Healthcare Communications in the Digital World: Mitigating the Risks in a Highly Regulated Environment

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Healthcare Communications in the Digital World

Introduction

In this digital age, pharmaceutical and biotech companies know that they need to reach their key audiences of patients and physicians where they live and meet — both offline and online. To effectively leverage the online component, companies need to incorporate digital and social media strategies into their standard communications practices, but many are often hesitant to do so. This hesitancy stems in part from a lack of clarity regarding U.S. Food and Drug Administration (FDA) marketing guidelines as they relate to online communications.

Though the FDA has not provided explicit regulations for digital communications, companies can still follow established regulatory standards for marketing and communications when engaging online, whether that involves social media, digital storytelling, Web experiences or search marketing.

It is not the medium that matters — it is the message or story that needs to be conveyed. The purpose of this paper is to highlight the current regulatory landscape that pharmaceutical and biotech companies live in and discuss ways in which companies can develop digital and social media strategies in a highly regulated environment. Part I looks at the current healthcare industry landscape; Part II provides guidelines for how companies can engage online; and Part III showcases the Four Digital Pillars, a framework for assessing opportunity online.

Part I: The Industry Landscape

Consumers are seeking their health information online now more than ever. A recent survey by Manhattan Research LLC concluded that 60 million American adults considered themselves Health 2.0 consumers. This designation includes the use of health blogs, online support groups, prescription rating sites, and other social media applications for healthcare and medical purposes.¹

While consumers, patients, physicians, shareholders and investors are actively engaging online, many pharmaceutical and biotech companies are not. Recent information shows that while the typical company spends 37 percent of its marketing budget online, drug companies spend on average about only 4 percent of their public relations and marketing budgets online — significantly less than companies in any other industry.², ³

Because patients and physicians are actively seeking out and sharing health information online, there is a strong need for companies to start experimenting with Web portals and online communities and move beyond the traditional, static Web page model of advertising. According to WebProNews, “there has been a fundamental shift in our culture and it has created a new landscape of influencers and an entirely new ecosystem for supporting the socialization of information — thus facilitating new conversations that can start locally, but have a global impact.” The healthcare industry depends on the transfer of credible information, and by ignoring the communication opportunities available online, companies miss out on increased business vitality and growth.
Part II: Guidelines for How Companies Can Engage in Digital Communications

Currently, there are no FDA regulations specific to digital communications. But the agency’s regulations through the Division of Drug, Marketing and Advertising Communications (DDMAC) for pre-market and post-market communications, such as rules for adverse event reporting, fair balance and promotion of off-label uses, can and should apply to digital communications. (See sidebar for definitions).

Recently, we have seen the FDA making dramatic efforts to engage its audience online. In December 2008, the FDA announced that it would partner with WebMD LLC, an online medical and health search engine and information site, to expand consumer access to the agency’s health information. The FDA has also begun posting a list online of drug products with potential signal of serious risk. Furthermore, the FDA recently launched @FDArecalls on Twitter and an FDA desktop widget to provide consumers with notifications regarding recalls, market withdrawals and safety alerts. These are strong signals that the FDA is embracing the digital age and that it has gained understanding of how the medium works. We anticipate that the agency will be able to provide more specific guidance to pharmaceutical and biotech companies in the very near future.

Fair Balance:
Drug advertisements cannot be false or misleading, cannot omit material facts, and must present a fair balance between benefit risk and information.

Off-Label Promotion:
Patients may ask questions or discuss alternative indications of a drug that has not been tested or approved. Drug companies are prohibited from off-label promotion and should not be associated with these discussions.

Adverse-Event Reporting:
In discussing their experiences with drugs, patients may describe negative side effects or state that they believe the drug does not work. Companies must report these adverse events.

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Based on the FDA’s direct-to-consumer advertising regulations, the following chart provides a guideline for companies when engaging in digital communications. There are a variety of digital mediums that companies can use as long as the current rules for non-digital engagement correspond.

