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# Medical Device Companies' Concerns About Social Media Remain Justified

***Medical Device Law Update***

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Consumers increasingly rely on the Internet and social media outlets such as Facebook, Twitter and Wikipedia for health information. In 2009 alone, more than 80 million consumers, about 35 percent of all U.S. adults, used social media for health and medical purposes. And a whopping 8 in 10 Internet users, or 61 percent of U.S. adults, have researched online for health and medical information. Despite consumers' growing dependence on this medium for health information, the Food and Drug Administration (FDA) has not yet issued definitive regulations or guidelines addressing drug and device manufacturers' use of social media to market their products. For this reason, medical device companies understandably have been reluctant to use social media to provide even the most basic information about FDA-regulated products for fear of criminal investigations, government fines and civil lawsuits.

The industry's reluctance appears to be well founded as demonstrated by the FDA's most recent enforcement action concerning promotional materials. On August 4, 2010, the FDA's marketing regulatory arm, the Division of Drug Marketing, Advertising, and Communications (DDMAC), posted to the FDA website a notice of violation letter ("untitled letter") to a major pharmaceutical company. The letter accuses the company of using the popular social networking site, Facebook, to improperly promote its leukemia drug. According to the letter, the company's U.S. website contains a "Facebook Share" widget that allows Facebook users to share company generated information with other Facebook users (i.e., "shared content").

The "Facebook Share" widget is a clickable button placed by the company on the webpage for the leukemia drug. Visitors are able to share the webpage by clicking the button, which generates shared content - a link and brief description of the webpage for the drug - to be shared with the Facebook user's friends. For example, shared content from a "Facebook Share" widget from one of the consumer WebPages for the drug makes a claim that it is a "next-generation treatment for Ph+ Chronic Myeloid Leukemia in adult patients in chronic or accelerated phase who are resistant to Gleevec."

The FDA alleges that the above shared content, and similar shared content, contain false and misleading information about the drug's risks and benefits. "The shared content is misleading because it makes representations about the efficacy of (the drug) but fails to communicate any risk information associated with the use of this drug," said the FDA letter, signed by Karen Rulli, acting group leader of DDMAC. "In addition, the shared content inadequately communicates (the drug's) FDA-approved indication and implies superiority over other products," by claiming it was a "next generation" treatment, Rulli wrote.

Medical device companies can take the following lessons from this company's experience:

- **FDA Focused on the Content, Not the Medium:** The DDMAC's focus was not on the social media aspect of the information, but on the company's violations of existing FDA guidelines. DDMAC applied the same standard to the company's shared content for its leukemia drug as it does to all forms of medical product marketing. In other words, regardless of medium, a medical product manufacturer should not omit risks, broaden indications, provide unsubstantiated superiority claims, or overstate the efficacy of a medical product.

- **FDA Reaffirmed That It Does Not Recognize the One-Click Rule:** The DDMAC reminded the company that if risk information is not contained in the original shared content, the inclusion of a hyperlink to websites that do contain risk information is insufficient to mitigate the violation.

Although not the first shot across the bow, the FDA's latest actions suggest that it is serious about policing the Internet and various forms of social media in the future. Until the FDA issues formal guidelines or promulgates new regulations regarding these types of communications, medical device companies must presume that the FDA will review any existing social media communications under existing FDA regulations. For that reason, companies must develop consistent policies governing employee use of social media; closely monitor and enforce these policies; and track FDA warning and untitled letters to avoid an enforcement action by the FDA.

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