help-Seeking Guidance] (listing also depression, hyperlipidemia, hypertension, and diabetes as under-treated, under-diagnosed illnesses).

<sup>13</sup> Watch Over DTC Ads, *supra* note 1.

about the risks and negative effects of certain treatments; (3) may not advance—and may even threaten—public health; (4) encourage overuse of prescription drugs; and (5) encourage use of costly treatments, instead of less expensive treatments that may be equivalent, raising healthcare costs.<sup>14</sup>

Despite concerns regarding DTC advertising, the FDA recognizes that drug and device advertisements “can provide useful information for consumers to work with their healthcare professionals to make wise decisions about treatment.”<sup>15</sup> Moreover, removing DTC advertisements could “affect public health” by leaving people who would benefit from a new drug or device unaware of its availability, causing them not to seek treatment in absence of such advertising.<sup>16</sup> While the FDA has the jurisdiction to regulate online DTC advertisements, an increase in the number of materials submitted, coupled with a significant number of new online platforms, has made the FDA’s job of review and enforcement with regards to such materials very difficult.<sup>17</sup>

The rate at which technology and social media or interactive promotional media<sup>18</sup> develops continues to surpass FDA’s ability to stay up-to-date with the various ways in which companies are using such platforms for promotion. There are numerous types of interactive promotional media, including blogs,<sup>19</sup> microblogs,<sup>20</sup> podcasts,<sup>21</sup> video sharing,<sup>22</sup> widgets,<sup>23</sup> wikis,<sup>24</sup> social networking sites,<sup>25</sup> content communities, collaborative projects, and virtual social or game worlds. Moreover, more than fifty percent “of leading pharma[ceutical] companies expect social networking, [podcasts,] online video and other types of digital marketing to grow in use as critical tools for communicating disease state and product information.”<sup>26</sup> To satisfy FDA’s statutory

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<sup>14</sup> *Id.*

<sup>15</sup> *Id.* See also FDA Help-Seeking Guidance, *supra* note 12.

<sup>16</sup> Shelia Campbell, *Potential Effects of a Ban on Direct-to-Consumer Advertising of New Prescription Drugs*, CBO.gov (May 26, 2011), <http://www.cbo.gov/publication/42186>.

<sup>17</sup> Thomas Sullivan, *Policy Updates and Enforcement Developments From FDA’s Medical Products Centers: Tips on Social Media*, POLICY AND MEDICINE (Dec. 22, 2011, 5:28 AM), <http://www.policymed.com/2011/12/policy-updates-and-enforcement-developments-from-fdas-medical-products-centers-tips-on-social-media.html>.

<sup>18</sup> These words may be used interchangeably throughout this article but are meant to indicate the use of any interactive online platform that allows for real-time communications and interactions (e.g., Facebook, YouTube, Twitter, Instagram, etc.).

<sup>19</sup> Promotion of Food and Drug Administration-Regulated Medical Products Using the Internet and Social Media Tools; Notice of Public Hearing, 74 Fed. Reg. 48,083-01, 48,085, Sept. 21, 2009 [hereinafter FDA Social Media Hearing Notice]. Web logs, or “blogs,” are generally informal journal-type updates that encourage dialog about a subject. *Id.* at 48,085.

<sup>20</sup> *Id.* A “microblog” is similar to a blog but much shorter. *Id.* Twitter is a microblog service. *Id.*

<sup>21</sup> *Id.* Podcasts are video or audio clips that users can listen to or watch from a remote location. *Id.*

<sup>22</sup> *Id.* Video sharing allows the public to upload video clips to the internet (e.g., YouTube). *Id.*

<sup>23</sup> *Id.* Widgets are a graphic control on a Web page that allows the user to interact with it. *Id.* Widgets can be posted on multiple sites, host ‘live’ content, and are often on-screen tools. *Id.*

<sup>24</sup> *Id.* Wikis are webpages that anyone with access can modify (e.g., Wikipedia). *Id.*

<sup>25</sup> *Id.* Social networks allow users to connect with others (e.g., Facebook and LinkedIn). *Id.*

<sup>26</sup> Tanya Irwin, *Pharma Jumps On Social Media Bandwagon*, MediaPost (Oct. 29, 2012), <http://www.mediapost.com/publications/article/186133/pharma-jumps-on-social-media-bandwagon.html>.

obligation to issue social media guidance by July 9, 2014,<sup>27</sup> the Agency released its “first” 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” (“Guidance”).<sup>28</sup> While this guidance primarily focuses on how manufacturers can fulfill their post-marketing submission requirements for interactive promotional media, the FDA’s overall approach to interactive promotional media may provide useful insight for industry and stakeholders about the concerns noted above, and what the FDA’s interactive promotional media regime may hold in the near future.

This article analyzes several issues for the FDA and manufacturers to consider in finalizing the post-marketing guidance and drafting future interactive promotional media guidance, which the Agency has already announced.<sup>29</sup> Part II provides a brief history of the FDA’s regulation of DTC advertisements. Parts III and IV discuss the FDA’s oversight and enforcement with regards to such advertisements. Parts V and VI examine the difficulties posed by internet and social media advertisements, and examines several current examples of such advertisements. Finally, Part VII proposes several recommendations for consideration by the FDA and industry when promulgating guidance.

## II. HISTORY OF DTC ADVERTISING AND PROMOTION

The Pure Food and Drugs Act of 1906<sup>30</sup> was one of Congress’ first attempts to regulate prescription drugs, however, the legislation only contained provisions about product labels.<sup>31</sup> In addition, the Federal Trade Commission (FTC) “did not have the authority to regulate deceptive advertisements unless it could prove that such advertisements injured another company.”<sup>32</sup> To address this gap in regulation, Congress replaced the 1906 Act with the Federal Food, Drug, and Cosmetic Act of 1938 (FDCA).<sup>33</sup> The

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<sup>27</sup> Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144, § 1121, 126 Stat. 993, 1112 (2012) [hereinafter FDASIA].

<sup>28</sup> U.S. FOOD AND DRUG ADMIN., *Guidance for Industry: Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics*, FDA.GOV (Jan. 2014), [www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM381352.pdf](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM381352.pdf). [hereinafter FDA Post-Marketing Interactive Promotional Media Guidance].

<sup>29</sup> U.S. Food and Drug Admin., *Guidance Agenda: New & Revised Draft Guidances CDER is Planning to Publish During Calendar Year 2014*, FDA.GOV (Jan. 31, 2014), <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. *Id.*

<sup>30</sup> Pure Food and Drugs Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (1906) (repealed 1938).

<sup>31</sup> Francis B. Palumbo & C. Daniel Mullins, *The Development of Direct-to-Consumer Prescription Drug Advertising Regulation*, 57 FOOD & DRUG L. J. 423, 424-25 (2002).

<sup>32</sup> *Id.* at 425.

<sup>33</sup> Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (as amended 21 U.S.C. §§ 301 *et seq.*).

passage of the FDCA was necessary because among other things, the United States had seen a significant evolution of advertising practices such as radio, and the use of drug and cosmetic advertisements in magazines and newspapers since 1906.<sup>34</sup> The final legislation, however, only granted the FDA jurisdiction over the labeling of all drugs and omitted advertising provisions. Instead, “Congress amended the Federal Trade Commission Act in 1938 to give jurisdiction over all drug advertising to the FTC.”<sup>35</sup>

In 1962, “the Kefauver-Harris Drug Amendments to the FDCA transferred regulatory authority over prescription drug advertising from the FTC to the FDA, by enacting section 502(n).”<sup>36</sup> Although the FDA promulgated detailed drug advertisement regulations a year later, in 1963, the promulgated regulations were designed for promotions directed to physicians.<sup>37</sup> This was unsurprising, however, because Congress did not intend for the FDA to regulate drug advertisements to consumers and such advertisements barely existed in 1962.<sup>38</sup> Thus, under the FDCA, the FDA has responsibility for regulating the FDA-approved labeling,<sup>39</sup> promotional labeling,<sup>40</sup> and advertising for prescription drugs. Section 201(m) of the Act, defines labeling to include all “written, printed, or graphic” materials “accompanying” a regulated product.<sup>41</sup> The FDA argues that although this definition of labeling is not limited to materials that physically accompany a product the textual relationship between the materials and the product is fundamental, and the Supreme Court agrees with this position.<sup>42</sup>

The FDCA “does not specifically define” prescription drug “advertising” or “advertisement,” but the FDA generally interprets the term to “include information (other than labeling) that is sponsored by a manufacturer and is intended to supplement or explain a product.”<sup>43</sup> If a promotional activity or material is considered advertising or labeling, the activity or material must contain adequate directions and information for

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<sup>34</sup> Palumbo, *supra* note 31, at 425 (citation omitted).

<sup>35</sup> *Id.* at 426 (citing Wheeler-Lea Act, 52 Stat. 111, ch. 49 (1938)).

<sup>36</sup> *Id.* Prior to the 1962 Amendments, the FDA and the FTC had entered into a “Working Agreement” in 1954.

<sup>37</sup> Lars Noah, *Advertising Prescription Drugs to Consumers*, 32 GA. L. REV. 141, 142 (1997).

<sup>38</sup> See H.R. REP. NO. 87-2464, at 2 (1962) (describing as one of the principal purposes of the legislation . . . to make available “adequate information concerning safety and effectiveness of *drugs advertised to physicians*”).

<sup>39</sup> FDA Help-Seeking Guidance, *supra* note 12.

<sup>40</sup> *Id.* Promotional labeling is generally any labeling other than the FDA-approved labeling. *Id.*

<sup>41</sup> 21 U.S.C. § 321(m) (2012). The FDA regulations define advertising subject to regulation 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 . . . .” 21 CFR § 202.1(l)(2) (2013). See also *VE. Irons, Inc. v. United States*, 244 F.2d 34, 39 (1st Cir. 1957).

<sup>42</sup> *Kordel v. United States*, 335 U.S. 345, 349–350 (1948).

<sup>43</sup> Direct-to-Consumer Promotion; Public Hearing, 60 Fed. Reg. 42,581-01, 42,581 (Aug. 16, 1995) [hereinafter 1995 DTC Hearing]. This includes, “advertisements in published journals, magazines,



use that are the “same in language and emphasis” as the product’s approved labeling.<sup>44</sup> This requirement can be fulfilled by including the product’s full approved labeling (the “package insert”) with the promotional material.<sup>45</sup>

Section 352(n) of the FDCA requires drug advertisements, in written or electronic form, to contain the brand name, list of ingredients, and a “brief summary” of side effects of the drug.<sup>46</sup> The brief summary must provide all of the drug’s side effects or risks listed in the drug’s FDA-approved prescribing information (PI), contraindications, warnings, precautions, and indications for use.<sup>47</sup> The FDA regulations also established the “fair balance doctrine,” which provides that the entire advertisement must present a balanced account of all clinically relevant information.<sup>48</sup> A drug’s risks must be presented prominently and legibly so that the advertisement does not put more emphasis on the drug’s benefits than its risks.<sup>49</sup> Additionally, a drug is misbranded if its advertising is “false or misleading, fails to reveal material facts, or fails to present a fair balance of information.”<sup>50</sup>

### III. FDA Regulation of Prescription Drug Advertising

The FDA first addressed DTC promotion of pharmaceuticals in the mid-1970s by “issuing a regulation that authorized advertising of prescription drug prices to consumers so long as a company made no representations about the safety or effectiveness of the product,”<sup>51</sup> but was “shocked” by the rise of DTC advertisements in the 1980s.<sup>52</sup> In 1981, Boots Pharmaceuticals issued the first DTC prescription drug advertisement in the United States for Rufen, an anti-arthritis drug.<sup>53</sup> A 1982 speech by the FDA Commissioner, Arthur Hull Hayes, Jr. predicting the “exponential growth” in DTC advertisements, was seen by the industry as evidence that the FDA would permit such

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other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems.” *Id.*

<sup>44</sup> 21 U.S.C. § 352(f) (2012); *see also* 21 CFR § 201.100(d) (2013).

<sup>45</sup> 1995 DTC Hearing, *supra* note 43.

<sup>46</sup> 21 U.S.C. § 352(n) (2012) (a drug is misbranded “unless the manufacturer . . . includes in all advertisements . . . [a] brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations. . . .”).

