FDA on warpath for Google links

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Last month, the industry was taken aback by a spate of warning letters issued by the US Food and Drug Administration (FDA) to 14 companies over sponsored links to their drugs on the internet. The crackdown is seen by some as a signal that the FDA is taking a hard line under President Barack Obama.

Although warning letters have targeted internet ads before, this is the first time sponsored links have been specifically targeted. These are the promotional blurbs that are listed on the right-hand side of search engines, such as Google. Companies with letters include big pharma, such as GlaxoSmithKline in Brentford, UK; Johnson & Johnson in New Brunswick, New Jersey; Eli Lilly in Indianapolis; Merck in Whitehouse Station, New Jersey; Novartis in Basel; and Pfizer in New York; but also big biotech firms with products, such as S. San Francisco, California–based Genentech and Cambridge, Massachusetts–based Biogen.

The agency's Division of Drug Marketing, Advertising, and Communications (DDMAC) sent the letters "to convey the message that there's a new sheriff," says attorney Edward Allera, who chairs the FDA/biotech section at Washington, DC–based Buchanan Ingersoll & Rooney. "It's part of setting the tone that we're going to see," he says.

FDA spokesperson Rita Chappelle explains that violations were found during "regular monitoring and surveillance of direct-to-consumer [DTC] ads." Promotional materials must disclose risk information, so when a drug's benefits are touted whereas risks are left unmentioned, warning letters are issued at once. This time, the offending ads involved 48 separate drugs, including 19 with serious risks listed as warnings on their boxes.

For example, the Google blurb for Biogen's Tysabri (natalizumab) reads only: "Multiple Sclerosis? Satisfied with your MS medication or looking for something different? www.tysabri.com." Chappelle adds that it is not enough to say that risk information can be found by clicking on a website link. "If we saw an ad on TV for the benefits of Levitra [Bayer's erectile dysfunction drug] and a phone number to call to find out about risks, would that be a level playing field?" she asks. (Bayer Healthcare, of Wayne, New Jersey, was among the companies to get a letter.)

The agency does not regularly monitor the internet, argues Peter Pitts, president of the Center for Medicine in the Public Interest in New York and formerly an associate commissioner at the FDA. "They have neither the expertise nor the manpower. If they did, they would have [cracked down on sponsored links] five years ago," he adds. Pitts, who helped draft most of the FDA's current guidance on direct-to-consumer advertising, is also director of global healthcare at Porter Novelli, a public relations firm.

Pitts notes that the FDA does not provide any specific guidance about pop-ups on search engines, so the DDMAC's letters came as a surprise to many in industry. "You can't simply make pronouncements based on how you felt on Tuesday when you woke up," says Pitts. "But they [agency officials] can feel the political winds. They know that more warning letters is going to be better than fewer." Drug companies will have to find ways to work with the tightened FDA, although 'fruitcake' medical claims by herbal vendors and others on the internet will continue unregulated, Allera points out.

The crackdown may have caught not only the industry off guard, but also the broader agency, which did not know DDMAC sent the letters until after the fact, sources inside the FDA told Pitts. Firms had 15 days to respond to the issues raised or face further action, according to Chappelle—but, a week after receiving the letters, most companies had scrapped their sponsored links. "What people do in these situations is simply pull back," Allera says, as none of them wants to make an enemy of the FDA with a legal challenge they might lose.

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