

Drug marketing and the new media

Social media represent a new way for drug companies to interact with consumers. But transitioning medical communication and marketing campaigns to the internet poses several thorny legal and regulatory issues. Sarah Webb investigates.

In March, the US Food and Drug Administration (FDA) announced that it will be issuing a guidance on the promotion of FDA-regulated products using social media. The agency is currently plowing through hundreds of public comments received after a hearing on this issue held last November (cataloged at <http://www.fda.gov/aboutfda/centersoffices/cder/ucm184250.htm>). Among the questions that FDA is currently pondering are, How can companies be held accountable for communications about their products? How can the text space limitations of internet media and regulations requiring fair balance be reconciled? What kinds of control should the FDA exert over internet dialog about drug products, whether that discussion occurs on company-sponsored web sites or elsewhere? (See <http://fdasm.com> for comments.)

Whereas interactive social media marketing is widespread in many industries, including healthcare, it seems that both FDA and the drug industry are playing catch-up. According to Jonathan Richman, of the marketing agency Bridge Worldwide in Cincinnati, who has an online social media wiki, Dose of Digital (<http://www.doseofdigital.com/healthcare-pharma-social-media-wiki/>), the number of social media sites devoted to pharmaceuticals and healthcare has exploded from just a handful in 2009 to more than 200 today (Table 1). Consumers are not only passive receivers of information, but also content providers, actively shaping the dialog with industry on web-based communities. In the absence of clear regulatory guidance, companies are considering their options: do they wait for FDA or do they create social media policies and strategies of their own?

Rules of engagement

Even before the November FDA hearing, some drug companies had already been cautiously dipping their toes into Web 2.0. One reason for this is that the appetite for healthcare-related information is huge. According to a 2008 Pew Internet and American Life study¹, a majority of American adults (61%) use the internet to find health information. Although 41% of these so-called e-patients read the comments

on interactive pages, such as blogs, far fewer—less than 10% percent—are actively involved in producing healthcare content online. “It’s obvious that there is an unprecedented demand for reliable healthcare information on the internet,” says Jeffrey Francer, assistant general counsel for the Washington, DC-based Pharmaceutical Research and Manufacturers of America, which represents pharmaceutical and biotech companies. “The challenge will be how we do that in certain media.”

Whether or not drug companies create or sponsor social media sites, a world of health information already exists outside company control on sites, such as Wikipedia and WebMD, on Twitter and Facebook, and in independent online communities of people interested in particular health issues. This presents particular concerns for companies selling prescription drugs.

As Fabio Gratton, chief innovation officer of the healthcare marketing agency Ignite Health of Irvine, California, notes, monitoring information on outside sites raises legal issues in itself. If companies are aware of healthcare conversations that unfold on these channels and choose not to comment, they could find themselves in a situation in which they observe misleading, or even dangerous information, such as an inaccurate dosage for one of their products, being promulgated. If a company doesn’t have a way to enter that conversation and correct that information, Gratton says, they could be considered negligent.

Allowing companies to correct content opens a whole other set of issues, both in terms of regulation and the social etiquette of doing so. “You can’t just dump a brochure in there,” Gratton says. “And once you step in how far do you go?” Regulations need to establish consistent practice, both in terms of correcting information and dealing with comments about off-label uses, he adds.

Ultimately, companies would like to do more than just monitor the internet for incorrect information or adverse events: they would like to build relationships with consumers. “[Social media is] not limited to promotion, I think it’s about communication,” says Mark Gaydos, senior director of regulatory affairs

for Sanofi-aventis in Bridgewater, New Jersey. He adds, “Social media offers opportunities to listen [to] and understand patients and physicians and then to better address their needs.” Companies also see the more conversational format as a way to improve the perception of the pharmaceutical industry among the public at large. “I don’t think anyone would argue that the pharma industry has a trust problem with consumers. One of the ways that we can start to counter that is to have [a] real voice through social media,” says Rohit Bhargava, a blogger and member of media relations firm Ogilvy in Washington, DC.

