



FDA COMMUNICATIONS



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A WHITE PAPER

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Disclaimer

Nothing contained herein constitutes as legal advice nor is the information contained herein a substitute for consulting legal counsel regarding the regulation of communications regarding medical products.

The purpose of this paper is to assess the regulatory actions of FDA’s Office of Prescription Drug Promotion (OPDP) resulting from the increased use of digital and social media by pharmaceutical companies seeking to provide information about medical products and promotion.

Summary Overview

With the advent of the Internet, and subsequently social media, there has been a fundamental shift in the way the world communicates, seeks, and shares information. This is particularly true in healthcare, where increasing numbers of consumers, patients, and healthcare providers search for and share health-related information online and build relationships in social venues in the course of their medical decision-making.¹

While traditional communications regarding medical treatments — pharmaceutical and biologic medicines — are highly regulated by the U.S. Food and Drug Administration (FDA), there has been a lack of regulatory guidance regarding the Internet and social media by that agency. This has created hesitation and concerns among many responsible for healthcare communications and marketing when it comes to the use of digital platforms in general, and social media in particular.

Despite the concerns associated with a lack of guidance from FDA, industry has been increasing its digital engagement in the provision of resources on the Internet and via social media. In November 2009, FDA held a public meeting on the Promotion of FDA-Regulated Medical Products Using the Internet and Social Media Tools² with the aim of producing a draft guidance soon thereafter, but which has not been forthcoming as of March 2013.

This paper examines the four-year period from 2008 to 2012 during which the Office of Prescription Drug Promotion (OPDP) issued a total of 173 regulatory action letters to pharmaceutical and biotech companies regarding communications about their products. This specific time period was chosen to coincide with the development and rapid uptake of social media and the increased migration into digital healthcare through the provision of expanded Web-based properties and apps. The letters issued by OPDP took the form

¹ For an excellent overview of U.S. adults seeking health information on the Internet, see Susannah Fox, Maeve Duggan, *Health Online 2013*, Pew Internet & American Life Project, January 15, 2013, at <http://pewinternet.org/Reports/2013/Health-online.aspx>.

² FDA has constructed a Web page dedicated to this meeting that includes the transcripts from the two-day meeting at <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm184250.htm>.

of Warning Letters (WLs) or Notice of Violation (NOV) Letters — also sometimes referred to as Untitled Letters.³

Most of these letters address multiple regulatory violations made by prescription drug manufacturers or their agents. These violations were also cited across a spectrum of communications vehicles, including both digital and traditional platforms. The purpose of this paper is to assess the regulatory actions of FDA's OPDP as a result of the increasing uses of digital and social media to provide information about medical products.

To accomplish this, a few key factors were examined. First, a comparison of violations that involved digital platforms and those that involved nondigital platforms was made. Second, the seriousness of the violations was assessed by comparing the number of violations involving digital and nondigital properties that received Warning Letters.

These comparisons indicate that despite the perceived increase of regulatory risk associated with these media platforms, an examination of regulatory enforcement patterns instead finds that traditional media platforms have garnered more regulatory actions from FDA than have digital media:

- Of the 675 violations examined during the years 2008-2012, 43 percent (n=290) involved digital media vehicles while 57 percent (n=385) involved traditional media.
- Of the 176 regulatory action letters sent to companies by FDA, less than 1 percent (actual n=1) involved a social media platform as the basis for the letter.
- A Warning Letter, the more serious type of regulatory action letter issued by OPDP, was issued nearly three times more often for violations involving traditional media vehicles than those involving digital media.
- The proportion and number of Warning Letters issued against digital media vehicles has declined every year since 2009.

We do not know the proportion of digital versus nondigital platforms used in industry communications about pharmaceutical and biotech products; thus, it cannot be said that either digital or nondigital incurs “less risk.”⁴ However, the lack of clarity respecting the rules around Internet and social media use does not appear to translate into a greater pattern of enforcement against digital media.

³ The compilation of Warning and Notice of Violation letters issued by FDA's OPDP can be found at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/default.htm>.

⁴ For example, if digital communications comprise only 20 percent of industry's communications efforts regarding products, yet comprise 40 percent of the violations, then digital would be disproportionately represented in the regulatory actions of OPDP.

