May 8, 2008

PRESCRIPTION DRUGS

Trends in FDA's Oversight of Direct-to-Consumer Advertising

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Highlights

Highlights of GAO-08-758T, a testimony before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives

Why GAO Did This Study

The Food and Drug Administration (FDA) is responsible for overseeing direct-to-consumer (DTC) advertising of prescription drugs, which includes a range of media, such as television, magazines, and the Internet. If FDA identifies a violation of laws or regulations in a DTC advertising material, the agency may issue a regulatory letter asking the drug company to take specific actions. In 2002, GAO reported on delays in FDA's issuance of regulatory letters.

GAO was asked to discuss trends in FDA's oversight of DTC advertising and the actions FDA has taken when it identifies violations. This statement is based on GAO's 2006 report, *Prescription Drugs: Improvements Needed in FDA's Oversight of Direct-to-Consumer Advertising*, GAO-07-54 (November 16, 2006). In this statement, GAO discusses the (1) DTC advertising materials FDA reviews, (2) FDA's process for issuing regulatory letters citing DTC advertising materials and the number of letters issued, and (3) the effectiveness of FDA's regulatory letters at limiting the dissemination of false or misleading DTC advertising.

For its 2006 report, GAO examined FDA data on the advertising materials the agency received and reviewed the regulatory letters it issued citing prescription drug promotion from 1997 through 2005. For this statement, GAO also reviewed data from FDA to update selected information from the 2006 report.

To view the full product, including the scope and methodology, click on GAO-08-758T. For more information, contact Marcia Crosse, (202) 512-7114, crossem@gao.gov.

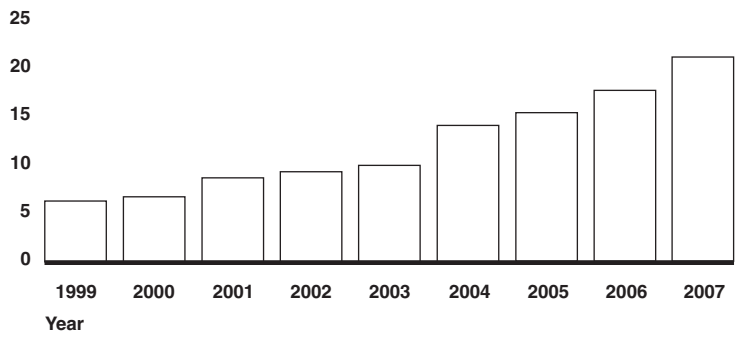
What GAO Found

Since 1999, FDA has received a steadily increasing number of advertising materials directed to consumers. In 2006, GAO found that FDA reviewed a small portion of the DTC materials it received, and the agency could not ensure that it was identifying for review the materials it considered to be highest priority. While FDA officials told GAO that the agency prioritized the review of materials that had the greatest potential to negatively affect public health, the agency had not documented criteria to make this prioritization. GAO recommended that FDA document and systematically apply criteria for prioritizing its reviews of DTC advertising materials. In May 2008, FDA indicated that it had documented criteria to prioritize reviews. However, FDA still does not systematically apply its criteria to all of the DTC materials it receives. Furthermore, GAO noted in its 2006 report that FDA could not determine whether a particular material had been reviewed. GAO recommended in that report that the agency track which DTC materials had been reviewed. FDA officials indicated to GAO in May 2008 that the agency still did not track this information. As a result, the agency cannot ensure that it is identifying and reviewing the highest-priority materials.

GAO found in 2006 that, since a 2002 policy change requiring legal review of all draft regulatory letters, FDA's process for drafting and issuing letters was taking longer and the agency was issuing fewer letters per year. FDA officials told GAO that the policy change contributed to the lengthened review.

In 2006, GAO found that the effectiveness of FDA's regulatory letters at halting the dissemination of violative DTC materials had been limited. By the time the agency issued regulatory letters, drug companies had already discontinued use of more than half of the violative advertising materials identified in each letter. In addition, FDA's issuance of regulatory letters had not always prevented drug companies from later disseminating similar violative materials for the same drugs.

Number of Materials Directed to Consumers Submitted to FDA, 1999 through 2007



Source: GAO analysis of FDA data.

Note: Totals include final DTC materials, Internet materials—some of which may be directed to medical professionals—and materials designed to be given to consumers by medical professionals.