



# DIGITAL ACCESS TO SCHOLARSHIP AT HARVARD

## FDA and Social Media: The Impact of Social Media on Prescription Drug Advertising

The Harvard community has made this article openly available.  
[Please share](#) how this access benefits you. Your story matters.

<b>Citation</b>	Kassity Yefei Liu, FDA and Social Media: The Impact of Social Media on Prescription Drug Advertising (September 2011).
<b>Accessed</b>	February 19, 2015 9:21:01 AM EST
<b>Citable Link</b>	<a href="http://nrs.harvard.edu/urn-3:HUL.InstRepos:8789614">http://nrs.harvard.edu/urn-3:HUL.InstRepos:8789614</a>
<b>Terms of Use</b>	This article was downloaded from Harvard University's DASH repository, and is made available under the terms and conditions applicable to Other Posted Material, as set forth at <a href="http://nrs.harvard.edu/urn-3:HUL.InstRepos:dash.current.terms-of-use#LAA">http://nrs.harvard.edu/urn-3:HUL.InstRepos:dash.current.terms-of-use#LAA</a>

*(Article begins on next page)*

FDA and Social Media: The Impact of Social Media on Prescription Drug Advertising

**Kassity Y. Liu**

Class of 2012

September 2011

*This paper is submitted in satisfaction of the course requirement.*

## **Abstract**

The U.S. Food and Drug Administration (FDA) regulates the promotion of prescription drugs.

With the emergence of Web 2.0 technology and social media, the FDA faces new regulatory challenges as pharmaceutical companies have started to use social media tools to market prescription drugs to consumers. This paper first explores the history of social media, its use by the FDA, and its growing use by the pharmaceutical industry. The paper then discusses some of the actions that the agency has taken to respond to the industry's use of social media. Lastly, the paper takes a look at the FDA's repeated delays in issuing social media guidance, and discusses some of the "social media guidance" that pharmaceutical companies have received from other individuals and groups.

## Table of Contents

Introduction.....	1
Background.....	2
<i>What is Social Media?</i> .....	2
<i>Use of Social Media by the FDA</i> .....	5
<i>The Pharmaceutical Industry and Social Media</i> .....	7
FDA Guidance on Social Media Advertising.....	10
<i>NOV and Warning Letters</i> .....	14
<i>Hearing on Social Media</i> .....	17
<i>Delay in Social Media Guidance</i> .....	22
Other “Social Media Guidance”.....	24
Conclusion.....	27

## Introduction

The use of social media has pervaded and reshaped our society. From Facebook to Twitter to LinkedIn, social media websites have provided individuals with newer and faster ways to communicate to one another. In 2012, eBizMBA estimated that 700 million unique users visited Facebook per month, 200 million users visited Twitter, and 100 million users visited LinkedIn.<sup>1</sup> These statistics are staggering. The entire population of the United States, as reported by the U.S. Census Bureau, only totals a lofty 312 million.<sup>2</sup>

With the growing use of social media, many businesses in the U.S. have started to use social media as a method of advertising their products to consumers. Large conglomerates such as General Electric and Procter & Gamble have incorporated social media into their advertising and promotional efforts.<sup>3</sup> Companies including AT&T and Dell use Facebook, Twitter, and YouTube to communicate with consumers and market their products.<sup>4</sup> In 2010, Facebook boasted that over 1.5 million local businesses had active Facebook pages.<sup>5</sup>

However, even with these statistics, pharmaceutical companies in the U.S. have taken a cautious approach to social media. In 2008, the pharmaceutical industry only allocated a “tiny fraction” of “less than 4% of the more than \$4 billion it spent on direct-to-consumer advertising”

---

<sup>1</sup> <http://www.ebizmba.com/articles/social-networking-websites>, last updated Sept. 12, 2011.

<sup>2</sup> <http://www.census.gov/main/www/popclock.html>, U.S. Census Bureau, last updated Sept. 17, 2011.

<sup>3</sup> W. Glynn Mangold, David J. Faulds, “Social media: The new hybrid element of the promotion mix,” *Business Horizons*, Vol. 52, Issue 4, 358 (2009).

<sup>4</sup> AT&T’s Facebook page, <http://www.facebook.com/ATT>. AT&T’s Twitter accounts, <http://twitter.com/#!/ATTNews> and <http://twitter.com/#!/attblueroom>. Listing of Dell’s Twitter accounts, <http://content.dell.com/us/en/corp/social-media-twitter.aspx>. AT&T’s YouTube page, <http://www.youtube.com/shareatt>.

<sup>5</sup> <http://www.digitalbuzzblog.com/facebook-statistics-facts-figures-for-2010/>, accessed on Jul. 15, 2011.

on social media advertising.<sup>6</sup> Unlike advertising in other industries, prescription drug advertising is regulated by the U.S. Food and Drug Administration.<sup>7</sup> This means that pharmaceutical companies are only allowed to advertise their products under a regulatory scheme that is set up by the FDA. Although some venturesome pharmaceutical companies have chosen to invest their dollars in social media advertising before the FDA gives the industry clear guidance, many have been waiting for the FDA to publish a guidance document on social media advertising.

In my paper, I plan on addressing the current state of social media use by pharmaceutical companies. First, I will give a brief background on social media, its use by the FDA, and its growing use by the pharmaceutical industry. Second, I will take a look at what the FDA has already done to respond to the use of social media by pharmaceutical companies. And third, I will examine the “social media guidance” that the pharmaceutical industry has received from other individuals and groups, focusing on Facebook’s recent decision to change its comment policy and the impact of this change. I will then conclude.

## **Background**

### *What is Social Media?*

Most people agree that we live in a world of social media. But what is “social media” and what does it provide its users? Depending on how broadly the term “social media” is defined, its roots can be traced back to as early as 1971, when the first email communication was sent.<sup>8</sup>

In their article on social media challenges, Andreas Kaplan and Michael Haenlein define social media as a “group of Internet-based applications that build on the ideological and technological foundations of Web 2.0, and that allow the creation and exchange of User

---

<sup>6</sup> Jeremy A. Greene, Aaron S. Kesselheim, “Pharmaceutical Marketing and the New Social Media,” *N. Engl. J. Med.*, Vol. 363, No. 22, 2087 (2010).

<sup>7</sup> U.S. Food and Drug Administration, “Prescription Drug Advertising: Questions and Answers,” [www.fda.gov](http://www.fda.gov).

<sup>8</sup> <http://mashable.com/2011/01/24/the-history-of-social-media-infographic/>, accessed on Jul. 15, 2011.

Generated Content.”<sup>9</sup> Web 2.0 roughly came into being in the early 2000s, when online users started to use a new generation of web technologies.<sup>10</sup> These new technologies created an online platform where content was no longer created and maintained by one user, but where an online community of users could continuously make changes to existing content in a collaborative fashion.<sup>11</sup> The Internet had become a forum that allowed users to interact and communicate with one another using newer and more eclectic forms of content. This content, known as User Generated Content (UGC), differed drastically from the content that existed prior to the days of Web 2.0, and paved the way for the development of modern day social media.<sup>12</sup>

Social media today exists in many forms. Blogs, social networking sites, collaborative projects, content communities, virtual social worlds, and virtual game worlds can all be classified as types of social media applications.<sup>13</sup> The popularity of social media has skyrocketed in the past decade. With the introduction of MySpace, Facebook, and other social media sites, a large number of businesses and individuals have explored its uses and developed new social media tools. Kaplan and Haenlein reported that 75% of Internet users in the second quarter of 2008 used social media in some shape or form; this represented an increase of nearly 50% from 2007.<sup>14</sup>

---

<sup>9</sup> Andreas M. Kaplan, Michael Haenlein, “Users of the world, unite! The challenges and opportunities of Social Media,” Vol. 53, Issue 1, 61 (2010).