<sup>47</sup> 21 C.F.R. § 202.1(e) (2013). This information includes: (1) who should not take the drug; (2) when the drug should not be taken; (3) possible serious side effects, and if known, what can be done to lower the chances of having them; and (4) frequently occurring, but not necessarily serious side effects.

<sup>48</sup> FDA Glossary, *supra* note 2.

<sup>49</sup> *See* 21 C.F.R. § 202.1(e)(5)-(7) (2013). For example, the risks should not appear in much smaller type than the benefits and be placed in a corner of the advertisement far from the benefits because they are likely to be overlooked.

<sup>50</sup> Noah, *supra* note 37, at 145 (citing 21 C.F.R. § 202.1(e)(5) (1997)).

<sup>51</sup> *Id.* at 147; *see also* *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 762–70 (1976).

<sup>52</sup> Wayne L. Pines, *A History and Perspective on Direct-to-Consumer Promotion*, 54 *FOOD & DRUG L. J.* 489, 491 (1999).

<sup>53</sup> Palumbo, *supra* note 31, at 424 (citation omitted).

advertisements, and consequently, the FDA received “a large influx of proposed DTC ad[vertisements].”<sup>54</sup>

Due to uncertainty regarding how to regulate DTC advertisements, the FDA issued a formal request to industry in September 1982 “for a voluntary moratorium on DTC advertisements, to allow FDA time to research the issue.”<sup>55</sup> During the moratorium, the FDA sponsored a series of public meetings and conducted several studies on the effects of DTC advertisements.<sup>56</sup> In September 1985, FDA removed the moratorium stating that DTC advertisements must meet the same legal requirements as those directed at physicians.<sup>57</sup> Despite the FDA’s recognition that there were differences between the expertise and knowledge of healthcare professionals and consumers as recipients of drug promotion,<sup>58</sup> the FDA maintained that pre-existing regulations governing drug advertisements would sufficiently safeguard consumers. Thus, DTC advertisements had to be fairly balanced and meet the brief summary requirements.

Companies, however, started to expand the types of DTC advertisements that they produced. As a result, FDA recognized three broad categories of advertisements: (1) reminder advertisements,<sup>59</sup> (2) help-seeking or disease-oriented advertisements,<sup>60</sup> and (3) product-claim or indication advertisements. Reminder and help-seeking advertisements are exempt from the brief summary and fair balance requirements because they do not reveal a drug’s risks or benefits.<sup>61</sup> Most DTC promotions are product-claim advertisements, which must identify the drug’s brand and generic names and accurately state an FDA-approved use for the drug.<sup>62</sup> The product claim advertisement must present the benefits and risks of a drug in a balanced fashion,<sup>63</sup> and should say that the drug is given by prescription only. While the distinction between advertisement types was useful to the FDA and drug or device companies, the tremendous growth in the use of DTC advertisements demanded more guidance from the Agency.

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<sup>54</sup> Pines, *supra* note 52, at 492.

<sup>55</sup> Palumbo, *supra* note 31, at 424.

<sup>56</sup> See Louis A. Morris & Lloyd G. Millstein, *Drug Advertising to Consumers: Effects of Formats for Magazine and Television Advertisements*, 39 FOOD DRUG COSM. L. J. 497 (1984).

<sup>57</sup> Direct-to-Consumer Advertising of Prescription Drugs; Withdrawal of Moratorium, 50 Fed. Reg. 36,677-02 (Sept. 9, 1985).

<sup>58</sup> 1995 DTC Hearing, *supra* note 43.

<sup>59</sup> *Id.* Reminder advertisements call attention to the name of the drug product, but do not include specifications or the drug’s use. *Id.*

<sup>60</sup> *Id.* Help-seeking advertisements describe the symptoms of a disease or condition, but must not reference a specific drug. *Id.*

<sup>61</sup> FDA Glossary, *supra* note 2. A benefit is help provided by a drug for the person who is taking it. *Id.*

<sup>62</sup> U.S. FOOD AND DRUG ADMIN., *Product Claim Ad (Correct)*, FDA.GOV (Sept. 13, 2012), <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/PrescriptionDrugAdvertising/ucm082284.htm>.

<sup>63</sup> FDA Glossary, *supra* note 2. A claim says something about the advertised drug or what it does. *Id.*



## i. FDA DTC Advertising Guidance

Reliance on pre-existing drug advertisement regulations created “confusion among consumers”<sup>64</sup> and several problems for manufacturers pursuing DTC broadcast advertisements. The FDA asked manufacturers in a July 1993 letter to voluntarily submit proposed DTC materials prior to use, providing the FDA with an opportunity to review and comment upon proposed materials before they reached consumers.<sup>65</sup> Two years later, FDA convened a public hearing to address the difficulties posed by new communication technologies.<sup>66</sup> At the time, broadcast advertisements were required to contain a brief summary, unless “adequate provision [was] made for dissemination” of the approved labeling in connection with the presentation.<sup>67</sup> While companies could meet this requirement for healthcare providers by “providing the page number for the advertised product in the Physicians’ Desk Reference (PDR), along with a toll-free telephone number” to request a copy of the prescribing information (PI), this was inadequate for most consumers. It was also impractical for a thirty-second television advertisement to contain a brief summary because it would take minutes for the summary to play or scroll down a television screen. As a result of this issue, companies used mostly reminder and help-seeking advertisements on television, which were exempt from the brief summary and fair balance requirements.<sup>68</sup>

Once manufacturers started using the internet for DTC advertising, issues arose, prompting consumer groups, medical associations, and even some manufacturers to ask the FDA to adopt more comprehensive regulations.<sup>69</sup> As a result, the FDA held a series of meetings with manufacturers in 1995 and convened an Internet Conference in October 1996 to help guide the Agency in making policy decisions regarding the promotion of drugs on the internet.<sup>70</sup> The FDA, however, issued its first warning letter prior to the 1996 Internet Conference and began targeting websites that used improper drug promotion, “sweeping” approximately 1,200 internet websites in search of deceptive health claims.<sup>71</sup> Shortly thereafter, the FDA finalized guidance regarding DTC broadcast advertisements, which recognized a distinction between print and broadcast advertisements.<sup>72</sup>

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<sup>64</sup> Pines, *supra* note 52, at 496.

<sup>65</sup> FDA Form 3439, Interim Form for Application to Market a New Drug, Biologic, or Antibiotic Drug for Human Use; Availability, 61 Fed. Reg. 24313-02 (May 14, 1996).

<sup>66</sup> FDA Public Hearing on Direct-to-Consumer Promotion (Oct. 18-19, 1995); *see also* 1995 DTC Hearing, *supra* note 43.

<sup>67</sup> 21 C.F.R. § 202.1(e)(1) (2013).

<sup>68</sup> 1995 DTC Hearing, *supra* note 43.

<sup>69</sup> Leah Brannon, *Regulating Drug Promotion on the Internet*, 54 FOOD & DRUG L. J. 599 (1999) (citation omitted).

<sup>70</sup> FDA Social Media Hearing Notice, *supra* note 19.

<sup>71</sup> Brannon, *supra* note 69, at 601 (citation omitted).

<sup>72</sup> U.S. FOOD AND DRUG ADMIN., *Guidance for Industry, Consumer-Directed Broadcast Advertisements*, FDA.GOV (Aug. 1999), <http://www.fda.gov/RegulatoryInformation/Guidances/ucm125039.htm>. [hereinafter 1999 DTC Broadcast Guidance]. *See also* 21 C.F.R. § 202.1(e)(1) (2013) (regulating print and broadcast advertisements differently).

While print advertisements must include the brief summary, broadcast advertisements must disclose the product's major risks in either the audio or audio and visual portions of the presentation—known as the “major statement.”<sup>73</sup> The amount and type of included risk information will vary by drug because each drug has different risks. Sponsors of broadcast advertisements are also required to present a brief summary or make “adequate provision . . . for dissemination of the approved or permitted package labeling in connection with the broadcast presentation.”<sup>74</sup> Thus, the regulations specify that the major statement, together with adequate provision for dissemination of the drug's approved labeling, can fulfill the mandated risk information disclosure.<sup>75</sup>

In February 2004, the FDA published several draft guidance documents pertaining to DTC advertisements.<sup>76</sup> The documents provide recommendations and factors industry should consider when creating help-seeking and disease awareness advertisement, and disclosing risk information in the brief summary in print advertisements. In 2007, Congress passed the Food and Drug Administration Amendment Act (FDAAA), which included Section 901, requiring that the major statement relating to side effects and contraindications in broadcast advertisements be presented in a clear, conspicuous, and neutral manner.<sup>77</sup> In addition, Section 906 requires advertisements to include a specific statement and contact information that encourages consumer reporting of negative side effects to the FDA.<sup>78</sup> Two years later, the FDA issued further guidance that outlined several factors that the FDA would consider when evaluating the presentation of risk information in DTC advertisements. These factors include (1) the amount of information conveyed by a promotional piece; (2) materiality and comprehensiveness; (3) the nature of benefit claims; and (4) format.<sup>79</sup> The guidance also provides recommendations

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<sup>73</sup> 1999 DTC Broadcast Guidance *supra* note 72.

<sup>74</sup> *Id.* Broadcast advertisements must reference: (1) directions to contact a healthcare professional; (2) a toll-free telephone number; (3) the current issue of a magazine that contains a print advertisement; and (4) a website address. *Id.*

<sup>75</sup> *Id.* at 2 (citing Section 502(n) of the FDCA).

<sup>76</sup> See FDA Help-Seeking Guidance, *supra* note 12. See also U.S. FOOD AND DRUG ADMIN., *Draft Guidance for Industry: Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements*, FDA.GOV (Jan. 2004), <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm069984.pdf>. The third draft guidance addressed medical devices, not covered in this paper.

<sup>77</sup> U.S. FOOD AND DRUG ADMIN., *Draft Guidance for Industry: Direct-to-Consumer Television Advertisements – FDAAA DTC Television Ad Pre-Dissemination Review Program*, FDA.GOV, 1–2 (March 2012), <http://www.fda.gov/downloads/Drugs/Guidances/UCM295554.pdf> [hereinafter FDA TV Pre-dissemination Guidance].

<sup>78</sup> U.S. FOOD AND DRUG ADMIN., *Report to Congress: DTC Advertising's Ability to Communicate to Subsets of Population; Barriers to Participation of Population Subsets in Clinical Trials*, FDA.GOV, 4 (Sept. 2009), <http://www.fda.gov/downloads/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCA/SignificantAmendments/totheFDCA/FoodandDrugAdministrationAmendmentsActof2007/FDAAImplementationChart/UCM213016.pdf> [hereinafter FDA 2009 Rept. to Congress].

<sup>79</sup> U.S. FOOD AND DRUG ADMIN., *Draft Guidance for Industry: Presenting Risk Information in Prescription Drug and Medical Device Promotion*, FDA.GOV, 10 (May 2009), <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM155480.pdf> [hereinafter FDA Risk Information Guidance].

regarding the use of text that is “superimposed on other images in videos or broadcast ad[vertisement]s (SUPERS) and other visual components, such as graphics, within an ad[vertisement]” that may be applicable to DTC advertisements online or in social media.<sup>80</sup>

In 2012, the FDA issued draft guidance to clarify “the requirements for product name placement, size, prominence, and frequency in promotional labeling” and drug ad[vertisement]s.”<sup>81</sup> The guidance pertains to product names in “electronic and computer-based promotional labeling and advertisements, such as Internet promotion, social media, e-mails, CD-ROMs, and DVDs.”<sup>82</sup> In addition, the guidance recognizes that electronic and computer-based media do not contain text pages like print media, but do contain “running text<sup>[83]</sup> equivalent to many pages of traditional printed text.”<sup>84</sup> Although the guidance is not specific to DTC advertisements, it provides practical recommendations that may be applicable to social media and internet DTC advertisement.