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<tr>
<th>What Companies CAN Do</th>
<th>What Companies CANNOT Do</th>
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<tr>
<td>• Advertise a product online using video and audio content, as long as the product’s name and the most important risk-related information (known as the major statement) are presented.</td>
<td>• Indicate off-label use of a drug online. Regardless of the medium, drug companies cannot discuss alternative ways to use a drug that is not FDA approved.</td>
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<td>• Sponsor and/or share help-seeking information online (such as a Web site or online community devoted to raising disease awareness) when it is not attached to a specific drug or product. The FDA does not regulate help-seeking material.</td>
<td>• Omit material facts online. All facts about a product must be present along with mention of that product online. Providing a link on a third-party site to another page that defines all drug information is one way to avoid misrepresentation.</td>
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<td>• Provide a link in an online press release or other product-related content that links to information about the drug and its possible side effects. This is known as the one-click rule.</td>
<td>• Use the word new to describe a product after it has been on-market for six months. Companies must edit and monitor online information about a drug to ensure that it is up to date.</td>
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<td>• Investigate online information posted by third parties (such as an online social forum or patient blog) to prevent off-label promotion. If a company discovers an adverse event reported online (by a patient, patient family or physician), it must be reported to the FDA.</td>
<td>• Claim that a product is the drug of choice, unless there is sufficient information to back it up. Seemingly informal online engagement, such as a company blog, can allow for these slip-ups, so it must be noted that when describing a drug online, the same rules of engagement apply to a blog as they do to a print advertisement.</td>
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<td>• If a company sponsors or supports a Web site on which there is an opportunity to report an adverse event by a user, it must be monitored. The discovery of an adverse event report on a Web site not affiliated with a company should be reported, but cannot legally be enforced.</td>
<td>*Interpretations of FDA regulations presented in this chart are based on Envision Solutions’ white paper “Connecting with Patients, Overcoming Uncertainty: A white paper on Managing the Risks and Regulatory Issues Associated with Successful Pharmaceutical Social Media Monitoring and Marketing.”</td>
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<tr>
<td>• Present product reminder information online, including the name of the product and dosage form, but companies cannot advertise the indications or make claims.</td>
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*Interpretations of FDA regulations presented in this chart are based on Envision Solutions’ white paper “Connecting with Patients, Overcoming Uncertainty: A white paper on Managing the Risks and Regulatory Issues Associated with Successful Pharmaceutical Social Media Monitoring and Marketing.”*
Part III: The Four Digital Pillars

Digital Storytelling

Key Takeaway: Corporate blogs, YouTube channels and social press releases are all compelling ways for pharmaceutical and biotech companies to raise visibility and reach a greater audience online.

Digital storytelling, at its most basic level, is the act of extending storytelling skills to the digital arena through the use of online media. In addition to text, audio and visual elements can augment the key message theme, resulting in a more compelling and engaging experience for the audience.

One effective example of digital storytelling is what Johnson & Johnson Services Inc. (J&J) has done by creating a YouTube channel. J&J launched its YouTube health channel (http://www.youtube.com/JNJhealth) in May 2008 and uses it primarily as a way to communicate health information and news with its users. The page has a weekly focus (obesity, attention-deficit hyperactivity disorder and breast cancer have all been discussed on the channel through recorded video) and shows physicians and patients discussing different health-related topics. As of early February 2009, the YouTube channel had more than 550 subscribers, in addition to more than 37,000 page views. The channel links to J&J’s blog (http://www.jnjbtw.com) and the blog regularly features updates about the channel in tandem. This is a great example of how the company leverages online media platforms to extend its corporate and patient storytelling efforts.
Another tool for digital storytelling is the social media press release. Essentially, this type of release is designed to incorporate digital elements (such as links and audiovisual content) that can be easily shared and distributed, to be incorporated to blogs, corporate Web sites and online news wire Web sites. An example is when Cephalon Inc. took its press release a step further in creating an online video announcement for one of its flagship products. In order to increase awareness of its TREANDA product, Cephalon created a digital press release to announce the FDA approval of TREANDA for non-Hodgkin lymphoma (NHL). A video posted online showed patients on TREANDA talking about the benefits of the drug and their personal experiences dealing with NHL. The video complied with FDA regulations by expressly stating side effects and any other drug-related information expected of an FDA-approved television commercial. While the point of the TREANDA announcement was the fact that it had been approved for a second indication, Cephalon was able to enhance its message by sharing it in a digital format. Furthermore, a social media press release like the TREANDA release or another, already approved television commercial can be uploaded to a company YouTube channel page to increase views.

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**SOCIAL MEDIA**

*Key Takeaway: Social media and online networking sites are fast becoming the easiest way for patients to exchange information online; pharmaceutical and biotech companies can and should be a part of the conversation, especially as it pertains to their products.*

In the past few years, social media and social networking sites have become a hotbed for free information exchange among patients and physicians. While the venues may have become more sophisticated, this free exchange of information has long been a hallmark of the healthcare world, via free-form chat boards hosted by specific disease and patient advocacy groups. It is human nature for people who are impacted by disease to look to others for advice, information and fellowship.

Companies are nervous about engaging on today’s social networking sites because of the likelihood of seeing adverse event and side effects discussed informally. Even informal discussion of adverse events must be reported to the FDA for consideration. Although there has not yet been a specific ruling governing digital adverse event reporting, existing rulings about reporting adverse events should and do apply.

One example of a social media site with corporate sponsorship is [http://www.myalli.com](http://www.myalli.com), an online, social community for patients using the weight loss drug Alli. The site, hosted by GlaxoSmithKline plc (GSK), provides branded product information and a range of opportunities for visitors to join the discussion, view patient profiles, get tips and tricks for diet success, etc. GSK has established a positive
presence in the community of existing and potential patients that it will be able to leverage well into the future.

In the past, drug companies have partnered with disease advocacy groups to create non-branded, disease-focused Web sites in addition to branded, product-driven Web sites. Companies can get more interactive with the patient and potential patient community by supporting non-branded, disease education Web sites. However, the information flow should be two-way, not the traditional one-way, brochure-typified strategy found on conventional drug sites. ChildrenWithDiabetes.com, Johnson & Johnson’s sponsored diabetes information portal for families with diabetic children, is a strong example of a less branded, disease education and social community Web site.