<sup>10</sup> *Id.* at 60-61. The term was first adopted by Tim O’Reilly and Dale Dougherty in 2004, when they used it to suggest that a new version of the World Wide Web had replaced the old, Web 1.0. Jack M. Maness, “Library 2.0 Theory: Web 2.0 and Its Implications for Libraries,” *Webology*, Vol. 3, No. 2, Art. 25 (2006).

<sup>11</sup> Kaplan, *supra* note 9.

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

<sup>13</sup> *Id.* at 62.

<sup>14</sup> *Id.* at 59.

In 2010, the Nielsen Company revealed that the U.S. had the largest number of social media users, totaling more than 140 million unique users in December 2009 alone.<sup>15</sup> With the large number of users in the U.S., businesses in many industries have started to invest their resources in social media. Many businesses have used social media to market their products, share and collect information, and promote their public image.<sup>16</sup> In 2008, General Electric and Procter & Gamble were able to effectively use social media in their promotional efforts.<sup>17</sup> Their success and the success of many other companies demonstrate that social media can indeed be used for promotional and marketing purposes.

But social media does not merely provide businesses with the opportunity to share information with their customers. Its foundations lie in Web 2.0, so it naturally gives consumers the opportunity to respond to online promotional material and to communicate their opinions with other consumers. Herein lies a danger to businesses. As easy as it is for a business to tell millions of individuals about one of its new products, a dissatisfied customer can post spiteful comments about the company and discourage these same individuals from purchasing the product. To limit the effects of negative publicity, businesses can put in place strong “reputation management and social media marketing strategies,”<sup>18</sup> but even with the most robust management system in place, admittedly it would still be difficult for a business to monitor the online actions of millions of users.

With this understanding of social media, I will now address a few of the different types of social media in the context of the FDA and the pharmaceutical industry.

---

<sup>15</sup> [http://news.cnet.com/8301-1023\\_3-10457480-93.html](http://news.cnet.com/8301-1023_3-10457480-93.html), accessed on Jul. 15, 2011.

<sup>16</sup> Mangold, *supra* note 3, at 357-58.

<sup>17</sup> *Id.* at 358.

<sup>18</sup> <http://www.optimum7.com/internet-marketing/social-media/dangers-of-social-networking-sites.html>, accessed on Aug. 26, 2011.



## *Use of Social Media by the FDA*

Although some may argue that the FDA's use of technology is antiquated,<sup>19</sup> the agency has adopted and implemented a number of different technology initiatives over the years. In the late 1980s, the FDA approved the use of computer-assisted new drug applications (CANDAs) which eventually led to the development of the Electronic Regulatory Submission and Review (ERSR) Program.<sup>20</sup> This program significantly improved the FDA's submission and review process for new drug applications and still operates as an integral part of the agency today. Similarly, in the 1990s, the FDA started using the Internet by running a "highly successful, well-designed webpage, [www.fda.gov](http://www.fda.gov), aimed at disseminating information electronically."<sup>21</sup> This webpage continues to provide important information such as regulatory information, guidance documents, and health warnings to consumers and businesses.

With the development of Web 2.0 and new online technology, the FDA has also embraced the use social media sites such as YouTube, Facebook, and Twitter.<sup>22</sup> The agency launched its YouTube channel on September 6, 2007, marking its first foray into social media.<sup>23</sup> YouTube allows its users to upload, share, and view videos online. When adding videos, users can include short descriptions of their videos or enable other users to comment on their videos. Currently, the FDA uses its YouTube channel as an online tool to "share public health

---

<sup>19</sup> Scott Gottlieb comments that the FDA's use of technology is antiquated because the agency was unable to navigate a company's recent electronic application. [http://www.eyefda.com/eye\\_on\\_fda/2011/06/fdas-social-media-assets-twitter-overview.html](http://www.eyefda.com/eye_on_fda/2011/06/fdas-social-media-assets-twitter-overview.html), accessed on Jul. 2, 2011.

<sup>20</sup> Joel F. Studebaker, "Computers in the New Drug Application Process," *J. Chem. Inf. Comput. Sci.*, Vol. 33, No. 1, 86 (1993); <http://www.fda.gov/ohrms/dockets/98fr/980237ss.pdf>, accessed on Aug. 17, 2011.

<sup>21</sup> David E. Melaugh, "The Food and Drug Administration and the Internet," 4 (1999).

<sup>22</sup> [http://www.eyefda.com/eye\\_on\\_fda/2011/09/an-overview-of-fdas-utilization-of-digital-media.html](http://www.eyefda.com/eye_on_fda/2011/09/an-overview-of-fdas-utilization-of-digital-media.html), accessed on Sept. 15, 2011.

<sup>23</sup> *Id.*

information with users.”<sup>24</sup> The agency usually posts a short description of each video but does not enable commenting on their videos. Some of the FDA’s most recent uploads include a “brief video about how to safely choose and use an over-the-counter medicine” and a video on “[g]etting kids to eat the fiber they need.”<sup>25</sup> The agency organizes its videos based on subject matter and groups videos into different playlists.<sup>26</sup> Since the beginning of September 2011, the webpage has been viewed more than 100,000 times and currently has 4,000 YouTube subscribers.<sup>27</sup>

In addition to YouTube, the FDA also uses Facebook to publish information on recalls, warning letters, and other agency actions.<sup>28</sup> Facebook is a social networking site that provides users with a wide range of services. Users have to first create their own account, but upon creating an account, users can use Facebook to communicate with other Facebook users, upload pictures and videos, share their interests by “liking” a fan page, and do much more. When users “like” a page, updates from that page automatically populate their personal Facebook news feeds. Currently, over 14,000 Facebook users have indicated that they “like” the FDA’s Facebook fan page. Users like the FDA who create their own fan pages can post information, pictures, videos, and links to their pages and invite others to “like” their pages. The FDA has also adopted a comments policy that provides clear commenting guidelines and reasons for comment

---

<sup>24</sup> U.S. Food and Drug Administration, “Total number of views of FDA YouTube channel during the month (1),” [www.fda.gov](http://www.fda.gov).

<sup>25</sup> <http://www.youtube.com/user/USFoodandDrugAdmin>, accessed on Sept. 15, 2011.

<sup>26</sup> *Id.*

<sup>27</sup> <http://www.youtube.com/user/USFoodandDrugAdmin>, accessed on Sept. 15, 2011.

<sup>28</sup> [http://www.eyeonfda.com/eye\\_on\\_fda/2011/09/an-overview-of-fdas-utilization-of-digital-media.html](http://www.eyeonfda.com/eye_on_fda/2011/09/an-overview-of-fdas-utilization-of-digital-media.html), *supra* note

removal on its fan page.<sup>29</sup> The enforcement of such a policy is unclear, but as long as Facebook users are allowed to remove offensive comments from their fan pages, users would have the power to police their own pages.

