

# Antisocial Media

Without clear guidelines for social media, pharma marketers are left sitting on their hands. **Ben Comer** examines the challenges and innovations needed to move ahead

The potential value of social media as a platform for pharmaceutical promotion and education can hardly be overstated, given the scale and targeting precision inherent in the medium. So why aren't pharmas jumping in with both feet?

Despite some experimentation with the space in 2008 (Johnson & Johnson's acquisition of the Children with Diabetes social network), and a learning experience or two (Shire received a warning letter about a video on YouTube), new regulatory problems have surfaced. What is surprising about these new problems is that they are happening internally, in board rooms, rather than publicly, in the form of DDMAC back-and-forths. FDA has been conspicuously silent regarding guidelines for new media advertising, referring questions to longstanding policies governing journal advertising and promotion.

"By now, every major pharmaceutical company has a Web 2.0 task force," says Marcia Harwitz, director, healthcare pharmaceutical engagement marketing at Razorfish. Within these task forces are two different and many times oppositional factions: marketers and lawyers. According to Alan Minsk, partner and chair of the food & drug practice team at law firm Arnall Golden Gregory LLP, in-house regulatory and legal staff are facing increased pressure to do more. "From a regulatory perspective, the more control [over a given website or online community]

## Culture Clash

### ■ Fair Balance

Real-time conversations aren't usually annotated, but marketers need to create ways to present fair balance without being disruptive. Incorporate risk information seamlessly.

### ■ Adverse Events (AE)

The more personal info required in signing up for a sponsored online community, forum or blog, the more a sponsor will need to investigate AE discussions. Create a self-reporting mechanism for consumers to report AEs.

### ■ Off label

Off-label discussions are off limits on a company-controlled online venue. Research third-party websites, gather information, and put up ads where appropriate.

a company is willing to give up, the better. From a marketing perspective, the more specific consumer information obtained, and control exercised, the better. That creates tension," says Minsk.

As marketers have become more sophisticated online, simply directing consumers to a webpage or getting them to click on a banner isn't sufficient. In order to deliver personalized content that's relevant and engaging to a consumer, marketers need to acquire personal information. That presents a problem, since social media exists to foster free-flowing online conversations. If commentators on a corporate-owned and controlled forum, blog or social network, for instance, are discussing that company's prescription product, two major legal issues could arise.

The first is adverse event (AE) reporting. If a company wants to control a site where consumers are invited to comment, it will either need to have a "huge back-end department" to screen comments for objectionable content, or it will have to "develop a policy that absolves [the company] from liability," says Harwitz. What does that policy look like? "It depends on the company," says Harwitz. If people aren't asked to identify themselves in a meaningful way, a company may not be obligated to report potential AEs posted online. Additionally, some companies are piloting reporting techniques whereby consumers are offered a mechanism to report AEs

directly on the site, by email submission or phone.

At a digital pharma conference last October, Craig Audet, vice president, US regulatory affairs, marketing products at Sanofi-Aventis, enumerated the four FDA criteria necessary to file an AE report: an identifiable patent, an identifiable reporter, a specific medication and an adverse experience. “What is the due diligence on finding out who an AE commentator is [online]?” asked Audet, before answering his own question: “There isn’t an answer out there.”

In the absence of clear guidelines, a company must at the very least investigate a post related to an AE, to check the credibility of the commentator, says Minsk. “FDA is not expecting you to hunt down information, but if you’re controlling the content, you’ll want to be able to show that you’ve investigated.” If a company isn’t controlling the content, in the case of a third-party forum, blog or social network, it probably isn’t as liable for the content, notes Minsk.

The second major concern deals with comments regarding off-label uses of a given product. “Off-label discussions should be avoided on company sponsored websites, communities, KOL blogs and other



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*Alan Minsk, partner and chair of the food & drug practice team at Arnall Golden Gregory LLP*

tion by noting that CWD’s charter will continue to exist “as an unbiased, independent voice for the diabetes community... That means we will continue to invite support from, and encourage participation by, ALL companies involved in making a difference in the lives of our families.” According to the community’s terms of use, “commercial advertising or product promotion of any kind is prohibited.” Although J&J is prohibited from advertising on the network directly, LifeScan’s OneTouch UltraSmart product managers have entered chat rooms to answer questions from CWD members, for example.

GlaxoSmithKline’s online community and blog for weight loss treatment Alli is widely cited as a stellar example of pharma entering the social media sphere. However, Alli is an OTC product, and not subject to AE reportage and off-label promotion.

Third-party social networks and video hosting sites, such as Facebook and YouTube, provide marketers with access to large swaths of consumers seeking specific health information. But pharma’s participation with Facebook has been limited so far, although Abbott and J&J’s McNeil Pediatrics have made some inroads by establishing groups based on disease states—ADHD Moms, for McNeil, and an HIV PSA campaign with Magic Johnson, for Abbott. Pharmaceutical product-specific marketing, however, is still absent from the site. Several pharma have created YouTube channels, but the comment feature available to YouTube users is either disabled or heavily monitored and screened for objectionable content. Disabling comments on YouTube or Facebook prevents a two-way conversation with consumers, rendering the “social” media elements decidedly antisocial.

DDMAC’s warning letter to Shire (following a company-sponsored YouTube video testimonial featuring Ty Pennington) made waves among marketers, since it represented the first and only public statement made by FDA that is even peripherally related to YouTube. DDMAC said the video overstated the efficacy of Adderall XR, and also omitted risk information. Marketers concluded from the letter that DDMAC is requiring fair balance information to be included within any corporate-sponsored video disseminated online. “Pharma companies have to think of innovative ways to get around fair balance,” says Harwitz, if they hope to enter the social media platform in a meaningful way. That will require a certain amount of company brass. “If you’re going to engage in this type of media, you’re going to have to take some risks.”



## Hitchcock addressed J&J's acquisition of CWD, saying it would continue as an unbiased source for diabetes

media, but banner ads, for example, on independent sites where content isn’t controlled by the advertiser, are not violative,” said Mark Gaydos, senior director US regulatory affairs, marketed products at Sanofi-Aventis, at the digital pharma conference. “The analogy would be a reprint of an ad in a journal [containing off-label product content].”

Jeff Hitchcock founded the aforementioned Children with Diabetes (CWD) social network in 1995. Johnson & Johnson, which owns LifeScan, a leading manufacturer of blood glucose monitoring systems, acquired the property last March. In a letter to the CWD community, Hitchcock qualified the acquisi-