

“What keeps you up at night?”

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FDA, pharmaceutical industry and internet search providers meet to discuss online drug ads

By Bruce D. Armon and Amy L. Piccola

On November 12-13, 2009, the Food and Drug Administration (“FDA”) held a public hearing titled “Promotion of FDA-Regulated Medical Products Using the Internet and Social Media Tools.”

The stated goal of the hearing was to help guide the FDA in making policy decisions regarding the promotion of pharmaceuticals and medical devices via the Internet and social media tools such as Facebook and Twitter.

The pharmaceutical industry’s use of online advertising has been hindered in the past by a lack of guidance from the FDA on how guidelines for advertising in traditional media outlets translate to the Internet. In fact, in 2008, drug manufacturers spent over \$3 billion on television and magazine ads and only \$130 million on Internet ads — a startling disparity in spending in light of the fact that an estimated 83% of Internet users search for health information online.¹

The FDA currently requires that all advertisements containing the brand name of a prescription drug also contain a disclosure of risks and contraindications. These requirements do not take into account the limited copy space of online ads. In March 2009, the FDA sent warning letters to 14 pharmaceutical companies alleging that the companies’ Internet search ads violated these guidelines by providing benefit, but not risk or contraindication information. The FDA’s letters focused on sponsored links that are typically generated when Internet users type the name of a disease or product into a search engine. The immediate result of the warning letters was a marked decrease in the number of online drug ads and increased demands by the pharmaceutical industry for more guidance from the FDA.

Prior to the November 12-13 meeting, the Pharmaceutical Research and Manufacturers of America (“PhRMA”), highlighted the benefits of online communication and urged the FDA to adopt guidelines that would allow the pharmaceutical industry to take advantage of the medium. During the hearing, PhRMA suggested that the FDA adopt an easy to recognize logo that would act as a

¹ *Drug Makers to Press for Guidance on Web Marketing*, THE WALL STREET JOURNAL, B4 (Nov. 12, 2009).

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“stamp of approval,” indicating to consumers that they were visiting a legitimate site with accurate information. Critics of PhRMA’s recommendation were not sure whether this is feasible due to the ever-changing content of webpages.

Among the pharmaceutical companies presenting were Eli Lilly, Johnson & Johnson and Pfizer, each urging the FDA to adopt guidelines taking into account the specifics of online advertising. During the hearings, representatives of Internet search engines, including Yahoo! and Google, also provided comments. According to a Yahoo! spokesperson, online drug ads have “lost the clarity and the transparency for the users” since the FDA sent its warning letters in March 2009. After the FDA sent the letters, the pharmaceutical industry, to eliminate the need to fit the information required by the FDA into limited copy space, created advertising that does not mention brand names. In its testimony to the FDA, Yahoo! suggested implementation of guidelines that require search ads’ landing pages, but not the ads themselves, to contain all of the required safety information. Google, during a much-discussed presentation, suggested that “product claim” ads include a warning line with up to 62 characters’ worth of information on contraindications and a link to more information. The company also suggested that “Black Boxed” sponsored links should contain a warning line including a safety and prescribing statement.

The FDA will continue to accept comments on this issue until February 28, 2010. It is not expected to issue guidance in the near future. If you require assistance with providing comments to the FDA or have other questions regarding Internet advertising, please contact the authors of this Alert or any other member of Saul Ewing’s Life Sciences Practice Group.

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