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PRESCRIPTION DRUGS

Improvements Needed in FDA's Oversight of Direct-to-Consumer Advertising

GAO Accountability · Integrity · Reliability

Highlights

Highlights of GAO-07-54, a report to congressional requesters

Why GAO Did This Study

The Food and Drug Administration (FDA) is responsible for overseeing direct-to-consumer (DTC) advertising of prescription drugs. 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. GAO was asked to discuss (1) trends in drug company spending on DTC advertising and other activities; (2) what is known about the relationship between DTC advertising and drug spending and utilization; (3) the DTC advertising materials FDA reviews; (4) the number of regulatory letters that cited DTC materials and FDA's process for issuing those letters; and (5) the effectiveness of these letters at limiting the dissemination of violative DTC advertising. GAO reviewed research literature, analyzed FDA's processes, and examined FDA documentation.

What GAO Recommends

GAO recommends that FDA (1) document criteria for prioritizing DTC materials for review, (2) systematically apply its criteria to materials it receives, and (3) track which materials it reviews. In its comments on a draft of this report, HHS disagreed with the recommendations, stating that they would require vastly increased staff. GAO believes that FDA already has most of the information that would be required to establish a systematic process for screening DTC materials.

www.gao.gov/cgi-bin/getrpt?GAO-07-54.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Marcia Crosse at (202) 512-7119 or crossem@gao.gov.

What GAO Found

Drug company spending on DTC advertising—such as that on television and in magazines—of prescription drugs increased twice as fast from 1997 through 2005 as spending on promotion to physicians or on research and development. Over this period, drug companies spent less each year on DTC advertising ($4.2 billion in 2005) than on promotion to physicians ($7.2 billion in 2005) or research and development ($31.4 billion in 2005).

Studies GAO reviewed suggest that DTC advertising has contributed to increases in drug spending and utilization, for example, by prompting consumers to request the advertised drugs from their physicians, who are generally responsive to these requests. Evidence suggests that the effect of DTC advertising on consumers can be both positive, such as encouraging them to talk to their doctors, and negative, such as increased use of advertised drugs when alternatives may be more appropriate.

FDA reviews a small portion of the DTC materials it receives. To identify materials that have the greatest potential to impact public health, FDA has informal criteria to prioritize materials for review. However, FDA has not documented these criteria, does not apply them systematically to all of the materials it receives, and does not track information on its reviews. As a result, the agency cannot ensure that it is identifying or reviewing those materials that it would consider to be the highest priority.

FDA has taken longer to draft and review regulatory letters and the agency has issued fewer letters per year since 2002, when legal review of all draft regulatory letters was first required. From 2002 through 2005, from the time FDA began drafting a regulatory letter for a violative DTC material, it took the agency an average of 4 months to issue a regulatory letter, compared with an average of 2 weeks from 1997 through 2001. FDA has issued about half as many regulatory letters per year since the 2002 policy change.

The effectiveness of FDA's regulatory letters at halting the dissemination of violative DTC materials has been limited. The 19 regulatory letters FDA issued in 2004 and 2005 were issued an average of 8 months after the materials were first disseminated. By the time FDA issued these letters, companies had already discontinued use of more than half of the violative materials. When the cited materials were still being disseminated, drug companies complied with FDA's requests to remove the materials, and identified and removed other materials with similar claims. FDA's issuance of regulatory letters did not always prevent drug companies from later disseminating similar violative materials for the same drugs. These issues are not new. In 2002, GAO reported that, by delaying the issuance of regulatory letters, the 2002 policy change had adversely affected FDA's ability to enforce compliance. At that time, GAO recommended, and FDA agreed, that letters be issued more quickly. GAO continues to believe this is necessary in order to limit consumers' exposure to false or misleading advertising.