Section 1: Regulatory Background

Communications related to the marketing of pharmaceutical and other medical products by manufacturers are highly regulated by the U.S. Food and Drug Administration (FDA) through the Office of Prescription Drug Promotion (OPDP), formerly known as the Division of Drug Marketing, Advertising, and Communications (DDMAC). It is the stated mission of this office “[t]o protect the public health by assuring prescription drug information is truthful, balanced and accurately communicated. This is accomplished through a comprehensive surveillance, enforcement and education program, and by fostering better communication of labeling and promotional information to both healthcare professionals and consumers.”

In pursuit of this mission, OPDP reviewers regularly examine promotional materials and marketing activities undertaken by medical product manufacturers in any form. This includes, but is not limited to, direct-to-consumer (DTC) advertising, Web pages, videos, sales aids, speeches, presentations, and even oral statements made to the media or by representatives of the manufacturer. Specifically, OPDP is looking to ensure fair, balanced approaches to promotional labeling and marketing, and that materials are not false or misleading within the meaning of the laws and regulation that relate to drug promotion.

When a violation is perceived by OPDP, one of two types of letters is sent by OPDP outlining the specifics of the violation: a “Notice of Violation” (NOV) letter or, in a case where the violation may be considered more serious, a “Warning Letter” (WL). During the 1990s, OPDP (then DDMAC) issued scores of letters to companies each year citing violations regarding their communications related to the medical products they marketed. By contrast, during the 2000s levels of activity dropped considerably; the OPDP now generally issues between 20 and 35 enforcement letters each year. These letters are a primary means by which the agency articulates policy regarding advertising and promotion of medical products.

The following is a partial list of definitions set out in the text of NOV and WLs sent by FDA to pharmaceutical companies. These are the violations that were tracked in the development of this paper:

- **Risk Minimization or Omission:** Promotional materials are misleading if they fail to reveal material facts with respect to consequences that may result from the use of the drug as recommended or suggested by the materials.
- **Overstatement of Efficacy:** Promotional materials are misleading if they contain representations that a drug is better or more effective than has been demonstrated by substantial evidence or substantial clinical experience.

- **Unsubstantiated Claims:** Promotional materials are misleading if they suggest data or conclusions from nonclinical studies in a way that suggests clinical significance when in fact no such clinical significance has been demonstrated.
- **Superiority Claims:** Promotional materials are misleading if they contain a drug comparison that represents or suggests that a drug is safer or more effective than another drug, when this has not been demonstrated by substantial evidence or substantial clinical experience.
- **Broadening of an Indication:** Promotional materials are misleading if they suggest that a drug is more effective or useful in a broader range of conditions or patients than has been demonstrated by substantial evidence or substantial clinical experience.
- **Promotion of an Unapproved Use:** Promotion of the use of a drug or biologic that is not contained in the FDA-approved product labeling.
- **Promotion of an Investigational Drug:** A sponsor or investigator, or any person acting on behalf of a sponsor or investigator, shall not represent in a promotional context that an investigational new drug is safe or effective for the purposes for which it is under investigation or otherwise promote the drug.
- **Other:** In addition, the agency will issue notices for other types of violations, which are listed in this category collectively and include Inadequate Indication, Misleading Presentation, and Failure to Submit for Review.

The only other means to provide insight into FDA's regulatory thinking is through the development and issuance of formal guidance documents. Historically, the agency has had to respond with new guidance to address emerging issues in the context of medical product promotion.⁵

Given the fact that guidance documents are very slow to produce (sometimes taking years), enforcement letters provide a more expedient and immediate window into FDA's policy interpretation.

⁵ A listing of FDA Guidance documents related to drug advertising and promotion can be found at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm064956.htm>.

Section 2: Emergence of Digital and Social Media as a Marketing Tool

Over time, the marketing of prescription products has evolved, either by virtue of changes in policy or through the development of new communications platforms. For example, 1999 saw a watershed occur when FDA released *Guidance for Industry: Consumer-Directed Broadcast Advertisements*, which provided clarification on the FDA's regulation of broadcast DTC advertising.⁶

Just prior to the issuance of that guidance, FDA began to consider the unique questions posed by the emergence of the Internet respecting promotional communications. In the fall of 1996, FDA took a first step to address issues associated with digital media and the promotion of drug products when it held a public meeting on the matter, entitled "FDA and the Internet — Advertising and Promotion of Drug Products," although it did not produce any resulting guidance.⁷

Uses for the Internet continued to evolve and took a quantum leap with the development of sophisticated and powerful search tools that enabled patients and caregivers to seek large amounts of information about medical conditions and treatments. Search tools facilitated a great migration to the Internet for the purpose of seeking health information.

