



Opportunities and Challenges

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The FDA must balance its own desire for public safety and proper industry regulation with the understanding that the pharmaceutical industry's interests align in many instances with its own.

Social Media Marketing and Pharmaceuticals



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In no small part due to the explosion of the Internet and social media, today's marketplace is a diverse and opportunity-laden environment. Whether discussing

running shoes or airplane tickets or computer software, consumers, retailers, and providers have unprecedented access to information and the opportunity to share stories, relate issues, discuss workarounds, and seek alternatives like no other time in history. However, heavily regulated industries, like those inhabited by pharmaceutical companies, face significant hurdles as they seek to participate in the online community.

FDA regulations on pharmaceutical companies are complex and often resistant to change. Even companies practicing traditional methods of marketing outreach have paid out hundreds of millions of dollars in civil and criminal penalties in just the last five years. Furthermore, the FDA has not yet finalized its social media and Internet guidelines despite mounting industry and congressional pressure. Yet the recent release of draft guidances—one related to traditional marketing outreach and the other to social media and Internet promotion of drugs and medical devices—suggests that the FDA is aware of existing concerns and issues in the regulatory sphere and is working to find comprehensive solutions that will address current regulatory gaps. Although these draft guidances deal with separate issues and concerns, this article will discuss both proposals and how together they may provide a road map for drug and device marketing in the Internet age.

These draft proposals begin to paint a picture of what may be the regulatory framework for the pharmaceutical industry over the next generation of marketing. Yet even without final regulations, recent legal precedent combined with the new FDA proposals and developing industry practices highlight a path to potential success for pharmaceutical companies in the Internet age. There are opportunities for forward-thinking businesses to expand both in the traditional realm as well as into the online marketplace and establish themselves as leaders in disseminating use-

ful drug-related materials and information in a legal and pragmatic way. However, the exercise of caution is required.

Traditional FDA Approach

Off-label promotion by pharmaceutical manufacturers is considered “misbranding” under the Federal Food, Drug, and Cosmetic Act (hereinafter “FDCA” or “the Act”). Thus, when a drug is placed in interstate commerce without adequate directions for use or appropriate warnings, it is the FDA's view that such promotion may be construed as “misbranding” in violation of the Act.

In the last few years alone, pharmaceutical companies have agreed to pay billions of dollars to resolve U.S. Department of Justice allegations of off-label promotion of unapproved uses of pharmaceuticals. A sampling of these off-label penalties, which are available at <http://www.justice.gov>, includes:

- In January 2009, Eli Lilly was fined \$1.42 billion to resolve a government investigation into allegations of the off-label promotion of the antipsychotic drug Zyprexa. The government also alleged that Lilly “trained its sales force to disregard the law” in promoting the drug.
- In April 2010, AstraZeneca was fined \$520 million to resolve allegations that it illegally promoted the antipsychotic drug Seroquel. The drug was approved for treating schizophrenia and later for bipolar mania, but the government alleged that AstraZeneca promoted Seroquel for other non-approved indications.
- In November 2011, Merck agreed to pay a fine of \$950 million related to the alleged illegal promotion of the painkiller Vioxx, which was withdrawn from the market in 2004 after studies concluded the drug increased the risk of heart attacks. Merck admitted to having promoted Vioxx as a treatment for

rheumatoid arthritis before it had been approved for that use.

- In July 2012, GlaxoSmithKline agreed to pay a fine of \$3 billion to resolve allegations regarding civil and criminal liabilities regarding its promotion of drugs, as well as its failure to report safety data. GlaxoSmithKline admitted to misbranding the drug Paxil for treat-

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ing depression in patients under 18, even though the drug had never been approved for that age group.

A December 2012 decision by the Second Circuit in *United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012) pushed back against FDA regulatory practices on two levels. First, regarding the disparity between allowing off-label use while prohibiting off-label promotion, the Second Circuit concluded: “Prohibiting off-label promotion by a pharmaceutical manufacturer while simultaneously allowing off-label use paternalistically interferes with the ability of physicians and patients to receive potentially relevant treatment information; such barriers to information about off-label use could inhibit, to the public’s detriment, informed and intelligent treatment decisions.” *Id.* at 166. Second, the court discussed the First Amendment implications present in federal regulations that prohibit truthful speech:

The fear that physicians, sophisticated and experienced customers, would

make bad decisions if given truthful information cannot justify content-based burdens on speech. Bans against truthful, nonmisleading commercial speech... usually rest solely on the offensive assumption that the public will respond irrationally to the truth.... The First Amendment directs courts to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good.

