Examining The FDA’s Oversight Of Direct-To-Consumer Advertising

The FDA’s role as consumer protector has been adversely affected by recent changes in the way it notifies companies of their violations of rules governing DTC advertising of prescription drugs.

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ABSTRACT: Our analysis examined the effects of the Food and Drug Administration’s (FDA’s) 1997 draft guidance regarding advertisements for prescription drugs broadcast directly to consumers. We found that although direct-to-consumer (DTC) advertising spending by pharmaceutical companies has increased, more than 80 percent of their promotional spending is directed to physicians. DTC advertising appears to increase the use of prescription drugs among consumers. The FDA’s oversight has not prevented companies from making misleading claims in subsequent advertisements, and a recent policy change has lengthened the FDA’s review process, raising the possibility that some misleading campaigns could run their course before review.

From 1997 through 2001 prescription drug spending increased at an annual rate of about 18 percent, and spending on direct-to-consumer (DTC) advertising of prescription drugs rose nearly 150 percent. In their paper Joel Weissman and his colleagues discuss the potential health consequences of DTC advertising of prescription drugs. The U.S. General Accounting Office (GAO) recently issued a report that examined the extent, effects, and federal oversight of DTC advertising since the Food and Drug Administration’s (FDA’s) 1997 draft guidance on broadcast advertisements for prescription drugs. Here we summarize the findings of that report.

Scope of DTC ad spending. Between 1997 and 2001 spending for DTC advertising increased 145 percent, while other promotional spending increased 66 percent. According to industry estimates, in 2001 pharmaceutical companies spent $2.7 billion on DTC advertising and $16.4 billion on other promotional activities. Almost all spending on DTC advertising is concentrated among a small number of drugs that treat chronic conditions. For example, 86 percent of sales for the fifty most advertised drugs in 2000 were for drugs that treat allergy/asthma, arthritis, and high cholesterol. Most promotional spending is
targeted to physicians. In each year from 1997 to 2001, providing drug samples to physicians and sending sales representatives to meet with physicians accounted for more than 80 percent of promotional expenditures.6

Effect on use of drugs. Drugs that are promoted directly to consumers often are among the best-selling drugs, and sales for such drugs have increased faster than sales for drugs that are not heavily advertised to consumers. Most of the spending increase for heavily advertised drugs is the result of increased utilization, not price increases. For example, between 1999 and 2000 the number of prescriptions dispensed for the fifty most heavily advertised drugs rose 25 percent, but the number dispensed for drugs that were not heavily advertised increased only 4 percent.7

Similar to the findings reported by Weissman and colleagues, consumer surveys conducted by the FDA and others have consistently found that DTC advertisements influence consumers to ask their physician for a specific brand-name prescription drug. We found that the percentage of patients doing so was consistent across studies—about 30–35 percent of those who remembered seeing a DTC ad. In the consumer surveys we examined, about 5 percent of consumers requested and received a prescription from their physician for a drug they were not currently taking, in response to a DTC advertisement (the percentage ranged from 2 percent to 10 percent). By our estimate, this means that in 2000 about 8.5 million consumers received a prescription after viewing a DTC advertisement and asking their physician for the drug.8

Limits Of FDA Oversight

The FDA regulates the promotion of prescription drugs, including the content of DTC advertisements. Regulations require that advertisements present accurate information and fairly represent both the benefits and risks of the drugs being advertised. Under the regulations, pharmaceutical companies are required to submit all drug advertisements to the FDA for review when they are first disseminated to the public. In 1997 the FDA issued draft guidance to clarify and offer options on how these regulations applied to DTC advertisements on radio and television.

The FDA focuses its reviews on advertisements that will be widely circulated or that are the most likely to impart misleading impressions of a drug to consumers. For example, it reviews all broadcast DTC advertisements because of the large number of people who will see them.

Effect of the FDA’s regulatory letters. When the FDA identifies a DTC advertisement that violates FDA guidelines, it sends a regulatory letter to the company responsible for the advertisement, asking that the company cease disseminating the advertisement. From August 1997 through August 2002 the FDA issued eighty-eight regulatory letters for DTC ad violations.9 The FDA issues regulatory letters for only a small percentage of the advertisements it reviews. Between 1991 and 2001, for example, it issued letters for about 5 percent of the broadcast advertisements it reviewed.

FDA officials told us that pharmaceutical companies have complied with the FDA’s requests to cease dissemination of misleading DTC drug advertisements in every case to date. For that reason, and because the FDA does not want to remove a beneficial drug from the market, the FDA has yet to employ any of the harsher remedies available. For example, the FDA has not initiated court action to seize drugs for which advertisements are false or misleading, nor has it asked a court to stop the advertisement and direct the company to run a corrective campaign.