Lastly, the FDA also uses Twitter to microblog about recalls, warning letters, health, safety, and a number of other topics and events.<sup>30</sup> Twitter is a social networking site that allows users to share short posts of up to 140 characters. The FDA currently has ten Twitter feeds including @FDArecalls, @FDA\_Drug\_Info, and @FDADeviceInfo.<sup>31</sup> The activity and following of each “vary greatly.”<sup>32</sup>

Even though the FDA has successfully navigated the realm of social media, the agency can still make improvements. To further optimize its use of social media, the FDA can also use Twitter to increase traffic to its Facebook and YouTube pages. The agency can increase its social media presence by using additional tools that are available via Twitter and other social media sites.

### *The Pharmaceutical Industry and Social Media*

Despite the widespread use of social media by the FDA, the agency still has not properly advised pharmaceutical companies on the use of social media advertising. Perhaps due to a lack of clear guidance, the pharmaceutical industry has mostly refrained from engaging in social

---

<sup>29</sup> [http://www.eyeonfda.com/eye\\_on\\_fda/2011/09/an-overview-of-fdas-utilization-of-digital-media.html](http://www.eyeonfda.com/eye_on_fda/2011/09/an-overview-of-fdas-utilization-of-digital-media.html), *supra* note 22; [http://www.facebook.com/FDA?sk=app\\_7146470109](http://www.facebook.com/FDA?sk=app_7146470109), accessed on Sept. 15, 2011.

<sup>30</sup> There are ten FDA Twitter feeds. Eye on FDA has “compiled a list that reflects . . . what the FDA is tweeting among its various feeds at any given time.” <sup>30</sup> [http://www.eyeonfda.com/eye\\_on\\_fda/2011/09/an-overview-of-fdas-utilization-of-digital-media.html](http://www.eyeonfda.com/eye_on_fda/2011/09/an-overview-of-fdas-utilization-of-digital-media.html), *supra* note 22. The list can be accessed at <http://twitter.com/#!/list/eyeonfda/fda-tweets>.

<sup>31</sup> <http://twitter.com/#!/list/eyeonfda/fda-tweets>, *supra* note 30.

<sup>32</sup> [http://www.eyeonfda.com/eye\\_on\\_fda/2011/09/an-overview-of-fdas-utilization-of-digital-media.html](http://www.eyeonfda.com/eye_on_fda/2011/09/an-overview-of-fdas-utilization-of-digital-media.html), *supra* note 22.

media promotional activities.<sup>33</sup> In their article, “Pharmaceutical Marketing and the New Social Media,” Jeremy Greene and Aaron Kesselheim reported that the “drug industry [only] allocated [a small fraction of] less than 4% of the more than \$4 billion it spent on direct-to-consumers advertising” for social networking sites in 2008.<sup>34</sup> Greene and Kesselheim noted that this was “surprising” given the large number of consumers who used social media worldwide.<sup>35</sup> However, they posited that the reason why many pharmaceuticals companies were hesitant about using social media was because they did not know which types of promotional messages would be allowed.<sup>36</sup> “To encourage appropriate use of prescription drugs, the FDA has sought to ensure that promotional statements make claims about approved indications only and neither overstate the benefits nor understate the risks.”<sup>37</sup> But because the agency still has not provided guidance on how to strike a “fair balance” between a drug’s risks and benefits in social media advertising, pharmaceutical companies have been cautious with their approach to social media.

Greene and Kesselheim also noted that pharmaceutical companies in the past “have tended to wait for the FDA to establish explicit codes of acceptable marketing practices before devoting substantial resources to a new medium.”<sup>38</sup> Many commentators have suggested that

---

<sup>33</sup> See [http://news.cnet.com/8301-31921\\_3-20098572-281/will-the-fda-regulate-social-media-q-a/](http://news.cnet.com/8301-31921_3-20098572-281/will-the-fda-regulate-social-media-q-a/), accessed on Sept. 5, 2011 (reporting that PhRMA, a trade association representing pharmaceutical makers, says that pharmaceutical companies are still waiting for FDA’s guidance on social media).

<sup>34</sup> Greene, *supra* note 6.

<sup>35</sup> *Id.*

<sup>36</sup> *Id.* at 2087-88.

<sup>37</sup> *Id.* at 2087.

<sup>38</sup> Examples include direct-to-consumer advertising in print media and prescription drug advertising in broadcast media. For both types of advertising, the industry did not invest significant dollars in these new mediums until the FDA issued guidance documents. *Id.*

pharmaceutical companies are currently waiting for the FDA to do the same for social media.<sup>39</sup>

However, a few observe that some pharmaceutical companies have started to increase their social media spending, and hypothesize that the pharmaceutical industry may increase social media spending to “\$1.86 billion in 2015.”<sup>40</sup>

Regardless of whether pharmaceutical spending on social media will increase in the next few years, current examples of pharmaceutical companies that have invested significant resources in social media include Pfizer, Johnson & Johnson, Novartis, Bayer, Glaxo-Smith-Kline, and Merck.<sup>41</sup> All of these listed companies currently operate Twitter accounts;<sup>42</sup> a few also use other social media sites such as Facebook and YouTube;<sup>43</sup> and a couple have even developed their own social media sites such as CML Earth and Think Science Now Blog.<sup>44</sup>

---

<sup>39</sup> <http://adage.com/article/news/drug-makers-wait-fda-ruling-social-media-dtc-ads/149214/>, accessed on May 5, 2011; <http://www.npr.org/blogs/health/2011/08/22/139859210/why-drug-companies-are-shy-about-sharing-on-facebook>, accessed on Sept. 2, 2011; <http://www.toprankblog.com/2011/01/social-media-marketing-pharma/>, accessed on May 5, 2011.

<sup>40</sup> Visible Intelligence, “Is the Return Greater Than the Risk for Pharma Companies Investing in Social Media,” 2011. *See also* [http://www.marketwatch.com/story/ondine-biomedical-announces-2011-second-quarter-financial-results-2011-08-10?reflink=MW\\_news\\_stmp](http://www.marketwatch.com/story/ondine-biomedical-announces-2011-second-quarter-financial-results-2011-08-10?reflink=MW_news_stmp), accessed on Sept. 5, 2011 (noting that Ondine Biomedical increased its marketing and sales expenses for social media purposes).

<sup>41</sup> [http://inventorspot.com/articles/top\\_ten\\_drug\\_companies\\_social\\_media\\_31760](http://inventorspot.com/articles/top_ten_drug_companies_social_media_31760), accessed on Jul. 6, 2011 (lists the top ten drug companies in social media).

<sup>42</sup> Pfizer’s Twitter account, <http://twitter.com/#!/Pfizer>; Johnson & Johnson’s Twitter account, <http://twitter.com/#!/JNJComm>; Novartis’ Twitter account, <http://twitter.com/#!/novartis>; Bayer’s Twitter account, <http://twitter.com/#!/BayerUSNews>; Glaxo-Smith-Kline’s Twitter account, <http://twitter.com/#!/gsk>; Merck’s Twitter account, <http://twitter.com/#!/MERCK>.

<sup>43</sup> Pfizer’s YouTube channel, <http://www.youtube.com/PfizerNews>; Pfizer’s Facebook page, <http://www.facebook.com/Pfizer?sk=wall>; Johnson & Johnson’s YouTube channel, <http://www.youtube.com/user/JNJhealth>; Glaxo-Smith-Kline’s YouTube channel, <http://www.youtube.com/user/GSKvision>.