Id. (internal citations omitted). The court went so far as to look to the public policy benefits of off-label promotion, noting:

In fact, in granting safe harbor to manufacturers by permitting the dissemination of off-label information through scientific journals, the U.S. Food and Drug Administration itself recognizes that public health can be served when health care professionals receive truthful and non-misleading scientific and medical information on unapproved uses of approved drugs.

Id. at 166–67.

The court clearly disfavored the “paternalistic assumption” that the public will use truthful, non-misleading commercial information unwisely. Such paternalism is all the more troublesome when the speech is being directed to the medical community, which the FDA can assert no regulatory authority over. A medical clinician should have the opportunity to become more knowledgeable about a particular drug and the First Amendment protects pharmaceutical representatives who provide truthful information related to potential uses of a product from criminal prosecution.

Ultimately, the *Caronia* court concluded that “the government cannot prosecute pharmaceutical manufacturers and their representatives under the FDCA for speech promoting the lawful, off-label use of and FDA-approved drug.” *Id.* at 169. The court was clear that this holding did not prevent the FDA from regulating the marketing or promotion of prescription drugs and limited its decision to the truthful off-label promotion of prescription drugs. However, the court cautioned that more narrowly tailored regulation of speech by the FDA as it concerns off-label use might survive judicial scrutiny.

FDA Enforcement in a Post-*Caronia* World

While the *Caronia* case sparked widespread speculation that FDA enforcement actions would be widely curtailed, the FDA has continued to pursue off-label promotion claims against manufacturers and their sales forces. The real impact is that the FDA now often relies on allegations of fraud under the False Claims Act to remove the prosecution from the scope of *Caronia*. Recent settlements reflect the limited nature of the holding of *Caronia*:

- In December 2012, Amgen agreed to pay a \$762 million fine to resolve criminal and civil allegations that the company illegally introduced and promoted several drugs including Aranesp, a drug to treat anemia, for an off-label treatment that had never been FDA-approved.
- In November 2013, Johnson & Johnson agreed to pay a \$2.2 billion fine to resolve criminal and civil allegations relating to the marketing of prescription drugs Risperdal, Invega, and Natrecor. As part of the agreement, Johnson & Johnson admitted that it promoted Risperdal for the off-label treatment of psychotic symptoms in non-schizophrenic patients, although the drug was approved only to treat schizophrenia.

This post-*Caronia* approach is further clarified in the March 3, 2014 FDA release entitled *Guidance for Industry: Distributing Scientific and Medical Publications on Unapproved New Uses—Recommended Practices*. (<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM387652.pdf>). In summary, the draft guidance expands upon the types of materials that may be distributed (subject to the FDA’s enforcement discretion) and, for the first time, includes clinical practice guidelines. Of particular interest is the extent to which the guidance illustrated that the FDA appears to be modifying its position on restrictions on truthful, non-misleading, off-label speech in light of the *Caronia* decision. The revised draft guidance does not include the same blanket prohibitions included in the earlier pre-*Caronia* guidance.

Under the revised draft guidance, some highlighting and summarizing is permitted as long as it does not promote an off-label use or is misleading. Although the

FDA clearly still believes that it can regulate non-misleading speech, it has backed off somewhat (perhaps in light of *Caronia*), and sought to bolster its position by adhering closely to the statutory prohibitions in the FDCA with a focus on establishing fraudulent marketing of off-label uses by relying on a manufacturer's alleged failure to meet FDA efficacy standards. Yet these

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regulations do not speak to the growing online marketplace and community that businesses and individuals increasingly inhabit to conduct business.

Pharma, Physicians, and the Internet

Increasingly, the major pharmaceutical companies take the view that social media and other online resources can provide an important tool to advertise products, provide information to physicians and the general public, solicit public opinion, and ensure that products are used safely and effectively. Moreover, as the public and physicians become increasingly Internet savvy, this resource continues to grow rapidly.

Dr. Freda Lewis-Hall, the Chief Medical Officer for Pfizer, reported in a 2009

FDA hearing that the average physician spends about eight hours a week using the Internet for professional purposes, 87 percent of physicians are interacting with drug and device companies online, and 60 percent of physicians are interested in participating in online communities. She opined that the majority of physicians want to engage with health care companies in the social media space to obtain drug information. These physician participation statistics are probably even more striking today. Yet the regulations regarding Internet marketing, particularly on social media sites, and pharmaceutical responsibilities regarding third-party provided information, remain undefined. Furthermore, along with widely used social media sites like Facebook, Twitter, and LinkedIn, social media sites designed exclusively for physicians are beginning to become major players in the pharmaceutical marketplace.

