



## CONTACT INFORMATION

1000 Park Forty Plaza  
Suite 440  
Durham, NC 27713

P: (919) 403-6583  
F: (919) 433-0220

[connect@cuttingedgeinfo.com](mailto:connect@cuttingedgeinfo.com)

## ePHARMA TOPICS

Casey Ferrell recently developed a benchmarking report on digital marketing topics ranging from social media and mobile technology to marketing integration and regulatory compliance.

To find out more about the research, follow him on Twitter at:



Or join his LinkedIn network:



Reach him by phone at +1 (919) 403-6583 or by email at [casey\\_ferrell@cuttingedgeinfo.com](mailto:casey_ferrell@cuttingedgeinfo.com).

# Making Sense of Social Media in a Regulatory Vacuum

By Casey Ferrell  

Research Analyst, Cutting Edge Information

*This is the first in a series of white papers by Cutting Edge Information addressing the multi-faceted, rapidly changing ePharma landscape. Social media is transforming marketing departments at companies large and small across the globe, offering them unprecedented new ways of communicating with consumers. The highly regulated pharmaceutical industry is understandably cautious of joining the fray given the current regulatory vacuum, but while its participation lags behind other, less regulated industries, companies around the world are taking the inevitable first steps into the void.*

*Some have been met with success; others have provided lessons in what to avoid. Best practices are developing organically from the experience, expertise and enterprise of individuals and teams executing new, integrated communications strategies. These white papers will address topics ranging from the regulatory and legal environment to benchmarking, from policy and procedure to the people that carry them out.*

## The Wait for FDA Guidance Continues

Twitter recently turned five years old. The social media platform now generates one billion tweets per week, reaching a global audience of some 200 million people, a number four times higher than just two years ago. Facebook, with more users than the entire population of the U.S. and U.K. combined, overtook Google to become the most visited website on the Internet in 2010 and is forecast to generate more than \$4 billion in ad revenue in 2011. More than 30 billion pieces of information are shared on Facebook every month. More than 60% of people online use the Internet to research healthcare, mainly seeking information about drugs. These staggering statistics underscore the way in which social media has changed the very nature of business-as-usual.

As a result, businesses — large and small, local and global, from all sectors of the economy — are scrambling to find their digital voice, join the conversation and learn to manage, market and monetize their brand on the so-called Web 2.0. The life sciences industry, however, has by and large adopted a “nothing ventured, nothing lost” approach to social media.

Among the most highly regulated industries in the world, pharma has rightly developed a conservative business model, often letting other industries experiment with new technologies and practices until a consensus is reached on the most prudent ways to use them. Ironically, when it comes to social media and the Internet at large, a notable lack of regulation is holding the industry back.

[The FDA missed its second self-imposed deadline](#) for the release of its much-anticipated draft guidance on the use of social media and the Internet. To the consternation of the

life sciences industry, there appears to be no reliable timetable for when the FDA will get around to publishing the document. So while in the U.S., the industry remains in the dark as to what it can and cannot do with social media, agencies elsewhere are taking the lead.

## British Trade Association First to Weigh In

Like the FDA, the European Medicines Agency (EMA) offers no guidance on the use of social media. That has not stopped one European trade association from weighing in on the subject. The British Prescription Medicines Code of Practice Authority (PMCPA) released its own informal guidance on how to use digital communication. The PMCPA oversees the self-regulatory code of the Association of the British Pharmaceutical Industry (ABPI), the equivalent of PhRMA in the U.S.

[In the guidance](#), the PMCPA offers some insight into how it sees social media within the larger framework of its ABPI Code of Practice and poses answers to some of the questions the FDA is expected to tackle with its delayed guidance.

It should be noted that the FDA may not release a comprehensive guidance addressing all of the topics, instead accomplishing this through multiple guidance releases. An FDA spokesperson told *PR Week*, which broke the news that the agency would miss the second deadline, that the delays stem from the careful vetting process that guidances undergo as well as the need to make the guidance applicable to the general practices of utilizing social media, as opposed to addressing specific platforms like Facebook and Twitter, which may or may not remain relevant in the rapidly changing social media landscape. All this amounts to evidence that the FDA is not likely to provide a prescribed

path for the successful use of social media any time in the near future.

