

Connecting with Patients, Overcoming Uncertainty

September 2007

A white paper on Managing the Risks and Regulatory Issues Associated with Successful Pharmaceutical Social Media Monitoring and Marketing

In the absence of FDA guidance on marketing in blogs, social networks and other social media forms, drug firms' marketing, compliance and legal staffs must work closely to design initiatives that are sensitive to FDA concerns. This paper provides a framework to clarify and mitigate the risks of a range of social media initiatives.

3 **Part I: Social Media, Healthcare and the Pharmaceutical Industry**

The Internet's influence on healthcare providers, patients and drug firms has grown dramatically in the past decade. Social media's impact will grow as patients become more assertive in their healthcare decisions.

Who should read this section: those new to social media communications.

7 **Part II: An Overview of the Legal and Regulatory Environment for Direct-to-Consumer Promotion**

A few key principles underlie the FDA's regulatory approach to pharmaceutical marketing. Incorporating them into social media initiatives will decrease the potential for unwanted FDA scrutiny.

Who should read this section: those with limited knowledge of current FDA regulations or seeking a "refresher" course.

17 **Part III: Social Media Marketing: A Strategic Regulatory Framework**

The authors propose a framework that will help drug firms discuss, evaluate and minimize potential compliance risks associated with social media monitoring and marketing.

Who should read this section: marketers, regulatory compliance and legal professionals involved in social media monitoring and marketing programs.

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About

TNS Cymfony

Cymfony, a division of TNS Media Intelligence, tells brands and companies what people are saying about them whether the people are bloggers, traditional journalists or even influential consumers. By sifting and interpreting the millions of voices at the intersection of traditional and social media, Cymfony delivers consumer insights that help companies identify the people, keep on top of the issues and respond to the trends impacting their business - at the speed of the market. For more information visit www.cymfony.com or contact Jim Nail at either 617-673-6027 or jnail@cymfony.com.

Envision Solutions, LLC

Envision Solutions, LLC is a full-service healthcare marketing communications consulting firm. The company provides innovative products and services to not-for-profit and for-profit organizations. Envision Solutions core competencies are in the areas of analysis, strategic and tactical recommendation development, training and content development. Please visit www.envisionsolutionsnow.com for more information about the firm or contact Fard Johnmar at either 212-501-6101 or info@envisionsolutionsnow.com

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The information presented in this paper was prepared and assembled by TNS Cymfony and its partners, Seyfarth Shaw, LLP and Envision Solutions, LLC. While this paper provides an overview of related statutes, regulations and principles concerning Direct to Consumer (DTC) promotion, it does not purport to be an exhaustive and final authoritative assembly of federal laws and regulations. The dynamic nature of law in general and its interpretation by courts require those affected by such laws and regulations to remain current with the current interpretation and implementation of those laws and regulations. It is our hope, however, that the information provided within this paper will help clarify what is an evolving area of pharmaceutical law. This paper is not intended to provide specific regulatory or legal advice. Readers should consult their company's standard operating procedures, marketing and regulatory departments, and legal counsel in meeting federal and state requirements for DTC promotion.

Purpose of this White Paper

The pharmaceutical industry is very interested in using social media to promote products, services and issues important to it.¹ However, many drug firm executives are uncertain about how to tackle the legal and regulatory issues associated with social media communications. TNS Cymfony and its legal (Seyfarth Shaw, LLP) and strategic marketing (Envision Solutions, LLC) partners have developed this white paper to help the industry:

- Recognize why social media is influencing patients and healthcare providers and how this affects drug firms.
- Comprehend how the FDA currently regulates pharmaceutical marketing.
- Understand how drug firms are communicating with patients and providers online in the absence of firm FDA guidance.
- Develop a strategic framework that will help executives understand and manage the regulatory risks associated with social media communications.

The thesis of this paper is that, based on existing principles and precedents in the regulation of direct-to-consumer advertising, marketing, legal and regulatory compliance professionals can have a productive collaboration in helping their companies incorporate emerging social media forms into their promotional mix.

Why do we feel this paper is important? According to the Pew Internet & American Life Project, the Internet is transforming healthcare in the United States. Pew reports that nearly 113 million Americans have searched online for health-related information.² This means patients are being exposed to online health content created by a variety of official and unofficial sources.

Increasingly, health content on *social media* sites like blogs, podcasts and social networks is sometimes more trusted than information developed by drug firms, government organizations and non-profits. According to JupiterResearch, nearly 80% of those who have used the Internet to “connect to others” trust peer-created health information “to some degree.”³

This white paper will help marketing, legal and regulatory compliance professionals collaborate in helping their companies use social media in their promotional mix.

1. This paper will focus specifically on issues pertaining to pharmaceutical DTC marketing. Other life science companies in areas such as medical devices, genetics or biotechnology may face similar issues.

2. Susannah Fox, *Online Health Search 2006* (Washington, DC: Pew Internet & American Life Project, 2006).

3. Monique Levy, *Assessing the Risk and Opportunity of Social and One-to-One Media* (New York: JupiterResearch, 2007).

To date, pharmaceutical companies have engaged in little social media marketing activity for two reasons:

1. **Lack of knowledge.** Many drug firm executives are still unaware that healthcare blogs, discussion boards and other patient created content are becoming trusted sources of information for physicians, patients and others.
2. **Uncertainty.** The Internet has been a major force in healthcare for more than 10 years and the Food and Drug Administration (FDA) has not developed detailed guidance for drug firms seeking to market to patients and physicians on Web sites, in e-mail and in search advertising.

We understand that by publishing this white paper we are stepping into uncharted territory:

- We cannot anticipate how the FDA will regulate the industry's social media marketing activities. However, we hope the broad principles we present help you successfully handle unfamiliar situations.
- Every pharmaceutical company has its own regulatory culture and may interpret FDA regulations conservatively or liberally. Marketers can build a productive relationship with their internal legal and regulatory colleagues to design social media programs.
- This white paper is not exhaustive. You will very likely encounter situations that fall outside of the scope of this paper. However, we hope the framework we propose helps you successfully handle unfamiliar situations.

But, as the industry's experience with Internet marketing shows, drug firms can incorporate emerging media into their marketing plans with careful consideration of key factors.

While this paper cannot substitute for FDA guidance, it can give marketing, legal and compliance professionals a common understanding of the regulatory environment, examples of how pharmaceutical companies are moving ahead with social media initiatives and a framework for discussing the elements of their own company's social media programs.

Part I: Social Media, Healthcare and the Pharmaceutical Industry

With 113 million Americans relying on the Internet to find health information, it is clear that Dr. Google and Nurse Yahoo! have become critical components of the nation's healthcare system.⁴ Consumers are going online to find information about the latest health scare, their children's sniffles or chronic disease management. Physicians are relying on search engines to help them diagnose rare illnesses. Also, clinical researchers are using online patient communities to recruit patients for clinical trials.

