GAO Highlights

Highlights of GAO-14-561, a report to congressional committees

June 2014

TOBACCO PRODUCT REGULATION

Most FDA Spending Funded Public Education, Regulatory Science, and Compliance and Enforcement Activities

Why GAO Did This Study

Tobacco use is the leading cause of preventable death and disease in the United States. In 2009, the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) granted FDA, an agency within the Department of Health and Human Services (HHS), authority to regulate tobacco products, including marketing and distribution to youth. The act established CTP, which implements the act by educating the public on the dangers of tobacco use; developing the science needed for tobacco regulation; and developing and enforcing regulations on the manufacture, marketing, and distribution of tobacco products. The act authorized FDA to assess and collect user fees from tobacco manufacturers and importers.

The Tobacco Control Act mandated that GAO review the authority and resources provided to FDA for regulating the manufacture, marketing, and distribution of tobacco products. This report examines (1) how FDA spent tobacco user fees for key activities using its authorities granted in the act, and (2) any challenges FDA encountered in using its authorities. GAO analyzed data on tobacco user fees collected and spent on key activities by FDA as of March 31, 2014; reviewed documents related to FDA's key activities, as well as relevant laws, regulations, and guidance; and interviewed CTP, public health, and tobacco industry officials.

HHS reviewed a draft of this report and agreed with GAO's reiteration of its previous recommendation that performance measures for all tobacco product reviews are needed.

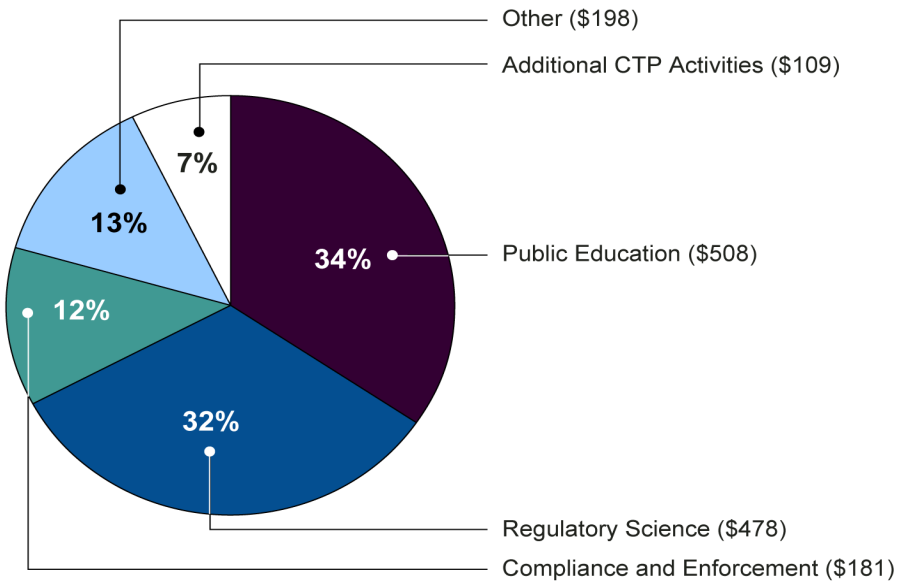
View GAO-14-561. For more information, contact Marcia Crosse at (202) 512-7114 or crossem@gao.gov.

What GAO Found

As of March 31, 2014, the Food and Drug Administration (FDA) spent about $1.48 billion (79 percent) of the $1.88 billion in total tobacco user fees it collected since fiscal year 2009. FDA spent the majority of tobacco user fees on key activities led by the agency's Center for Tobacco Products (CTP), which is funded solely by tobacco user fees. These included activities related to public education (including public education campaigns and communicating CTP activities); regulatory science (including research, product review, and developing the science to support regulations and guidance); and compliance and enforcement (including tobacco retailer inspections; manufacturer and import inspections and enforcement; promotion, advertising, and labeling surveillance; and outreach and small business assistance).

Proportion of FDA Tobacco User Fee Spending by Activity as of March 31, 2014

Dollars (in millions)



CTP- Center for Tobacco Products

Source: GAO analysis of FDA data. | GAO-14-561.

While FDA has taken steps to address some of the challenges it has faced, including challenges related to starting up a new center, it continues to face challenges, including setting and monitoring review time frames. Until recently, CTP has not had performance measures for making final decisions on new tobacco product submissions by which to assess its progress, as GAO previously recommended. FDA has announced performance measures for two of its new tobacco product review processes (to take effect in October 2014), but not for the type of new tobacco product submission that comprises the bulk of FDA's review backlog. The agency has indicated that it intends to establish such performance measures, but until it does so, the agency's ability to assess its efforts will be limited. This will be particularly pressing as FDA moves forward with plans to deem additional types of tobacco products to be subject to its regulatory authority.