But marketing professionals across virtually all industries attest to the importance of social media to brand management and perception. They are the eyewitnesses to a major shift in the dominant marketing paradigm, away from single-channel communication in which the communicator controls the message toward a new reality in which consumer-created content has at least as much if not more influence on a brand's success or failure. It's imperative for companies, regardless of industry, to learn how social media fits within their larger marketing mix and maximize the benefits social media offers while minimizing the risks it poses. Figure 1 reflects data from ongoing research by Cutting Edge Information showing the current percentage of of the overall marketing mix occupied by social media efforts.

What is the pharmaceutical industry to do, then? Some companies are at the vanguard with aggressive strategies to join the social media revolution. Others are still waiting on the sidelines. Regardless of pharmaceutical companies' level of participation, the need to forge ahead remains compelling. While the wait for the FDA to join the conversation continues, companies will read the tea leaves

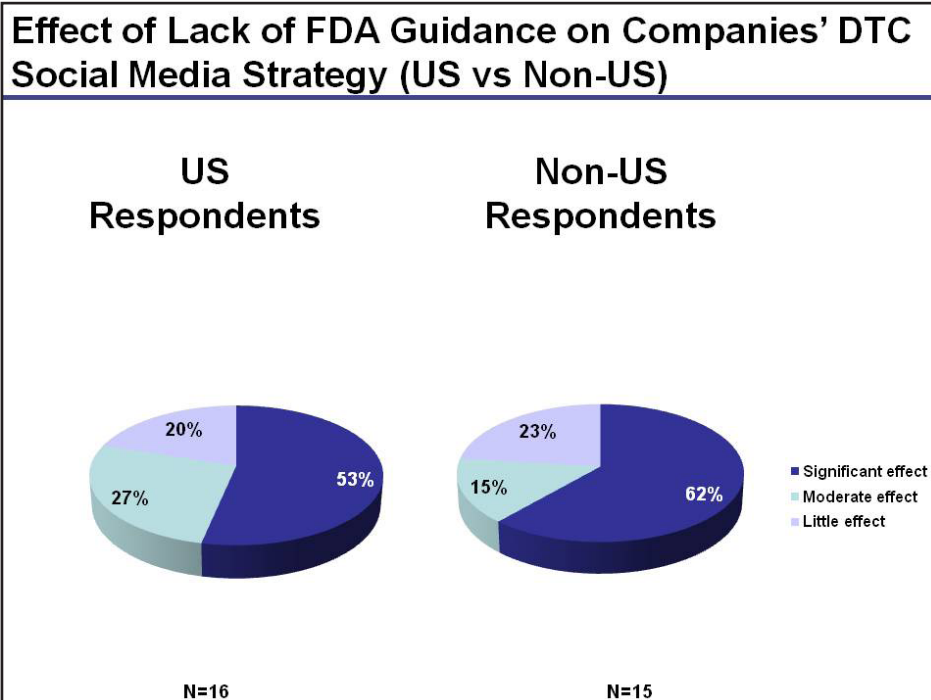


Figure 1: Survey respondents both within and outside of the U.S. feel the lack of FDA guidance has significant effects on strategy.

contained in the British trade association's self-imposed guidance for clues to how to proceed.

### Lessons From the PMCPA Guidance

Overall, the British guidance is in line with the stricter regulatory environment in the E.U., where DTC advertising is impermissible. However, informative parallels can still be drawn.

The guidance warns against any communication with the public that would be considered "promotional" according to previously iterated portions of the ABPI Code of Practice. Communicating with health professionals via social media platforms, therefore, is problematic because there may be no guarantee that the message will not transmit beyond the intended audience to the public at large.

The guidance, written in the question-and-answer format, answers the question, “Can pharmaceutical companies communicate with health professionals via social media?” with the following:

“The use of social media to promote, increase awareness and encourage engagement with health professionals about prescription medicines is very likely to be seen as promotion as set out in [the Code]. Pharmaceutical companies are allowed to promote their medicines to health professionals and the Code will apply whether the setting is a face-to-face meeting, through the distribution of paper-based or electronic promotional material, on a social networking site, in an online forum or by email.