However, some are concerned that the Internet is doing more harm than good. For example, in 2006, the Pew Internet & American Life Project reported that most Americans are not practicing due diligence when they are searching for health information on the Web.⁵ Pew found that "most Americans start at a general search engine when researching health and medical advice online." Unfortunately, Pew also reports that "three-quarters of Internet users who look online for such advice do not consistently check the source and date of the information they find."

Why aren't Americans critically examining online health content? The answer may lie in what they are finding. A study published in 2007 by Envision Solutions, LLC suggests that US health searchers are being exposed to and using a significant amount of peer-developed social media content.⁶ This is significant because the United Kingdom's Economic and Social Research Council suggests that online health searchers favor information from individuals who share their problems and concerns – i.e., people just like them.⁷

How the Internet and Social Media Influence Health Industry Stakeholders

Two trends have contributed to an increase in the volume and impact of online dialogue. 1) Consumers are more assertive in their health decision making; 2) There is an increase in public mistrust of the pharmaceutical industry. These have a significant impact on all segments of the healthcare industry, especially physicians, corporations and government agencies. Following are some examples of how this is happening.

Dr. Google and Nurse Yahoo! have become critical components of the nation's healthcare system.

4. Fox, *Online Health Search 2006*, i.

5. *ibid.*, iv.

6. Anonymous, *Diving Deeper Into Online Health Search* (New York: Envision Solutions, LLC, 2007), 4.

7. Anonymous, *Prescriptions for Health Advice Online* (UK, Economic and Social Research Council, 2007), <http://www.esrc.ac.uk/ESRCInfoCentre/PO/releases/2007/march/health.aspx?ComponentId=18643&SourcePageId=19082> (accessed July 16, 2007).

The Internet and the Provider-Patient Relationship

Traditionally, healthcare providers have been primarily responsible for education on disease identification and management. Today, especially in Europe and North America, people are increasingly taking greater control of their health decisions.

The Internet has been central to this change: Patients are regularly bringing information they have found on the Web to their providers for discussion and clarification.⁸ Thirty million Americans consider the Internet their first source of health information and over 100 million research health issues online annually.⁹ In turn, this changes their relationship with healthcare providers: instead of being subordinate to their physicians, patients are demanding partnerships with them.

In addition, as the media began to regularly report about the pharmaceutical industry's influence on medical care, physician education and other areas of the healthcare system, information once little-known to consumers such as marketing techniques and other information about how the industry operates became a regular topic on the news. Prominent examples of negative events that have become international news include the withdrawal of Vioxx and illegal marketing of the painkiller OxyContin. As a result, consumer skepticism and even distrust about industry claims has increased.

Social Media and the Pharmaceutical Industry

The nature of social media leads to it being highly placed in search engines.

Social media has enhanced the power of the assertive and informed consumer who has access to extensive health information. The public (and journalists) regularly read information featured on blogs, podcasts, online forums and other forms of social media. The nature of social media leads to it being highly placed in search engines, bringing it to the attention of the millions of people searching the Internet for health information, and placing it alongside more traditional online sources like WebMD. For example, according to a study conducted by Envision Solutions, LLC, 5% of U.S. Internet users looking for information about the antidepressant Lexapro visited the popular blog crazymeds.org between mid-December 2006 and mid-January 2007.¹⁰

Currently, there are four types of social media content creators who are having the most impact on public perceptions of pharmaceutical companies and their products (see Table 1). Unfortunately for the industry, much of this content has not been very flattering. Social media has provided an outlet for a range of whistle blowers, industry insiders and drug industry critics to express their dissatisfaction with industry practices. However, it has also created a new support network where patients share perspectives on their condition and treatment options.

8. Cees MJ van Woerkum, *The Internet and Primary Care Physicians: Coping With Different Expectations* (US, American Journal of Clinical Nutrition, 2003), 77(4): 1016S-1018S.

9. Lisa Phillips, "Pharmaceutical Marketing Direct-to-Patient Becomes a Reality" (New York: eMarketer, 2006), http://www.emarketer.com/Reports/All/Em_pharma_aug06.aspx?src=report_more_info_sitesearch (accessed August 22, 2007).

10. Anonymous, *Diving Deeper*, 25.

Table 1: Four Types of Social Media Content Creators Impact Pharmaceutical Companies

- **Whistleblowers:** Drug firm employees alleging that their companies have engaged in illegal or unethical behavior are turning to blogs to make their case. The most notable industry whistleblower is Dr. Peter Rost, who writes the blogs Question Authority (<http://peterrost.blogspot.com>) and BrandWeekNrx (<http://brandweeknrx.com>). Dr. Rost has broken a number of stories that have later become international news.

For example, in April 2007 an AstraZeneca employee called Dr. Rost alleging that the company was marketing its major breast cancer drug, Arimidex, illegally. Pressing for more information, Rost received a newsletter in which a regional sales director suggested that AstraZeneca Arimidex sales representatives view physicians as a “big bucket of money.” Rost later published a widely referenced post about the newsletter, which was highlighted by several mainstream media, including Fortune.¹¹

- **Drug Company Employees and Advisors:** Physicians, researchers, sales representatives and other executives are turning to the Internet to post anonymously about their experiences with pharmaceutical companies. One of the most popular online drug industry forums is CafePharma (<http://www.cafepharma.com/boards>), an online bulletin board for sales representatives. Investors, media, physicians and others regularly scour CafePharma for information about drug sales, executive performance and reactions to major corporate announcements.

For example, in a June 2007 New York Times article about the bulletin board, Lloyd Mandel of Atlantic Management Resources said that he uses the site to gather information about staff changes at companies he is scouting for executive recruiting purposes. However, the Times also noted that CafePharma’s users doubt the veracity of much of the information posted on it.¹²

- **Industry Opponents:** Increasingly, opponents of pharmaceutical industry marketing and educational activities are turning to blogs to make their case. For example, after writing a scathing New York Times editorial about drug firm support of continuing medical education (CME) in June 2007, Dr. Daniel Carlat started a blog (<http://carlatpsychiatry.blogspot.com>). Dr. Carlat’s Weblog is quickly becoming a popular resource for critical commentary on CME and drug promotion.¹³

Others have turned to the video sharing Web site YouTube to criticize industry marketing practices. In April 2007, the Media Education Foundation (MEF) released a series of critical videos titled “Big Pharma, Big Bucks” on YouTube. To date, MEF’s videos has been viewed more than 14,000 times and referenced on a number of popular blogs.

- **Patients:** For more than a decade, patients have been posting information about their experiences with prescription medicines on online forums and blogs. Recently, as social media has grown in popularity, this activity has accelerated. Today, patients are becoming prime information sources about a range of subjects, including drug safety and efficacy. One of the most popular patient-developed blogs is Crazy Meds (www.crazymeds.org), a compendium of information about user experiences with psychiatric medications.

