TOBACCO PRODUCT REGULATION

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

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).

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.