If a company wanted to promote a medicine via Twitter it would have to ensure that if the medicine was prescription only, the audience was restricted to health professionals and that the message, in addition to any link to further information, complied with the Code. In addition companies would also have to ensure that recipients had agreed to receive the information. Given these restrictions and the character limit on Twitter, it is highly unlikely that the use of this medium to promote prescription only medicines would meet the requirements of the Code.”

The portion of the code in question differentiates between “proactive” information (i.e. promotional, and therefore not permissible) versus reference or reactive information (permissible). It will be of great interest to European operations to see where the PMCPA draws the line for social media. As BayerUK found out this year, Tweets mentioning a product name and an indication with a link to an approved press release were found to be in violation of the code and were viewed to be promoting a drug to the general public, an

“Some companies are at the vanguard with aggressive strategies to join the social media revolution. Others are still waiting on the sidelines. Regardless of pharmaceutical companies’ level of participation, the need to forge ahead remains compelling.”

obvious non-starter in any EU market. Indeed, the early returns on the PMCPA’s view of Twitter as a communication channel paints a picture of strictly limited use.

While the guidance advises companies to avoid disseminating unsolicited material, it does leave room for them to respond via social media to consumer questions (reactive) and to provide basic information for general consumption (reference), so long as it is not promotional in nature. In fact, the guidance codifies this by answering the question, “Can pharmaceutical companies use social media to communicate with the public?” in the affirmative, so long as it complies with the existing code.

What this means to marketing efforts in the U.K. is clear: social media cannot be used to promote brands or products, but it can be used for other kinds of communication. This is heartening to companies in the U.S., which are learning that social media platforms are relatively poor commercial advertising channels but hold great promise for other marketing functions such as brand building, customer service, corporate communications, public relations, and patient compliance and adherence, among others. The opportunity to

continue using social media as a means toward these ends remains open.

The guidance also touches on adverse event reporting, suggesting that any adverse event that is discovered by a pharmaceutical company on a site that it sponsors must be reported, if it meets the reporting threshold. It leaves unanswered the bigger question of whether such events found on third-party websites must also be reported. However, the widely cited concern by companies that engaging in social media will lead to the discovery of countless adverse events [is not supported by research](#). The ABPI later released a separate Q&A document providing further clarity on AE reporting.

Of note is the guidance's discouragement of several online activities. Companies making corrections to Wikipedia, for example, are urged to link simple cross-references to regulatory documents, but not individual portions of them. Similarly, the PMCPA raises the issue of whether a company making one correction to an entry would then be beholden to track, verify and authenticate any — and all — future edits to said page. Another interesting note from the guidance comes from its recommendation on linking to outside websites from a company's own website. It suggests the content found on the outside website would be subject to the Code of Practice in the same way the company's own website would. No mention is made with regard to links placed in non-owned, third-party channels, such as Facebook. But the prevailing wisdom is that a company's Facebook page or Twitter account have, in essence, the same propriety as the company's own website and links from those locations would be subject to the same scrutiny. This will prove problematic in social media exchanges, in which link-sharing is a form of currency popular among peers.

Visit our website, [www.CuttingEdgeInfo.com](http://www.CuttingEdgeInfo.com), where you can find our ongoing surveys. Participants who complete a survey will receive a complimentary summary of the resulting report's findings. Survey participants who agree to a brief interview will receive a complimentary copy of the entire report.

Finally, the guidance warns companies against blog sponsorship, either of their own or of those belonging to outside thought leaders. The nature of a blog, the guidance states, is such that a company will never have adequate control over the parameters of the discussion to the degree necessary to avoid comments by the author or the audience that violate the code.

Overall, the guidance issues some fairly stern criteria for certain types of digital communication, but it leaves the door open on one of the most important functions of social media: engaging with consumers, patients, physicians and pharmacists in online conversation. So long as it cannot be construed as promotional, according to the ABPI, the ongoing dialog can continue. Whether and when the ripples of this first attempt at digital communication guidance are felt across the pond remains to be seen. [PhRMA indicated it has no plans to issue a preemptive doctrine](#) of its own before the FDA releases its long-awaited guidance, but PhRMA did publicly call out the FDA recently for its delay. Two years after holding public hearings on the topic, pressure is mounting for the FDA to deliver on its promise.