11. John Simons, “A Big Pharma Whistleblower Blogs On Drugs” (US, Fortune, June 11, 2007), 143.

12. Barnaby J. Feder, “A TheirSpace for Drug Sales Reps (New York: New York Times, June 11 2007).

13. Daniel Carlat, “Diagnosis: Conflict Of Interest” (New York: New York Times, June 13, 2007).

Pioneers in Social Media Marketing for Pharmaceuticals

Some have suggested that one way to regain the public's trust is for pharmaceutical firms to produce social media that will enable them to engage in online conversations with consumers and healthcare professionals.¹⁴ Despite the obstacles and uncertainty with this approach, a few pharmaceutical companies have started to experiment with social media:

- Biopharmaceutical company Cephalon has taken a small step into the healthcare blogosphere by developing a series of blogs about ADHD (www.adhdbalance.net). While the blogs do not feature comments from site visitors, they feature first-hand commentary by patients, psychologists and others. Cephalon also appears to review posts prior to publication on the blog.
- In June 2007, Johnson & Johnson quietly launched a corporate blog, JNJ BTW (www.jnjbtw.com), featuring commentary from one of the company's communications executives, Marc Monseau.
- GlaxoSmithKline (GSK), introduced a blog in 2005, Avenir de la Santé (www.avenirdelasante.com), featuring commentary about the French healthcare system.
- GSK followed this effort by producing alliConnect (www.alliconnect.com), a blog supporting its over the counter (OTC) weight loss aid Alli, a lower-dose version of the prescription medicine, Xenical.¹⁵

14. Shahid Shah, "Pharma: Have No Fear of the Blogosphere" (Envisioning 2.0, 2006), <http://fardj.prblogs.org/2006/02/05/guest-article-pharma-have-no-fear-of-the-blogosphere> (accessed August 22, 2007).

15. Fard Johnmar, *FDA's Regulation Of OTC Products & the Alli Social Media Experiment* (New York: Healthcare Vox, 2007), http://www.healthcarevox.com/2007/06/fdas_regulation_of_otc_product.html (accessed July 16, 2007).

Part II: An Overview of the Legal and Regulatory Framework for Direct-to-Consumer (DTC) Promotion

In the past 13 years, DTC promotion has grown to \$5 billion annually and expanded into every major medium. The FDA has established a set of core principles that have been adapted to the needs of different media. In the absence of the detailed guidance for the Internet that exists for TV and print advertising, marketers have adapted these principles. Understanding this evolution can help drug companies design their social media marketing initiatives.

The Role of DTC Advertising in Healthcare

Most publicly-available healthcare information (other than that gained through conversation with healthcare professionals) is currently delivered in print form (as leaflets, or as patient package inserts); through conventional media (as newspapers, radio and terrestrial and non-terrestrial TV); over the Internet (on Web sites, in e-forums or in chat rooms); through e-mail alerts; and via telephone hotlines.

On the one hand, studies have shown that DTC advertising has helped patients discuss their presenting complaints, their diagnostic implications, the meaning of the diagnosis in the context of the patient's life and the full range of treatment options available with their healthcare professional. On the other hand, DTC promotion has been criticized for focusing some healthcare professional/patient discussions on specific brand-name drugs and trivial complaints, and in this context may have detracted from more meaningful discussions about health. In one survey, some clinicians regarded DTC advertising as commonly misleading and adding costs without tangible benefits.¹⁶ In another, it has been found that using DTC promotion as a source of information about the risk of a particular medicine has not been helpful.¹⁷

The FDA can be expected to continue to evolve the regulatory framework with three goals:

- 1) Enhance the benefits of empowering patients to make well-informed healthcare decisions;
- 2) Ensure access to complete, accurate and balanced information about their treatment options; and
- 3) Minimize the potential downside of encouraging patients to demand treatments they don't need.

To ensure patients can make well informed healthcare decisions, the FDA will continue to evolve a set of core principles underlying DTC promotion.

16. Lipsky MS, Taylor CA, *The Opinions and Experiences of Family Physicians Regarding Direct-to-Consumer Advertising* (J Fam Pract 1997), 45: 495-9.

17. Sullivan DL, Schommer JC, Birdell SW, *Consumer Retention of Risk Information from Direct-to-Consumer Advertising*, (Drug Info J 1999) 33:281-9.

The Legal and Regulatory Environment

By passing the Food, Drug and Cosmetics Act (FDCA, or the Act) to replace the 1906 Food and Drugs Act, Congress firmly established the federal government's role in regulating the pharmaceutical industry and ensuring the safety of the nation's prescription drug supply.

The Act authorizes the government to review and approve prescription drug labeling that provides information about the approved use of a drug. Section 502(n) of the Act provides the FDA with authority to regulate advertisements and other promotional material, called *promotional labeling*, disseminated by or on behalf of the advertised product's manufacturer, packer or distributor;¹⁸ the implementing regulations (Title 21, Code of Federal Regulations [CFR] section 202.1), provide specifics about the content of such labeling.

The Act defines labeling as "all labels and other written, printed or graphic matters (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."¹⁹ This concept is understood broadly to include: package inserts, brochures and reprints of academic articles, which are all considered forms of labeling. These materials can be in electronic or printed form. The electronic form can be broadcast media or more recently Internet product information Web sites. It is not necessary for a manufacturer to include this information with the shipment of the actual package in order for it to be considered labeling.²⁰

Promotional labeling concerns any form of materials that a drug company issues or places for publication in any form of media that is directed to consumers and patients. This promotion includes but is not limited to ads printed in magazines, journals and newspapers; ads broadcast over television, radio and telephone; brochures, letters and flyers sent through the mail; and videotapes, pharmacy counter displays, billboards, patient compliance program materials and Internet related media.

Nothing in the law or regulations prohibits Direct to Consumer (DTC) promotion in any advertising medium, even if the drug being advertised is a controlled substance. In addition, the FDA generally cannot and usually does not require that prescription drug advertisements be reviewed and approved prior to their use. Prior FDA review of advertisements occurs only in very narrow circumstances, primarily for products receiving accelerated approvals. However, many drug firms voluntarily seek prior comment from the FDA on draft broadcast ads for their products thereby reducing the likelihood that they may face an enforcement action for unbalanced promotional materials.

18. The FDA often uses the term "sponsor" to encompass the range of companies involved in the supply chain of the pharmaceutical industry (such as manufacturer, packer and distributor) whom the more generic terms "drug company" or "drug firm".

19. 21 U.S.C. § 321(m) (2000).

20. *Kordel v. United States*, 335 U.S. 345, 350 (1948) (holding that a manufacturer who provides vendors with both the product and brochures can be found guilty of misbranding even though the product and "label" were shipped separately. "The fact that [the brochures] went in a different mail was wholly irrelevant.")

The regulations specify, among other things, that prescription drug advertisements cannot be false or misleading, cannot omit material facts, and must present a *fair balance* between benefit and risk information. As DTC promotions have grown in TV and print, a body of principles as well as specifically allowed and prohibited actions have been codified. As the Internet has become a more important promotional medium, many of the same principles have been applied to it even though the FDA has yet to formalize Internet promotion guidelines.

Recently, social media has emerged as a potentially powerful new avenue of DTC promotion. While the FDA has not proposed any specific regulations of social media activities, it is reasonable to assume that the Agency will evolve the existing principles and concepts to the unique characteristics of social media.

