April 8, 2014

TOBACCO PRODUCTS

FDA Spending and New Product Review Time Frames

GAO Highlights

Highlights of GAO-14-508T, a testimony before the Subcommittee on Health, Committee on Energy and Commerce, House of Representatives

Why GAO Did This Study

In 2009, the Tobacco Control Act granted FDA authority to regulate tobacco products such as cigarettes. The act authorizes FDA to assess and collect user fees from each tobacco manufacturer and importer for FDA activities related to tobacco product regulation. The act also requires that manufacturers submit information—for example, a statement of the tobacco product's ingredients—to be reviewed by FDA in order to market new tobacco products. FDA reviews the products using a public health standard, taking into account the risks and benefits of tobacco products on the population as a whole, including users and nonusers. The act represents the first time that FDA has had the authority to regulate tobacco products.

This testimony highlights and provides selected updates to key findings from our September 2013 report, entitled, *New Tobacco Products: FDA Needs to Set Time Frames for Its Review Process* (GAO-13-723). This report examined (1) the extent to which FDA spent its tobacco user fee funds, and (2) the status of CTP's reviews of new tobacco product submissions. GAO reviewed FDA data on tobacco user fees collected by FDA and spent by all of CTP's offices. GAO also analyzed CTP data on product submissions, including whether specific steps in the review process had been completed.

What GAO Recommends

In its September 2013 report, GAO recommended FDA establish time frames for making decisions on submissions. FDA plans to identify time frames in spring 2014 and implement them by October 2014.

View GAO-14-508T. For more information, contact Marcia Crosse at (202) 512-7114 or crossem@gao.gov.

What GAO Found

The Food and Drug Administration (FDA) spent (obligated) less than half of the $1.1 billion in tobacco user fees it collected from manufacturers and others from fiscal year 2009 through the end of fiscal year 2012; however, FDA's spending increased substantially in fiscal year 2013. Through December 31, 2013, FDA spent nearly 81 percent of the approximately $1.75 billion in fees collected by that time. According to officials in FDA's Center for Tobacco Products (CTP), the center established by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) to implement the act's provisions, the time it took to award contracts contributed to the center spending less than it had planned to spend. In fiscal year 2013, FDA was able to carry out a number of activities that were originally planned for fiscal years 2011 and 2012, such as efforts to educate youth on the dangers of tobacco use. About 79 percent ($1.12 billion) of user fees spent as of December 31, 2013, was spent by three CTP offices: Office of Health Communication and Education, Office of Science, and Office of Compliance and Enforcement.

As of January 7, 2013, CTP had finished initial, but not final, review steps for most of about 3,800 submissions it had received for new tobacco products (those not on the market on February 15, 2007). Ninety-nine percent of the submissions received were made under the substantial equivalence (SE) pathway, through which CTP determines whether the product has the same characteristics as a predicate tobacco product (a product commercially marketed in the United States on February 15, 2007, or previously found to be substantially equivalent) or has different characteristics that do not raise different questions of public health. For most SE submissions received by January 7, 2013, CTP took more than a year and a half from the date a submission was received to the date CTP's initial review steps were completed; initial review steps precede a scientific review step during which CTP determines whether the product is substantially equivalent to a predicate product. CTP made its first decisions on SE submissions in late June 2013—about 3 years after FDA's receipt of the first SE submission—and as of December 31, 2013, had made final decisions for 30 of the 4,490 SE submissions the agency had received. CTP officials stated that CTP requests for additional information from manufacturers for submissions and having to hire and train new staff impacted the time it took to review submissions. GAO also found that CTP has not had performance measures that include time frames for making final decisions on SE submissions by which to assess its progress. Time frames would allow CTP to evaluate its efficiency and effectiveness and help it make appropriate adjustments.