<sup>44</sup> CML Earth, <https://www.us.cmlearth.com/cmlearth/>; Think Science Now Blog, <https://science.pfizer.com/>.

In his online marketing blog, Dave Folkens encourages more pharmaceutical companies to use social media.<sup>45</sup> He argues that it is important for drug companies to build a social media presence because “consumers will be talking about [them] whether [they] are [using social media] or not.”<sup>46</sup> Folkens believes that pharmaceutical companies can effectively navigate the current regulatory environment by “work[ing] closely with their legal team along with marketing professionals with a strong understanding of social media engagements.”<sup>47</sup> By using these resources and others to tap into social media, pharmaceutical companies can revolutionize the way they connect with their customers and market their products.

### **FDA Guidance on Social Media Advertising**

In the U.S., the FDA regulates prescription drug advertising.<sup>48</sup> This authority passed from the Federal Trade Commission (FTC) to the FDA in 1962 when Congress amended the Food, Drug, and Cosmetic (FD&C) Act to provide for specific guidelines for prescription drug advertising.<sup>49</sup> The FD&C Act does not define the term “advertisements,” but the FDA has “interpret[ed] the term to encompass information, other than labeling, that promotes a drug product and is sponsored by a manufacturer.”<sup>50</sup> The Act requires that all pharmaceutical companies include their drug’s “established name . . . , the formula showing quantitatively each

---

<sup>45</sup> <http://www.toprankblog.com/2011/01/social-media-marketing-pharma/>, *supra* note 39.

<sup>46</sup> *Id.*

<sup>47</sup> *Id.* Folkens also believes that pharmaceutical companies that “have long applied Direct-to-Consumer (DTC) advertising” can use this knowledge to operate in the social media sphere. He reports that only one out of 52 warning and notice of violation letters sent to companies in 2010 involved the use of social media. *Id.*

<sup>48</sup> 21 U.S.C. § 352(n).

<sup>49</sup> Peter Barton Hutt, Richard A. Merrill, and Lewis A. Grossman, *Food and Drug Law*, 3rd ed., 535 (2007).

<sup>50</sup> Francis B. Palumbo, C. Daniel Mullins, “The Development of Direct-to-Consumer Prescription Drug Advertising Regulation,” *Food and Drug Law Journal*, Vol. 57, No. 3, 428 (2002).

ingredient of [the] drug . . . , and . . . such other information . . . relating to [the] side effects, contraindications, and effectiveness” of the drug in the drug’s advertisements.<sup>51</sup>

To implement its authority, the FDA issued a set of regulations “shortly after . . . the 1962” amendments to the FD&C Act.<sup>52</sup> These regulations were later revised in the late 1960s “to prohibit specific practices to which the agency had strong objections.”<sup>53</sup> The regulations impose two main requirements on prescription drug manufacturers. First, prescription drug advertisements have to include a brief summary of the drug’s “side effects, contraindications, and effectiveness.”<sup>54</sup> Second, these advertisements have to present a balanced account of the drug that fairly portrays its risks and benefits.<sup>55</sup> This second requirement, commonly known as the “fair balance” requirement, is more often cited by the FDA in its warning letters to prescription drug advertisers.<sup>56</sup>

Within the FDA, prescription drug advertising is regulated by the Division of Drug Marketing, Advertising, and Communications (DDMAC). The division distinguishes between two main types of advertising: advertising that is directed at consumers (i.e., direct-to-consumer (DTC) advertising) and advertising that is directed at healthcare professionals. Within DTC advertising, the FDA further differentiates between product-claim, reminder, and help-seeking advertisements.<sup>57</sup> Product-claim advertisements make claims about a specific product; therefore,

---

<sup>51</sup> 21 U.S.C. § 352(n).

<sup>52</sup> Hutt, *supra* note 49.

<sup>53</sup> *Id.*

<sup>54</sup> *Id.* at 539. *See also* 21 C.F.R. § 202.1(e)(1).

<sup>55</sup> Hutt, *supra* note 49, at 539. *See also* 21 C.F.R. § 202.1(e)(5)(ii).

<sup>56</sup> Hutt, *supra* note 49, at 539.

<sup>57</sup> U.S. Food and Drug Administration, “Regulating Prescription Drug Promotion,” [www.fda.gov](http://www.fda.gov).

these advertisements have to satisfy the brief summary and fair balance requirements.<sup>58</sup>

Reminder advertisements reveal the name of a drug product and may contain certain descriptive information but do not discuss the use of a product or make any claims about the product.<sup>59</sup>

These advertisements are also regulated by the FDA. However, they are exempt from the brief summary and fair balance requirements; presumably, the FDA only regulates them to verify that they do not make any product claims and are not being used to promote drug products with serious warnings known as “black box” warnings.<sup>60</sup> Lastly, help-seeking advertisements do not mention any drug product and thus are not regulated by the FDA.<sup>61</sup>

For regulated DTC advertising, DDMAC requires drug companies to present “adequate contextual and risk information . . . in understandable language” to consumers that would enable them to form an accurate opinion of a drug’s risks and benefits.<sup>62</sup> Pharmaceutical companies are not required to obtain preclearance for their advertisements,<sup>63</sup> but they are required to submit all of their advertisements to the FDA prior to or at the time they are initially published.<sup>64</sup>

To ensure regulatory compliance, the FDA also monitors DTC advertisements on a daily basis. Third parties such as “concerned citizens, healthcare practitioners, and competitor pharmaceutical companies” can also alert the agency about potential violations.<sup>65</sup> If DDMAC finds that there has been a violation, it typically issues one of two letters: a Notice of Violation

---

<sup>58</sup> *Id.* For broadcast product-claim advertisements, because it would be impractical for these advertisements to summarize a drug’s risks during the length of the broadcast, companies only need to provide “convenient access to the approved labeling.” *Id.*

<sup>59</sup> *Id.*

<sup>60</sup> *See id.*

<sup>61</sup> *Id.*

<sup>62</sup> Palumbo, *supra* note 50, at 429.

<sup>63</sup> Except for drugs that were approved under accelerated procedures. 21 C.F.R. § 314.550.

<sup>64</sup> 21 C.F.R. § 314.81.

<sup>65</sup> Palumbo, *supra* note 50, at 429.



(NOV) letter for minor violations, or a warning letter for more serious violations. For both NOV and warning letters, the division usually asks the identified pharmaceutical company to discontinue its violative advertisements and any other advertisements that may also be violative for similar reasons. The company is also asked to respond to the FDA within a certain period of time, usually spanning ten to fourteen days for NOV letters and fifteen days for warning letters.<sup>66</sup> For warning letters because they are of a more serious nature, the FDA is also “promis[ing] to proceed against the manufacturer if it does not initiate corrective action.” A list of all NOV and warning letters to pharmaceutical companies are posted online.<sup>67</sup>

With the growing use of social media, the FDA and the pharmaceutical industry are faced with new challenges involving DTC advertising. Even though many drug companies can use social media to market their products in new ways, some are concerned that they cannot satisfy the brief summary and fair balance requirements using social media and many others argue that they should not have to satisfy the same requirements.<sup>68</sup> Some commentators even argue that pharmaceutical companies should not be allowed to promote their products using social media tools.<sup>69</sup> In the following sections, I will discuss some of the actions taken by the FDA with respect to social media advertising. I will also take a look at the agency’s recent decisions to delay issuing guidance on social media.