FDA Adapts Principles to Different Types of Promotions

The principle of fair balance has emerged as a foundational aspect of all forms of DTC promotions. Simply put, fair balance requires that claims of drug benefits, such as safety and effectiveness, must be balanced with relevant disclosures of risks and limitations of efficacy.

The FDA recognizes three different types of advertisements and specifies the product claim restrictions and fair balance requirements of each:

- 1) *Product-claim ads* are regulated by FDA and are those ads which generally include both the name of a product and its use, or make a claim or representation about a prescription drug. Because a claim about the drug's benefits is made, risks must be disclosed in order to achieve fair balance. As you will see below, the FDA allows a range of risk statements, suitable to the physical or time constraints of the medium.
- 2) *Reminder ads* are also regulated by FDA and are ads that may disclose the name of the product and certain specific descriptive information such as dosage form (i.e., tablet, capsule, or syrup) or price information; they are not allowed to give the product's indication (use) or to make any claims or representations about the product. They specifically are not allowed for products with serious warnings (called "black box" warnings) in their labeling. The regulations specifically exempt reminder ads from the risk disclosure requirements because they were historically designed generally to remind healthcare professionals of a product's availability. Healthcare professionals presumably know both the name of a product and its use.
- 3) *Help-seeking ads* discuss a disease or condition and advise the audience to "see your doctor" for possible treatments. Because no drug product is mentioned or implied, this type of ad is not considered to be a drug ad, is not regulated by FDA and need not include any risk information.

Because product-claim ads are the most prevalent and the most complicated from a compliance standpoint, they will be the focus of the rest of this paper.

Fair balance...
the description of risks
as well as benefits of a
drug is a foundational
concept in DTC
promotional regulations.

The FDA Adapts Key Principles to Different Media

Brief summary...
a statement of risk
information excerpted
from the full FDA
approved product
labeling.

The FDA recognizes that characteristics of different media require different approaches to achieving fair balance in product claim ads (see Table 2). To accommodate the different abilities of each medium to contain more or less information, the FDA has created other foundational concepts including the *brief summary*, *major statement* and *adequate provision*.

Major statement...
disclosure of the most
significant risks that
appear in the
product labeling.

For print advertisements, the regulations specify that the ad disclose every risk in the product's approved labeling through what is called a *brief summary* of risk information included in the product's FDA-approved labeling. In print media such as magazines, this often takes the form of an additional page (often the reverse side of the ad page) with extensive textual material that encompasses the relevant information from the full FDA-approved product labeling.

Adequate provision...
the convenient access
option for dissemination
of... package labeling
in connection with the
broadcast presentation.

For broadcast advertisements, however, the regulations are more complex. First, ads are required to disclose the most significant risks that appear in the labeling in either the audio or audio and visual parts of the presentation; this is sometimes referred to as the *major statement*. The regulations further require that broadcast advertisements either contain a brief summary of "all necessary information related to side effects and contraindications" or make *adequate provision* for dissemination of the product's FDA-approved labeling (and the risk information it contains) in connection with the ad. The phrase adequate provision requirement (21 CFR 202.1(e)(1)) requires the "convenient access option for dissemination of the approved or permitted package labeling in connection with the broadcast presentation." The regulations thus specify that the major statement, together with adequate provision for dissemination of the product's approved labeling, can provide the information disclosure required for broadcast advertisements. The FDA allows a variety of methods to meet the "convenient access option." These methods increasingly include a Web site reference that contains full product information.

Perhaps due to changing consumer habits and the inherent limitation of time, space and future reference in print and broadcast media, the most dramatic increase in marketing and promotion vehicles in recent years has been the Internet. Its ability to present a wealth of information about a drug has led to the increasing use of Web sites to fulfill the 'adequate provision' requirement of broadcast advertisements.

Table 2: Selected Requirements for Contents of Print and Broadcast Product Claim Advertisements		
Advertising medium	Regulatory requirements	Explanation
Print and broadcast	Cannot be false or misleading	Must present balanced information that is not inconsistent with uses in the allowed product label
	Must present fair balance	Must include and present in a manner that alerts consumers to risks and benefits of a drug product
	Must present “facts material”	Must present information relevant to representations made, and describe consequences or risks that may result from recommended use
Print only	Must describe risks	Must disclose all risks in a “brief summary” of the product’s labeling
Broadcast only	Must describe significant risks in a “major statement”	Must present significant side effects and contraindications in audio or audio and visual form
	Must make “adequate provision” for directing consumers to labeling information (e.g. print or Internet link), or provide a brief summary of all necessary information related to risks	Must provide additional sources where consumers can find complete information, such as a toll-free telephone number, a Web site, and a print advertisement in a magazine, and by contacting their health care professional (e.g. physicians, pharmacist); otherwise must summarize risks

Enforcement Options

The FDA’s options to address promotional materials that are false, misleading or unbalanced are as follows:

- (i) Untitled letters – notices of violations issued to drug companies directing that they discontinue use of the false or misleading advertising materials;
- (ii) Warning Letters – issued to drug companies for more serious violations, such as those possibly posing serious health risks to the public;
- (iii) Injunctions and consent decrees;
- (iv) Referrals for criminal investigation or prosecution; and
- (v) Seizure of offending promotional materials.

In the absence of FDA guidance for DTC Internet promotion, drug companies have adapted the principles of fair balance, product-claim ads and help-seeking ads.

The Evolution of Key Principles to Internet DTC Promotions

Despite the growing popularity of electronic promotion and the increasing use of the Internet as a source for gathering healthcare information, the FDA has yet to issue specific guidelines about the content of DTC Web sites for branded drugs, and rather suggests that guidelines for other electronic media (i.e. television and radio) also apply to such messages for branded drugs online. Even in the absence of specific guidance, drug companies have adapted concepts such as fair balance, product-claim ads and help-seeking ads to promotional Web sites. Table 3 highlights some of the ways drug firms have commonly complied with DTC principles while conducting online marketing/monitoring activities.

For example, TurnToHelp.com is sponsored by Reckitt Benckiser Pharmaceuticals, but avoids discussing treatments for opioid dependence. Thus, this site falls under the classification of a help-seeking ad, is not considered a promotion, and is not regulated by the FDA. But the manufacturer also has a site for its anti-addiction drug Suboxone (<http://suboxoneheretohelp.com>) which is required to provide fair balance and features prominent links to “Safety Information” and the full prescribing information.

An important difference from other forms of media, such as print or broadcast, is that the navigation of a Web site can result in different users obtaining different levels of information from the same site. While adequate provisions may be contained within a Web site, given the amount of information that Web sites may provide and the amount of user variation in the navigation of that site, it is apparent that it would be fairly simple to create a Web site that would allow consumers to completely miss or choose to avoid important risk information about the drug. Chantix’s manufacturers have addressed this by including a link to prescribing information prominently in the structure of the chantix.com Web site.