A prime example is Sermo (see www.sermo.com), an online community for physicians founded in 2006. Sermo was originally founded by doctors for doctors. Originally imagined as an adverse effect reporting system without industry influence, Sermo is now a vibrant place where physicians can post observations and questions about clinical issues and hear other doctors' opinions. In just a few short years, Sermo has grown to include over 270,000 licensed U.S. physicians—40 percent of the entire physician population of the United States. However, Sermo, and other sites like it, have raised a variety of issues. Sermo makes money by selling access to the social content to pharmaceutical companies and other businesses. Physicians on Sermo can post anonymously, and it's not clear whether pharma companies have any ability to offer direct corrections for such information posted there that is known to be incorrect or offer advice to physicians who anonymously admit to mis-prescribing medication or ignoring common practices in their treatment of patients. Moreover, in 2009 Sermo sold Bloomberg access to physician comments on certain companies and products, further muddying the waters with regard to regulation and appropriate industry behavior. With these growing online opportunities comes growing concern about what constitutes appropriate best practices.

FDA Social Media Draft Guidance Development

The enormous penalties levied against those the FDA has determined violate existing regulations reflect only punishment for fraud in traditional forms of marketing—direct representative-to-physician interactions and traditional print media guides and information. The expansive audience now available to pharmaceutical manufacturers via Internet-based marketing leads to questions about the scope of potential penalties for web-based violations, and this, along with the growing online marketplace, has led to an industry outcry for clear regulations from the FDA. The FDA, along with the regulated community, has been grappling for some time over what might constitute the proper use of social media, which offers distinct challenges and opportunities compared to traditional forms of marketing.

It has been five years since the widely attended 2009 FDA hearing to discuss Internet issues related to pharmaceutical companies and two years since the Food and Drug Administration Safety and Innovation Act was signed into law on July 9, 2012, which instructs the FDA to release guidelines for Internet-based promotion of medical products, including social media, within two years. While public outcry grew and congressional mandate loomed, releases of three draft guidelines this year, one on January 13, 2014 and two more specific follow-ups on June 17, 2014, are beginning to show the FDA's approach to the changing online landscape facing pharmaceutical companies. These will most likely have a significant impact upon how pharmaceutical manufacturers conduct business in the online marketplace, particularly as the guidance generally affirms FDA and Department of Justice commitments to prosecution of off-label marketing.

Further demonstrating the FDA's awareness of potential issues arising from the scope of the Internet and social media marketplace, recent Corporate Integrity Agreements ("CIA") have required clauses specific to online practices as a condition of settlement of alleged industry violations. For example, a June 2012 CIA between GlaxoSmithKline and the DOJ included:

At a minimum, the Policies and Procedures must address the following:...

h. the materials and information that may be distributed or made available by GSK through social media and/or through direct-to-consumer advertising. These policies and procedures shall be designed to ensure that GSK's activities in this area and the information distributed or made available complies with all applicable Federal health care program and FDA requirements, and have been reviewed and approved by GSK before they are disseminated.

See, Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and GlaxoSmithKline LLC, June 2012, at 13, available at <http://www.justice.gov/sites/default/files/opa/legacy/2012/07/02/hhs-oig-corp-integrity-agreement.pdf>.

Most recent CIAs include similar language, all related to the distribution of materials intended to inform consumers. Thus, even without formally establishing standards, the FDA and DOJ have begun to regulate social media interactions.

The first of the guidance documents was the long-awaited social media guidance titled Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics, (<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM381352.pdf>, hereinafter "Interactive Media Guide"), issued on January 13, 2014. Some of the basic concepts expressed are:

1. A company will not be deemed responsible for visitor posts on company-run social media (blogs, chat rooms, message boards, etc.) so long as the visitor has no affiliation with the company and the company has no influence over the user-generated content.
2. A company is responsible for content generated by an agent or employee.
3. Every advertisement on social media must contain a "fair balance" of the risks and benefits of a drug product and complete disclosure of the product's approved indications for use.
4. Marketing material postmarketing submission requirements must be complied with for any site where the company "exerts influence," even if the influence is limited in scope. For example, if the

firm collaborates on or has editorial, preview, or review privilege over the content provided, then it is responsible for that content. However, if the company *only* provides financial support to the site, and its influence is otherwise limited, there is not a reporting requirement.