## ii. FDA’s Off-Label Guidance

In late 2011, the FDA released draft guidance regarding industry’s use of websites and emerging electronic media to respond to unsolicited requests for off-label information.<sup>85</sup> The guidance, however, was not the social media and internet guidance that industry had long awaited.<sup>86</sup> Nevertheless, the FDA provided examples in the guidance of what might constitute solicitation by a manufacturer through social media, including: “(1) [t]weeting study results and suggesting that an off-label use is safe and effective; (2) [e]stablishing standard response websites that in part include off-label information; (3) [e]ncouraging third-party bloggers to post about off-label use; (4) [c]reating a username, e-mail address, or URL that suggests off-label use; or (5) [r]equesting users to post videos about their product experience on a site such as YouTube, resulting in videos on off-label use.”<sup>87</sup> The examples provided by FDA demonstrate that the Agency

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<sup>80</sup> See *id.* at 18. Factors include: (1) not presenting words in all upper case; (2) using competing or unrelated SUPERS; (3) using busy scenes, frequent scene changes, or vivid and compelling visuals; or (4) length of time a SUPER is on a screen.

<sup>81</sup> U.S. FOOD AND DRUG ADMIN., *Draft Guidance: Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling*, FDA.GOV, 1 (January 2012), <http://www.fda.gov/downloads/Drugs/.../Guidances/ucm070076.pdf> [hereinafter FDA Ad and Promotional Guidance].

<sup>82</sup> *Id.* at 2.

<sup>83</sup> *Id.* at 3 (noting that FDA interprets the *running text* “to mean the body of text in a piece, as distinct from headlines, taglines, logos, footnotes, graphs, or pictures”).

<sup>84</sup> *Id.* at 5.

<sup>85</sup> U.S. FOOD AND DRUG ADMIN., *Draft Guidance: Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices*, FDA.GOV (Dec. 2011), <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM285145.pdf> [hereinafter FDA Off-Label Guidance].

<sup>86</sup> U.S. FOOD AND DRUG ADMIN., *Public Hearing on Promotion of FDA-Regulated Medical Products Using the Internet and Social Media Tools* (Nov. 12–13, 2009), <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm184250.htm> [hereinafter 2009 FDA Internet and Social Media Hearing].

<sup>87</sup> John Sullivan, et al., *The FDA and the Regulation of Social Media*, CORPORATE COUNSEL (Jun. 27, 2012), available at <http://www.dechert.com/files/Publication/ef3f4a16-9d0a-4178-b84c->

“will hold companies responsible for their direct actions” and may also hold companies “responsible for third-party postings . . . if the company explicitly encouraged that third-party to post improper information” and even if the company did not request that content.<sup>88</sup> For example, if a user discusses off-label uses of a drug in a video posted on the internet, even though the company did not request off-label videos, the FDA may consider such videos solicited.<sup>89</sup>

Despite the FDA’s recognition that the internet and social media have fundamentally changed the way that companies communicate with the public, the FDA recommended that any substantive responses from companies to unsolicited requests for information regarding off-label use of drugs not occur through the internet or interactive promotional media due to the inherently public and permanent nature of these communications.<sup>90</sup> Ultimately, industry expressed concern about the draft guidance issued by the FDA, maintaining that it “will unnecessarily stifle the flow of accurate scientific information that has otherwise been intended both by the industry and FDA, as well as handicap the unique benefits of social media that FDA should embrace in order to further public health.”<sup>91</sup> As a result, most drug and device companies have remained risk averse when it comes to using social media or the internet for DTC advertisements and are far behind in their implementation and use of social media.<sup>92</sup> Ironically, the FDA has become increasingly skilled with using social media tools on its own behalf.<sup>93</sup> The FDA’s failure to articulate clear internet and social media guidelines and its use of regulatory letters and enforcement actions to hold companies accountable has generated additional uncertainty within the industry.

### iii. FTC “.com” Guidance and Current Use of Social Media

The FTC recently released guidance on “.com Disclosures,”<sup>94</sup> which could have several implications for products regulated by the FDA, if the FDA decides to follow the FTC’s approach. For example, the FTC guidance recommends that disclosures which are an “integral part of a claim or inseparable from it should not be communicated through a hyperlink.”<sup>95</sup> Specifically, the FTC states that hyperlinks, even one labeled “Important Health Information,”<sup>96</sup> “should not be used . . . [for] important health and safety

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ac2ee9197917/Presentation/PublicationAttachment/c775d639-aa34-4047-97c4-b27872755ac2/FDA%20Dechert.pdf.

<sup>88</sup> *Id.*

<sup>89</sup> FDA Off-Label Guidance, *supra* note 85, at 5.

<sup>90</sup> *Id.* at 10.

<sup>91</sup> Jamie Kendall & Noah Mallon, *Does FDA’s Draft Guidance on Responding to Unsolicited Off-Label Requests Align With FDA’s Mission to Promote the Public Health?*, 2-3 FDLI, FOOD AND DRUG POLICY FORUM (Mar. 14, 2012).

<sup>92</sup> Digital Budget for Pharma Expected to be 20% for 2013, *supra* note 9.

<sup>93</sup> *FDA’s Social Media Assets – Twitter Overview*, EYEONFDA (June 23, 2011), [http://www.eyeonfda.com/eye\\_on\\_fda/2011/06/fdas-social-media-assets-twitter-overview.html](http://www.eyeonfda.com/eye_on_fda/2011/06/fdas-social-media-assets-twitter-overview.html).

<sup>94</sup> FEDERAL TRADE COMMISSION, *.com Disclosures: How to Make Effective Disclosures in Digital Advertising*, 10 (Mar. 2013), <http://www.ftc.gov/os/2013/03/130312dotcomdisclosures.pdf> [hereinafter FTC Online Guidance].

<sup>95</sup> *Id.*

<sup>96</sup> *Id.* at 10 (example 4).

information” because “required disclosures about serious health and safety issues are unlikely to be effective when accessible only through a hyperlink.”<sup>97</sup> The FTC, however, provides no evidence as to why such health information hyperlinks are unlikely to be effective. Nevertheless, the FTC maintains that “integral” or “inseparable” disclosures “should be placed on the same page and immediately next to the claim, and be sufficiently prominent so that the claim and the disclosure are read at the same time.”<sup>98</sup> The FTC also reiterates that “any disclosure that is integral to the primary claim should be immediately adjacent to that claim.”<sup>99</sup>

The FTC recognized that when disclosure in a space-constrained advertisement is not possible, “it may, under some circumstances, be acceptable to make the disclosure clearly and conspicuously on the page to which the advertisement links.”<sup>100</sup> When using a hyperlink to lead to a disclosure, the FTC recommends: (1) making the link *obvious*; (2) labeling the hyperlink appropriately to convey the importance, nature, and relevance of the information that it leads to;<sup>101</sup> (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.<sup>102</sup>

The FTC also recommended designing advertisements so that “scrolling” “is not necessary in order to find a disclosure”; however, if scrolling is necessary, the FTC recommended using text or visual cues to encourage consumers to scroll to view the disclosure.<sup>103</sup> Moreover, the FTC indicated that companies should consider how linking or “mouse-overs” may work on computers but may not work mobile devices.<sup>104</sup> The guidance explains that if an advertisement without a disclosure would be deceptive, unfair, or violate one of the FTC rules, and “if a particular platform does not provide an opportunity to make clear and conspicuous disclosures, then that platform should not be used to disseminate advertisements that require disclosures”<sup>105</sup> Although not directly applicable to products regulated by the FDA, the FDA may use the FTC’s guidance as it begins drafting additional guidance regarding DTC advertisements in online media and social media platforms in 2014.

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<sup>97</sup> *Id.* at 10, A6.

<sup>98</sup> *Id.* at 10.

<sup>99</sup> *Id.* at A6 (example 4).

<sup>100</sup> *Id.* at ii.

<sup>101</sup> *Id.* at 11–12 (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.” The FTC added that labels such as “important information” or limitations may also be inadequate. While the FTC said there is “no one-size-fits-all” word or phrase to use in a hyperlink label, “more specificity” is better).

<sup>102</sup> *Id.* at ii (emphasis added).

<sup>103</sup> *Id.* For example, “see below for important information”; but not “details below” because it provides “no indication about the subject matter or importance of the information that consumers will find and are not adequate cues.” *Id.* at 9.

<sup>104</sup> *Id.* at 12.

<sup>105</sup> *Id.* at iii.

#### IV. FDA OVERSIGHT AND ENFORCEMENT OF DTC ADVERTISING

The FDA's Office of Prescription Drug Promotion (OPDP)<sup>106</sup> regulates drug advertising and promotion. OPDP has four DTC review groups that review final DTC materials, provide advisory comments on draft materials that companies submit voluntarily, and review materials cited in complaints submitted by competitors or consumers.<sup>107</sup> Because the FDA regulations require that companies submit final DTC promotional materials to the FDA at the time of their initial dissemination to the public<sup>108</sup> (often referred to as "postmarketing submission" requirements), the OPDP review groups monitor television, magazines, and manufacturer websites to ensure compliance. OPDP also monitors DTC advertisement to ensure that advertisements are not false or misleading;<sup>109</sup> that advertisements have adequate contextual and risk information; and that advertisements are presented in understandable language to fulfill the fair balance requirement.<sup>110</sup> Additionally, OPDP monitors DTC advertisements through a routine surveillance and monitoring program, including the "Bad Ad" Program.<sup>111</sup>

If OPDP finds a DTC advertisement or promotional piece that violates the law or guidelines issued by the FDA, it issues a regulatory letter to the manufacturer disseminating the violative material.<sup>112</sup> There are two types of letters that OPDP issues: a Notice of Violation (NOV) Letter (or "untitled letter") for minor violations, and a Warning Letter for more serious violations.<sup>113</sup> Other enforcement actions include product seizures, criminal actions, injunctions, and consent decrees.<sup>114</sup> The FDA may also hold any person who disseminates a false or misleading drug DTC advertisement liable for civil monetary penalties.<sup>115</sup> Despite having these enforcement tools, OPDP has previously faced difficulty prioritizing and taking enforcement actions against

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<sup>106</sup> This office was previously DDMAC, and before that had several other names. Pines, *supra* note 52, at 495–96.

<sup>107</sup> *Prescription Drugs: Trends in FDA's Oversight of Direct-to-Consumer Advertising, Testimony Before the Subcomm. on Oversight and Investigations, Comm. on Energy & Commerce, U.S. Gov't Accountability Office*, GAO-08-758T, 5 (May 8, 2008) (statement of Marcia Cross, Director, Health Care) [hereinafter GAO-08-758T].

<sup>108</sup> 21 C.F.R. § 314.81(b)(3)(i) (2013). This is to be transmitted on an FDA Form 2253.

<sup>109</sup> U.S. FOOD AND DRUG ADMIN., *From the manufacturers' mouth to your ears: Direct to consumer advertising* (June 6, 2013), <http://www.fda.gov/drugs/resourcesforyou/specialfeatures/ucm319379.htm>. Drug promotion is considered false or misleading if it: (1) promotes the drug as being more effective than actually demonstrated; (2) implies that a drug is safer or has fewer or less severe side effects than demonstrated; (3) claims, without substantial evidence, that its product is better than a competitor's drug; (4) gives a false, misleading or unbalanced presentation of risk information; and (5) promotes the product as being able to treat conditions not approved by FDA. *Id.*

<sup>110</sup> FDA Risk Information Guidance, *supra* note 79, at 4.

<sup>111</sup> U.S. FOOD AND DRUG ADMIN., *Truthful Prescription Drug Advertising and Promotion* (Nov. 26, 2013), <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/DrugMarketingAdvertisingandCommunications/ucm209384.htm>.

<sup>112</sup> GAO-08-758T, *supra* note 107, at 1–2.

<sup>113</sup> *Id.* at 6. FDA may require a "correction advertisement" for serious violations. *Id.*

<sup>114</sup> *Id.* at 6, note 8.