Additional DTC Marketing Issues: Avoiding Off-Label Promotion, Properly Handling Adverse Events

Aside from the principle of fair balance, social media potentially raises issues with two other concerns that are central to the FDA’s regulation of the drug industry:

- *Off-label promotion*: patients may ask questions or discuss uses of a drug that have not been tested and approved. Drug companies are prohibited from off-label promotion and so are understandably reluctant to be associated with these discussions.
- *Adverse event reporting*: in discussing their experiences with drugs, patients may describe side effects they experience or state that they don’t believe the drug worked for them. Due to the unique characteristics of social media, drug firms are unclear about whether or not social media carries the same obligation to report these events that FDA regulations specify for other marketing activities.

While planning to address fair balance in a social media initiative, drug companies should also evaluate and plan carefully to remain compliant with these issues. The following sections provide a more detailed overview of the current environment and the aspects of social media that may introduce risk.

Off-Label Promotion

The FDCA requires, among other things, that manufacturers label their products with safety warnings and directions for use. Over time, the FDA has come to understand this requirement as mandating that drug manufacturers label their product with a description of all intended uses. The FDA will not approve a labeled use of a drug for which substantial evidence of safety and efficacy has not been presented.²¹ Thus, the Agency has declared, “All drugs and devices must bear labeling with adequate directions for each intended use. If labeling for a drug or device fails to contain adequate directions for each intended use, the drug or device is deemed to be misbranded... and subject to seizure or other enforcement actions.”²²

One of the primary areas of concern to the FDA in DTC marketing is off-label promotion: used for a condition or in a manner not appearing on the FDA approved label.²³ While doctors may prescribe a drug for a use that is not included on the approved label for that drug, the FDA prohibits drug companies from promoting those uses.

The FDA and various court decisions have recognized that off-label prescribing is a legitimate part of the practice of medicine and in some areas of medicine, such as oncology, off-label use is recognized as a standard of care. The FDA’s policy on off-label prescribing states that “a physician may, as part of the practice of medicine lawfully prescribe a different dosage for his patient, or may otherwise vary the conditions of use from those approved in the package insert.”

Social media forums create risks for drug companies engaged in hosting or sponsoring Web sites because visitors to the site may post comments that contain mentions of off-label uses of their products. If the company attempts to exercise editorial control they may be viewed as implicitly endorsing the content since they are approving some content as appropriate and preventing other content from being posted. Thus, even though the postings are not generated by a company or its employees, it could be viewed as having the company’s approval. In Part III, we will discuss approaches to creating an editorial policy to minimize these risks.

Social media sites may include discussion of off-label uses of a drug. Handled incorrectly, a company may be viewed as endorsing the use and violate off-label promotion regulations.

21. 40 Henry, 368.

22. *Final Guidance on Industry-Supported Scientific and Educational Articles*, 62 Fed. Reg. 64,074, 64,075 (Dec. 3, 1997) (“The courts have agreed with the agency that section 502(f)(1) of the act requires information not only on how a product is to be used (e.g., dosage and administration), but also on all the intended uses of the product.”) (Emphasis added). In support of this claim, the agency cites *Alberty Food Products v. United States*, where the Ninth Circuit held that a manufacturer misbrands a product when its label does not reflect the therapeutic uses suggested in newspaper advertisements. 185 F.2d 321 (9th Cir. 1950).

23. James M. Beck & Elizabeth D. Azari, FDA, *Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 FOOD & DRUG L.J. 71, 71 n.2, (1998). One FDA presentation defined off-label drugs as medicines “use[d] for indication[s], dosage form[s], population[s] or other use parameter[s] not mentioned in the approved labeling.” Janet Woodcock, Lecture to Drug Information Association, *A Shift in the Regulatory Approach*, (June 23, 1997), at www.fda.gov/cder/present/diamontreal/regappr/sld001.htm (accessed August 27, 2007).

Adverse Event Reporting

In light of recent drug safety problems (e.g. Vioxx, Avandia, etc), healthcare officials and companies are clamoring for more effective, efficient and real-time ways to conduct *pharmacovigilance*, the scientific and data gathering activities relating to the detection, assessment and understanding of adverse events.

Adverse events...
any undesirable event
that is associated with
the use of a drug.

Drug companies are required to report known instances of adverse events with a drug to the FDA in accordance with regulations.²⁴ An adverse event is any undesirable event that is associated with the use of a drug or biological product in humans whether or not considered product-related.²⁵

Adverse event information should be reported to the FDA if the drug company has knowledge of the four basic elements for an individual case safety report:

- 1) An identifiable patient;
- 2) An identifiable person reporting the event;
- 3) A suspect drug or biological product; and
- 4) An adverse experience or fatal outcome suspected to be due to the suspect drug or biological product.

Safety signals...
an excess of adverse
events compared to
what would be
expected.

Pharmacovigilance principally involves the identification and evaluation of *safety signals* – an excess of adverse events compared to what would be expected to be associated with a product’s use. Safety signals can arise from post-marketing data and other sources, such as preclinical data and events associated with other products in the same pharmacologic class. It is possible that even a single, well-documented case report can be viewed as a signal, particularly if the report describes a positive re-challenge or if the event is extremely rare in the absence of drug use.

Marketing activities may generate reports of adverse events such as collection of consumer information via toll-free hotlines or market research whose purpose involves gathering information about patients’ experiences with products.

In most cases, social
media monitoring will
not result in requiring
adverse event reporting.

Drug companies are obligated to review any Internet sites which they create and manage for adverse experience information, but are not required to review any independent or third-party Internet sites. The drug company’s own Internet sites should contain contact information not only for product informational purposes, but also for adverse event reporting related to the company’s product.

24. Sponsors of approved NDAs or ANDAs, manufacturers of marketed prescription drugs for human use without approved NDAs or ANDAs, and licensed manufacturers of approved biologic product license applications are required to report adverse experiences to the FDA under 21 CFR 310.305, 314.80, 314.98, and 600.80.

25. *Guidance for Industry Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines*. U.S. Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research (CDER) Center for Biologics Evaluation and Research (CBER) (March 2001).

However, if the firm becomes aware of an adverse experience on an independent Internet site, the firm should review it to determine if it includes the four basic elements that make it a reportable event to the FDA.²⁶

In most cases, social media monitoring will not result in reportable events as the required identifiers will not be available in a verifiable manner. Postings on chat rooms or other social media outlets will typically not contain enough information to warrant an obligation or a prudent need to act further. However, drug companies need to be aware that while reporting social media adverse events may not be required, a high frequency of such reports suggests a possible connection of a drug to the unverifiable reports. They may wish to use these reports as a sign that a study may need to be undertaken to explore the possible link.

Drug companies may provide the FDA with additional information relevant to a drug safety issue at any time. A drug company also may request that the Agency update its communication of emerging drug safety information if the firm provides additional information supporting the request.

The challenge today is to move safety programs from detection to prediction, from a reactive to a proactive posture in pharmacovigilance efforts. Real-time data generation and alerts via the Internet offer companies a more effective manner in which to uncover safety signals. Acting on these signals earlier and proactively may help drug companies take actions that prevent damaging public relations, minimize product liability issues or even removal of a drug from the market. Clearly, social media sites offer companies versatile new tools for gathering data that may provide safety signals, provided that valid, verifiable information can be separated from “noise” such as false reports, events not associated with the proper use of the drug and anonymous reports or unverified content.