Concepts three and four were of particular concern to many commentators. Concept three left some concerned about the ability of companies to meet such a standard on character-limiting social media sites, like Twitter, which has a 140 character limit. Commentators on concept four noted the issue of "exerting influence" is problematic and, despite some helpful hypotheticals in the guidance, ambiguous. Big Pharma has an interest, perhaps even a responsibility, to be involved in e-media forums where the public or the scientific and medical community is seeking interactive information on pharmaceutical products. However, the draft guidance arguably produces a push-pull reaction. Pharmaceutical companies must ask: do we engage or, by engaging, do we run the risk of having an added regulatory burden by having to file FDA reports concerning participation on the site?

Almost immediately, one drug maker ran afoul of the draft guidance. The Facebook page of Switzerland-based drug maker, IBSA Institut Biochimique S.A. ("IBSA"), appeared innocent enough:

If you have just been diagnosed with hypothyroidism or are having difficulty controlling your levothyroxine blood levels, talk to your doctor about prescription Tirosint, a unique liquid gel cap form of levothyroxine.

Yet, in an untitled letter to the drug maker on February 24, 2014, and seemingly with *Caronia* in mind, the FDA advised IBSA that its Facebook webpage was false or misleading because it made representations about the efficacy of Tirosint, but failed to communicate any risk information associated with its use and omitted material facts regarding Tirosint's FDA-approved indications. *See, <http://www.fda.gov/downloads/drugs/guidancecomplianceinformation/enforcementactivitiesbyfda/warninglettersandnoticeofviolationletterstopharmaceuticalcompanies/ucm388800.pdf>.*

The FDA advised IBSA that the webpage misbranded Tirosint within the meaning of the FDCA and made its distribution

violative of federal regulation. Specifically, the FDA referenced 21 U.S.C. 352(a), (n); 321(n); 331(a); and 21 CFR 202.1(e)(5). Further, the FDA reminded the company that Tirosint is associated with a number of serious risks and includes a Boxed Warning indicating that Tirosint should not be used for the treatment of obesity or for weight loss, among other potential

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risks associated with the use of this medication. The FDA also alleged that IBSA had failed to disclose important limitations on the approved indications of the product, increasing the risk that the product would be used in patients with conditions that were expressly excluded from the approved indications for use. The FDA directed IBSA to immediately cease activity violative of the Act and to submit a plan for discontinuing the use of all non-compliant promotional materials. In what would ultimately foreshadow the focus of future guidance on social media promotion of off-label uses, the FDA noted that IBSA had failed to disclose *any* (emphasis FDA's) of the risks associated with the product's use. *Id.* at 13.

Despite the public attention given to IBSA's ill-advised social media posting, **Social Media**, continued on page 92

Social Media, from page 19 the pharmaceutical industry and medical community have made significant strides in recent years to ensure that physicians are receiving full and complete information concerning the medications they are prescribing for their patients. The June 17 FDA releases show some respect for this self-regulation while continuing to maintain some of the hardline policies concerning to industry participants.

Evolution of FDA Social Media Guidances

The June 2014 dual draft guidelines, “Guidance for Industry: Internet/Social Media Platforms with Character Space Limitations—Presenting Risk and Benefit Information for Prescription Drugs and Medical Device” (<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM401087.pdf>, hereinafter the “Character Limitations Guide”) and “Guidance for Industry: Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation about Prescription Drugs and Medical Devices” (<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM401079.pdf>, hereinafter the “Third-Party Guide”), act to clarify many of the regulations proposed in the Interactive Media Guide.

The Character Limitations Guide holds strong on the limits proposed in the Interactive Media Guide, maintaining strict balancing guidelines for any post claiming benefits related to specific brand name medications. The Character Limitations Guide states:

Regardless of character space constraints that may be present on certain Internet/social media platforms, if a firm chooses to make a product benefit claim, the firm should also incorporate risk information within the same character-space-limited communication. The firm should also provide a mechanism to allow direct access to a more complete discussion of the risks associated with its product.

Moreover, each claim must also include the brand name of the product and the generic name of the drug, as well as a hyperlink to a more complete discussion of the associated risks of the medication. The FDA’s example of an allowable tweet—“NoFocus

(rememberine HCl) for mild to moderate memory loss-May cause seizures in patients with a seizure disorder www.nofocus.com/risk”—shows the requirements for balancing information included in any benefit claim. While this may discourage some companies’ entry into certain social media spheres, it is important to note that the FDA would allow claims on character limiting sites, like Twitter, to be broken up into multiple tweets, so long as each tweet includes the appropriate balancing information.