Then, beginning in 2004,⁸ new media platforms collectively referred to as "social media" launched, experiencing widespread uptake first among individual adopters and later with large, established institutions, both public and private. The "social" part of these platforms encouraged the exchange of information, making them an ideal means of communicating with customers and a vehicle for providing customer service. So strong was the current that by 2009, social media assets were increasingly deployed by traditional media outlets as well as reporters. Social media quickly morphed from a form of communication among friends to large networks connecting individuals with companies and institutions.

Because the nature of social media is participatory, these platforms represent a significant departure from past communications vehicles, raising new policy questions and creating unique circumstances and regulatory questions not addressed by existing FDA guidance documents related to medical product promotion.

⁶ See FDA *Guidance for Industry: Consumer -Directed Broadcast Advertisements* at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070065.pdf>, August, 1999.

⁷ For a transcript of the meeting, see the FDA website at <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm175775.htm>.

⁸ In February 2004 Facebook was launched, followed by YouTube in February 2005 and Twitter in March 2006, representing three primary major platforms that became drivers of "social media" by virtue of the social basis and nature of their use.

With the rapid deployment and uptake of social media, the agency held a public meeting November 12-13, 2009, aiming to produce a guidance document by the end of 2010. To date, however, no such guidance has been forthcoming.⁹

While many industries began to employ social media platforms in order to engage with the public, the lack of regulatory guidance has resulted in far less robust participation by the pharmaceutical industry in social and digital media development. Participants have proceeded with a great deal of caution due in no small part to concerns that, without guidance, they risk running afoul of regulatory parameters for the promotion of prescription products. Boundary lines have not been clarified, insinuating greater regulatory risk for these media platforms.

In spite of this, some pharmaceutical companies have pioneered work in social media circles, creating YouTube channels, Facebook pages, and, above all, multiple Twitter feeds. For the past five years there has been an increased presence of pharmaceutical companies in these media, and while participation is not as robust as that of most non-regulated industries, there is a healthy presence by medical product manufacturers.

A survey of social media use by pharmaceutical companies during the summer of 2012 found a minimum of 211 Twitter feeds being sponsored by pharmaceutical, biotech, and device companies in multiple countries. Sponsors included some of the largest and some of the smallest companies, and in combination they had sent more than 145,000 tweets since their inception — with one particular company having sent out an aggregate of over 23,000 tweets. There also were more than 115 Facebook pages sponsored by companies, and several YouTube channels containing hours and hours of uploaded video. These feeds provide a range of information to stakeholders, including corporate news, philanthropic endeavors, career and job opportunities, disease awareness, and product-specific information.

In addition to social media, there has been a proliferation of other digital matter — for example, websites and multimedia news releases containing video, podcasts, and photos. Apps for smartphones and tablets assist patients in monitoring aspects of their healthcare, and in some cases act as medical devices for use by both patients and physicians. In fact, FDA has created a section of the agency's Web page devoted to mobile medical apps¹⁰ and has

⁹ In January 2012, FDA issued a guidance entitled "*Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices*," which mentioned social media platforms in relation to the subject matter, but which was not a comprehensive "social media guidance". See the guidance at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM285145.pdf>

¹⁰ See FDA's Web Page "Mobile Medical Applications" at <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ucm255978.htm>

developed a draft guidance.¹¹ Research has consistently demonstrated that the act of seeking healthcare information and resources online is growing and pervasive among American adults.¹²

Given the lack of guidance by FDA, an examination of regulatory action letters over the period of time during which social media became prominent could provide insight into (1) whether digital communications led to a change in regulatory actions and (2) potential agency points of view derived from action letters involving social media.

¹¹ See FDA Draft Guidance on Mobile Medical Apps, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm263280.htm#1>.