---

<sup>66</sup> *Id.*; Office of Inspector General, “FDA Warning Letters: Timeliness and Effectiveness,” 1999, accessed at <http://oig.hhs.gov/oei/reports/oei-09-97-00381.pdf> on Sept. 12, 2011.

<sup>67</sup> <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm197224.htm>.

<sup>68</sup> Stephen Barlas, “Web of Confusion: FDA Tries to Clarify Rules for Internet Advertising,” *Pharmacy and Therapeutics*, Vol. 35, No. 1, 2010; <http://www.nature.com/nbt/journal/v28/n5/full/nbt0510-396.html>, accessed on Sept. 5, 2011 (noting that “[m]ost of the discussions at the FDA hearings boiled down to the question of whether FDA would allow presentations of risk information to differ depending on the media format”).

<sup>69</sup> <http://adage.com/article/news/advertising-fda-debate-social-media-dtc-drug-ads/140533/>, accessed on Sept. 5, 2011.

### *NOV and Warning Letters*

The FDA usually issues NOV and warning letters to companies to give them the opportunity to voluntarily correct their violations before the agency initiates an enforcement measure.<sup>70</sup> In practice, warning letters are only issued for “violations of regulatory significance” whereas NOV letters are issues for all other violations that “do not meet the threshold of regulatory significance.”<sup>71</sup> Both types of letters are informal and do not commit the FDA to take any enforcement action.

The agency has only recently begun to issue NOV and warning letters to pharmaceutical companies regarding social media advertisements. In 2009, DDMAC issued 14 NOV letters to pharmaceutical companies, informing them that their search advertisements – 95-character advertisements that ran next to search results – had to start including risk information.<sup>72</sup> The agency made clear that by omitting risk information the companies were publishing false and misleading advertisements, which violated federal regulations.<sup>73</sup> But up until issuing these letters, the FDA had been vague about whether the same regulatory requirements applied to internet search advertisements. And after the agency’s dramatic showing, many commentators started to question why the FDA did not develop guidance around new media mediums to help pharmaceutical companies navigate these new waters.<sup>74</sup>

---

<sup>70</sup> Hutt, *supra* note 49, at 1339, 1341.

<sup>71</sup> *Id.* at 1340-41.

<sup>72</sup> [http://www.nytimes.com/2009/04/17/business/media/17adco.html?\\_r=1&scp=1&sq=FDA%20Sows%20Confusion&st=cse](http://www.nytimes.com/2009/04/17/business/media/17adco.html?_r=1&scp=1&sq=FDA%20Sows%20Confusion&st=cse); accessed on Sept. 5, 2011.

<sup>73</sup> *Id.* See also <http://pharmexec.findpharma.com/pharmexec/article/articleDetail.jsp?id=592363>, accessed on Aug. 10, 2011 (stating that the search advertisements violated the “fair balance” requirement but failing to state risk information).

<sup>74</sup> *Id.*; [http://www.eyefonda.com/eye\\_on\\_fda/2009/04/14-warning-letters-in-a-day.html](http://www.eyefonda.com/eye_on_fda/2009/04/14-warning-letters-in-a-day.html), accessed on Aug. 10, 2011.

Then in 2010, the number of NOV and warning letters issued by DDMAC increased to 52.<sup>75</sup> Of the 52, thirteen letters were related to online media including “emails, websites, website videos, social media, and/or webcasts.”<sup>76</sup> During the first two quarters of 2011, there have been a total of seventeen NOV and warning letters.<sup>77</sup> The majority of these violations dealt with non-digital media, but one involved a video that was hosted on YouTube.<sup>78</sup>

In their article, “Roadmap to social media for pharmaceutical companies,” Lauren Tully and Lindsey Rozek report that “there appear to be three main problem areas for pharmaceutical social media marketing: omission of risk, broadening of indication, and overstatement of efficacy.”<sup>79</sup> For the first of these, Tully and Rozek observe that many prescription drug advertisements are misleading because “they fail to reveal facts that are material in light of the representation made by the materials or with respect to consequences that may result from the use of the drug as recommended or suggested by the materials.”<sup>80</sup> For the second, the two acknowledge that drug companies are not required to disclose every indication, side effect, and contraindications of a drug in their advertisements, but that they have to give a “true statement of the effectiveness of the drug for [its advertised] purpose.”<sup>81</sup> Then lastly, for overstatement of

---

<sup>75</sup> [http://www.eyeonfda.com/eye\\_on\\_fda/2011/01/ddmac-warning-and-nov-letters-lookback-for-2010.html](http://www.eyeonfda.com/eye_on_fda/2011/01/ddmac-warning-and-nov-letters-lookback-for-2010.html), accessed on Aug. 10, 2011.

<sup>76</sup> King & Spalding, “2010 Year in Review: DDMAC and APLB Warning Letters and Untitled Letters,” 2011, accessed at <http://www.kslaw.com/imageserver/KSPublic/library/publication/ca032211.pdf> on Aug. 10, 2011.

<sup>77</sup> [http://www.eyeonfda.com/eye\\_on\\_fda/2011/08/warning-letter-and-nov-summary-2nd-quarter-2011.html](http://www.eyeonfda.com/eye_on_fda/2011/08/warning-letter-and-nov-summary-2nd-quarter-2011.html), accessed on Sept. 15, 2011.

<sup>78</sup> *Id.*

<sup>79</sup> Lauren A. Tully and Lindsey P. Rozek, “Roadmap to social media for pharmaceutical companies,” *Med Ad News* (2011).

<sup>80</sup> *Id.*

<sup>81</sup> *Id.*

efficacy, Tully and Rozek suggest that drug companies should avoid representing that a drug is more effective than it has been demonstrated to be in clinical trials or other research studies.<sup>82</sup>

But despite the growing number of NOV and warning letters that target social media advertisements, only one letter to date relates to violations that are uniquely tied to social media. Pharmaceutical giant Novartis was using a “Facebook Share” widget in 2010 to market its leukemia drug, Tasigna, on individuals’ profile pages and news feeds.<sup>83</sup> The widget posted a short description of the drug along with graphics and website links on a Facebook user’s profile page and his or her friends’ news feeds if a user indicated that they wanted to “Share” information about the drug.<sup>84</sup> The FDA found the shared content to have violated agency regulations because the content failed to disclose risk information about the drug, wrongfully indicated that the drug applied to all leukemia patients when the drug was only approved for a subset of them, and classified the drug as a “next generation” treatment even though there was no clinical data to support this contention.<sup>85</sup>

The Novartis letter demonstrates that the agency is willing to use informal compliance measures to regulate social media advertising. However, the restrictions that the letter places on Novartis brings to question whether it would even be possible for pharmaceutical companies to use social media tools such as the “Facebook Share” widget and Twitter to market their products.

---

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

<sup>83</sup> <http://www.clickz.com/clickz/news/1727022/pharma-facebook-fda-cites-novartis-violations>, accessed on Aug. 15, 2010.

<sup>84</sup> Kellie B. Combs, “FDA Social Media Warning Letter: A Fragmented Approach to a Comprehensive Problem,” Washington Legal Foundation, Vol. 19, No. 26 (2010).

<sup>85</sup> *Id.*

Given the space limitations of these tools, it would be difficult for companies to disclose detailed risk information about their products to consumers.<sup>86</sup> Consequently, if pharmaceutical companies are required to satisfy the same regulatory requirements for social media advertising as they are for print advertising, then many of them may be foreclosed from using these types of social media tools. But because the FDA still has not issued formal guidance on social media advertising, it remains unclear whether social media advertisements are in fact subject to the same regulatory standards as other forms of advertisements.