The Third-Party Guide, on the other hand, demonstrates a greater respect for self-regulation and corporate responsibility, as well as recognizing the near-impossibility of policing the world of online forums. The FDA makes clear that companies are not responsible for correcting information created by third parties, and that if companies do choose to correct the information, not only do the corrections not need to satisfy other regulatory requirements regarding labeling and advertising, but also that the company is only responsible for correcting the misinformation in the section it identifies as incorrect, not the website or forum as a whole, though it must correct both positive and negative misinformation within the specified section. Furthermore, the company has no requirement to continue to monitor that website or forum for incorrect or misleading information even if it acted previously to correct misinformation. The FDA does warn that a company should maintain records of any corrections made, but this draft policy gives wider ranging options for participation in the online marketplace in this industry.

With these releases, the FDA appears to be coming closer to a final regulatory scheme for social media and online content in the prescription drug realm. As consumers and companies continue to move forward in a world increasingly dominated by social media, challenges and opportunities abound. On the one hand, there are the missteps, as we see in the case of IBSA. On the other hand, the pharmaceutical industry is moving ahead of the curve to use social media to ensure that its prescribing physicians are well educated and their patients provided the best possible care. The draft guidelines issued by the FDA are important pieces of this puzzle and may be the final steps in allowing pharmaceutical companies to begin estab-

lishing set standards for online marketing and information dissemination via public and industry-specific social media.

Product Liability Risk and Social Media

From a litigation standpoint, the increased use of social media for the dissemination of information concerning pharmaceutical products presents unfamiliar new challenges. Compliance with regulation, no matter how rigorous, may not provide pharmaceutical manufacturers with protection against product liability risk. The use of social media, particularly on platforms with space limitation, may potentially give rise to failure to warn claims by plaintiffs’ lawyers who claim that a patient’s physician was not provided complete information concerning a potential adverse reaction.

The FDA’s draft Space Limitations Guidance provides allowable methods of promoting products on micro-blogging platforms, such as Twitter. In issuing this draft guidance, however, the FDA cautions manufacturers to carefully consider whether all of the required information can be adequately conveyed in a character space-limited communication and, if it cannot, to reconsider the social media’s platform as a promotional tool.

Although the guidance requires a drug maker to provide: (1) a direct hyperlink to comprehensive risk information and (2) at a minimum, the “most serious risks” associated with the product, plaintiffs’ counsel always argue that the company failed to adequately warn about the single most important adverse reaction—the particular adverse reaction suffered by the plaintiff sitting in the courtroom.

The Correcting Misinformation Guidance also raises potential litigation concerns. Although the Correcting Misinformation Guidance makes clear that manufacturers are not obligated to affirmatively seek out and correct product misinformation on third-party websites, plaintiffs pushing the envelope may argue that a manufacturer that becomes aware of misinformation, particularly concerning safety, has an affirmative duty to correct that misinformation under common law negligence concepts, regardless of the limiting language contained in the FDA’s guidance.

From a litigation perspective, the sheer magnitude of social media platforms and the enormous amount of content continually generated on these platforms creates unique challenges for defense counsel. Could a single improvident statement or omission on a social media platform give rise to a claim for negligent misstatement?

A good plaintiffs' lawyer will always be trolling for documents that seek to show a company exaggerating the efficacy and safety of its products. If such "puffing" occurs on third-party sites over which it may be argued the company has even a modicum of control, the risk is potentially even greater.

Conclusion

While maintaining a competitive marketing strategy is increasingly important in today's medical marketplace, it is also critical to remain in compliance with FDA statutes and regulations regarding advertising and promotion of medical products, particularly in light of the astronomical civil penalties imposed and "Scarlet Letter" treatment of manufacturers through FDA issuance of Warning Letters and press releases.

Ultimately, the draft guidance proposals issued by the FDA offer the beginnings of a framework for pharmaceutical companies to build from. While initial FDA pursuit of manufacturers for the dissemination of information through the Internet and social media may have a chilling effect on what would otherwise present a vast opportunity for the manufacturer to provide critical information to physicians and consumers alike, within the draft guidances issued, there is room for the industry to begin to establish best practices for online promotion. Moreover, while FDA policies remain strict in some areas, other proposals indicate an awareness of the unique challenges the social media sphere creates. With the FDA's policies continuing to evolve, the bold will venture into the vast marketplace presented by social media. And as these policies mature with industry input and application experience, the FDA must balance its own desire for public safety and proper industry regulation with the understanding that the pharmaceutical industry's interests align in many instances with its own.