<sup>115</sup> FDA 2009 Rept. to Congress, *supra* note 78, at 4.



submitted promotional materials that may be violative due to the increasing number of materials submitted.<sup>116</sup>

Although the FDA established criteria to prioritize review of DTC advertisements in 2008, the criteria still do not ensure that OPDP systematically screens the DTC materials it receives against the established criteria to identify those advertisements that are the highest priority for review.<sup>117</sup> Further, a policy change requiring the FDA's Office of Chief Counsel (OCC) to review all draft regulatory letters (e.g., NOV's and Warning Letters) that took place in 2002 led to the FDA issuing about half as many letters as it had previously.<sup>118</sup> Moreover, while companies complied with the FDA requests to remove materials that were still being disseminated and issuing corrective materials, these actions generally did not occur until five to twelve months after the FDA's regulatory letter was sent.<sup>119</sup> As a result, some products remained on the market, on average for about seven months, despite their violative nature.<sup>120</sup> In addition, regulatory letters did not always prevent drug companies from later disseminating similar violative materials for the same drugs.<sup>121</sup>

OPDP began to refocus its attention on DTC advertising on the internet in 2010, when it issued thirteen regulatory letters related to online media including "emails, websites, website videos, social media, and/or webcasts."<sup>122</sup> In 2011, the FDA issued seven warning letters related to misleading online promotion, most involving "the placement and/or lack of prominence of risk information."<sup>123</sup> Some commentators have attributed the decrease in internet-promotion related Warning Letters issued by the FDA to companies relying more on help-seeking and reminder type sponsored links in order to avoid the brief summary requirement.<sup>124</sup> In 2012, OPDP issued twenty-five untitled letters and three Warning Letters for promotional violations, bringing its total to 173 regulatory action letters regarding communications about FDA regulated drugs or devices between 2008 and 2012.<sup>125</sup> Overall, between 2008 and 2012, the FDA found

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<sup>116</sup> In 2008, DDMAC received 10,861 Internet DTC materials. *See id.* at 6.

<sup>117</sup> GAO-08-758T, *supra* note 107, at 8–9.

<sup>118</sup> *Id.* at 3–4, 11. As a result, letters were issued on average 8 months after violative materials were first disseminated; when "companies had already discontinued more than half of the violative" advertisements.

<sup>119</sup> *Id.* at 12.

<sup>120</sup> *Id.*

<sup>121</sup> *Id.* at 5. For example, of the 89 drugs for which FDA cited violative DTC materials from 1997 through 2005, 25 drugs had DTC materials cited in more than one regulatory letter, sometimes for similar types of violations.

<sup>122</sup> Kassity Liu, *FDA and Social Media: The Impact of Social Media on Prescription Drug Advertising*, JOLT DIGEST (Apr. 17, 2012), <http://jolt.law.harvard.edu/digest/digest-note/fda-and-social-media-the-impact-of-social-media-on-prescription-drug-advertisin>.

<sup>123</sup> Jacqueline West, *National Marketing Gone Unintentionally Global: Direct-to-Consumer Advertising of Pharmaceutical Products and the Internet*, 11 J. INT'L BUS. & L. 405, 414–15 (2012).

<sup>124</sup> *Id.* at 415 (citing 2009 FDA Internet and Social Media Hearing, *supra* note 86, at 438–40).

<sup>125</sup> Mark Senak, *FDA Communications: Oversight in a Digital Era, 2008-2013*, EYEONFDA (Apr. 2013), <http://www.eyeonfda.com/wp-content/uploads/2013/03/FDA-Communications-Oversight-in-a-Digital-Era1.pdf>.



“290 digital violations.”<sup>126</sup> Of these violations, over half were for companies that failed to include risk information or minimized the risk, while eighteen percent overstated efficacy.<sup>127</sup> However, of the 173 regulatory action letters, “less than 1 percent involved a social media platform as the basis for the letter.”<sup>128</sup>

Nevertheless, the lack of transparency in the FDA’s enforcement discretion, coupled with the FDA’s vague guidance is problematic for several reasons. First, these new avenues of communication create ways for companies to reach millions of patients who may need treatments or are avoiding seeing a doctor. As a result, patients may not be receiving information that could change their health and lives. Second, the lack of guidance and transparency raises First Amendment issues because advertisements are a form of commercial speech.<sup>129</sup> Third, the current regulatory regime hurts physician training and education because doctors may also be motivated to learn about new drugs through DTC advertisements they see directly or through conversation with their patients.<sup>130</sup> Despite these negative effects, the FDA has been unable to tackle the challenges of DTC promotion online.

## V. THE DIFFICULTIES POSED BY SOCIAL MEDIA AND INTERNET DTC ADVERTISEMENTS

The use of DTC advertisements in social media and on the internet creates several challenges for companies. First, providing fair balance is difficult because Twitter, sponsored links, and share widgets generally do not have enough space for the FDA required risk disclosures. For static websites, companies had been using an industry-created practice known as the “one-click-away” rule, which assumes that it is sufficient to present some information about a drug, absent risk disclosure, so long as information regarding the risk is only “one-click away.”<sup>131</sup> However, “the mere possibility of access to risk information does not necessarily translate into a realistic presentation of risks.”<sup>132</sup> Drug and device companies widely used “one-click away” until April 2009, when the FDA issued fourteen (NOV) letters to manufacturers who sponsored search-engine advertisements on Google for drugs.<sup>133</sup>

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<sup>126</sup> Mark Senak, *Comparing Types of Violations Between Digital and Non-Digital*, EYEONFDA (Apr. 11, 2013), [http://www.eyefonda.com/eye\\_on\\_fda/2013/04/comparing-types-of-violations-between-digital-and-non-digital.html](http://www.eyefonda.com/eye_on_fda/2013/04/comparing-types-of-violations-between-digital-and-non-digital.html). This represented only 43% of the total violations. *Id.*

<sup>127</sup> *Id.* (finding 56% of digital violations failed to include risk information or involved minimization of risks).

<sup>128</sup> Senak, *supra* note 125.

<sup>129</sup> See e.g., *Thompson v. Western States Med. Ctr.*, 122 S.Ct. 1497 (2002) (striking down a provision in the FDA Modernization Act (FDAMA) that prohibited pharmacies from advertising compounded products); *Virginia Board of Pharmacy v. Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976) (invalidating a ban on drug price advertising).

<sup>130</sup> See *Patient Ed: How Patients Learn in the Digital Age*, *supra* note 6.

<sup>131</sup> Doug Flora, *The FDA and Social Media: A Primer*, THE FOSBURY FLOP (Sept. 27, 2010), <https://reputationcommunications.wordpress.com/2010/09/27/the-fda-and-social-media-a-primer/>.

<sup>132</sup> Jeremy A. Greene & Aaron S. Kesselheim, *Pharmaceutical Marketing and the New Social Media*, 363 NEW ENG. J. MED. 2087, 2088 (2011).

<sup>133</sup> Stephanie Clifford, *FDA Rules on Drug Ads Show Confusion as Applied to Web*, NYTIMES.COM, Apr. 16, 2006, [http://www.nytimes.com/2009/04/17/business/media/17adco.html?\\_r=0](http://www.nytimes.com/2009/04/17/business/media/17adco.html?_r=0).

The NOV letters asserted that information in a sponsored link that includes a website address consisting of the trade name for a drug, and that appears on the results page of an internet search engine when a keyword search is conducted, is not a reminder advertisement but instead is “labeling” and “advertising.”<sup>134</sup> As a result, OPDP 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.”<sup>135</sup> The FDA stated that its promotional laws “are the same regardless of the medium.”<sup>136</sup> Thus, the FDA found the sponsored link misleading because it suggested efficacy without disclosing risk information.<sup>137</sup> The FDA also found a sponsored link misleading, even though it made “no explicit claim about the drug.”<sup>138</sup> These actions illustrate how the 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.<sup>139</sup>

In 2010, the FDA also sent its first untitled letter regarding information generated by the “Facebook Share” widget on one of Novartis’s websites. Clicking on the widget sent Novartis-authored information about the leukemia drug Tasigna to a user’s Facebook page. The FDA stated that the “shared content [wa]s misleading because it ma[de] representations about the efficacy of Tasigna but fail[ed] to communicate any risk information associated with the use of this drug.”<sup>140</sup> In order 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.”<sup>141</sup> As a result, the FDA may determine that placing risk disclosures “one-click away” is sufficient if the text of the sponsored link discusses only the disease, does not name the product, makes no implied or express product claims, and the product is instead first named, along with risk disclosures, on the other side of the link.<sup>142</sup> Until the FDA issues further guidance, however, the requirements in this area remain uncertain. While the FDA

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<sup>134</sup> Thomas Sullivan, *FDA: Examination of Online DTC Promotion*, POL’Y & MEDICINE (Jun. 1, 2011), <http://www.policymed.com/2011/06/fda-examination-of-online-direct-to-consumer-prescription-drug-promotion-notice-for-comment.html>.

<sup>135</sup> *Id.* The FDA was especially concerned because one drug had a boxed warning, and another a bolded warning.

<sup>136</sup> Clifford, *supra* note 133 (risk information “was required despite the length limitation of Internet search ads”).

<sup>137</sup> U.S. FOOD AND DRUG ADMIN., *Letter from Sangeeta Vaswani, DDMAC, to Christopher Graham, sanofi-aventis U.S. LLC*, FDA.GOV (Mar. 26, 2009), <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM166248.pdf>.

<sup>138</sup> Sullivan, *supra* note 87.

<sup>139</sup> *Id.* (noting that the FDA has issued over a dozen such untitled letters on sponsored links or share widgets).

<sup>140</sup> U.S. FOOD AND DRUG ADMIN., *Letter from Karen R. Rulli, DDMAC, to Lisa Drucker, Novartis Pharmaceuticals Corp*, FDA.GOV. (Aug. 4, 2010), <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM221325.pdf>.

<sup>141</sup> *Id.*

<sup>142</sup> Sullivan, *supra* note 87.

could potentially adopt an approach similar to the use of “major statements” adopted by the FTC for broadcast advertisements, “possibly via a link to another web page,” this may be “unworkable, since the text of a ‘major statement’ may be too lengthy . . . for the space limitations of Internet links and widgets.”<sup>143</sup> Accordingly, a link to safety information is not likely to suffice.

An approach that is “more consistent” with the FDA’s guidance is to present safety information on the vertical display of a webpage, which may allow an individual to “utilize scrolling in order to view the complete information.”<sup>144</sup> If this approach is utilized, risk information should be visible when the user first opens the webpage. The FDA’s guidance also addresses the use of headers and signaling.<sup>145</sup> Thus, companies should use “signals such as ‘continued,’ ‘more’ and ‘select,’” if safety information continues from page-to-page, which is likely “given the smaller footprint and displays” available in social and mobile platforms.<sup>146</sup>

Unlike television, social media is unique because consumers have the opportunity to respond to online promotional material and communicate their opinions with others. This capability, however, presents risks for drug companies because dissatisfied patients can post harmful information that may discourage others from taking the medication and may even discourage online viewers from seeing a doctor, which may have public health implications. There is also concern that companies 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 their products in online discussions.”<sup>147</sup> Moreover, it may no longer be technically possible for companies to distinguish a manufacturer website from a manufacturer initiated chat room or comment area 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.”<sup>148</sup>

Without further guidance from the FDA, the difficulties posed by interactive promotional media will continue. For example, in December 2012, the FDA sent a Warning Letter to AMARC Enterprises regarding its cancer supplement (non-FDA approved) Poly MVA. The letter—the first of its kind—cited a March 10, 2011 post on AMRAC’s Poly MVA Facebook page, in which a consumer noted how the product had “done wonders for me.”<sup>149</sup> FDA took issue with the fact that AMRAC “liked” this favorable consumer

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<sup>143</sup> *Id.*

<sup>144</sup> Sara Stults, *It Doesn’t Have to Hurt: A Social Media Primer*, FDLI UPDATE MAGAZINE (Sept.-Oct. 2011).

<sup>145</sup> *Id.*

<sup>146</sup> *Id.*

<sup>147</sup> Greene & Kesselheim, *supra* note 132.

<sup>148</sup> West, *supra* note 123 (explaining the application left no control over the content of the Sidewiki to the site owner).

<sup>149</sup> U.S. FOOD AND DRUG ADMIN., *Warning Letter to Mr. Albert Sanchez, CEO, AMARC Enterprises, Inc.*, FDA.GOV (Dec. 11, 2012), <http://www.fda.gov/iceci/enforcementactions/warningletters/2012/ucm340266.htm> 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

testimonial, however, FDA did not “restrict consumers from ‘liking’ a drug or device company’s Facebook page or posts.”<sup>150</sup> Nevertheless, it is 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+.<sup>151</sup> Waiting for further guidance from the FDA, however, is not an option for drug or device companies because consumers have used these platforms for years to discuss products, and the industry’s absence from this conversation is counterproductive.