### *Hearing on Social Media*

On November 12-13, 2009, the agency also held a public hearing to address the growing use of social media by pharmaceutical companies and other companies that market FDA-regulated products (e.g., medical devices, biologics).<sup>87</sup> The FDA acknowledged the “massive expansion of new tools and technologies, such as blogs, microblogs, podcasts, social network sites . . . , video sharing, widgets, and wikis,” and invited public speakers to comment on issues ranging from adverse event reporting to accountability and transparency.<sup>88</sup>

Among the questions asked by the FDA was: how should companies present information about their products using social media tools “to ensure that user[s] ha[ve] access to a balanced

---

<sup>86</sup> If pharmaceutical companies are forced to include risk information in these types of short advertisements, this may result in even more confusing and misleading advertisements. *See* [http://www.nytimes.com/2009/04/17/business/media/17adco.html?\\_r=1&sq=FDA%20Sows%20%20Confusion&st=cse&adxnnl=1&scp=1&adxnnlx=1316930641-WScVld6Dhgv18IRmBctyEg](http://www.nytimes.com/2009/04/17/business/media/17adco.html?_r=1&sq=FDA%20Sows%20%20Confusion&st=cse&adxnnl=1&scp=1&adxnnlx=1316930641-WScVld6Dhgv18IRmBctyEg), *supra* note 72 (noting that as companies changed their search advertisements to comply with FDA warnings, industry executives said that their advertisements became “even more confusing and misleading”).

<sup>87</sup> U.S. Food and Drug Administration, “Promotion of Food and Drug Administration-Regulated Medical Products Using the Internet and Social Media Tools; Notice of Public Hearing,” *Federal Registrar*, Vol. 74, No. 181, 2009.

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

presentation of both risks and benefits of medical products.”<sup>89</sup> Recall that the agency’s regulations require prescription drug advertisements to contain a brief summary of the drug’s side effects, contraindications, and effectiveness.<sup>90</sup> These regulations also require drug advertisements to present a fair balance between information relating to the risks and benefits of the drug.<sup>91</sup> Furthermore, in order to be truthful and nonmisleading, “risk information [about the drug] must be presented with a prominence and readability reasonably comparable to claims about [the] drug’s benefits.”<sup>92</sup> All pharmaceutical companies are also “responsible for submitting copies of promotional materials to [the] FDA.”<sup>93</sup>

During the public hearing, Tony Blank speaking on behalf of AdvaMed argued that the FDA needs to take into account the various aspects of social media (e.g., type of medium, space limitations) when it develops guidelines for the biomedical and pharmaceutical industries.<sup>94</sup> Many other speakers expressed similar viewpoints, proposing that the FDA needs to adopt guidance measures that are Internet-specific and take into account the limitations and advances of social media technology.<sup>95</sup> Rohit Barghava and several other speakers supported adopting a

---

<sup>89</sup> *Id.*

<sup>90</sup> 21 C.F.R. § 202.1(e)(1).

<sup>91</sup> 21 C.F.R. § 202.1(e)(5)(ii).

<sup>92</sup> “Promotion of Food and Drug Administration-Regulated Medical Products Using the Internet and Social Media Tools; Notice of Public Hearing,” *supra* note 87. *See also* 21 C.F.R. § 202.1(e)(7)(viii).

<sup>93</sup> “Promotion of Food and Drug Administration-Regulated Medical Products Using the Internet and Social Media Tools; Notice of Public Hearing,” *supra* note 87.

<sup>94</sup> Public Hearing on Promotion of FDA-Regulated Medical Products Using the Internet and Social Media Tools, “Transcript of Day 1 on November 12, 2009,” accessed at <http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/UCM193462.pdf> on Sept. 21, 2011.

<sup>95</sup> These other speakers included Ben Wolin, Chris Schroeder, Rohit Barghava, Cliff Thumma, amongst others. *Id.*; Public Hearing on Promotion of FDA-Regulated Medical Products Using the Internet and Social Media Tools, “Transcript of Day 2 on November 13, 2009,” accessed at <http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/UCM193463.pdf> on Sept. 21, 2011.

one-click rule where consumers could gain access to important safety information about a product by clicking on a link in its social media advertisement.<sup>96</sup> Barghava argued that due to space limitations on social media sites such as Twitter, it is difficult for many companies to include enough information in their advertisements to satisfy regulatory requirements.<sup>97</sup> Therefore, the one-click rule presents an effective solution to this problem because it not only provides consumers with access to a product's important information but also allows pharmaceutical companies to continue advertising their products via Twitter and other social media tools. Philomena McArthur, Senior Director of Regulatory Affairs at Johnson & Johnson, also suggested that "rollover and scrolling functions can enable direct connections to safety and efficacy information" when using social media tools with space limitations.<sup>98</sup>

Representatives from Yahoo! and Google also presented information on new social media tools that they were developing to help pharmaceutical companies advertise their products in ways that comply with regulatory requirements.<sup>99</sup> In addition to talking about the differences between social media and other existing forms of media (e.g., print, TV), Yahoo! Vice President Dave Zinman also talked about the different expectations that individuals have when they look at content online versus watching it on TV. For example, he explained that most "people don't have the attention span" to watch longer broadcast-compliant videos online because they "don't have to wait" or at least do not expect to wait "for [a] video to finish to get to the content [they want]."<sup>100</sup> Therefore, to remedy this problem, he suggested that pharmaceutical companies should be allowed to run shorter video advertisements coupled with important safety information

---

<sup>96</sup> *Id.*

<sup>97</sup> "Transcript of Day 1 on November 12, 2009," *supra* note 94.

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

<sup>99</sup> *Id.*

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

about a drug that is shown at the same time the video is shown.<sup>101</sup> Consumers viewing these videos can then take as long as they want to look over the drug’s important safety information and to click on links that would reveal more product and safety information.

However, some speakers also expressed concerns about the growing use of social media by the pharmaceutical and medical device industries. Steven Findlay representing the Consumers Union argued that the FDA should prevent companies from “layering” information about their products in a way that would bury important risk and safety information.<sup>102</sup> He opined that companies should not be allowed to advertise only “good stuff” about their products to consumers and to require them to click-through to any critical side effect information.<sup>103</sup> Displaying product information in this way would mislead consumers into believing that a drug is more safe and effective than it is. Findlay also suggested that prescription drug and medical device companies should not be allowed to use space-limited mediums to advertise their products directly to consumers (e.g., text messaging, social networking bulletin boards).<sup>104</sup> He recommends that the best and most legitimate way for companies to use social media tools to communicate with consumers is through their company websites.<sup>105</sup>

Ben Wolin, speaking from the other side, supported the adoption of a one-click rule but expressed doubts about using other browsing features (e.g., scrolling) because oftentimes the “text gets so minimized . . . [that] you can’t find it . . . [and] it’s really not achieving what [companies and the FDA] want it to achieve.”<sup>106</sup> Allan Coukell, the Director of the Pew

---

<sup>101</sup> *Id.*

<sup>102</sup> “Transcript of Day 2 on November 13, 2009,” *supra* note 95.

<sup>103</sup> *Id.*

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

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

<sup>106</sup> “Transcript of Day 1 on November 12, 2009,” *supra* note 94.



