

FDA warning letters on internet ads unlikely to result in fines but could signal tighter regulation, sources say

by Marc Longpré in San Francisco and Jacqueline Kwong in New York

* Agency needs to address issue more fully, industry observers say

* Lawsuits could result from warning letters

Warning letters from the Food and Drug Administration to nearly all the major pharmaceutical companies regarding online advertising is unlikely to result in financial penalties but could be a signal the agency is set to crack down on direct-to-consumer advertising more generally, industry experts said.

The warning letters could also lead to lawsuits against the companies, with state attorneys general and plaintiff attorneys potentially aided by the agency's action, sources said.

The letters were sent to 14 major pharmaceutical companies, including Eli Lilly (NYSE:LLY), Merck (NYSE:MRK), Pfizer (NYSE:PFE) and GlaxoSmithKline (NYSE:GSK), and addressed the advertisements that run next to Google search results. Those advertisements needed to include the risk information relating to the specific drug being advertised, the letters said.

"A warning letter is a very significant thing for a company," said John Kamp, executive director of the Coalition for Healthcare Communications. "I'm fearful that this means a strange crackdown on FDA regulated information when all that unregulated information is out there."

Rahsaan Thompson, a partner with Quarles & Brady, agreed that the warning letters were being taken seriously by companies. Some companies are already amending their advertisements and ensuring that the internet banners do not refer to a specific brand or drug, he said. When consumers click on these banners, viewers are taken to the website of the drug or its manufacturer, he added.

However, these amended advertisements are only a temporary solution, said Thompson. Consumers are eventually going to complain that they are getting "duped" if a banner, with no mention of a specific drug or brand name, takes them to a pharmaceutical company's website, he added.

Although Thompson said he did not believe that the pharmaceutical industry would ignore these letters, he noted that potential fines would be hefty. The fine will depend on each situation and how many times the company is cited for a violation, but the FDA will not go easy on these companies and will issue large fines to set an example for the rest of the industry, he noted.

Kathleen Sanzo, a partner with Morgan Lewis, said she believed that companies were going to pour more resources into disease awareness websites as a result of these letters. While these sites are a less than an optimal method of product promotion, pharmaceutical companies will not be deterred from advertising on the internet, Sanzo said.

Companies are going to need to convince the FDA of the appropriateness of their internet ads, said Patrick Hurd, senior counsel at LeClairRyan. Drug makers are aware that the FDA can quickly curb the amount of internet advertising with really drastic actions, and companies are going to want to avoid any punishments, he added. Hurd noted that potential drastic actions would include fines and obtaining injunctions to prevent further internet advertisements from the company.

Kamp called the letters "startling" and said it was time the agency took a comprehensive look at the internet and social media and how it might improve regulated communications in the space. Separately, a source in Washington who specializes in health care issues said he still expects Congress to address direct-to-consumer advertising at some point. Rep. Henry Waxman (D-CA), chairman of the House Energy and Commerce Committee, has been vocal in his opposition to the ads. The source also said he expected state lawsuits to begin to address the online advertising issue.

The FDA is really trying to impose old-fashioned regulations to a new and modern form of technology, said Sanzo. Putting all of the information that is required by the FDA on an internet banner is going to be impossible, she added. "I just don't think this is going to work," Sanzo said.

Thompson agreed with Sanzo, and added that the FDA regulations have not caught up with the technology currently being used. Putting so much information on a small internet advertisement is not going to be very attractive to consumers, he said.