Research suggests that DTC advertising has a number of benefits for patients and consumers. For example, a recent study found that DTC advertisement for aromatase inhibitors “was associated with increases in appropriate prescriptions with no significant effect on inappropriate prescriptions.”<sup>152</sup> Another study showed “no strong indication that either consumer- or provider- directed promotion substantially raised retail-level prices.”<sup>153</sup> In fact, while some physicians believe that DTC advertisements misinform patients, overemphasize drug benefits, encourage drug overutilization, and ultimately increase the cost of healthcare,<sup>154</sup> such beliefs fail to recognize that over seventy-five percent of the prescription drugs patients receive are generic.<sup>155</sup> Moreover, even if patients ask for a branded drug, insurers often mandate the generic and most state laws require generics unless a physician indicates the brand-name drug is medically necessary.<sup>156</sup> In addition, a recent survey of physicians showed that almost fifty percent agreed that DTC advertisements inform, educate, and empower patients; sixty-eight percent agreed that DTC advertisements encourage patients to contact a physician; sixty-four percent agreed that DTC advertisements promote patient dialogue with healthcare providers; and over fifty percent agreed that DTC advertisements removed

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*tremendously. It enabled me to keep cancer at bay without the use of chemo and radiation...Thank you AMARC.”*

<sup>150</sup> Jose Sierra, *Navigating FDA Guidance on Facebook and Social Media*, PHARMARISC.COM (Mar. 18, 2013), <http://pharmarisc.com/2013/03/navigating-fda-guidance-on-facebook-and-social-media/>.

<sup>151</sup> *Id.*

<sup>152</sup> *Industry on DTC Advertising Study: An Informed Patient Enables Better Care*, COALITION FOR HEALTHCARE COMMUNICATION (Dec. 3, 2012), <http://www.cohealthcom.org/2012/12/03/industry-on-dtc-advertising-study-an-informed-patient-enables-better-care/>.

<sup>153</sup> *Study Cites Benefits of Pharma’s Promotional Efforts*, COALITION FOR HEALTHCARE COMMUNICATION (Mar. 4, 2013), <http://www.cohealthcom.org/2013/03/04/study-cites-benefits-of-pharma%E2%80%99s-promotional-efforts/>.

<sup>154</sup> *Majority of physicians believe DTC ads should be cut back*, WORLD OF DTC MARKETING.COM (Apr. 30, 2013), <http://worldofdctmarketing.com/majority-of-physicians-believe-dtc-ads-should-be-cut-back/prescription-drug-dtc-marketing/> (showing that of 104 physicians, 48% somewhat agreed that DTC advertisements misinform patients; 46% somewhat agreed that DTC advertisements overemphasize drug benefits; 56% somewhat agreed that DTC advertisements encourage drug overutilization; and 78% agreed that that DTC advertisements ultimately increases the cost of healthcare).

<sup>155</sup> Thomas Sullivan, *Prescription Drug Sales 2009 – IMS Data*, POL’Y & MEDICINE (Apr. 7, 2010), <http://www.policymed.com/2010/04/prescription-drug-sales-2009—ims-data.html>.

<sup>156</sup> William H. Shrank, et al., *State Generic Substitutes Can Lower Drug Outlay Under Medicaid*, HEALTH AFFAIRS (July 2010), <http://scholar.harvard.edu/files/nkc/files/2010-generic-substitution-laws-healthaffairs.pdf> (detailing how all states have adopted some variation of a generic substitution law).

stigma associated with certain diseases.<sup>157</sup> These findings should encourage industry to increase its presence and investment in interactive promotional media.<sup>158</sup>

In fact, pharmaceutical companies have approximately 200 Twitter feeds, over 150 sponsored or funded YouTube channels, and over 100 Facebook pages,<sup>159</sup> several of which are very successful. The explosion of social media use by pharmaceutical companies has led to some companies creating guidelines for their employees governing what can and cannot be posted online. For example, in 2010, Roche distributed a guidance letter to employees that outlined personal and professional principles for online activities when speaking about Roche.<sup>160</sup> Similarly, AstraZeneca published a white paper that “outlin[es] its guidelines for social media use”<sup>161</sup> and hosted a Twitter chat to raise awareness about its patient prescription program.<sup>162</sup> Manufacturers can also utilize social media to control their image; Eli Lilly has an online presence with a blog, Facebook page, and a Twitter feed, which focus on public policies about pharmaceuticals, as well as a YouTube page that features videos about Eli Lilly’s research and philanthropic work.<sup>163</sup>

In 2011, Pfizer Canada posted a flow chart online that instructs companies on how to respond to social media communications.<sup>164</sup> Johnson & Johnson has created an active social presence that utilizes a blog that is supplemented with YouTube and Facebook pages.<sup>165</sup> Manufacturers have also utilized social media for more specific, targeted campaigns that focus on particular illnesses and treatments. For example,

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<sup>157</sup> Majority of physicians believe DTC advertisements should be cut back, *supra* note 154.

<sup>158</sup> See Clark Herman, *Companies Trim Social Media Spending, While Platform Priorities Shift*, PHARMEXEC.COM (Dec. 4, 2012), <http://blog.pharmexec.com/2012/12/04/companies-trim-social-media-spending-while-platform-priorities-shift/> (noting that while social media use among pharmaceutical 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%”).

<sup>159</sup> Mark Senak, *Offshore Tweets and Pharma*, EYEONFDA (Feb. 21, 2013), [http://www.eyeonfda.com/eye\\_on\\_fda/2013/02/offshore-tweets-and-pharma.html](http://www.eyeonfda.com/eye_on_fda/2013/02/offshore-tweets-and-pharma.html).

<sup>160</sup> ROCHE, *Social Media Principles* (August 2010), [http://www.roche.com/social\\_media\\_guidelines.pdf](http://www.roche.com/social_media_guidelines.pdf).

<sup>161</sup> ASTRAZENECA, *White Paper: Social Media in the Pharmaceutical Industry*, [http://www.brandchannel.com/images/papers/522\\_2011-02\\_AZ\\_Social\\_Media.pdf](http://www.brandchannel.com/images/papers/522_2011-02_AZ_Social_Media.pdf) (last visited Mar. 24, 2014).

<sup>162</sup> ASTRAZENECA, *Healthcare Engagement Strategy 2012 ‘Open Dialogue’ Award #hesawards*, <http://engagementstrategy.com/articles/astrazeneca-healthcare-engagement-strategy-2012-open-dialogue-award/>

<sup>163</sup> Ed Silverman, *Lilly and Social Media*, PHARMALOT (Sept. 14, 2012), available at <http://web.archive.org/web/20120921045628/http://www.pharmalot.com/2012/09/lilly-and-social-media>. See also Eli Lilly and Co., FACEBOOK, <https://www.facebook.com/elilillyandco> (last visited Mar. 24, 2014); Newsroom, NEWSROOM.LILLY.COM, <http://newsroom.lilly.com/> (last visited Mar. 24, 2014) (featuring Eli Lilly’s three different Twitter accounts, press releases, and a media center); and Lily Health, YOUTUBE, <https://www.youtube.com/user/lillyhealth> (last visited Mar. 24, 2014).

<sup>164</sup> Jim Edwards, *Pfizer Goes on Facebook Offensive with “Social media Playbook” and Blog Response Flowchart*, CBS NEWS, Jan. 8, 2011, <http://www.cbsnews.com/news/pfizer-goes-on-facebook-offensive-with-social-media-playbook-and-blog-response-flowchart/> (indicating how to deal with both congenial commenters and “trolls” who make more inflammatory comments).

<sup>165</sup> Blog, JOHNSON & JOHNSON, <http://www.jnjbtw.com/> (last visited Mar. 24, 2014).

Boehringer Ingelheim started the “Drive4COPD,” a campaign that calls on consumers to get screened for chronic obstructive pulmonary disease (COPD), and uses Twitter, Facebook, YouTube, and Flickr to promote the campaign.<sup>166</sup> Similarly, Novo Nordisk has a Twitter feed, “Race with Insulin,” which features IndyCar racer Charlie Kimball, who discusses his experience with diabetes.<sup>167</sup> In addition, UCB, Inc. collaborated with PatientsLikeMe to establish a free online community for people with epilepsy.<sup>168</sup> More recently, Janssen posted what appears to be a branded Facebook advertisement for Axert, a migraine treatment.<sup>169</sup> Finally, Sanofi launched Facebook and Twitter pages for diabetes.<sup>170</sup> On the company’s Facebook page, any clinical questions are directed to a separate tab and often answered privately; on the company’s Twitter page, medical concerns are addressed via direct message.<sup>171</sup>

While these examples demonstrate promise, manufacturers that decide to use such social media platforms should use caution until the FDA produces more specific guidance regarding the use of interactive promotional media. Such guidance is particularly important given that the FDA recently issued an Untitled Letter notifying Institut Biochimique SA (IBSA) that its Facebook page for Tirosint was “false and misleading because it ma[de] representations about the efficacy of Tirosint, but fail[ed] to communicate any risk information associated with its use and it omit[ted] material facts.”<sup>172</sup> FDA was particularly concerned because Tirosint is associated with a number of serious risks and includes a Boxed Warning, and by failing to “communicate **any** of the risks associated with its use,” the “Facebook webpage misleading suggests that Tirosint is safer than has been demonstrated.”<sup>173</sup>

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<sup>166</sup> DRIVE4COPD, <http://drive4copd.org/> (last visited Mar. 24, 2014).

<sup>167</sup> Charlie Kimball, @racewithinsulin, <https://twitter.com/racewithinsulin> (last visited Mar. 24, 2014); see also Deborah Weinstein, *Charlie Kimball talks Novo Racing with insulin*, MEDICAL MARKETING & MEDIA (Apr. 16, 2013), <http://www.mmm-online.com/charlie-kimball-talks-novo-racing-with-insulin/article/289037/>.

<sup>168</sup> UCB and PatientsLikeMe Partner to Give People With Epilepsy a Voice in Advancing Research, PATIENTSLIKEME (Jun. 15, 2009), <http://www.patientslikeme.com/press/20090615/18-ucb-and-patientslikeme-partner-to-give-people-with-epilepsy-a-voice-in-advancing-research->.

<sup>169</sup> Wendy Blackburn, *Pharma’s First Branded Facebook Ad?*, EPHARMA RX (Oct. 12, 2012), <http://blog.intouchsol.com/2012/10/first-branded-pharma-facebook-ad.html>.

<sup>170</sup> Sanofi US Diabetes, <https://www.facebook.com/SanofiUSDiabetes> (last visited May 6, 2014); SANOFI DIABETES, [http://twitter.com/Diabetes\\_Sanofi](http://twitter.com/Diabetes_Sanofi) (last visited May 6, 2014).

<sup>171</sup> Ben Paynter, *How Sanofi Is Writing The Social Media Rules For Big Pharma Without Running Afoul Of The FDA*, FAST COMPANY (Aug. 20, 2012), <http://www.fastcompany.com/3000457/how-sanofi-writing-social-media-rules-big-pharma-without-running-afoul-fda>.

<sup>172</sup> U.S. FOOD AND DRUG ADMIN., *Warning Letter to Mr. Clarence E. Johns, Ph.D., Institut Biochimique SA*, FDA.GOV (Feb. 24, 2014), <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM388800.pdf>.

<sup>173</sup> *Id.* (bold in original).



## VI. RECOMMENDATIONS: WHAT CAN WE LEARN FROM FDA'S "FIRST" SOCIAL MEDIA GUIDANCE?

Answering the calls from industry, patients, and Congress, the FDA issued its “first” draft social media 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” (“Guidance”).<sup>174</sup> The Guidance document 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.”<sup>175</sup> The 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 the FDA’s postmarketing submission requirements”; and (3) makes “recommendations for how companies 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.”<sup>176</sup>

Specifically, the Guidance states that companies are responsible for submitting post-marketing information if they “own, control, create, influence, or operate” the interactive promotional media platform.<sup>177</sup> The FDA emphasizes that a manufacturer is responsible for promotion both on websites that it owns or controls *and* third-party websites, if the manufacturer or 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.”<sup>178</sup> Manufacturers are generally “not responsible for [user generated content (UCG)] 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),” such as content posted on social media sites by third-parties or individual users.<sup>179</sup>

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<sup>174</sup> U.S. FOOD AND DRUG ADMIN., *Guidance for Industry: Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics*, FDA.GOV (Jan. 2014), [www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM381352.pdf](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM381352.pdf) [hereinafter FDA Post-Marketing Interactive Promotional Media Guidance].