Prescription Project, also voiced his concerns about using space-limited platforms. Coukell argued that social media advertisements should be held to the same regulatory standards as other types of media promotion because “space is essentially unlimited [on the Internet], unlike TV and broadcast media.”<sup>107</sup> Consequently, Twitter and other social media tools with space limitations should not be used if they do not allow companies to effectively communicate important risk and safety information about their products to consumers. But before the agency should issue any guidance on the use of social media tools with space limitations, Coukell also advised the FDA to conduct studies on consumer comprehension of risk information presented in “various abbreviated forms.”<sup>108</sup>

In addition to addressing regulatory concerns for social media, speakers at the hearing also talked several other issues including: what communications are pharmaceutical and medical device companies accountable for online, “what parameters should apply to the posting of corrective information” online, and when is it appropriate to use links. In general, speakers agreed that companies should strive to be transparent with respect to their influence and control over content but should not be responsible for monitoring and policing the Internet.<sup>109</sup> Presenters supported having clear linking and posting policies on company-controlled websites and utilizing links and other tools that would give online users the opportunity to report misuse.<sup>110</sup> And most parties agreed that companies should adhere to present best practices until the FDA issues formal guidance on the use of social media.

---

<sup>107</sup> *Id.*

<sup>108</sup> *Id.*

<sup>109</sup> Kurt Mueller, “FDA Social Media Hearing Summary,” Roska Digital Advertising, 2009, accessed at <http://www.slideshare.net/RoskaDigital/key-takaways-from-the-fda-internet-and-social-media-hearing> on Sept. 21, 2011.

<sup>110</sup> *Id.*

### *Delay in Social Media Guidance*

Following the November hearing, the FDA initially announced that it would issue guidance on social media by the end of 2010.<sup>111</sup> Jean-Ah Kang, Special Assistant to DDMAC Director Tom Abrams, told Medical Marketing & Media that the agency was on track to at least issue partial guidance on some of the issues raised by the FDA and addressed by speakers during the hearing.<sup>112</sup> As the 2010 year came to an end however the agency announced that it would not be issuing guidance on social media until the first quarter of 2011.<sup>113</sup> In its email to Eye on FDA, DDMAC stated that the agency's new goal was to issue a guidance document during the first quarter of 2011 that addressed one of several important issues.<sup>114</sup> Key among these issues was “[r]esponding to unsolicited requests,” a topic that was not raised by the FDA during the November hearing and was only briefly discussed by one of the speakers.<sup>115</sup> But this new issue may be one that concerned many pharmaceutical companies because they are exposed to unsolicited requests via social media sites such as Facebook, Twitter, and YouTube on a daily basis.<sup>116</sup>

---

<sup>111</sup> U.S. Food and Drug Administration, “Guidance Agenda: New Draft Guidances CDER is Planning to Publish During Calendar Year 2010,” [www.fda.gov](http://www.fda.gov).

<sup>112</sup> Matthew Arnold, “Kang: online guidances due in 2010,” *Medical Marketing & Media*, Jun. 1, 2010.

<sup>113</sup> [http://www.eyeonfda.com/eye\\_on\\_fda/2010/12/breaking-its-official-fda-delaying-social-media-guidance-until-at-least-q1-2011.html](http://www.eyeonfda.com/eye_on_fda/2010/12/breaking-its-official-fda-delaying-social-media-guidance-until-at-least-q1-2011.html), accessed on Sept. 21, 2011.

<sup>114</sup> *Id.*

<sup>115</sup> Mark Gaydos, representing the Social Media Working Group, expressed concerns about situations where companies are faced with unsolicited comments and questions. “Transcript of Day 1 on November 12, 2009,” *supra* note 94.

<sup>116</sup> More pharmaceutical companies may be concerned about this issue today, especially after Facebook implemented a new policy that requires drug companies to allow other Facebook users make unsolicited comments on their company pages. [http://www.intouchsol.com/insights/articles/05-19-11/How\\_Facebook\\_s\\_new\\_comment\\_policy\\_impacts\\_your\\_pharma\\_Facebook\\_Page.aspx](http://www.intouchsol.com/insights/articles/05-19-11/How_Facebook_s_new_comment_policy_impacts_your_pharma_Facebook_Page.aspx), accessed on Jul. 15, 2011.

However, during the first quarter of 2011, DDMAC Director Abrams attended the Drug Information Association's (DIA) annual marketing meeting and announced that "industry and agencies should not expect major changes in social media marketing rules."<sup>117</sup> After being asked about advice that he would give to companies regarding the use of social media, Abrams replied that companies should continue to "follow existing regulations and policies" because he does not expect the agency's guidance to include any "new regulations or new standards" for social media.<sup>118</sup> Abrams suggested that the agency would still be issuing industry guidelines by April, but as we quickly approach the final months of the 2011 year, it is clear that the agency no longer has plans to issue social media guidelines by the end of the year.<sup>119</sup>

Many individuals and companies have expressed frustration at the FDA's decision to delay social media guidance yet again.<sup>120</sup> In his blog on the FDA, Jeffrey Wasserstein jokingly comments that the FDA may not need to bother with issuing guidance when it has NOV letters and other enforcement measures at its disposal.<sup>121</sup> The Public Relations Society of America recognizes that the agency has been assigned a difficult task, but still urges the FDA to quickly

---

<sup>117</sup> <http://www.cohealthcom.org/2011/02/28/ddmac-tells-industry-at-dia-%E2%80%9Cfollow-the-regs%E2%80%9D-until-social-media-guidance-is-issued/>, accessed on Sept. 21, 2011.

<sup>118</sup> *Id.*

<sup>119</sup> The agency's new guidance agenda for 2011 does not include the "Promotion of Prescription Drug Products Using Social Media Tools," which was included in its 2010 agenda. <http://pharmamkting.blogspot.com/2011/06/fda-drops-social-media-from-its-2011.html>, accessed on Sept. 21, 2011.

<sup>120</sup> *Id.*; <http://prsay.prsa.org/index.php/2011/08/25/prsa-requests-clear-social-media-guidelines-from-fda/>, accessed Sept. 21, 2011.

<sup>121</sup> [http://www.fdalawblog.net/fda\\_law\\_blog\\_hyman\\_phelps/2011/05/social-media-why-bother-issuing-guidance-when-you-can-issue-untitled-letters.html](http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2011/05/social-media-why-bother-issuing-guidance-when-you-can-issue-untitled-letters.html), accessed on Sept. 21, 2011. But perhaps the FDA should use positive guidance instead of negative enforcement measures to regulate the use of social media.

adopt guidelines so that patient communities and pharmaceutical companies can benefit more readily from the use of social media.<sup>122</sup>

### **Other “Social Media Guidance”**

Even though the FDA has not issued formal guidance on social media advertising, pharmaceutical companies have started to publish their own social media guidelines. In 2010, Roche distributed a guidance letter to employees that encouraged them to “approach online worlds in the same way [they] do the physical one – by using sound judgment and common sense.”<sup>123</sup> Pfizer Canada posted a flow chart online that instructs pharmaceutical companies on how to respond to social media communications.<sup>124</sup> And AstraZeneca, in December 2010, published a white paper that “outlin[es] its guidelines for social media use by the pharmaceutical industry.”<sup>125</sup>

Recently, in May 2011, Dr. Bertalan Mesko launched the Open Access Social Media Guide for Pharma (Open Access Guide), which is an online guide that provides pharmaceutical companies, medical professionals, and patients with information on social media use.<sup>126</sup> Most notably, the Open Access Guide delivers guidance to pharmaceutical companies on how to use Facebook, Twitter, Wikipedia, and other social media tools.<sup>127</sup> For using Facebook, the Open

---

<sup>122</sup> <http://prsay.prsa.org/index.php/2011/08/25/prsa-requests-clear-social-media-guidelines-from-fda/>, accessed on Sept. 21, 2011.

