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FOOD AND DRUG ADMINISTRATION

FDA Faces Challenges Meeting Its Growing Medical Product Responsibilities and Should Develop Complete Estimates of Its Resource Needs

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Highlights

Highlights of GAO-09-581, a report to congressional requesters

Why GAO Did This Study

Twenty years ago, GAO reported that the Food and Drug Administration (FDA) was concerned that it lacked resources to fulfill its mission, which includes oversight of the safety and effectiveness of medical products—human drugs, biologics, and medical devices—marketed for sale in the United States. Since then, FDA, GAO, and others have raised concerns regarding FDA's ability to meet its oversight responsibilities.

GAO was asked to review the resources supporting FDA's medical product oversight responsibilities. GAO examined trends in (1) FDA's funding and staffing resources for its medical product oversight responsibilities from fiscal years 1999 through 2008, and (2) FDA's medical product oversight responsibilities during this same period. GAO analyzed FDA data on the agency's resources and workload, reviewed relevant federal laws, and interviewed FDA officials. GAO also examined more-detailed data on FDA's fiscal year 2004 through 2008 resources and workload in four key areas, representing a range of FDA's oversight responsibilities, both before and after a medical product is marketed in the United States.

What GAO Recommends

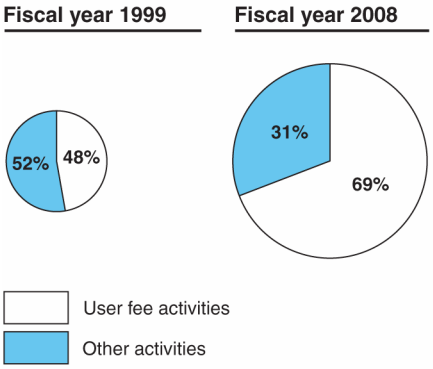
GAO recommends that the Commissioner of FDA take steps to establish a comprehensive and reliable basis for substantiating the agency's resource needs. FDA agreed with our recommendations.

View GAO-09-581 or key components.
For more information, contact Marcia Crosse at (202) 512-7114 or crossem@gao.gov.

What GAO Found

Funding and staffing resources for FDA's medical product programs increased between fiscal years 1999 and 2008, primarily as a result of increased user fees paid by industry, which are made available through appropriations acts to support the agency's processes for reviewing new medical products. Total funding increased from about $562 million in fiscal year 1999 to about $1.2 billion in fiscal year 2008, with user fee funding accounting for more than half of this increase. A large and growing portion of funding supported activities for which user fees are collected, resulting in a declining share of funding available for other activities. FDA officials said that this has seriously limited the agency's ability to fulfill its oversight responsibilities in some areas, particularly those not funded with user fees.

Portion of Total Medical Product Program Funding Allocated to User Fee and Other Activities, Fiscal Years 1999 and 2008



Source: GAO analysis of FDA data.

FDA faced challenges fulfilling and managing its growing medical product oversight responsibilities, which agency officials attributed to resource constraints. FDA's statutory responsibilities grew during this period and a growing number of medical products subject to FDA oversight and establishments manufacturing these products for the U.S. market also added to the agency's workload. However, FDA could not provide data showing its workload and accomplishments in some areas, such as its review of reports identifying potential safety issues with specific medical products. Without such information, FDA cannot develop complete and reliable estimates of its resource needs. While FDA officials said that the funding amounts requested for and provided to FDA during the past 2 years will permit the agency to respond to its most urgent needs and priorities, officials also noted that they did not receive enough resources to meet some statutory requirements, such as biennially inspecting certain manufacturing establishments. Furthermore, officials said that the agency faces significant challenges fulfilling its mission to oversee the safety and effectiveness of medical products.