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DRUG SAFETY

FDA Has Begun Efforts to Enhance Postmarket Safety, but Additional Actions Are Needed

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Highlights

Highlights of GAO-10-68, a report to the Ranking Member, Committee on Finance, U.S. Senate

Why GAO Did This Study

There have been long-standing concerns regarding the Food and Drug Administration's (FDA) oversight of postmarket drug safety. In 2006, GAO reported that FDA had not clearly defined the roles of two offices involved in making decisions about postmarket safety—the Office of New Drugs (OND) and the Office of Surveillance and Epidemiology (OSE). GAO and others reported additional concerns such as limitations in the data FDA relies on to identify postmarket drug safety issues and the systems it uses to track such issues. At that time, GAO made recommendations, including that FDA improve the independence of its program for resolving scientific disputes related to postmarket drug safety. In 2007, legislation further expanded FDA's postmarket responsibilities. This report examines the steps that FDA is taking to (1) enhance its processes for making decisions about the safety of marketed drugs, (2) improve access to data that help the agency identify drug safety issues, and (3) build its capacity to fulfill its postmarket drug safety workload. GAO reviewed FDA policies and planning documents, and interviewed FDA officials.

What GAO Recommends

GAO recommends that FDA develop a comprehensive plan to prepare OSE for the transfer of additional regulatory authorities from OND. FDA agreed with GAO's recommendation.

View GAO-10-68 or key components.
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What GAO Found

FDA is beginning to address previously identified weaknesses in its oversight of postmarket drug safety issues, but challenges remain. The agency is changing its postmarket decision-making process as part of its Safety First Initiative, which includes formalizing interactions between OND and OSE and providing OSE with added responsibilities. The one authority FDA transferred from OND to OSE is a premarket review responsibility. FDA officials said the agency plans to transfer authority for two postmarket responsibilities for reviewing certain types of drug safety studies, but the agency does not have a time frame for their transfer. Officials said that OSE must still gain experience leading the one transferred responsibility and expand its staff before it can assume these additional responsibilities. While most of the OSE and OND employees GAO interviewed indicated that OSE's role in managing safety issues has increased since 2006, most OSE employees GAO interviewed said that OND's perspective still carries more weight in decision making. OND recently created safety management positions in each of its 17 divisions; OSE expanded its similar positions from 9 to 25, although an employee said turnover has made it difficult for the OSE managers to gain experience. FDA is also revising its program for resolving scientific disputes, but these changes have not increased its independence, as GAO recommended.

FDA plans to implement new data systems and is increasing access to external data to assist with drug safety decisions. FDA plans to implement new systems in 2010 to improve the timeliness, quality, and analysis of reports of adverse events associated with human drug use. FDA has also increased funding for contracts with private companies and is in the early stages of forming partnerships with federal data holders to access external data. As mandated in the 2007 legislation, FDA is developing the Sentinel System, a network of external data providers intended to enhance drug safety surveillance, but the agency is in the early stages of developing it.

FDA faces challenges meeting an expanding workload. The agency indicated that expanded responsibilities resulting from the 2007 legislation increased its workload, and both OND and OSE employees described difficulties meeting their responsibilities. FDA indicated that since fiscal year 2008, OND staff increased from 736 to 928 and OSE staff increased from 114 to 193. However, an agency review suggests that OSE may still need to more than double its staff of 193 by fiscal year 2011 to meet its new responsibilities. Although OSE has increased its staff, officials cited hiring challenges, such as competition from the private sector, that may make it difficult to hire staff quickly enough to meet the increasing workload. FDA also expects to complete a growing number of drug safety studies, but technological and staffing challenges limit its capacity to conduct these studies. To assist its decision making, FDA has increasingly sought advice from members of its external drug safety advisory committee. However, the agency has encountered difficulty filling several committee vacancies. An official said FDA is reviewing candidates with the goal of filling these vacancies as soon as possible.