Pharmacovigilance should move from reactive to proactive. Social media offers a versatile tool for gathering data.

Table 3: Common Examples of How Pharmaceutical Companies Have Complied With FDA Regulations

Regulatory Issue	Compliance Measures*
Off-Label Promotion	<p>Pharmaceutical companies have avoided off-label promotion in Internet marketing campaigns by:</p> <ol style="list-style-type: none"> 1) Carefully controlling medical content on corporate Web sites. Example: www.lexapro.com 2) Supporting “unbranded” educational Web sites developed by third party organizations. Content is neither reviewed, approved or censored by company representatives. Example: www.depressionisreal.org 3) Developing corporate disease awareness Web sites where content is vetted by internal legal/regulatory officials. Example: www.adhdbalance.net

* Please note that the examples outlined in Table 3 are not exhaustive and may not be in compliance with certain corporate regulatory requirements.

26. *Guidance for Industry Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines* at page 19.

Table 3: Continued (Common Examples of How Pharmaceutical Companies Have Complied With FDA Regulations)

Regulatory Issue	Compliance Measures*
Adverse Event Reporting	<p>Drug firms have traditionally managed adverse event reporting by:</p> <ol style="list-style-type: none"> 1) Managing adverse event reports from identifiable (non-anonymous) patients by following internal policies and procedures. 2) Avoiding review of online and offline material that may contain information about adverse events reported by identifiable patients.
Fair Balance	<p>On the Internet, pharmaceutical marketing executives have adhered to fair balance requirements by:</p> <ol style="list-style-type: none"> 1) Following the “one click” rule. This means that detailed information about a drug’s safety and efficacy profile is made available via a prominently displayed hyperlink on a Web site, which allows users to access it quickly. Example: www.zyprexa.com (link: Zyprexa Prescribing Information) 2) Developing a clear and concise statement outlining a drug’s major side effects and publishing it on key Web pages. Example: www.chantix.com (see bottom of Web page for major statement)

* Please note that the examples outlined in Table 3 are not exhaustive and may not be in compliance with certain corporate regulatory requirements.

Part III: Unbranded, Corporate and Product Social Media Marketing: A Strategic Regulatory Framework

In Part II of this white paper we discussed the major FDA regulations governing pharmaceutical promotions. This section focused on three key principles that marketers should factor into any DTC promotional activity:

- *Fair Balance*: Ensuring the public receives information about a drug’s safety and efficacy profile.
- *Off-Label Promotion*: Avoiding marketing a product for a non-FDA approved condition.
- *Adverse Event Reporting*: Looking for and reporting information that may suggest a link between the use of a product and an adverse event or side effect.

Although the FDA has not released firm guidance on pharmaceutical Internet communications, we have many years of *received precedent* to guide us. Drug companies have developed a body of best practices that enable them to pursue their marketing goals via the Internet in keeping with the spirit of FDA regulations for print and broadcast ads:

- Following the “one-click” rule – i.e., prominently displaying a hyperlink to information about medication side effects on all product Web sites – to adhere to fair balance regulations.
- Carefully vetting content produced by company representatives or third-parties posting on drug-related Web sites to avoid off-label promotion.

In addition, drug industry trade group PhRMA’s voluntary guidelines on DTC promotion provide valuable information on how to improve product marketing.²⁷ Many drug firms have followed PhRMA’s recommendation to ban reminder advertisements.

At *minimum*, drug firms thinking about communicating via social media should design their programs to be consistent with these principles and be ready to discuss their efforts with the FDA. But, how should they do this? After all, social media introduces new challenges such as timeliness (e.g., quick response to breaking news), two-way dialogue (e.g., reactions to comments posted on blogs) and consumer-to-consumer communication that carry unknown risks.

A first step in applying these precedents to social media communications is to determine whether it is a product-claim or help-seeking promotion. For example:

Drug firms should use “received precedent” of DTC promotion to guide development of social media marketing initiatives.

27. Anonymous, “PhRMA Guiding Principles” (Washington, DC: The Pharmaceutical Research and Manufacturers of America, 2005), http://www.phrma.org/publications/policy_papers/phrma_dtc_guiding_principles/ (accessed August 27, 2007).

- Branded social media marketing may fall under the category of product-claim ads. As discussed on page 9, if a blog or podcast includes both the name of the drug and its indication, it is likely to be considered a product-claim ad.
- Unbranded social media communications may be viewed as help-seeking ads because this type of promotion does not discuss a product. Enhancing an existing help-seeking Web site with a discussion board to enable visitors to exchange experiences with a condition is likely to be considered a help-seeking activity as long as any such discussion board avoids off-label content.

For initiatives that this evaluation deems likely product-claim activities, pharmaceutical marketers should be able to adapt practices from other promotional activities to minimize the risk of FDA action. For example:

- Fair balance via the “one-click” rule: A branded blog or discussion forum should provide patients with detailed fair balance information by displaying relevant hyperlinks prominently which link to the same product information that would be found on a branded Web site.
- Avoid off-label promotion by:
 - Distributing unbranded corporate information via controlled social media channels like podcasts, where content can receive thorough review to remove any un-permitted promotional content (e.g. off-label promotion) before it is distributed. In addition, many drug firm podcasts do not invite or include consumer commentary, which reduces the chances that it will contain off-label information.
 - Sponsoring unbranded social media developed by a third party – material should not be reviewed, approved or censored by the drug firm.
 - In certain cases, carefully vetting commentary on a product bulletin board or blog to ensure that all off-label content is not published.
- Adhere to adverse event reporting requirements by understanding that discussions of adverse events do not meet the FDA’s pharmacovigilance standards on many sites, but will in some cases; specifically: 1) Anonymous posts or those written under a pseudonym may not be reportable if the veracity of the posting is in doubt; 2) Pharmaceutical social networks with identifiable and credible users (i.e., physicians) may require robust adverse event reporting protocols.

With a thorough understanding of received precedent and FDA regulations regarding help-seeking and product-claim promotion, pharmaceutical marketers should be well on their way to developing a low-risk social media campaign. However, they are not yet in the clear. This is because the FDA may view certain corporate marketing activities – whether or not they are branded – as promotional. Drug firms may still run afoul of the FDA if they do not apply generally accepted compliance standards to social media. In the next section, we provide a strategic framework that will help pharmaceutical executives do this.

Red Means Stop, Green Means Go: A Regulatory Framework for Successful Social Media Monitoring and Marketing

As children, we were taught by our parents to cross the street safely by following one simple rule: “Red means stop, green means go.” We have applied this parental advice to pharmaceutical social media communications. As discussed above, we suggest that drug marketers must be especially careful to follow FDA regulations regarding: off-label promotion, adverse event reporting and fair balance.