<sup>123</sup> F. Hoffmann-La Roche Ltd., “Roche Social Media Principles,” 2010.

<sup>124</sup> <http://blog.appliedclinicaltrials.com/2011/06/22/fda-remains-silent-on-social-media-regulation/>, accessed on Aug. 18, 2011.

<sup>125</sup> <http://healthworkscollective.com/jamierauscher/23427/who-will-drive-social-media-use-health-care-part-2>, accessed on Aug. 18, 2011.

<sup>126</sup> The Open Access Guide is updated regularly by a community of online professionals, and its goal is to facilitate the collaborative creation of online guidelines for pharmaceutical companies using social media. *Id.*

<sup>127</sup> Open Access Social Media Guide for Pharma, accessed at <http://www.webicina.com/solutions/pharmaSM/> on Aug. 18, 2011.

Access Guide recommends that companies should communicate regularly with users, clearly define their moderation policy for removing comments, and closely monitor their fan page walls.<sup>128</sup> The guide also includes links to negative and positive examples of pharmaceutical companies using Facebook.<sup>129</sup>

On August 15, 2011, Facebook also issued its own “social media guidance” for pharmaceutical companies.<sup>130</sup> The company had emailed its pharmaceutical clients back in May, informing them about its upcoming policy change.<sup>131</sup> Facebook’s new comment policy required drug companies to allow other Facebook users to comment on their fan page walls. The social media giant explained that this change would encourage more two-way dialogue between companies and people on Facebook, which has always been one of the company’s foremost objectives.<sup>132</sup>

Pharmaceutical companies have responded differently to Facebook’s policy change. Some companies such as AstraZeneca and Johnson & Johnson have closed their fan pages.<sup>133</sup> Others have announced that they are redesigning their Facebook pages to comply with its new

---

<sup>128</sup> *Id.*

<sup>129</sup> *Id.*

<sup>130</sup> <http://justincaseyouwerewondering.com/2011/08/17/facebook-not-fda-issues-social-media-guidance-for-pharma/>, accessed on Aug. 18, 2011.

<sup>131</sup> [http://www.intouchsol.com/insights/articles/05-19-11/How\\_Facebook\\_s\\_new\\_comment\\_policy\\_impacts\\_your\\_pharma\\_Facebook\\_Page.aspx](http://www.intouchsol.com/insights/articles/05-19-11/How_Facebook_s_new_comment_policy_impacts_your_pharma_Facebook_Page.aspx), *supra* note 116.

<sup>132</sup> *Id.*

<sup>133</sup> <http://2020health.wordpress.com/2011/08/17/commenting-now-open-on-pharmaceutical-company-facebook-pages/>, accessed on Aug. 18, 2011.

comment policy.<sup>134</sup> Still some have chosen to stay with Facebook and opened up their walls to public comments; conceivably, these companies have also ramped up their moderation efforts.<sup>135</sup>

The impact that Facebook's policy change had on pharmaceutical companies demonstrates how much influence Facebook and other social media sites have over the social media advertising. Many companies are concerned that allowing public commenting would lead to unsolicited requests and other undesirable statements. In its legal blog, Fuerst Ittleman notes that the public can now "comment about adverse side effects, promote off-label uses, or make inappropriate statements about pharmaceutical products."<sup>136</sup> Because drug companies fear that these comments could tarnish their brand image or force them to file adverse event reports with the FDA, many of them have moved away from using Facebook.

Justin Goldsborough comments in his blog that Facebook's recent decision to allow public comments on drug company pages has given the FDA another reason to "sit on its collective hands and adopt a 'wait and see' mentality without taking a true stand on how drug companies can or can't communicate with customers via social."<sup>137</sup> He predicts that Facebook's policy change "won't be that big of a deal" because the pharmaceutical industry will quickly learn how to use Facebook pages like other industries do today.<sup>138</sup> But an important distinction separates pharmaceutical companies from these other companies: the FDA's regulatory involvement. Therefore, it remains unclear whether Facebook's "social media guidance" will make it difficult for the pharmaceutical industry to fully embrace social media in the long-run.

---

<sup>134</sup> *Id.*

<sup>135</sup> <http://www.fuerstlaw.com/wp/index.php/25/facebook-changes-its-policy-regarding-pharmaceutical-companies-public-comment-walls/>, accessed on Aug. 18, 2011.

<sup>136</sup> *Id.*

<sup>137</sup> <http://justincaseyouwerewondering.com/2011/08/17/facebook-not-fda-issues-social-media-guidance-for-pharma/>, *supra* note 130.

<sup>138</sup> *Id.*

## Conclusion

As discussed in this paper, pharmaceutical companies have struggled with the use of social media during the past few years. The FDA continues to use enforcement measures such as NOV and warning letters to regulate social media content, while remaining silent about social media guidelines. Meanwhile, Facebook has decided to take matters into its own hands by delivering its own dose of “social media guidance.” As more pharmaceutical companies shy away from using social media, some commentators have started to consider whether it is time to give up on social media advertising for prescription drugs.<sup>139</sup>

In her article, “FDA’s Policy on Social Media,” Kristi Wolff identifies one of the key risks associated with using social media: the risk of losing control over one’s content.<sup>140</sup> She encourages companies to overcome this risk though by “be[ing] proactive and determin[ing] up front how to handle scenarios in which consumer generated content may create legal risk.”<sup>141</sup> Greene and Kesselheim also point out that many pharmaceutical companies are concerned that they will not be able to satisfy regulatory requirements “in the dynamic and expanding matrix of networked media.”<sup>142</sup> But with the development of resources such as the Open Access Guide,

---

<sup>139</sup> <http://impactiviti.wordpress.com/2011/07/08/time-to-give-up-on-pharma-and-social-media/>, accessed on Sept. 23, 2011 (arguing that social media and pharmaceutical advertising “don’t mesh well” because the former requires real-time, interactive dialogue whereas the latter usually consists of controlled, one-way communication); <http://www.pixelsandpills.com/2011/08/11/pointcounterpoint-time-give-social-media-rx-info/>, accessed on Sept. 23, 2011.

<sup>140</sup> Kristi Wolff, “FDA’s Policy on Social Media: Why It Matters for Marketers of OTC Drugs, Food, Dietary Supplements and Cosmetics,” FDLI Update Magazine, Associate Corner, March/April 2011.

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

<sup>142</sup> Greene, *supra* note 6, at 2088. For example, social media tools with space limitations have made it difficult for companies to present a fair balance of the risks and benefits of their products, and tools that allow for real-time communications have complicated how companies submit copies of their promotional material to the FDA.

these companies should be able to overcome this concern by following best practices and learning from others' experiences.

In conclusion, even though the FDA has not issued clear guidance on the use of social media, pharmaceutical companies should continue to explore this evolving area of technology. Social media has become an integral part of our society, and the pharmaceutical industry may have to learn how to use it sooner or later.