Healthcare companies can also engage patients with a smaller upfront investment through the use of a disease awareness blog, forums, conversations (via Twitter) and online communities such as Facebook. An example of this is seen through Abbott’s Labs are Vital campaign.

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For the initiative, Abbott Laboratories used an online social network community, Facebook, and an online video sharing site, YouTube, to promote its young scientist scholarship contest. The scholarship contest challenges students to create better ways to draw their peers’ attention to jobs in clinical science. The Labs are Vital campaign works in conjunction with a Facebook group that encourages students to work in a medical laboratory. The goal of the campaign was to recruit students into
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the science profession. Students who entered the contest had the chance to win a scholarship valued at up to $2,500 by submitting a video, advertisement or T-shirt design that encouraged others to consider careers in laboratory medicine. In creating the Labs are Vital campaign, Abbott fed the company’s long-term recruiting strategy by engaging young scientists online and broadened its consumer visibility with a younger, digital-savvy audience. In January 2009, the Labs are Vital Facebook page had 2,289 fans.

WEB EXPERIENCES

Key Takeaway: Conventional forms of communication, even online communication like most branded drug sites, do not allow for the kind of interactivity involved in Web experiences, such as hosting online podcasts and community forums on product or disease-specific microsites. Digital Web experiences are a seamless way to increase brand awareness and credibility.

A Web experience is an all-encompassing digital communications strategy that can include digital storytelling, social media and search. Digital elements such as virtual pressrooms, blogs, social community forums, and video and audio content are combined on one host site around a uniform cause or purpose.

Microsite definition:
A microsite is an Internet Web design term referring to an individual Web page or cluster of pages that are meant to function as a supplement to a primary Web site. The microsite’s main landing page most likely has a unique domain name or sub domain.

“The multipurpose Web site can serve as a one-stop shop for patients and their families who are curious about the latest disease news and who seek suggestions for living a healthy life.”
One such example of an effective branded Web experience is Abbott Laboratories’ Crohn’s disease microsite, Crohn’s Online (http://www.crohnsonline.com). In addition to general help-seeking information, the Web site includes an online community forum for users and a section for Abbott’s podcast series, “Crohn’s Casts.” The podcasts provide in-depth information on history, diagnosis, treatment and lifestyle issues associated with the disease. The multipurpose Web site can serve as a one-stop shop for patients and their families who are curious about the latest disease news and who seek suggestions for living a healthy life. The site also affords them the opportunity to connect with other patients.

The microsite Creaky Joints (http://www.creakyjoints.org) is an online hub for patients to learn about arthritis and to communicate with other patients via online support groups and community boards. Users have access to numerous resources, including podcasts, event listings, news updates and advice columns, enabling them to have an enriching experience. Genentech Inc., Pfizer Inc. and Wyeth are among the list of sponsors that support Creaky Joints.

Companies that sponsor and/or host sites like these demonstrate innovation and commitment to their patients by providing them with a venue where they can get the most up-to-date, relevant information and interact online, all at one destination.

**SEARCH MARKETING**

**Key Takeaway:** Search is the first place users go to access health information online. To increase visibility online, companies can employ search-engine optimization tactics, such as purchasing search-engine ads and/or experimenting with online text, including press releases, product and corporate Web sites.

Key word tagging and search-engine optimization are crucial tools for companies to employ in digital communications strategies. Savvy Web programmers understand the importance of keyword tagging in the actual coding for the Web site in the back end, enabling search engines to easily find relevant subject associated with the page, and ultimately making it easy for your key audience to find you. The key here is not only reaching the audience who is looking for your company, but also reaching audiences who do not know that they are looking for you. In addition to properly tagging your Web sites, marketers also need to be smart about correctly tagging and categorizing each Web page to ensure search-engine optimization.

Sponsored links are also an efficient way to optimize search. A sponsored link, such as those on Google, MSN Live Search and Yahoo!, is a purchased ad that appears on the home page when a user searches for a certain term. Sponsored links appear when certain words are entered into the search bar. In the case of healthcare, optimized words include conditions, diseases, product names and symptoms.
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Social media press releases should also be optimized for search. Press release wire services are now capable of issuing releases with embedded text that will be picked up by search engines and linked back to the company’s Web site or information. For example, a patient searching for treatment options in rheumatoid arthritis is more likely to be linked to a relevant press release if the release has embedded text that picks up the patient’s specific search terms.

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In conclusion

While pharmaceutical and biotech companies may be reticent to engage in the digital space, there are many safe and effective ways to enhance a company’s brand and visibility using digital tools. Online community forums, blogs, YouTube channels and physician podcasts are just some of the ways to increase visibility online. As the FDA begins to enter the digital space so, too, can pharmaceutical and biotech companies begin to engage there. Consumers and professionals expect credible, up-to-date and valuable health information at their fingertips, and today their fingertips are usually found on a computer or mobile device keyboard. With adequate attention paid to standard FDA regulations governing marketing communications, companies can successfully and safely navigate the digital world.

References