Repeat offenders. The FDA’s regulatory letters have not completely deterred pharmaceutical companies from making misleading claims in subsequent advertisements.
ing claims in subsequent advertisements. Since 1997 the FDA has issued repeated regulatory letters to several pharmaceutical companies, including fourteen to GlaxoSmithKline, six to Schering Corporation, and five to Merck and Company. Some companies have received multiple regulatory letters over time for new advertisements promoting the same drug. For example, the FDA issued four regulatory letters to stop misleading advertisements for the allergy drug Flonase marketed by Glaxo Wellcome in 1999 and 2000. The violations cited in the letters include unsubstantiated efficacy claims, lack of fair balance, failure to provide any risk information on the major side effects and contraindications of the drug, failure to make adequate provision for disseminating the product labeling, and failure to submit the advertisement to the FDA. In addition, in the past four years the FDA issued four regulatory letters to Pfizer regarding broadcast and print advertisements for its cholesterol-lowering drug Lipitor. Among other infractions, the FDA noted that the advertisements gave the false impression that Lipitor can reduce heart disease and falsely claimed that Lipitor is safer than competing products.

Limitations of FDA effectiveness. The FDA's ability to assess the compliance of pharmaceutical companies with its DTC advertising regulations is compromised because the FDA cannot verify that it receives all newly disseminated ads from pharmaceutical companies. The agency has issued six regulatory letters for misleading advertisements since 1997 that cited pharmaceutical companies for failing to submit their ads to the agency when they were first disseminated.

FDA officials told us that the agency contracts with a commercial service that monitors television advertising to find advertisements that pharmaceutical companies have failed to submit for review. However, the service does not identify all advertisements that are broadcast on smaller networks, such as some cable television stations, or in some local markets. Indeed, in one case a misleading advertisement was broadcast for two calendar years in Puerto Rico before the FDA became aware of it. A change in the Department of Health and Human Services (HHS) policy for reviewing regulatory letters in late 2001 has reduced the FDA's effectiveness in issuing regulatory letters in a timely manner—a key component of the FDA's oversight. Any inaccurate impressions of a drug that are caused by a misleading advertisement are minimized if the advertisement is quickly removed from dissemination. FDA officials told us that prior to the policy change, regulatory letters were issued within several days of the receipt of an advertisement identified as misleading. In late 2001 HHS instructed the FDA that no regulatory letters could be issued until the FDA's Office of the Chief Counsel (OCC) reviewed them. HHS implemented this new policy to ensure that all draft regulatory letters from the FDA were reviewed for "legal sufficiency and consistency with agency policy."

Since the policy change, OCC reviews of draft regulatory letters from the FDA have taken so long that misleading advertisements may have completed their broadcast life cycle before the FDA issued the letters. Five draft regulatory letters were submitted to the OCC between the date the policy took effect, 31 January 2002, and 5 September 2002 and were subsequently issued. The letters were issued from thirteen to seventy-eight days after they were first submitted to the OCC. We found that many television DTC advertisements are on the air for only a short time—about one-fifth of them for one month and about one-third for two months or less. Although we do not know the broadcast status of the advertisements targeted by the FDA's draft regulatory letters, misleading advertisements could remain on the air after they are identified if the FDA maintains its current review policies.

Concluding Comments

DTC advertising prompts millions of consumers to ask their doctors to prescribe specific brand-name drugs. As a result, the FDA must act effectively to minimize the public's exposure to misleading DTC advertisements. While the FDA's oversight is generally effec-
tive at halting the dissemination of advertisements it reviews and identifies as misleading, the recent change in procedures for reviewing draft regulatory letters directed by HHS has adversely affected the FDA’s ability to enforce its regulations.

This paper is based on the U.S. General Accounting Office report, Prescription Drugs: FDA Oversight of Direct-to-Consumer Advertising Has Limitations.

NOTES

2. The authors completed this report at the request of Senators Susan Collins (R-ME), James Jeffords (I-VT), and Barbara Mikulski (D-MD) and Representatives Joseph Hoeffel (D-PA) and Nick Rahall (D-WV). The full report is Prescription Drugs: FDA Oversight of Direct-to-Consumer Advertising Has Limitations, Pub. no. GAO-03-177, 28 October 2002, www.gao.gov/new.items/d03177.pdf (3 February 2003).


4. IMS Health, “Total U.S. Promotional Spending.”


6. These figures do not include educational meetings arranged by pharmaceutical companies for physicians, which are not generally considered to be promotional activities. Drug companies spent about $1.9 billion on educational meetings in 2000. Calculated from figures provided by PhRMA, Pharmaceutical Industry Profile 2002; IMS Health, “Total U.S. Promotional Spending”; and NIHCM Foundation, Prescription Drugs.

7. NIHCM Foundation, Prescription Drugs.

8. From GAO, Prescription Drugs, Appendix II, 28.


10. Company names listed here are based on the names as of the date of the last regulatory letter that they received.