July 2008

PRESCRIPTION DRUGS

FDA's Oversight of the Promotion of Drugs for Off-Label Uses

GAO Accountability • Integrity • Reliability

Highlights

Highlights of GAO-08-835, a report to the Ranking Member, Committee on Finance, U.S. Senate

Why GAO Did This Study

The Food and Drug Administration (FDA), an agency within the Department of Health and Human Services (HHS), regulates the promotion of prescription drugs to ensure that promotional materials are not false and misleading and that they comply with applicable laws and regulations. Among other things, FDA prohibits drug companies from promoting drugs for off-label uses—that is, for a condition or patient population for which the drug has not been approved or in a manner that is inconsistent with information found on the approved drug label. Although doctors may prescribe drugs off label, it is not permissible for drug companies to promote drugs for off-label uses. FDA may take regulatory actions for violations, and may also pursue enforcement action through the Department of Justice (DOJ).

GAO was asked for information about the promotion of drugs for off-label uses. GAO reviewed (1) how FDA oversees the promotion of off-label uses of prescription drugs and (2) what actions have been taken to address off-label promotions. GAO examined documentation related to the promotion of drugs for off-label uses and FDA correspondence with drug companies on identified violations and obtained information from DOJ on relevant actions. GAO also interviewed officials at FDA and the HHS Office of Inspector General and representatives of national medical and pharmaceutical associations.

To view the full product, including the scope and methodology, click on GAO-08-835. For more information, contact Marcia Crosse at (202) 512-7114 or crossem@gao.gov.

What GAO Found

FDA oversees drug promotion for off-label uses by reviewing promotional materials that drug companies submit to the agency. However, because FDA does not have separate oversight activities to specifically capture off-label promotion, its oversight occurs within a broader process that targets a variety of promotional violations. Furthermore, FDA reports it is unable to review all submissions because of the volume of materials it receives and prioritizes its reviews in order to examine those with the greatest potential impact on human health. However, FDA does not prioritize its reviews in a systematic manner but rather relies on its staff to sort through large volumes of material and select submissions for review. FDA is also hampered by the lack of a system that consistently tracks the receipt and review of submitted materials. To address these shortcomings, GAO recommended in 2006 that FDA track which materials it has reviewed. FDA has not acted on this recommendation and still lacks a standardized tracking system to monitor its review efforts. GAO believes that this recommendation remains valid. In addition to its reviews, FDA conducts monitoring and surveillance to identify violations that would not be identified through its review of submitted material—for instance, discussions between doctors and sales representatives. These efforts are also limited because FDA cannot observe all off-label promotion activities as they can take many forms and occur in a myriad of places.

FDA and DOJ have taken regulatory and enforcement actions against drug companies in response to off-label promotions. During calendar years 2003 through 2007, FDA issued 42 regulatory letters in response to off-label promotions requesting drug companies to stop dissemination of violative promotions. FDA took an average of 7 months to issue these letters from the time it first drafted them. In addition, drug companies that were cited for more serious violations took an average of 4 months to take the corrective actions requested. While FDA did not refer any of these violations to DOJ for enforcement action, during calendar years 2003 through 2007, DOJ settled both civil and criminal cases that involved, at least partially, off-label promotion. These actions were initiated as a result of violations identified by sources other than FDA and resulted in 11 settlements.

In commenting on a draft of this report, HHS raised concerns with GAO's assessment that FDA does not systematically prioritize all of the promotional materials it receives. It also stated that a tracking system would not improve the agency's ability to identify promotional violations. GAO found that FDA does not screen all promotional materials. GAO continues to believe that a tracking system would help ensure that staff screen all material received, facilitate a more systematic approach to FDA's reviews, and help the agency manage the program.