¹² For a range of valuable reports, see the Pew Internet & American Life Project series of reports on consumer health information seeking behaviors and the Internet, available at <http://pewinternet.org/topics/Health.aspx?typeFilter=5>. This includes a January 28, 2013, report entitled *Tracking for Health*, available at <http://pewinternet.org/Reports/2013/Tracking-for-Health.aspx>, as well as the *Health Online* report for 2013, available at <http://pewinternet.org/Reports/2013/Health-online.aspx>.

Section 3: Methodology, Analysis, and Findings

To analyze FDA regulatory actions respecting pharmaceutical product promotion and digital media, a database was constructed into which OPDP Warning Letters and Notice of Violation letters were entered for the years 2004–2013.

An examination of regulatory enforcement patterns was then conducted that focused solely on the years 2008–2012, inclusive. This included a total **173 enforcement letters** that were sent by OPDP to the manufacturers of drug and biologic products for violations in the promotion of their products. **These letters included violations carried by a total of 236 different communications vehicles**, including advertisements, exhibit booths, Web pages, sales aids, and many others. **These communications vehicles were the subject of 675 separate violations.**

Among other aspects, the following fields of information were collected:

- Date of letter
- Company name
- Product name
- Product indication
- Type of letter — Warning Letter (WL) or Notice of Violation (NOV)
- Type of communications vehicle carrying cited violations
- Medium
 - Traditional, print, or broadcast, video
 - Digital media (Web pages), including social media
- Label considerations
 - Whether product carried a Boxed Warning
- Type of cited violation
 - Risk Minimization or Omission
 - Superiority Claims
 - Overstatement of Efficacy
 - Unsubstantiated Claims
 - Broadening of Indication
 - Promotion of Investigational Drug
 - Promotion of Unapproved Use
 - Other

The distinction between nondigital and digital media was defined as follows: nondigital reflects traditional communications vehicles, meaning printed and broadcast materials and spoken word; digital includes websites, Internet advertising, social media vehicles, and video carried on websites or stored on DVDs.

The most common violation cited in these letters was the omission or minimization of risk information, which comprised 194 violations of the total, or nearly one in five (19%) of all violations cited. (Note: the category of “Other” comprises several distinct violations of lesser distinction.)



To assess the regulatory enforcement pattern between traditional media and digital media, data was examined to provide insight into five basic questions:

- 1. Communications Vehicle Involvement.** What was the frequency of enforcement among digital versus nondigital communications *vehicles* used by pharmaceutical companies in communicating about their medicines in the marketplace?
- 2. Violations Involvement.** What was the comparison of the number of *violations* involving nondigital communications versus digital communications?
- 3. Seriousness of Violations.** Was there a *greater frequency of more serious violations* during this time period for digital versus nondigital communications vehicles when communicating about medicines in the marketplace?
- 4. Year-by-Year Breakdown.** In looking at a year-by-year breakdown of violations comparing digital to nondigital violations, *is the rate of violations related to digital communications increasing with the heightened use of digital and social media?*
- 5. Frequency of Involvement of Social Media Assets.** What has been the *involvement of social media communications assets* in the generation of either a WL or an NOV from OPDP?

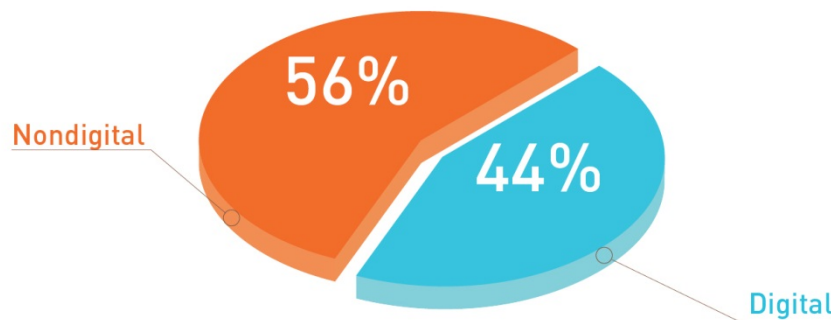
A deeper analysis of these questions follows.

1. Communications Vehicle Involvement

What was the frequency of enforcement among digital versus nondigital communications **vehicles** used by pharmaceutical companies in communicating about their medicines in the marketplace? A comparison of the frequency of digital communications vehicles being cited by OPDP to nondigital communications vehicles from 2008 to 2012 finds that traditional media communications vehicles incurred violations more often than those involving digital media platforms.

