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FOOD AND DRUG ADMINISTRATION

Comprehensive Strategic Planning Needed to Enhance Coordination between Medical Product Centers

GAO Highlights

Highlights of GAO-16-500, a report to congressional requesters

Why GAO Did This Study

FDA—an agency within the Department of Health and Human Services (HHS)—has faced challenges in carrying out its responsibilities to ensure the safety and efficacy of medical products sold in the United States. In 2012, Congress required FDA to develop a SIMP for the three centers overseeing medical products that identifies initiatives for improving efficiency, initiatives for workforce development, and measures for assessing the progress of these initiatives. FDA issued the SIMP in July 2013.

GAO was asked to examine FDA's implementation of the SIMP. In this report, GAO (1) evaluates the extent to which the SIMP serves as a strategic planning document, (2) describes the types of plan initiatives, and (3) describes the mechanisms FDA has to evaluate the effectiveness of its plan initiatives. GAO analyzed FDA documents and spoke to FDA officials to assess the SIMP's development and use, along with the implementation status and evaluation mechanisms used for the SIMP's initiatives. GAO also assessed FDA's plan against leading practices for strategic planning. Finally, GAO analyzed FDA workforce data on hiring and attrition for fiscal years 2012 to 2015.

What GAO Recommends

GAO recommended that the Secretary of Health and Human Services direct FDA to engage in a strategic planning process to identify challenges that cut across the medical product centers, and document how it will achieve measurable goals and objectives in these areas. HHS agreed with the recommendation.

View GAO-16-500. For more information, contact Marcia Crosse at (202) 512-7114 or crossem@gao.gov.

What GAO Found

The Food and Drug Administration (FDA) developed a strategic integrated management plan (SIMP) for its three centers that oversee medical products (biologics, drugs, and medical devices); however, GAO found that the plan does not incorporate leading practices for strategic planning or document a comprehensive strategy for the centers. FDA officials explained that circumstances at the time of the SIMP's development, including leadership gaps, limited FDA's ability to structure the plan into an effective strategic planning document. While officials said they use a variety of other key documents for strategic planning—such as agency-level and initiative-specific plans—these other plans also do not describe a long-term strategy for addressing key issues that cut across medical product centers. For example, these other FDA documents do not describe the agency's plans for collaboration between the centers that could benefit certain initiatives, improve their decision-making, and improve the quality of evidence and clarity of guidance. FDA officials acknowledged the growing need for strategic planning across the medical product centers to improve center collaboration and address emerging issues. The absence of a comprehensive long-term plan for medical product oversight may hinder FDA's efforts to address emerging issues that require center collaboration, such as access to quality data. Fully documenting such a strategy, either in a separate plan or through existing documents, would help the agency identify measurable goals and objectives for the centers that align with its mission and help communicate its priorities to key stakeholders.

In the SIMP, FDA compiled mostly preexisting initiatives to improve the efficiency of each center's activities and develop its workforce. GAO found that for improving efficiency, FDA selected 30 initiatives that it grouped into three different themes—smarter regulation, process improvement, and business modernization. FDA had fully implemented a third of the initiatives prior to the SIMP's issuance in 2013; another half were implemented by March 2016. As of this date, the remaining initiatives had yet to be fully implemented. For workforce development, FDA included 19 recruitment, retention, and training initiatives, which generally reflected differences in center activities. FDA implemented 15 initiatives prior to the SIMP's issuance and 2 additional initiatives since then. Of the remaining initiatives, 1 was terminated and, as of March 2016, FDA was in the process of implementing the other initiative.

Although not generally reported in the SIMP, FDA officials identified mechanisms to assess the effectiveness of the majority of the initiatives included in the plan. Of the 30 efficiency initiatives, FDA officials identified 8 that have formal evaluations (such as third-party assessments) and 9 that are assessed informally (such as by gathering feedback). For the remaining 13, officials said they are either exploring effectiveness measures or have no plans to assess them because they consider it to be unnecessary or impractical. FDA identified mechanisms to assess 12 of the 19 workforce development initiatives, including through recruitment performance metrics and surveys of training participants. For 4 initiatives, the centers each use different approaches to assess training. For the remaining 3 initiatives, FDA either is developing a mechanism or described past assessment activities.