<sup>175</sup> *Id.*

<sup>176</sup> *Id.* at 1.

<sup>177</sup> *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. The FDA further explained that manufacturers would be responsible for product promotional communications if the manufacturers exert influence over a website in “any particular, even if the influence is limited in scope,” such as content collaboration, “preview, or review privilege over the content.” *Id.*

<sup>178</sup> *Id.*

<sup>179</sup> *Id.* at 5 (citing 47 U.S.C. § 230(c)(1) (2012)) (“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



The FDA also explained that manufacturers are responsible for content generated by an employee or agent who is acting on behalf of the manufacturer to promote the manufacturer's product.<sup>180</sup> The remainder of the Guidance explains the frequency with which firms must submit promotional materials generated on interactive promotional media platforms.<sup>181</sup>

While the Guidance focuses on post-market submission requirements, the FDA's general approach to interactive promotional media may be instructive to industry and stakeholders that are trying to address concerns such as: (1) the reporting of adverse events; (2) the use of links; (3) required financial or employee disclosures (e.g., transparency); (4) the ability to comment or correct independent third-party misinformation about drugs or devices; and (5) the presentation of risk and benefit information in light of the space limitations and visual appearance of interactive promotional media platforms. Given that the FDA has already announced plans to publish three additional guidance documents on interactive promotional media this year, there are several factors that FDA and industry should consider.<sup>182</sup>

### A. The Use of Links & Risk Information

The FDA should formally permit companies to use the "one-click away" rule. The "one-click away" rule is consistent with FDA's approach to DTC television advertisements, which direct viewers to look for full prescribing and risk information either on the internet or in a print advertisement due to the lack of time and/or space in the television advertisement. Adopting this rule would satisfy concerns previously expressed by the FDA because the nature and use of hyperlinks on the internet makes it more likely that consumers would click on the hyperlink enabling them to view the risk information. In drafting this guidance, the FDA should consider the FTC's recently released guidance on ".com Disclosures." For example, the FDA should consider allowing the use of hyperlinks when disclosure in a space-constrained advertisement is not possible. Under these circumstances, the FDA could recommend (consistent with the FTC's guidance): (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 making it noticeable; (5) taking consumers directly to the disclosure on the click-through page; and (6) assessing the effectiveness of the hyperlink

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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) (2012).

<sup>180</sup> FDA Post-Marketing Interactive Promotional Media Guidance, *supra* note 174.

<sup>181</sup> *Id.*

<sup>182</sup> U.S. FOOD AND DRUG ADMIN., *Guidance Agenda: New & Revised Draft Guidances CDER is Planning to Publish During Calendar Year 2014*, FDA.GOV (Jan. 31, 2014), <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. *Id.*

by monitoring click-through rates.<sup>183</sup> The FDA could also monitor websites and social media to ensure that risk information truly was only one-click away and that a hyperlink actually takes consumers to a website or information that the FDA has actually reviewed and approved (e.g., labeling or PI).<sup>184</sup>

The FDA's guidance should also address the use of "rollover and scrolling functions" that can "enable direct connections to safety and efficacy information," when using social media tools with limited space.<sup>185</sup> The FDA could recommend that advertisements, which require "scrolling" to find required risk disclosure information, include text or visual cues to encourage consumers to scroll to view the disclosed information.<sup>186</sup> Moreover, the FDA could allow companies to use "mouse-overs" on computers to display required disclosures such as risk information, as long as the "mouse-overs" otherwise complied with the FDA's guidance on displaying risk information. Conversely, manufacturers may want to avoid scrolling or "mouse-overs" on mobile devices since use of such mechanisms on these platforms may prevent fair and balanced presentations of information. Manufacturers should also consider working with mobile medical application developers to address these issues early in the design and testing process to prevent any unnecessary updates or modifications once the application has launched, which may be costly or interrupt user functionality. For example, mobile applications that display promotional advertisements could be designed to prominently display links to risk information on all necessary screens.

Manufacturers should also consider factors unique to different platforms. For example, Twitter can inform many people quickly about drug approvals or the release of new data at a scientific meeting. Companies may also use unbranded tweets to allow linking to other branded sites. Tweets about drugs that do not carry a boxed warning, may use a BRAND (generic) name and "include other links directly to the brand site or other information mentioned in the Tweet;" the FDA may treat such tweets as reminder advertisements.<sup>187</sup> When the tweet is used to communicate about a drug with a "boxed warning, the tweet should include a URL that navigates directly to display the full PI; . . . format of the URL to the PI is important."<sup>188</sup> This page that is navigated to by the URL can contain "other fixed links to the brand website or other related information."<sup>189</sup> The use of claims in a tweet, however, is "problematic because the safety information cannot display completely with the 140-character limit."<sup>190</sup> Because the FDA does not consider linking to such information sufficient, the FDA regulations require that all risk information appear on the face of the sponsored link. One option that companies may pursue is "Deck.ly," a new technology that allows for the creation of tweets that

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<sup>183</sup> FTC Online Guidance, *supra* note 94.

<sup>184</sup> *Id.*

<sup>185</sup> Liu, *supra* note 122 (citing 2009 FDA Internet and Social Media Hearing).

<sup>186</sup> FTC Online Guidance, *supra* note 94, at ii. For example, "see below for important information"; but not "details below" because it provides "no indication about the subject matter or importance of the information that consumers will find and are not adequate cues." *Id.* at 9.

<sup>187</sup> Stults, *supra* note 144, at 27.

<sup>188</sup> *Id.*

<sup>189</sup> *Id.*

<sup>190</sup> *Id.*

are much longer than 140 character posts that were traditionally allowed on Twitter.<sup>191</sup> Interestingly, OPDP Director, Tom Abrams said that companies should be able to promote their drugs “using a space limited venue, such as 140 characters.”<sup>192</sup>

Because FDA also regulates pre-approval promotion, tweets describing new data, either for a marketed drug’s investigational use or for an investigational drug, “should not state any specific investigational uses or potential indications or include any claims of safety or efficacy.”<sup>193</sup> Manufacturers may “‘disseminate[e] . . . scientific findings in scientific or lay media’ without engaging in promotional activity, but promotional claims of safety or effectiveness for a use for which the product is under investigation are subject to FDA regulation as advertising or labeling.”<sup>194</sup> When not using the product name for the drug, the tweet may include the manufacturer name, data presented, and the study phase.<sup>195</sup>

The use of social bookmarking and sharing widgets pose different challenges for companies. When the “share” button is selected, a display of the widgets for bookmarking or sharing is provided for the user to select from and there is an option for email. Once a user selects share, content is passed from the original website and posted on a social sharing site. If a user posts branded promotional content without any modification, the content reflects what was reviewed and approved on the original website, thus attaching the manufacturer to the message.<sup>196</sup> Users, however, can edit content and post the content on a social sharing site. As a result, companies should consider establishing separation between what is manufacturer sponsored and what is not. If the manufacturer “does not create, control, maintain or participate in content on the social sharing site or someone’s social media page,”<sup>197</sup> the FDA may consider there to be enough separation. Thus, companies may benefit from deciding whether users can edit material, and if so, opt to permit posting of edits only after the manufacturer has reviewed the edited content.

Manufacturers should also consider paying close attention to comments added to company sponsored or supported websites by individual users of those sites due to the various differences from site-to-site. For example, “YouTube allows disabling the commenting feature, so a company can post a video without allowing comments” and Google added a “Safe Watch” feature, which allows channel owners with ten or more videos to control what videos show up on the watch pages of YouTube.<sup>198</sup> It is also possible to “disable video embedding to limit the use of company videos outside of

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<sup>191</sup> John Mack, *Breaking the 140-character Limit of Twitter Opens the Door to FDA-Compliant Branded Tweets*, PHARMA MARKETING BLOG (Feb. 11, 2011), <http://pharmamktng.blogspot.com/2011/02/breaking-140-character-limit-of-twitter.html>.

<sup>192</sup> Rachel Slajda, *FDA to Help Drugmakers Take to Twitter*, *Official Says*, LAW360, <http://www.law360.com/articles/432841/fda-to-help-drugmakers-take-to-twitter-official-says> (last visited March 24, 2014).

<sup>193</sup> Stults, *supra* note 144, at 27.

<sup>194</sup> FDA Help-Seeking Guidance, *supra* note 12, at 3 (citing 21 CFR § 312.7(a) (2013)).

<sup>195</sup> Stults, *supra* note 144, at 27.

<sup>196</sup> *Id.*

<sup>197</sup> *Id.*

<sup>198</sup> *Id.*

the company's more controlled YouTube environments.”<sup>199</sup> Google recently created the YouTube One Channel to give users a more friendly and flexible template.<sup>200</sup> The channel still allows companies to “turn off comments, and their content, while shareable, could be set to play only on YouTube” to prevent a video from playing on someone's Facebook feed “where companies could not necessarily monitor or respond to comments, but might be held to adverse events reporting requirements.”<sup>201</sup>

Facebook's official policy indicates that it will no longer grant companies the ability to disable comments on wall posts, photos, and videos, unless the company's Facebook page is a branded page “solely dedicated to a prescription drug;” companies, however, are still able to control the creation of original content or posts.<sup>202</sup> In response to these changes, some companies shut down their Facebook pages.<sup>203</sup> Other companies screen for and remove improper comments, but this creates additional responsibilities and costs associated with training personnel to screen for and remove such comments.<sup>204</sup> Companies should consider disclosing policies or “terms of use” that govern their interactive social media platforms, specifically accounting for the nuances and differences noted above, which some companies are already doing.<sup>205</sup> Such policies should be clear as to what UGC can consist of, which type of topics and language are permissible and prohibited (e.g., off-label uses), and how the manufacturer will pre-screen and remove content. Such policies may assist manufacturers in addressing third-party misinformation, as discussed below.

## **B. Correcting Independent-Third Party Misinformation**

The 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 promotional media, including with respect

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<sup>199</sup> *Id.*

<sup>200</sup> Matthew Arnold, *YouTube's Channels reboot gives pharmas pause*, MEDICAL MARKETING & MEDIA (Mar. 26, 2013), <http://www.mmm-online.com/youtubes-channels-reboot-gives-pharmas-pause/article/286156/>.

<sup>201</sup> *Id.*

<sup>202</sup> Jim Dayton, *How Facebook's new comment policy impacts your pharma Facebook page*, INSIGHTS (May 19, 2011), <https://www.intouchsol.com/Blog/how-facebooks-new-comment-policy-impacts-your-pharma-facebook-page>.

<sup>203</sup> Stephen Richer, *Facebook and FDA Put Drug Companies in Catch-22 Situation on Social Media*, WLF LEGAL PULSE (Aug. 17, 2011), <http://wlflegalpulse.com/2011/08/17/facebook-and-fda-put-drug-companies-in-catch-22-situation-on-social-media/> (noting that Johnson & Johnson closed four pages and AstraZeneca closed one page).

<sup>204</sup> Christian Torres, *Drug companies lose protections on Facebook, some decide to close pages*, WASH. POST, Aug. 12, 2011, [http://www.washingtonpost.com/national/health-science/pharmaceutical-companies-lose-protections-on-facebook-decide-to-close-pages/2011/07/22/gIQTQGFBJ\\_story.html](http://www.washingtonpost.com/national/health-science/pharmaceutical-companies-lose-protections-on-facebook-decide-to-close-pages/2011/07/22/gIQTQGFBJ_story.html).

<sup>205</sup> See e.g., Pfizer “Comment Missing?,” FACEBOOK, [https://www.facebook.com/Pfizer/app\\_10382229704881](https://www.facebook.com/Pfizer/app_10382229704881) (last visited March 24, 2014); Sanofi US “Rules of Engagement,” FACEBOOK, [https://www.facebook.com/sanofiUS/app\\_232554210116120](https://www.facebook.com/sanofiUS/app_232554210116120) (last visited Mar. 24, 2014); Merck “Commenting Guidelines,” FACEBOOK, [https://www.facebook.com/MerckBeWell/app\\_165561146901142](https://www.facebook.com/MerckBeWell/app_165561146901142) (last visited Mar. 24, 2014).

to third-party interactive media that they do not control or influence.<sup>206</sup> The 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,<sup>207</sup> that manufacturers can correct misinformation without triggering full requirements applicable to promotional materials (e.g., postmark submission). For example, an exemption from promotional labeling requirements could be established if: (1) language used to correct third-party misinformation remains consistent with the product's PI; (2) addresses the specific misinformation only; (3) provides a link to the approved labeling, if possible; and (4) 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.