During the years 2008-2012, there were 236 different communications vehicles cited in letters from OPDP.

Comparison of Digital vs. Nondigital Communication Vehicles Involved in OPDP Violations 2008-2012



Comparing the involvement of nondigital communications vehicles (brochures, exhibit booths, sales aids, etc.) to digital communications vehicles (websites, video contained on websites, e.g.), traditional vehicles had a higher representation of regulatory actions.

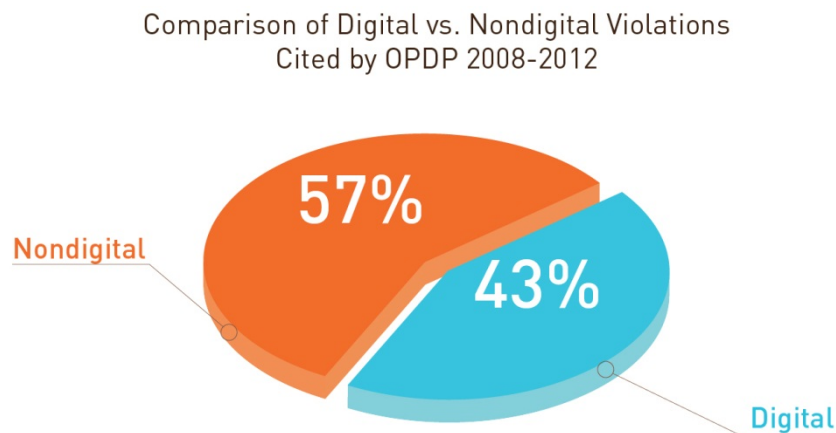
- Of the 236 **vehicles cited for violation**, a majority were in nondigital media. A comparison shows that 56 percent (n=133) of the vehicles cited as being in violation were nondigital properties, compared to 44 percent (n=103) involving digital-based communications vehicles. The bulk of the violations that occurred on digital properties consisted of copy on Web pages; the second most common violation was the use of sponsored links.

2. Violations Involvement

What was the comparison of the number of **violations** involving nondigital communications versus digital communications? A comparison of the frequency of OPDP violations in digital versus nondigital communications vehicles from 2008 to 2012 finds that traditional media communications vehicles incurred more violations than did digital media platforms.

Each communications vehicle can be cited for more than one violation. In all, there were 173 letters involving 236 communications vehicles carrying 675 different violations.

A comparison of the number of violations between digital and nondigital properties similarly showed that a greater proportion of the violations were nondigital in nature.



Each letter usually contains more than one violation and a letter can also contain violations involving more than one communications vehicle, each of which can be cited for multiple violations. Although there were 173 letters, the total number of violations cited in all of the letters issued in 2008–2012 was 676.

- Of all the **violations cited**, a majority involved nondigital media. A comparison shows that 57 percent (n=385) of the vehicles cited for violations were nondigital properties compared to 43 percent (n=290) involving digital-based communications vehicles.

3. Frequency of More Serious Violations

Was there a greater *frequency of more serious violations* during this time period for digital versus nondigital communications vehicles when communicating about medicines in the marketplace? The more serious violations, as expressed through the issuance of Warning Letters, occurred with more frequency respecting nondigital communications vehicles.

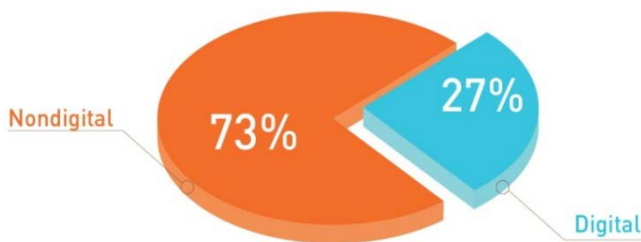
There are two kinds of letters issued by OPDP. The more serious letter, a “Warning Letter” (WLs), is used under circumstances where the agency sees clear violations in the communication. WLs are regarded as more serious than a Notice of Violation (NOV) letter — sometimes also referred to as an “Untitled Letter.”

Of the 173 letters sent by OPDP, 26 percent (n=45) involved the issuance of a WL and 74 percent (n=128) were NOV.

