Ensuring That Consumers Receive Appropriate Information From Drug Ads: What Is The FDA’s Role?

FDA enforcement actions against false and misleading advertisements have dropped sharply in recent years, raising concerns over consumer safety.

by Henry A. Waxman

ABSTRACT: The promise of direct-to-consumer (DTC) prescription drug advertisements lies in their potential to educate consumers about medical conditions and the possibility of treatment. But this promise can only be fulfilled if consumers are given clear and accurate information. The responsibility for ensuring that this occurs falls on the Food and Drug Administration (FDA). Recent congressional investigations have indicated that the agency is failing at this task, as FDA enforcement actions against false and misleading ads have declined precipitously in recent years. Other FDA efforts, such as its recently released guidelines on prescription drugs, do not appear to be helpful, potentially confusing consumers more than helping them.

The promise of direct-to-consumer (DTC) prescription drug advertising lies in its potential to educate consumers about medical conditions and the possibility of treatment. But this promise comes with significant peril. The two April 28 Health Affairs Web Exclusives illustrate some of the problems raised by prescription drug advertising, making it clear that doctors and patients both need and want better information about advertised drugs.1 The responsibility for ensuring that this information is clear and accurate falls on the U.S. Food and Drug Administration (FDA).

For the past several years my staff on the House Government Reform Committee has been assessing the effectiveness of FDA regulation of prescription drug ads. We have found that although the law prohibits manufacturers from making false and misleading claims about their products, the FDA is doing a poor job of enforcing this essential requirement.

In November 2002 we found that FDA enforcement actions against false and misleading drug ads declined precipitously in 2002, falling by more than 70 percent compared with the period from 1999 to 2000.2 This decline could not be explained by a change in the number of drug ads reviewed by the FDA (which increased) or a drop in complaints about ad content (which remained constant).

We also found that there were often sizable...

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delays in enforcement actions, exposing millions of consumers to false or misleading advertisements for months before the advertisements were withdrawn. In one case, the FDA cited the manufacturer of the flu medication Tamiflu for a false and misleading advertisement in May 2002—two and a half months after the ad was submitted to the FDA and well after the end of flu season. Soon after my staff completed its investigation, the U.S. General Accounting Office (GAO) released an analysis that reached similar conclusions.3 In response to these investigations, newly appointed FDA Commissioner Mark McClellan pledged more aggressive enforcement of the law, promising to take stronger enforcement actions and to reduce the delays in responding to false and misleading advertisements.4

My staff revisited this issue in January 2004 in an effort to determine whether the FDA had made progress in enforcing provisions barring false and misleading advertisements.3 Despite the FDA's promises, the investigation showed a continued decline in enforcement. It also showed that FDA delays in responding to false and misleading advertisements are getting longer. In 2003 the average delay between the placement of a false and misleading ad and an FDA action in response to that ad was 177 days—almost six months. In one case, the FDA did not send a warning letter until more than a year after the false and misleading advertisement had first appeared. In another case, where the FDA found that an ad for Oxycontin “grossly overstate[d] the safety” of the medication, the agency did not send a warning letter until three and a half months after the ad had first appeared.

In addition, we found that FDA actions had little deterrent effect. The FDA's enforcement actions in 2003 were restricted to sending warning letters to drug manufacturers requesting that they cease running an advertisement. Although the FDA has the authority to take stronger actions with more deterrent effect, such as court actions or ultimately fines, the agency has not done so.

In this context, it is not surprising that consumers are frequently exposed to false and misleading advertisements. There simply is no incentive for drug manufacturers to tell the whole truth to consumers, and there is no real penalty for them if they do not.

More recent FDA actions leave little room for optimism. In February 2004 the FDA released two guidance documents regarding prescription drug advertisements, one focusing on the risk and side-effect information provided to consumers alongside print advertisements and the second focusing on “help seeking” and other disease-awareness ads by drug companies. Unfortunately, these new FDA policies do not get at the crux of the problem: the FDA's abysmal failure to take strong action against false and misleading claims in prescription drug advertisements. They include no FDA commitment of increased enforcement against such advertisements. And the new policies encourage manufacturers to run more “help-seeking” advertisements, ads that mention a condition but do not mention a particular drug or manufacturer. There are no FDA requirements regarding the provision of risk or other information for these ads, which means that the potential for consumers to be misled will increase.

The new guidelines also appear to open the door to abuse by drug companies in other ways. For example, the FDA recommends that manufacturers provide the side-effect and warning information that is listed on the back of print ads in more consumer-friendly language. I agree that these warnings are hard to read and should be made more understandable to consumers. But in an example provided with the guidance, the FDA suggests that drug companies replace a warning directed to physicians that a drug may cause “acute liver failure” with a warning to consumers that the drug “can affect your liver function.” This type
of language downplays legitimate risks rather than informing consumers.

There is one new proposal that, if implemented, could help give patients the information they need. It is a provision contained in the new Medicare bill passed by Congress in November 2003.

I did not support this bill, because I believe that the harm it does to the Medicare system outweighs its meager drug benefits. However, I do support the provision that authorizes the Agency for Healthcare Research and Quality (AHRQ) to review and conduct evidence-based research on the comparative clinical effectiveness of prescription drugs—especially those widely used by Medicare and Medicaid beneficiaries. The goal of this provision is to give consumers a source they can trust: reports from a knowledgeable federal research agency on the comparative effectiveness of different treatments. All too often, drug companies promote their drugs as being safer or more effective than the competition, based on poorly designed studies and questionable sources of information. This law allows AHRQ to act as a neutral referee, giving consumers and doctors unbiased information on which they can base decisions.

It is unclear, however, whether the president and the Republican Congress will fund this provision. Funding for the new AHRQ research was not included in the president’s FY 2004 budget, and it was also excluded from the budget recently passed by the House of Representatives. Absent this funding, this law will become meaningless, and consumers will continue to be at the mercy of drug manufacturers for the information they receive on drugs’ effectiveness.

The president and Congress can help patients and health professionals by providing the funding for AHRQ to conduct credible testing of the effectiveness of prescription drugs. This action, coupled with a renewed FDA effort to enforce laws against false and misleading drug ads, can result in a more effective and efficient health care system, in which patients and doctors can make better decisions about needed treatments.

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