### C. Transparency & Disclosure

Manufacturers that post promotional content or corrective information on interactive promotional media should be transparent and make full disclosure about the relationship of the author to the manufacturer, to promote trust with consumers and reduce confusion about the source of the information. Transparency is critical for establishing an online community where members feel comfortable sharing information and learning from each other.<sup>208</sup> Consistent with the FDA's first Guidance, manufacturers should clearly identify UGC and communications of its employees or third-parties acting on behalf of the manufacturer. The FDA stated that such disclosure could be achieved by including a manufacturer's identifier (e.g., name or logo) as part of the communication. However, in future guidance, the FDA should provide greater clarity and/or additional examples regarding the identification issue. For instance, on Facebook, Twitter, LinkedIn, or other social media platforms, users have profiles that may indicate their place of employment (e.g., "Social Media Manager, Company XYZ"). Thus, the FDA should clarify whether communications in these platforms require any further disclosure. Similarly, in blogs, chat rooms, or other forums where users may not have profiles or are anonymous, the FDA should clarify whether the use of a disclaimer (e.g., "I am an employee at Company X ...") in posts is sufficient. The FDA should also clarify how prominent disclosures

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<sup>206</sup> 2009 FDA Internet and Social Media Hearing, *supra* note 86, at 64, 90, 407 (Nov. 12, 2009) (featuring Rohit Bhargava, Senior Vice President, Ogilvy 360 Digital Influence; John Mack, Publisher, Pharma Marketing News; and Maureen Miller, Account Supervisor & Social Media Lead, Compass Healthcare Communications).

<sup>207</sup> For example, if manufacturers should: (1) use large or bolded font, (e.g., **NEW or CORRECTION**); (2) include the date next to the corrected information and/or reference to the date of the misinformation; (3) include a hyperlink to the misinformation; (4) place the correction on a main webpage or directly where the misinformation was posted (e.g., subpage, Facebook comment); (5) give notice to all users of the interactive platform or only those users in the particular forum, blog or chat room; and (6) email or message users directly with corrected information (e.g., "Dear Consumer" letters).

<sup>208</sup> *State of Social Media and Healthcare*, [WORLDofDTCMARKETING.COM](http://WORLDofDTCMARKETING.COM), <http://worldofdtcmktg.com/social-media-healthcare/> (last visited Mar. 24, 2014).

should be (e.g., larger text, bold, at the beginning of the content, etc.) and where they should be placed within an interactive platform. Disclosure is important not only to promote trust with consumers, but also to minimize the appearance of impropriety or creation of misleading impressions.

Transparency and disclosure are also important on interactive promotional media because the FDA clarified in its first Interactive Promotional Media Guidance that the FDA regulates product promotion “conducted on [a] firm’s behalf,” and that companies are responsible for UGC and communications of its employees, agents, or anyone “who is acting on behalf of the firm to promote the firm’s product.”<sup>209</sup> The FDA explained that a manufacturer is responsible for content such as “comments on a third-party site about the firm’s product” that were written by a manufacturer’s “medical science liaison or paid speaker (e.g., a key opinion leader) acting on the firm’s behalf.”<sup>210</sup> Likewise, the FDA explained that a manufacturer is responsible for the content on a blogger’s site “if the blogger is acting on behalf of the firm.”<sup>211</sup> Thus, to the extent manufacturers allow employees, consultants, or agents to create corrective statements or UGC on the manufacturer’s behalf, they should require such individuals to disclose the relationship of the author to the manufacturer.

Manufacturers and/or their corporate executives may also implicate the FDA promotional regulations by using interactive promotional media. For example, the FDA recently sent a Warning Letter to Aegerion Pharmaceuticals, Inc., based on comments their chief executive officer (CEO) had made on the CNBC television show “Fast Money” suggesting that Aegerion’s drug, Juxtapid could be used effectively for unapproved indications.<sup>212</sup> Prior to this instance, the former CEO of InterMune was investigated and convicted of wire fraud for the creation and dissemination of a press release that contained false and misleading information about the efficacy of Actimmune.<sup>213</sup> Corporate executive use of interactive promotional media could also implicate Regulation Fair Disclosure (RegFD), which requires “that whenever a company, or a person acting on its behalf, discloses material, nonpublic information to analysts, investment professionals or company stockholders, the company must make that information simultaneously

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<sup>209</sup> FDA Post-Marketing Interactive Promotional Media Guidance, *supra* note 174, at 4.

<sup>210</sup> *Id.*

<sup>211</sup> *Id.*

<sup>212</sup> U.S. FOOD AND DRUG ADMIN., *Letter from Robert Dean, Div. Dir., FDA, to Marc Beer, Chief Exec. Officer, Aegerion Pharms. Inc.*, FDA.GOV (Nov. 8, 2013), <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/enforcementactivitiesbyfda/warninglettersandnoticeofviolationletterstopharmaceuticalcompanies/ucm374338.pdf>.

<sup>213</sup> See U.S. DEP’T OF JUSTICE, *Former InterMune Ceo Sentenced for False & Misleading Statements Related to Pulmonary Fibrosis Drug’s Clinical Tests* (Apr. 14, 2011), <http://www.justice.gov/opa/pr/2011/April/11-civ-475.html>. The headline of the press release read, “InterMune Announces Phase III Data Demonstrating Survival Benefit of Actimmune in IPF,” with the subheading “Reduces Mortality by 70% in Patients With Mild to Moderate Disease.” *Id.* Department of Justice (DOJ) said that a specialty pharmacy then distributed the misleading information in the press release to more than 2,000 pulmonologists and to patients taking Actimmune. See U.S. DEP’T OF JUSTICE, *Former InterMune CEO W. Scott Harkonen Indicted for Wire Fraud and FDA Violations* (Mar. 18, 2008), [http://www.justice.gov/opa/pr/2008/March/08\\_civ\\_217.html](http://www.justice.gov/opa/pr/2008/March/08_civ_217.html).



available through broadly disseminated public disclosure.”<sup>214</sup> Consequently, the Securities and Exchange Commission (SEC) could bring an enforcement action against a manufacturer or its executive who uses interactive promotional media to communicate about the success or failure of certain drugs or devices already on the market or in FDA approved clinical trials. Because such information is likely material, the manufacturer could face action unless investors and the markets “have been alerted as to which specific social media outlets would be used to disseminate such key information.”<sup>215</sup> As a result, manufacturers should consider updating internal policies, procedures, and training as necessary to outline the requirements that employees (including executives), consultants, or agents must follow if permitted to use interactive promotional media.

Manufacturers may also need to address whether licensed physicians who engage as paid contributors to a particular platform (e.g., blog) or as audience members need to make disclosures about their financial relationships with the manufacturer.<sup>216</sup> For example, a physician may receive funds for research or education from a manufacturer, but also be commenting about the same manufacturer’s product or a different product independent from this research or education. Given the increased transparency requirements stemming from the Physician Payments Sunshine Act,<sup>217</sup> manufacturers may need to require that such physicians include disclaimers that they are being compensated for the content or messages they generate or that their comments are not on behalf of the manufacturer, but they may receive compensation from the manufacturer for unrelated services. Lack of disclosure by physicians who contribute to interactive promotional media platforms (e.g., chat rooms or blogs) may result in decreased patient trust, as well as scrutiny from Centers for Medicare and Medicaid Services (CMS), the FDA, and federal or state prosecutors. Such scrutiny may even occur under state consumer protection laws, for a physician or other healthcare professional that fails to disclose their financial interests. These added risks further demonstrate the need to closely monitor manufacturers and corporate executives use of interactive promotional media.

#### **D. Adverse Event Reporting**

The FDA should articulate clear standards and guidance that instructs industry and related stakeholders about adverse event<sup>218</sup> reporting obligations in connection with interactive promotional media. Several FDA regulations require companies to report

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<sup>214</sup> *Disclosing Corporate Information Via Social Media: After Investigating the CEO of Netflix, the SEC Releases Helpful Guidance*, ARNOLD & PORTER LLP (Apr. 2013), <http://www.arnoldporter.com/resources/documents/ADV413DisclosingCorporateInformationViaSocialMedia.pdf>.

<sup>215</sup> *Id.*

<sup>216</sup> Susan D. Hall, *Does lack guidance for disclosing conflicts of interest on social media*, FIERCEHEALTHIT (Nov. 13, 2012), <http://www.fiercehealthit.com/story/docs-lack-guidance-disclosing-conflicts-interest-social-media/2012-11-13>.

<sup>217</sup> Medicare, Medicaid, Children’s Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests, 78 Fed. Reg. 9458, 9518 (Feb. 8 2013) (to be codified at 42 C.F.R. pt. 402, 403). 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.

<sup>218</sup> FOOD AND DRUG ADMIN., *What is a Serious Adverse Event?*, FDA.GOV (Jan. 10, 2013), <http://www.fda.gov/safety/medwatch/howtoreport/ucm053087.htm> (defining an adverse event as a patient



adverse events associated with drugs to the FDA.<sup>219</sup> Generally, manufacturers must report to the FDA when they “become aware” of a drug, biologic, or medical device adverse event (AE). The source of the adverse event information is generally not determinative of a manufacturer’s obligation to report (e.g., physician versus patient or consumer). Hundreds of millions of Americans are creating UGC on firm owned and third-party websites, including information on symptoms, side effects, and other health information. The FDA should carefully balance the need to report safety and risk information with the undue burden on industry associated with constantly monitor this kind of UGC on these platforms. The FDA should permit manufacturers to use a flexible approach for monitoring and reporting AE’s on interactive promotional media, and should articulate criteria that manufacturers could use to evaluate whether UGC contains sufficient information for a manufacturer to become “aware” of an AE.

For example, on a monthly or quarterly basis, the FDA could recommend that manufacturers monitor the interactive promotional media they have listed with the FDA or risk information that is contained in the products PI. Manufacturers could incorporate into their monitoring and surveillance for misinformation described above, key terms or phrases that may indicate possible AE’s (e.g., hospitalization, emergency room, etc.), which the FDA could provide examples of in future guidance. However, the FDA should not require—at least in terms of AE reporting—manufacturers to monitor or further investigate UGC that may reference commonly known side effects of a product (e.g., nausea, sweating, fever, etc.). While a manufacturer may collect or monitor this information voluntarily for other reasons (e.g., update labeling, learn of effects of drug combinations or interactions), it would be too burdensome for industry to investigate each instance in which a patient is having a side effect that is well known to the FDA and the manufacturer, and does not amount to an AE. To ensure compliance with AE reporting regulations, the FDA could ask manufacturers to initially submit a sample of AE’s (e.g., ten percent) that the manufacturer has identified (and reported to the FDA as required by the guidance) for the first month or quarter of each calendar year, rather than requiring the manufacturer to submit *every* suspected AE.<sup>220</sup> Thereafter, the FDA could require companies to certify in their monthly post-marketing submissions that the manufacturer is continuing to monitor and report AE’s consistent with their initial submission.

While companies may need to invest significant resources to monitor such reported AE’s,<sup>221</sup> companies that follow posts may: (1) help reduce the number of AE’s by getting early warnings of potential problems; (2) learn of any unexpected side effects

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experience associated with a drug that can include death, a life-threatening condition, hospitalization (initial or prolonged), disability or permanent damage, or a congenital anomaly or birth defect).

<sup>219</sup> 21 C.F.R. § 310.305 (2013) (NDAs); 21 C.F.R. § 312.32 (2013) (Investigational New Drug Safety Reports); and 21 C.F.R. § 314.80 (2013) (Post-Market).

<sup>220</sup> This could include screenshots of the UGC that the company identified, any response from the company (e.g., “please contact our AE hotline at 1-800-XXX-XXXX”), and a copy of the AE report if the company eventually chose to report it.