Warning vs. Notice of Violation Letters 2008-2012



Violations Digital vs. Nondigital



Of 45 WLs issued by OPDP during this period, only 12 cited digital communications vehicles while 33 were based on nondigital (traditional) communications, **meaning that a Warning Letter was almost three times more likely to be based on a traditional media communications vehicle than on a digital one.**

When looking at the communications vehicles involved in the generation of these letters, a similar result is seen. The total number of communications vehicles (brochures, DTC ads, websites, etc.) cited in these 45 WLs totaled 61. The number of communications vehicles that were based on traditional media vehicles numbered 45, while only 16 were digital.

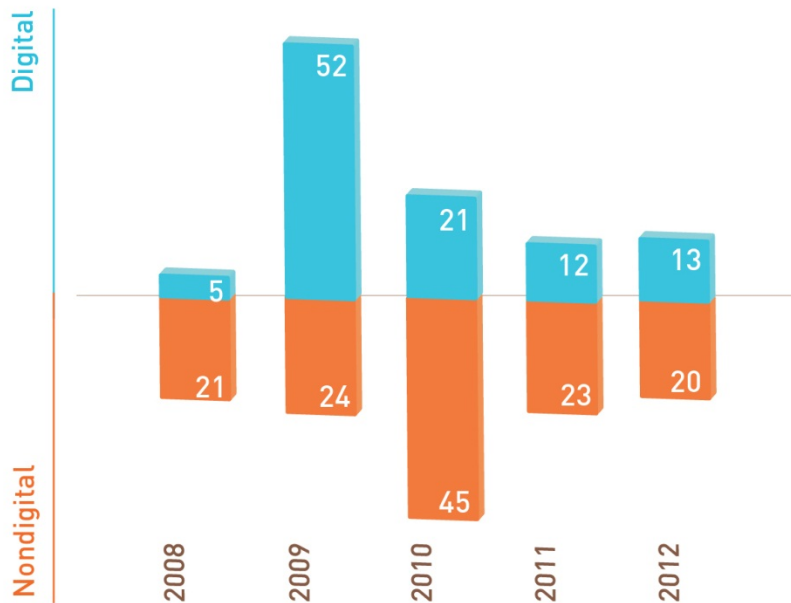
- Nondigital media have **gotten Warning Letters** nearly three times more often than digital media. Similarly, nondigital media communications vehicles have been named in Warning Letters three times more often than have digital vehicles.

4. Year-by-Year Breakdown

In looking at a year-by-year breakdown of violations comparing digital to nondigital violations, *is the ratio of violations increasing with the heightened use of digital and social media*? The proportion of letters aimed at digital media has not increased over time despite an increase in use of digital communications.

Given the increased use of digital assets and social media since 2008, it is important to determine whether regulatory enforcement patterns likewise demonstrate that digital media is being cited more frequently by OPDP.

Comparison of Digital vs. Nondigital Communications Vehicles Cited in Warning and NOV Letters by Year

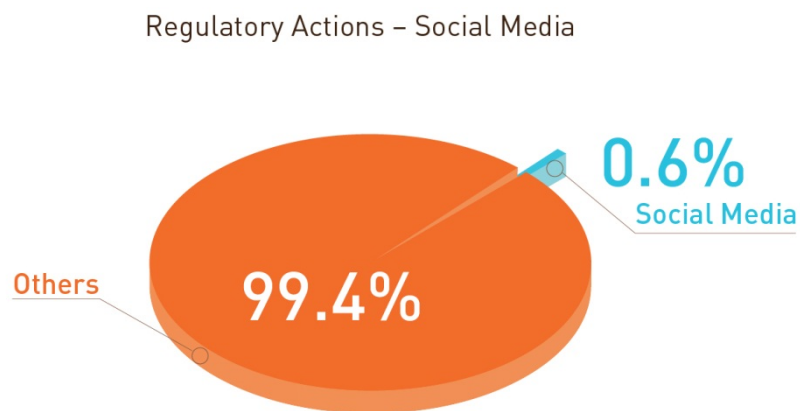


- A year-by-year examination of the **frequency of communications vehicles** triggering a violation reveals that in only one of the five years examined did digital media communications vehicles surpass traditional media vehicles. It should be noted that 2009 was the year that OPDP (then DDMAC) issued the 14 NOV letters citing digital communications vehicles regarding sponsored links. It is noteworthy that, given the higher levels of digital and social media use by pharmaceutical companies during the latter part of the time period examined, there is not a substantial increase in either the number or proportion of regulatory citations against digital communications vehicles.

