Social Media Marketing Can Be Embraced Safely With A Social Media Implementation Plan.

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Although most pharmaceutical companies continue to deal with challenges that could threaten their reputations and ability to manage risks, it comes as no surprise that many pharmaceutical companies are planning to invest large sums of money into effective social media marketing strategies from 2010 through 2015. This will be challenging from both a legal and marketing perspective while the industry awaits guidelines to follow. However, as with other industry areas under increased scrutiny, pharmaceutical companies need to adopt a proactive approach to use social media in their online marketing mix. Such an approach would effectively deal with potential violations and/or complaints as they happen, and help a company's ongoing efforts to rebuild its positive reputation among medical professionals, patients and regulatory bodies. Moreover, a government investigation could be headed and/or damages mitigated if a complaint should occur.

Pharma marketers are intimidated by social media for several reasons: (1) lack of control over brand messages; (2) fear of violating the U.S. Food and Drug Administration's ("FDA") cloudy regulations; and (3) the threat of class-action lawsuits brought as a result of consumers using social tools to report adverse drug effects. Indeed, in 2009, the FDA sent letters to 14 pharmaceutical companies stating that their search ads needed to include drug risk information in the text of the ads, causing marketers to pull these ads and become more cautious about their web promotion.[i] As a result, industry marketers are struggling to determine how to monitor social media -- in part to report adverse effects of their drugs and products as required by the FDA.

Last November, the FDA asked for public comments regarding how pharmaceutical companies should be held accountable for a communication about its product(s) and how much control they exert over activities on the Internet, regardless of whether the promotional activity occurs on company-sponsored venues or on third-party venues.ii Related to this, the FDA also asked whether or not pharmaceutical companies should correct misconceptions or misinformation about their products, including unapproved uses of their products that are being conveyed on a Web site outside their control, such as on a blog, social networking site, or a wiki Web site (i.e., Wikipedia). A substantial portion of the comments submitted to the FDA by the drug industry was devoted to the accountability issue and the related issue of correcting misinformation on social media sites.iii Key questions raised centered around: (1) who controls the content; (2) whether some communications are of no concern to the FDA; (3) owned, earned and shared media; (4) alternative schemas; (5) accountability; (6) what conversations constitute advertising; (7) content syndication; (8) user-generated content; (9) patient advocacy special case; and (10) safe harbor provisions for misinformation corrections. Additionally, it did not go unnoticed that the expansion of social media marketing creates the potential for inappropriate monitoring of online patient discussions.

If there is anything to be learned over the past couple of years it is that companies need to become more proactive and integrative in a broad range of substantive compliance strategies which include implementation of policies and procedures and monitoring. It is therefore imperative for pharmaceutical companies who are launching social media site initiatives to have a social media implementation plan in place despite the fact that the FDA has not yet squarely addressed the role of social media in drug advertising. Such a plan should include actions such as:

(1) Social Media Policy ("SMP") – include a notice of company transparency/disclosure and other policies relating to social media. This policy should apply to all social media activities whether owned or sponsored by the company.
(2) Social Media Guideposts – SOPs (internal and external)
(3) Social Media point person: someone who oversees all of the company's social media projects to assure compliance with guidelines.
(4) Become a dialogue company – learn how to listen and respond, not just push messages out (i.e., tweet)
(5) Monitoring – companies should monitor social media sites for unauthorized use or modification of its approved content and make a best effort to remove or correct the content.
(6) Third-party Disclosure and Disclaimer Policy for content involvement/influence
(7) Develop a moderation strategy
(8) Have all employees – including executives – on board
(9) Have a sustained vision/goal

While the implementation of an effective Social Media Implementation Plan may require reallocation of existing resources, the long-term benefits of establishing such a program significantly outweigh the initial costs. With these safeguards in place early on, companies will be better prepared if and when the FDA provides the industry with explicit guidance, and could potentially be viewed by the government as acting reasonably if forced to retroactively address a complaint and/or mitigate damages.

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[i] *See* http://online.wsj.com/article/SB10001424052748703808904574528284195982904.html.
[ii] *See* http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm184250.htm.

[iii] *See* http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm192703.htm (listing November 12, 2009 and November 13, 2009 FDA "Presentations from Public Hearing on Promotion of FDA-Regulated Medical Products Using the Internet and Social Media Tools").