<sup>221</sup> *Id.* See also Jonathan Richman, *Monitoring Adverse Events in Social Media for Pharma’s Biggest Brands: Hopeless Task or Simple Project?*, DOSE OF DIGITAL (Dec. 8, 2009), <http://www.doseofdigital.com/2009/12/monitoring-adverse-events-social-media-pharmas-biggest-brands/>.

in any specific populations; (3) get more information on the effects of various drug combinations or interactions; and (4) identify new information to educate physicians. Moreover, using interactive promotional media can expedite the process of capturing post-marketing data, which is critical for determining if a drug's label needs updating or a black box warning, or if the manufacturer should recall the drug. Incorporating this kind of system may build trust with patients and the FDA because it demonstrates a concern for patient safety and a commitment to post-market surveillance. Manufacturers may also want to restrict users from posting or commenting on personally identifiable health information (PHI) or AE's in public forums and should instead create a mechanism within the interactive promotional media platform (or application) for patients to report AE's, similar to FDA's MedWatcher Mobile App.<sup>222</sup> Such measures may help protect patient privacy and avoid the chance that users may request medical advice, including requesting advice from healthcare professionals who may provide content on the interactive platform.

### E. Practical Considerations for Industry

The FDA's recent guidance coupled with existing internet and social media campaigns, offer several factors for companies to consider moving forward. When addressing current interactive promotional media platforms as well as proposed new platforms, companies may want to form cross-cutting groups of medical, legal, regulatory, and marketing staff to ensure compliance with the FDA regulations and guidance.<sup>223</sup> When a manufacturer chooses to begin an online or social media presence, they should use a wireframe<sup>224</sup> to understand how the navigation and links for particular environments of website content flow. The website should have a home page that displays certain buttons (e.g., "Indications,") that remain consistent and available throughout the mobile presentation as a user navigates "through the different branded content options" or if the user "decides to share . . . the branded content . . .".<sup>225</sup> Companies should also optimize their websites for mobile device use to eliminate the need for consumers to scroll right or left and to avoid making consumers zoom in to locate benefit or risk information. All promotional materials should be on-label if branded, and companies should post the full PI on any interactive promotional media for branded content or if the drug has a boxed warning or REMS.<sup>226</sup>

When using websites and interactive promotional media, companies should be careful about having pop-ups, scrolling information, banners, comments, or videos that "causes [the] messages" of a disease awareness or help-seeking advertisement and a reminder advertisement "to be linked together by the audience."<sup>227</sup> Such combined communication—with information about the disease and the name of a drug—could

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<sup>222</sup> FOOD AND DRUG ADMIN., *MedWatcher Mobile App*, FDA.GOV (Feb. 13, 2014), <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/FormsandInstructions/ucm348271.htm>

<sup>223</sup> James Chase, *Pharma execs: MLR teams are friendlier on digital*, MMM (Oct. 22, 2012).

<sup>224</sup> Stults, *supra* note 144 (explaining that a wireframe is a digital tool that shows a visual structure, function and content description of the website pages, and how the navigation and links flow).

<sup>225</sup> *Id.*

<sup>226</sup> *Id.*

<sup>227</sup> FDA Help Seeking Guidance, *supra* note 12, at 6.

constitute an advertisement that communicates a drug's indication and efficacy, and thus, without the required risk disclosures and other required information, could cause the advertised product to be misbranded.<sup>228</sup> In designing platforms that may have overlapping messages or use different kinds of interactive promotional media, companies should account for perceptual similarities and timing of presentation.<sup>229</sup> However, manufacturers may have more flexibility in using different kinds of online media because a recent FDA study found no evidence that consumer understanding of risk information was effected by the "emotional (affective) tone of visual images or the consistency of the visual images with the risk information on the screen during the major statement."<sup>230</sup> Specifically, the FDA concluded that its Distraction Study showed that "presenting risk information at the same time in text and in audio improves consumers' understanding of the risk information."<sup>231</sup> Despite this flexibility, manufacturers designing interactive promotional media will have to pay close attention to consumers understanding of "composite scores"<sup>232</sup> in DTC advertisements. While the FDA is surveying print advertisements, the Agency noted that such research "[may] apply to any similar medium including static elements of Web sites."<sup>233</sup>

Next, companies should update (or where necessary create) and implement internal policies and procedures regarding the use of social media and the internet for DTC advertisements. Manufacturer policies should outline: (1) the requirements and standards for branded and unbranded social media activity; (2) how employees can interact with company sponsored or created websites as well as third-party websites; (3) who is responsible for monitoring and maintaining such websites; (4) who has the ultimate authority over the website; and (5) potential scenarios when legal counsel should be notified of consumer concerns. Moreover, companies should train employees on all social media-related or internet policies,<sup>234</sup> and set regular reviews to identify weaknesses and areas for new or additional training, particularly given the constant changes and updates to social media platforms and websites. In light of the AMARC letter, this training is particularly important to prevent employees who have control

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<sup>228</sup> *Id.* (also applicable to a disease awareness ad combined with a product claim ad or promotional labeling piece).

<sup>229</sup> *Id.* Companies should consider similarities in disease awareness communications and reminder or product claim promotions in terms of their themes, such as story lines, colors, logos, tag lines, graphics, etc. *Id.* at 7.

<sup>230</sup> Thomas Sullivan, *FDA Distraction Study – Shows No Distractions After All*, POL'Y AND MEDICINE (Feb. 20, 2012), <http://www.policymed.com/2012/02/fda-distraction-study-shows-no-distractions-after-all.html>.

<sup>231</sup> *Id.*

<sup>232</sup> Communication Composite Scores in Direct-to-Consumer Advertising, Meeting Notice, 78 Fed. Reg. 28224 (May 14, 2013) (explaining that "[t]he efficacy of a drug is measured by multiple endpoints that are sometimes combined into an overall score called a composite score").

<sup>233</sup> *Id.* at 28227.

<sup>234</sup> See e.g., FOOD AND DRUG ADMIN., Letter from Michelle Safarik, Regulatory Review Officer, FDA, to Brian Deutsch, Assoc. Regulatory Affairs, Warner Chilcott (US), LLC (May 5, 2011), <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/enforcementactivitiesbyfda/warninglettersandnoticeofviolationletterstopharmaceuticalcompanies/ucm254562.pdf>.

over Facebook or related social media platforms from “liking” content not created by the company, which may render it promotional and suggest to the FDA that there is some form of manufacturer control, influence, or further dissemination, even if an independent third-party created the content.

In addition, companies may want to set standard response times for comments or questions posted by users of websites and publicize such information regarding standardized response times. When responding to comments, companies should try to use language that patients can understand to avoid confusion.<sup>235</sup> Internal policies may also want to address: (1) use of rollovers to help define complicated medical terms; (2) use of images of real people, not actors, to tell compelling stories that highlight drug benefits, as long as these stories comply with FDA regulations; (3) use of callouts to highlight key brand messages; and (4) regular update of the website content, especially when there is news on a product or health condition to entice patients to come back to the website.<sup>236</sup>

## **F. The FDA’s Implementation of Interactive Promotional Media Standards**

The FDA’s future guidance should take into account the various aspects of social media (e.g., type of medium) and the rapid advances and updates that social media technology and platforms undergo. For example, similar to the FDA’s regulations and guidance governing current good manufacturing practices (cGMP) for drugs and devices, the FDA should ensure that social media and internet guidance reflect the same “current”<sup>237</sup> status. Specifically, the FDA should establish a streamlined process or mechanism by which the Agency can regularly update interactive promotional media guidance and standards or establish so called “current Good Social Media Practices” (cGSMP).

To accomplish this goal, the FDA could convene an Advisory Committee on Interactive Promotional Media, which could include members from the pharmaceutical and social media industry, the FDA, patients, and consumers. This Committee could meet on a quarterly basis, or more frequently as needed, to address key changes affecting interactive promotional media and meetings would be open to the public. The Committee could also propose specific topics for the FDA to research regarding interactive promotional media to determine its affect on consumers. For example, the FDA could study the effectiveness of conveying drug risk information through hyperlinks. The Committee could make recommendations to OPDP, such as those listed above, that the FDA could adopt after public notice and comment, unless OCC or the FDA’s Office of the Commissioner objects or a Citizen’s Petition<sup>238</sup> is filed. The FDA could publish the new changes immediately on its website and social media platforms, as well as in the Federal

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<sup>235</sup> Amy Norton, *Web info on prostate cancer tough to understand*, REUTERS (Oct. 25, 2012), <http://www.reuters.com/article/2012/10/25/us-prostate-cancer-idUSBRE89O1G620121025>.

<sup>236</sup> Richard Meyer, *Why Branded Websites Are So Important to Pharma*, WORLD OF DTC MARKETING.COM (Nov. 9, 2012), <http://worldofdtcmktg.com/why-branded-websites-are-so-important-to-pharma/prescription-drug-dtc-marketing/>.

<sup>237</sup> See FOOD AND DRUG ADMIN., *Facts About Current Good Manufacturing Practices (cGMPs)*, FDA.GOV (May 2, 2013), <http://www.fda.gov/drugs/developmentapprovalprocess/manufacturing/ucm169105.htm>. The “c” in cGMP stands for “current.” *Id.*

<sup>238</sup> See 21 C.F.R. § 10.30 (2013).

Register. The FDA could also create a list-serve for stakeholders to register and receive notification of these types of updates and changes.

This process could appease potential concerns from industry or consumers because groups would have several mechanisms to participate in the process to update social media and internet guidance and standards. If the FDA is unable to create this Committee, due to regulatory hurdles, Congress could authorize its creation by statute in the next User Fee Act negotiations<sup>239</sup> or through separate user fees for interactive promotional ideas, which Congress considered doing in the past. Companies may now be willing to pay user fees given the significant demand for clarity in using interactive promotional media, the fear of enforcement, the tremendous potential such tools have for public health and marketing, and the negative effects that accompany a continued lack of companies presence online.

## VII. CONCLUSION

With social media guidance amongst “the highest of FDA’s priorities,”<sup>240</sup> companies must begin to prepare their advertising and marketing departments accordingly, particularly with the FDA’s first Guidance, and three more on the horizon in 2014. This includes forming employee teams comprised of individuals with regulatory, marketing, legal, and medical experience to help the company navigate the current regulatory environment and learn how to market their products to consumers using interactive promotional media. Given the rapid increase in social media users, the benefits associated with company use of such platforms likely outweigh the risks and regulatory hurdles discussed in this article.

While there may be legal or regulatory consequences, “[t]he monetary costs of gaining access to social media are negligible, whereas the benefits associated with its use—increased brand awareness, greater market reach, quicker and more comprehensive feedback—are endless.”<sup>241</sup> Furthermore, continuing to delay social media use may only harm patients further because companies will be unable to fight the continued rise of third-party misinformation.<sup>242</sup> In addition, social media allows companies to grow new markets, “gain insight about new products, develop more targeted marketing practices,”<sup>243</sup> and better understand how factors such as drug availability, packaging, and pricing could be affecting usage patterns. Understanding the regulatory landscape of interactive promotional media will also be critical for companies to gain access to patients using mobile medical applications by sending effective patient educational information through general health and wellness applications, as well as those applications designed for medication adherence and drug-interaction warnings. Until

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<sup>239</sup> See FOOD AND DRUG ADMIN., *User Fees*, FDA.GOV (Jan. 10, 2014), <http://www.fda.gov/ForIndustry/UserFees/default.htm>.

<sup>240</sup> Slajda, *supra* note 192.

<sup>241</sup> Liu, *supra* note 122.

<sup>242</sup> Brian Reid, *The 5 Consequences of the Lack of FDA Social Media Guidance*, COMMON SENSE (Dec. 8, 2011), <http://blog.wcgworld.com/2011/12/the-5-consequences-of-the-lack-of-fda-social-media-guidance>.

<sup>243</sup> *Id.*

the FDA finalizes guidance on the use of links and character space limitations on such applications, however, much uncertainty remains in this area.

Because many patients use interactive promotional media to share and obtain information about drugs, the FDA's future guidance should enable companies to use these platforms in ways that can advance public health by disseminating reliable and accurate information about their products, without imposing undue regulatory burdens and requirements that infringe upon First Amendment rights. Ultimately, ensuring that patients and consumers can receive benefit and risk information about specific treatments and other disease information through interactive promotional media will accomplish the FDA's goals and purpose as a public health agency by informing patients and enhancing their health and safety.