5. Frequency of Involvement of Social Media Assets

What has been the *involvement of social media communications assets* in the generation of either a WL or NOV letter from OPDP? There has been only a single instance of an action letter (an NOV) issued about a social media vehicle, and very few issued have involved social media platforms.

In 2008 there were virtually no social media assets, and certainly no health apps sponsored by pharmaceutical or biotech companies. Over the next four years, pharmaceutical companies sponsored scores of Twitter feeds, Facebook pages, blogs, and YouTube channels sending out thousands of messages.



Given the participatory nature of the medium, a great deal of scrutiny has been given to social media. There are special concerns with respect to how FDA might treat circumstances that could raise regulatory questions particular to social media that would not apply to traditional media.

- Of the 173 letters during the four-year study period, **only a single letter has been issued respecting a social media platform** where it was the nature of the social media mechanism that brought about the violation, meaning that social media comprised less than 1 percent of the regulatory action letters issued by FDA. This one instance involved the use of a Facebook Share Widget. The influx of social media assets by pharmaceutical companies has not resulted in an increase in FDA regulatory actions regarding social media.

In addition to this particular letter, there have been other violations cited in letters that involved videos that had been placed on YouTube — a social media platform.

These represented violations that would have occurred whether or not the video was on a social media site.

In other words, the violation had to do not with the medium but with the message — and therefore these letters were not counted as social media violations. For example, in May 2011, a video posted on YouTube was cited in a letter because it included 60 seconds that described the benefits of a drug but provided no risk information. The fact that the video was posted to a social media site had nothing to do with the violation, and the material would have been violative in any other medium. However, during this time period, of the 14 videos that involved violations, only two were carried via social media sites, which would bring the percentage of social media violations up to 1.7 percent.

Conclusion

One of the most common uses for the Internet is seeking healthcare-related information in a variety of forms, including information about medication and treatments. Ironically, many of the manufacturers of those treatments have been cautious in their use of emerging digital platforms due to the lack of regulatory guidance for an industry that is highly regulated. In the absence of formal guidance, the most obvious means of assessing regulatory intent is through the issuance of regulatory action letters by FDA's Office of Prescription Drug Promotion.

A persistent question for industry relates to risks in association with the use of digital and emerging social media platforms. Is there greater risk in the use of digital media — and when violations are seen, are they necessarily more serious? In other words, is traditional media a safer means than digital media through which to communicate about medicines?

Despite years of effort, FDA has provided little regulatory insight regarding the burgeoning digital environment. An examination of regulatory patterns from FDA's advertising, marketing, and communications office — the Office of Prescription Drug Promotion — reveals that digital and social media properties

- have not increased the number of regulatory action letters involving digital communications;
- have not seen an increased proportion of violations versus traditional media properties;
- have not resulted in an increase in WLs directed to companies regarding digital communications; and
- have not been the subject of more than one letter regarding the use of a social media platform — and only a handful of letters have been issued respecting the involvement of a social media platform.

In short, there is nothing in the regulatory enforcement patterns of OPDP to suggest that digital and social media carry a higher risk of regulatory action by the agency. In fact, traditional communications vehicles — print, advertising, and video — not only continue to take the lion's share of enforcement, but also bear the brunt of more serious types of enforcement from the agency by receiving more Warning Letters than do digital communications efforts.

About the Author

Mark Senak is a senior vice president and partner in the Washington, D.C., office of Fleishman-Hillard. For many years, he has watched, analyzed, and provided commentary on the regulation of FDA and medical products on his blog, “Eye on FDA” (www.eyeonfda.com). He has also provided strategic advice and training for pharmaceutical companies as they prepare to go before FDA advisory committees for product approvals, Rx to OTC switches, policy discussions, or public hearings, and has emerged as a leading expert in the use of social media by the healthcare industry in general and the pharmaceutical industry in particular.

Mr. Senak is an experienced healthcare public affairs counselor and has worked with a broad range of clients, including pharmaceutical companies, medical societies, global development NGOs, and patient organizations, on a variety of issues.

