

## Why GAO Did This Study

FDA has faced challenges regulating medical products, owing in part to rapid changes in science and technology. In 2010, FDA established a regulatory science initiative that identified eight priority areas for medical products where new research was needed to advance its mission. Legislation enacted in 2012 required FDA to establish a plan for measuring its progress on its regulatory science efforts.

GAO was asked to examine FDA's progress on its regulatory science efforts related to medical products. In this report, GAO (1) evaluates FDA's strategic planning efforts to address its regulatory science priorities, (2) describes FDA's funding targeted at regulatory science projects, and (3) describes the achievements of selected FDA regulatory science projects. GAO compared related FDA strategic planning documents to federal internal control standards and leading practices for strategic planning. GAO reviewed FDA data on obligations targeted at regulatory science projects for fiscal years 2010 through 2014 and reviewed the achievements FDA reported from a sample of 17 projects, chosen to ensure nine FDA centers and offices and priority areas are represented.

## What GAO Recommends

To improve strategic planning for regulatory science efforts, FDA should (1) develop and document measurable goals, including targets and time frames, and (2) systematically track funding across its regulatory science priority areas. The Department of Health and Human Services agreed with GAO's recommendations.

View [GAO-16-432](#). For more information, contact Marcia Crosse at (202) 512-7114 or [crossem@gao.gov](mailto:crossem@gao.gov).

## MEDICAL PRODUCT OVERSIGHT

### FDA Needs More Strategic Planning to Guide Its Scientific Initiatives

## What GAO Found

The Food and Drug Administration (FDA) lacks measurable goals to assess its progress in advancing regulatory science—the science supporting its effort to assess the products it regulates. The agency issued strategic planning documents in 2011 and 2013 to guide its regulatory science efforts and identify priority areas for conducting work, but these documents do not specify the targets and time frames necessary for the agency to measure progress overall or within each of the eight priority areas related to medical products. According to leading practices for strategic planning, identifying and using consistent measurable goals in planning and progress documents is important to assessing effectiveness. While FDA cited examples of its achievements in regulatory science in a 2015 report, FDA cannot assess how those achievements constitute progress towards its goals. In addition, FDA lacks information about how funding targeted at regulatory science is distributed across the priority areas. Decisions to award these funds are made by individual FDA centers and offices, which generally did not collect information on the associated priority areas of funded projects. Rather, FDA retrospectively identified these areas for the purpose of GAO's review. The lack of consistent information limits FDA's ability to examine obligations across, or progress within, specific priority areas. Standards for internal control in the federal government state that complete and accurate data are needed to make operating decisions and allocate resources. Furthermore, multiple centers or offices fund projects toward a given priority area and leading practices for strategic planning encourage agencies to manage efforts that cut across the agency.

FDA obligations for regulatory science projects generally increased from fiscal years 2010 through 2014 and totaled more than \$507 million across that period. Nine centers and offices obligated funds, with totals for each center or office ranging from approximately \$450,000 to about \$200 million. The Office of the Chief Scientist (in particular, the National Center for Toxicological Research) funded 65 percent of the total obligations. FDA obligated funds towards each of the regulatory science priority areas, ranging from about \$3 million for *global product safety* to approximately \$203 million for *toxicology*. The *clinical evaluations and personalized medicine* and *medical countermeasures* priority areas were also among those with the greatest obligations.

For the 17 regulatory science projects GAO reviewed, FDA identified achievements ranging from the dissemination of project findings to changes in both agency and external stakeholder practices. For example, FDA reported that all projects resulted in some type of change within FDA. About half of the projects resulted in the agency developing standards, methods, tools, or training that it could use internally, and about one-third of the projects affected guidance or regulations. FDA also reported that about half of the projects resulted in the development of new tools or standards for use by industry or other stakeholders, in areas such as setting new standards for defibrillators to account for radio interference.