The social media landscape

Web 2.0 presents a culture clash, as the spontaneous, high-flying world of the internet meets the heavily regulated drug industry. “The very nature of the social web is a two-way interaction and content that is easily portable and sharable. The very nature of pharmaceutical communications and marketing is a very controlled, vetted, static piece that is one-way that



FDA and social media. Controlling the flow of information on drugs presents new challenges for the FDA and drug companies with the explosion of social media sites on the internet.

reduces all those risks. And so those two concepts have come to a head,” Gratton says. Once outside voices enter a conversation, companies lose control over their content.

Because companies are obligated to present both the benefits and risks of their products in their marketing materials, they have both legal and regulatory concerns about engaging in conversations about products online. The responsibility issues are clear for websites that a company controls or directly sponsors, and such materials are still relatively easy to regulate and review, Gratton says. But many web applications allow users to customize, personalize and even do mashups of information as they share it within their online communities. Such

Table 1 Selected companies participating in social media

Company	YouTube channel	Blog	Twitter	Facebook
23andMe	Yes (http://www.youtube.com/user/23andMe)	The Spittoon (http://spittoon.23andme.com/)	@23andMe	23andMe
AstraZeneca	Yes (http://www.youtube.com/user/azvideochannel#p/u)	AZ Health Connections (http://www.azhealthconnections.com/)	@astrazeneca, @astrazenecaus	AstraZeneca Community Connections, Nexium
Genentech	Yes (http://www.youtube.com/user/genentechvideo)	HER Story Community (http://www.herceptin.com/community/index.jsp) Heroes of Hope (http://www.heroesofhope.com/)	@genentechnews	Genentech
Genzyme	No	Face to Face (http://www.facetofacegenzyme.com/)		Genzyme
GlaxoSmithKline	Yes (http://www.youtube.com/user/GSKvision)	More Than Medicine (http://www.morethanmedicine.us.gsk.com/blog/)	@gskus	
Johnson & Johnson	Yes (http://www.youtube.com/user/JNJhealth)	Kilmer House (http://www.kilmerhouse.com/) BTW (http://www.jnjbtw.com/)	@JNJComm	Johnson & Johnson
Novartis	Yes (http://www.youtube.com/user/Novartis)		@novartis	
Patientslikeme	Yes (http://www.youtube.com/patientslikeme)	The Value of Openness (http://blog.patientslikeme.com/)	@patientslikeme	Patientslikeme
Pfizer	Yes (http://www.youtube.com/user/PfizerEurope)	Think Science Now (http://science.pfizer.com/blog/)	@pfizer_news	

situations run the risk of taking the original information out of context or even changing the meaning entirely. In the past, a company couldn't be held responsible for what outside individuals might do with static content. But the lines become blurred, he notes, when a company participates in the medium and turns on web-based features such as sharing and commenting. "Are you [the company] responsible for what other people are doing with that content?" Gratton asks. "Because, in a way, you have facilitated it."

Some firms are behaving cautiously. "I think there's still a lot of apprehension on the part of brands because they don't feel like they know what the rules are and they are afraid of getting randomly called out for doing something wrong that they didn't realize was wrong," Bhargava says. "So their default mode is to do nothing." For example, Indianapolis-based Eli Lilly has mostly avoided participating in social media. In her testimony to the FDA hearing in November, Lilly's director of regulatory affairs, Michelle Sharp, explained this was "largely because of a lack of clarity in understanding FDA's expectations as to how we could participate and comply with FDA requirements."

But other companies have moved forward, creating blogs, Facebook pages and Twitter accounts, even partnering with patient groups (Table 1). Some of these sites focus on particular health issues or company information rather than product brands.

Johnson & Johnson (J&J), headquartered in New Brunswick, New Jersey, first got involved in social media in 2006 with the development of a blog called Kilmer House (<http://www.kilmerhouse.com/>), which discusses the company's history, says Marc Monseau. As a director of corporate communications, Monseau spends nearly all his time on Web

2.0 communication. Six months after the first blog, a second, the JNJ BTW blog (<http://www.jnjbtw.com/>), was started, which talks about news within the company and the pharmaceutical industry. The company has also since set up a channel on YouTube, a Twitter feed and a Facebook page.

