

Recent FDA Warnings Could Signify A Shift

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The Food and Drug Administration appears to be gearing up for a more activist role.

On April 2, the agency sent 14 warning letters to drugmakers regarding their advertisements. The list included Sanofi Aventis for Plavix ads, GlaxoSmithKline for Avandia and others, and Merck and Eli Lilly for Cymbalta.

The warning was not about drug safety. Nor was it about mislabeling, or off-label promotion.

The issue that riled the FDA was drug firms' paid search advertising on the Internet.

It appears to be a repeat of the FDA's efforts to regulate direct-to-consumer TV advertising by pharma firms.

The drug industry is preparing for more FDA actions, says Kathleen Sanzo, head of the FDA/health care regulation practice at international law firm Morgan Lewis. She spoke with IBD.

IBD: What is the top issue pharma will face with the FDA?

Sanzo: Our clients have many issues in terms of dealing with the FDA, but principal among them is how the FDA will deal with drug safety issues.

With the passage of the Food and Drug Administration Amendments Act (signed into law by former President Bush in 2007), there is a lot of flexibility for the FDA to figure out how to best approach drug safety.

The FDA has been making progress in terms of issuing guidance documents and having dialogues with industry about the best way to do that.

Many companies have been issuing Risk Evaluation and Mitigation Strategies (REMS). These are programs to manage drug safety once the product is on the market.

There are many varieties of REMS, and they incorporate new and novel approaches to communications with health care providers and consumers. The FDA has been useful in trying to give guidance to industry about how to structure, develop and refine REMS.

But there's a lot of work to be done to determine whether or not REMS are effective. They require the drug companies to explain how the REMS work to health care providers and consumers.

They're now part of the product approval process and they do add to the cost of pharmaceuticals. There's no doubt about it.

IBD: Does the FDA even have the horsepower to meet its own goals?

Sanzo: The lack of resources at the FDA continues to cause disruption and delay in getting pharmaceutical and other medical products to market. The FDA has fewer people and hours to do it. Some new money is supposed to flow into FDA to hire new folks.

It will take a long time to get the new people hired, trained and get them to a point where they're actually making a difference in the time it takes to get products approved.

IBD: Let's talk about the FDA's decision to require more post-marketing studies, like the one demanded of Bristol-Myers Squibb and AstraZeneca for approval of their diabetes drug, saxagliptin.

Sanzo: The FDA has the authority to require companies to determine that drugs continue to be safe after they're out in the larger population.

My view is that many companies don't mind doing post-marketing studies if that's the qualification to get their products to market.

IBD: Are you saying the industry is not resisting post-marketing studies?

Sanzo: I don't think they'd volunteer to do post-marketing studies if they didn't have to. It's obviously a cost. And the post-marketing study may cause changes to labeling, further restrictions on marketing of products, or the ultimate -- withdrawal from the market.

I don't think the industry believes that all drugs need post-marketing studies.

There are some drugs that are fifth or sixth of that type into the market and are chemically similar to the four that are already there.

IBD: What's your take on the warning letters to 14 pharmas about their online search ads?

Sanzo: I'm looking at the one for Tysabri, which is for multiple sclerosis (made by Biogen-Idec). The warning letter found this line objectionable: "Satisfied with your MS medication or looking for something different? Go to www.tysabri.com."

The FDA's position is that the reference to multiple sclerosis without further discussion about the particular indications around MS that were part of the approval of the drug --

and the failure to suggest that this drug is toxic -- undermines the risk associated with taking the drug.

I think if you were a consumer and you saw that, you would go to the Web site to get more information.

It's hard to understand the basis on which the FDA took that action. There is no indication the FDA has any data to support its position that consumers stop their searches for drug information when they get the ad that comes up first.

I don't know that the FDA has the expertise to understand how consumers are interacting with this type of digital media.

They're a scientific organization. They don't have the right experts to understand how consumers are using this information.