If the FDA finds that a company is violating regulations in any of these areas, it could be subject to a warning letter, fine, legal action and resulting adverse publicity. With this in mind, we have evaluated a number of common social media communications tactics and organized them into three risk categories:

- **Red:** These are social media activities that may place a pharmaceutical company at high risk of violating FDA regulations.
- **Yellow:** Companies may be at moderate risk of being cited for non-compliance by implementing these tactics.
- **Green:** These activities carry low risk of violating FDA regulations, either because drug firms are already implementing them or they can be very tightly controlled.

Readers should recognize that this framework is not all-inclusive. Specifically:

- We are only evaluating the risk level of these activities from a regulatory perspective. Successful social media communications demands that companies be flexible and responsive. Before launching a campaign, drug firms must determine:
 - Whether their corporate culture is social media friendly (e.g., can executives engage in candid conversations with the public, are they willing to experience and constructively address negative online commentary?)
 - If their internal compliance officials interpret FDA regulations liberally or conservatively.
 - Their tolerance for uncertainty; social media is constantly evolving and is not yet easily measured with traditional metrics.

Tables 4-7 show a number of common social media communications tactics organized into red, yellow and green risk categories. For each activity we asked a simple question: What is the likelihood a company could be cited for violating fair balance, adverse event and off-label promotion regulations? In addition, we address help-seeking and product-claim activities separately, as each raise unique issues.



It is outside the scope of this paper to review each of these tactics in detail. However, we provide several examples of how we evaluated the risk level of key social media activities as models to guide marketing, compliance and legal professionals how they might use this framework in evaluating their company’s social media initiatives.

Monitoring Social Media – Understanding the Conversation

Many experts agree that the first step to preparing a social media communications strategy is to understand the topics and issues being discussed. Then, if you decide to participate in these discussions, your contributions will be relevant, interesting and welcomed by social media participants.

Drug firms have two options for identifying the important sites, reading the content and summarizing it for the planners and decision makers. Depending on the situation, they may dedicate internal staff or hire an external firm that specializes in this field. While both options have a moderate risk profile, marketers should understand the regulatory issues unique to each.

Table 4: Evaluation of Risks Associated with Monitoring Social Media

Risk Level	Social Media Activity	Off-Label Promotion	Adverse Event Reporting	Fair Balance Requirements
	Social Media Monitoring Using External Resources	Low	Moderate	Low
	Social Media Monitoring Using Internal Resources	Low	Moderate	Low

Monitoring Social Media Using Internal Resources (Risk Level: Yellow): Reviewing blogs, online bulletin boards and other forms of social media generally does not heighten a drug firm’s risk of violating fair balance or off-label promotion regulations. Drug firms must evaluate their responsibility to report adverse events which may be discussed, but most posts will not qualify as reportable events.

Most adverse events discussed in social media will not meet FDA criteria and thus will not trigger the requirement to report it.

Due to the anonymity of members of most social media sites, most social media posts will not meet the first two required elements of a reportable event (see page 14). Without an author’s real name and other identifying facts, the post will fail to meet the criterion of “an identifiable person reporting the event.” Similarly, most posts will fail to include “an identifiable patient,” whether the anonymous author claims to have had the experience himself or is describing someone else’s experience.

However, if a post includes all the required elements, it must be reported along with adverse events identified by all other means. To ensure compliance with adverse event reporting requirements when monitoring social media drug firms should:

- Develop criteria that will help staff determine if an adverse event is reportable.
- Train staff monitoring social media on these criteria and how to incorporate them into existing adverse event reporting activities.
- Evaluate all reports (even those that do not meet reporting criteria) to determine if they might suggest a potential previously unknown drug side effect .
- Alternatively, the firm could work with the FDA to develop a customized monitoring protocol that would streamline social media adverse event reporting.

Monitoring Social Media Using External Resources (Risk Level: Yellow): If an external vendor is monitoring social media on a company’s behalf, drug firms are still obligated

to report all verifiable adverse events that they become aware of through the activities of the external vendor.

Drug companies can minimize the potential for reportable events by defining external monitoring projects around topics where adverse events are less likely to be discussed: e.g., a study on consumers’ reaction to a DTC ad campaign, or patients’ experience with their doctor during treatment. However, following this strategy could create product liability issues for the drug firm in the event of subsequent injury if it could be argued that the company could have or should have known about the adverse reaction.²⁸

To increase the odds that outside vendors monitoring social media will be compliant with FDA regulations, drug firms could:








- Ensure the vendor understands the FDA’s adverse event reporting requirements.
- Develop procedures that will enable the third party to integrate verifiable reports into the drug firm’s existing adverse event reporting system.
- Require that all adverse events found during social media monitoring be reported to the company – whether they are verifiable or not; have an employee evaluate reports to determine if they meet the FDA’s requirements.
- Avoid monitoring social media sites that have a history of producing unverifiable or suspect information.

Help-Seeking Social Media Activities – Sharing Information

Social media activities focused on a disease state and not promoting a particular brand are likely to be viewed similarly to help-seeking ads. Many of these activities carry little regulatory risk. But social media’s unique characteristics create potential for drug firms to inadvertently violate certain regulations. Thorough planning can minimize the risk.

Even if a drug firm uses an external social media monitoring company, they are still required to report all verifiable adverse events they become aware of.

Table 5: Evaluation of Risks Associated with Help-Seeking Social Media Activities

Risk Level	Social Media Activity	Off-Label Promotion	Adverse Event Reporting	Fair Balance Requirements
	Non-Branded Advertising On Social Media Platforms	Low	Low	Low
	Developing Non-Branded Content For Distribution On Video-Sharing Websites (i.e., YouTube)	Low	Low	Low
	Developing Non-Branded Disease Awareness Corporate Podcast	Low	Low	Low
	Developing Corporate Disease Awareness Blog	Moderate	Moderate	Low
	Developing Non-Branded Corporate Disease Awareness Wiki	Moderate	Moderate	Low
	Non-Branded Participation In Social Media (e.g., Leaving Comments, Posting In Forums, etc)	Moderate	Moderate	Low
	Developing Corporate Disease Awareness Social Network/Bulletin Board	High	Moderate	Low

28. In addition to compliance with FDA regulations, social media planning discussions among marketing, legal and regulatory compliance should consider potential product liability issues associated with monitoring social media.

Developing Corporate Disease Awareness Social Network/Bulletin Board

(Risk Level: *Red*): Although unbranded or disease awareness social media can be thought of as a help-seeking ad, social media's nature of inviting consumer participation creates risks for both off-label promotion and adverse event reporting:

- A person using the network/bulletin board could report an adverse event with a company's product. If the individual is identifiable and credible, the drug firm will be responsible for sending this content to the FDA. The site should be monitored and adverse events reported as discussed above.
- The firm could be cited for off-label promotion if they are developing or hosting content that could lead to the discussion of unapproved conditions and such discussion is controlled by the company.

The degree of control that a company exercises over the discussion has the potential to violate off-label promotion restrictions.