In the absence of clear FDA guidelines for Web 2.0, the company has used their internal experience in drug product marketing and communication to develop internal policies. "We needed to get some experience to better understand how these sites and communities would work and understand how we would manage them as an organization," Monseau says. Moving incrementally has allowed J&J to build those internal policies, through conversations with their attorneys and regulatory group.

One concern is how to deal with adverse events that might be reported on a social media site, Monseau says. Though Monseau doesn't know of any such reports on J&J's social media websites, such a comment would be funneled through the appropriate regulatory channels within the company, just like a phone call. The more challenging space, he says, comes in third-party media such as Twitter. He would be equally obligated to report a potential adverse event he observes there, he says, in the same manner as when an event is described in a newspaper article.

The rise of the consumer

Regulatory issues are only one concern for companies using the internet. Given the reach of the web, they also must deal with consumers who have a greater platform than ever before. Whereas some sites are industry sponsored—BioMarin, in Novato, California, for example, sponsors a site for people affected with phenylketonuria (<http://www.pku.com/>)—

others have been established by health activists or nonprofit organizations who want to bring greater public awareness to particular conditions and provide information and support to patients. Questions remain about how the industry might participate in these independent communities.

As long as they're transparent about their identity and their affiliation, "industry has little to fear and a lot to gain," from participating in these communities, says Jack Barrette, CEO of WEGO Health, a Boston-based social network for advocates interested in health issues. At the November FDA hearings, Barrette and his colleagues presented the results of an October 2009 survey of their community members about issues surrounding company participation in social media. Approximately three-quarters of the 169 respondents agreed that the use of social media by healthcare companies both provides important updates about products or services and contributes accurate information about drugs and devices to conversations.

However, even though these consumers see value in the information that pharmaceutical companies can provide, clear rules of engagement and regulatory oversight are part of that process. Barrette cautions that just "because it's 2010, because there's social media, because we're all just talking here [doesn't mean] that companies are relieved of [the] obligation to be regulated and watch out for misinformation." A majority of respondents agreed that a company's social media participation should be regulated both for content that they create and for content that they sponsor, but less than half thought that regulation should extend to comments from company outsiders.

WEGO Health's survey also suggests that although health advocates want regulation

of social media and the inclusion of balanced information, they want that in a form that doesn't interfere with the way they experience the medium. Within social media conversations, etiquette extends beyond regulatory guidelines. A company representative needs to stay within the norms of the channel in which they're participating, says Bridge Worldwide's Richman. If a company representative jumps into a patient discussion about treatment options and promotes particular products, they might offend the community, Richman adds. "They'll most likely be punished by those patients more than by DDMAC [the FDA's Division of Drug Marketing, Advertising, and Communications that reviews prescription drug advertising and promotional labeling]."

Two online diabetes communities, TuDiabetes.org (<http://www.tudiabetes.org/>; in English) and EstuDiabetes.org (<http://www.EstuDiabetes.org/>; in Spanish), have already been navigating this terrain with industry representatives. Founded in 2007 by Manny Hernandez, president of the nonprofit organization Diabetes Hands Foundation, in Berkeley, California, the two communities have more than 20,000 members combined. In August 2009, a Roche representative joined TuDiabetes to post some information clarifying an FDA warning regarding a glucose meter that Roche produces. In that situation, Hernandez says, "there was clear value, clear benefit" from the contribution. Though this representative remains a member of the community, the post has been a one-time thing, Hernandez says.

But that doesn't mean that his community is ready for an influx of paid pharmaceutical representatives. In October, a pump company approached the TuDiabetes administrators asking if an embedded clinical manager could join their community as a resource for questions about products. Hernandez posed the question to the TuDiabetes community with a mixed reaction. Even those who weren't opposed to the idea didn't necessarily see a compelling reason to include a representative from outside the patient community, Hernandez says. Following the community's wishes, he declined.

But the communities have partnered with industry on education and diseases awareness campaigns. LifeScan, a Milpitas, California-based device company (owned by J&J) that produces glucose meters, has licensed their idea for patient-submitted photographs, called Word in Your Hand, to use on a company-sponsored site promoting diabetes awareness. TuDiabetes.org also partnered with Boehringer Ingelheim in Ridgefield, Connecticut, on a video contest about diabetes and the five senses in 2009.

Hernandez expects that with clear regulatory guidance from the FDA, the benefits of

dialog among consumers and pharmaceutical companies will outweigh the risks. Right now, the concern for companies is regulatory uncertainty, he says. Trust is the vital issue for patients, and communities are looking to FDA to define the terms on which companies can participate. "Once there are guidelines, you know what the rules of the game are. You know what the participants in the conversation can do or not do, and you can call them on that."

Consumer watchdog organizations are less enthusiastic about the moves of the drug industry into social media. As a public health agency, FDA should first look for evidence of health benefit from social media and that consumers comprehend risk and benefit information, says Allan Coukell, director of the Pew Prescription Project in Boston. "Before we create whole new modes of marketing, we should look for that information."

With conventional drug advertising, notes Diana Zuckerman, director of the National Research Center for Women and Families in Washington, DC, at least you have a clear idea of who is sponsoring the information. Anonymity is relatively common on the internet, however, raising concerns that a reader might not be fully informed of a poster's motivations or financial involvements. Social media is complicated, Zuckerman says. "You've got free speech issues. You've got motivational conflict-of-interest issues. There's a lot going on."

Navigating uncertain regulatory terrain

Most of the discussions at the FDA hearings boiled down to the question of whether FDA would allow presentations of risk information to differ depending on the media format, Richman says, much like the exceptions that exist for direct-to-consumer television ads. In those cases, advertisements have to both summarize risk information and provide additional ways that consumers can get more information through an internet link, toll-free number or print information. Stakeholders agree that descriptions of risk and benefit should be presented in ways that offer consumers meaningful, understandable information. Some of the lengthier descriptions might prove unwieldy in some new media environments, including Facebook status updates or on patient-sponsored forums, Richman adds.

But there's currently little consensus as to exactly how to make those messages both complete and short. "We need to get toward the idea that we're presenting information about treatment that should help someone with some sort of problem. In some cases, there's going to be some risks associated with that, and we have to be upfront with what those risks are," says Bhargava.

Some media channels, such as Twitter with its 140-character limit, present particularly challenging constraints. Within such a limited space, complete information about a drug requires directing the reader to another location, typically another website. As a result, many question whether Twitter should be used to promote products. On the other hand, FDA itself has used Twitter to announce drug approvals, presenting headlines of a news release followed by a link, suggesting that there may be responsible ways to use Twitter to talk about products.

Previously, many companies and marketers had assumed that a 'one-click' rule would satisfy fair balance requirements: as long as any internet advertisement contained a direct link to a webpage with the risk and benefit information, it would be in compliance. But the FDA struck down that notion in April 2009 when it issued warning letters to 14 pharmaceutical companies who had posted short online ads to appear in search engines, indicating that the ads did not include risk information.

Next steps

The FDA's public comments period closed on February 28. In the coming months, the agency will be deciding if additional guidance on social media is needed, and, if so, what kind. In the meantime, companies face two less than ideal options. If they wait, they may end up far behind their competitors with social media marketing. If they choose to move into social media, they will need to develop their own internal policies to stay within DDMAC guidelines. "The only solution beyond just waiting for some magical guidance from the FDA is going to be that the industry needs to come up with best practices on their own that they start to follow," says Bhargava. Though that will be a brave step for some companies, he expects that once a group of companies craft policies that are successful, "others will start to do that as well."

Jean-Ah Kang, special assistant to the DDMAC director, provided advice to companies interested in social media but wary about the regulatory climate in a January 28 conversation with Gratton². "I think having robust policies in place, regardless of whether the decision is made at the end of the day to engage or not, is a starting point." But she also urged companies to be careful. "If you choose to do promotion in that area just make sure that what we're looking at is in the best interest of public health."

Sarah Webb, Brooklyn, New York

1. Fox, S. & Jones S. *The Social Life of Health Information*. (Pew Research Center, Washington, DC, June 2009).
2. Gratton, F. A conversation with DDMAC's Dr. Jean-Ah Kang <http://fdasm.com/docs/FDA_Ignite_012810_Interview_Transcript.pdf>