The degree of control that a company exercises over the discussion has the potential to violate off-label promotion restrictions. Whether or not the company creates the content, if it exercises editorial control (i.e., the company actively moderates or edits content) it may be viewed as approving or endorsing the views and opinions expressed. If the company edits comments on a site, and leaves in place comments that include off-label uses of their drug, the company's editorial control may be viewed as adoption of the content and thus promotion of those off-label uses.

Drug firms can reduce the risks associated with developing a corporate disease awareness online bulletin board or social network by:

- Including a disclaimer that the views expressed on the site are those of the author and do not represent the company's views; and
- Avoiding censorship of any information on the online bulletin board; and
- Avoiding company comment on any postings; and
- Providing or allowing critical comment on any posting from health care professionals; and
- Developing internal policies that encompass these practices; and
- Ensuring that employees, marketing services firms and others involved in social media development and monitoring adhere to company policies and procedures.

Drug firms can minimize the risk of violating off-label promotion regulations by carefully designing site disclaimers, terms of use policies and editorial processes.

Alternatively, marketers may opt to monitor and moderate the content to eliminate any and all discussion of off-label uses. They may also want to delete spam, vulgar or obscene language or other objectionable material. However, companies should allow both positive and critical commentary on their drug and refrain from deleting negative posts. To ensure that this level of editorial control remains in compliance with FDA requirements, drug firms should:








- Develop a site terms of use policy that clearly informs site visitors/users why and how commentary is being vetted; and
- Develop company policies and procedures that help moderators understand what constitutes off-label commentary; and
- Regularly review and consistently delete posts that violate the site terms of use policy; and

- Ensure that employees, marketing services firms and others involved maintaining or monitoring the site follow these policies.

Product-Claim Social Media Activities – Engaging with Patients

Incorporating information about a drug brand into social media communications activities will imbue it with some of the features of a product-claim ad. This potentially increases the regulatory issues that must be addressed. Certain practices common to broadcast ads and branded Web sites help address these issues. In addition, marketers should plan to carefully manage the speed and fluid nature of these emerging media.

Table 6: Evaluation of Risks Associated with Product-Claim Social Media Activities

Risk Level	Social Media Activity	Off-Label Promotion	Adverse Event Reporting	Fair Balance Requirements
	Branded Advertising On Social Media Platforms	Moderate	Low	Low
	Developing Branded Content For Distribution On Video-Sharing Websites (i.e., YouTube)	Low	Low	Moderate
	Developing Branded Corporate Podcast	Low	Low	Low
	Developing Branded Blog	Moderate	High	Low
	Developing Branded Social Network/Bulletin Board	Moderate	High	Low
	Developing Branded Corporate Branded Wiki	High	Moderate	Moderate
	Branded Participation In Social Media (e.g., Leaving Comments, Posting In Forums, etc)	High	Moderate	High

Developing a Branded Blog (Risk Level: Red):

Blogs are often spontaneous, opinion-filled and free-wheeling. But this type of approach could lead to many regulatory issues. However, these risks can be lessened by:

- Ensuring that the branded blog is compliant with fair balance regulations by developing a brief statement of common drug side effects that appears in the blog. For example, if the drug is being advertised on television, adapting the major statement might be one option to increase compliance (see Part II for more information about the major statement.)
- Regularly reviewing reports of adverse events, and incorporating those that are identifiable and credible into existing reporting protocols.
- Carefully vetting blog material written by company employees, marketing services firms, etc. to ensure it complies with the product label.
- Establish a policy on editorial control of blog comments. As discussed in the section above, companies must develop proper disclaimers, site use policies, and internal policies and procedures to avoid inadvertently endorsing off-label uses discussed in comments.

Given these restrictions, drug firms should evaluate whether a product blog will be effective in satisfying patient/healthcare provider expectations for a blog. The caution and reviews needed to ensure the blog complies with FDA regulations may prohibit companies from fully satisfying blogging’s cultural requirements for candid conversation and quick response times.

Developing Branded Content for Distribution on Video-Sharing Web sites

(Risk Level: *Green*): A number of drug companies are considering whether and how to distribute branded content on video-sharing Web sites like YouTube (www.youtube.com). This is a relatively low-risk activity because firms normally include information about drug risks in the videos and the content is carefully vetted and controlled. Without this however, a company may violate fair balance requirements.

Distributing branded content on video-sharing Web sites is a relatively low risk activity.




To decrease the odds of being cited by the FDA for non-compliance, drug firms should:

- Ensure the video is accompanied by a brief overview of medical side effects.
- Provide additional product information that is easily accessible via a prominently displayed hyperlink embedded in the video content.

Corporate Communications Social Media Activities – New Channels for Key Messages

Social media creates new ways for companies to communicate with a variety of stakeholders. For corporate content that is already reviewed carefully for compliance, and for emerging distribution formats like online video and podcasts which minimize the response from the audience, social media presents few regulatory issues. For drug companies wanting to test new marketing tactics in this emerging space, these types of initiatives may be a good first step.

Table 7: Evaluation of Risks Associated with Corporate Communications Social Media Activities

Risk Level	Social Media Activity	Off-Label Promotion	Adverse Event Reporting	Fair Balance Requirements
	Developing Corporate Podcast	Low	Low	Low
	Distributing Corporate Content On Video-Sharing Websites (i.e., YouTube)	Low	Low	Low
	Developing Corporate Blog	Low	Moderate	Low

We hope it is clear by now that drug firms must think about whether they are adhering to relevant FDA regulations regarding fair balance, off-label promotion and adverse event reporting when conducting social media communications activities. High-risk tactics (red) should be attempted with great caution. Low-risk activities (green) should be relatively safe – as long as you are practicing regulatory diligence.

Conclusion

Social media has rapidly become an important information source for the millions of Americans that use the Internet to research medical conditions and treatment options. It has also begun to influence patients' decisions about their health. Handled correctly, social media can be an effective and exciting tool for pharmaceutical firms to directly communicate with patients, facilitate productive dialogue among a range of stakeholders and gain additional insight into patient experiences with a drug or procedure.

However, because it is new and evolving, social media offers marketing and communications opportunities that are yet to be comprehensively addressed in existing FDA guidance on DTC promotional activities.

In this paper, we have tried to illuminate areas of regulatory risk associated with social media communications so that drug companies will be alerted to likely pitfalls and better able to select appropriate strategies and tactics. We have shown:

- By thoughtfully adapting core principles underlying the regulation of DTC promotion to the Internet, drug companies have successfully connected with consumers online in the absence of specific FDA guidance.
- Some social media tactics incur particular risk of violating DTC promotional regulations regarding fair balance, off-label promotion, and adverse event reporting.
- A conservative way for drug companies to utilize social media will be to select avenues that correspond with a prudent interpretation of FDA regulations.
- With careful thought and planning, marketing, legal and regulatory compliance professionals can design successful and compliant social media communications programs.

Social media has only enhanced the public's ability to learn about health and successfully collaborate with their health care providers. These technologies also provide pharma companies with a platform that will help them produce and distribute relevant information to their stakeholders. Companies that embrace these new tools will be ahead of the curve. Those that do not will be at a profound disadvantage.