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DRUG MANUFACTURING

FDA Should Fully Assess Its Efforts to Encourage Innovation

GAO Highlights

Highlights of GAO-23-105650, a report to congressional committees

Why GAO Did This Study

FDA, a component agency within the Department of Health and Human Services' (HHS), is responsible for ensuring that drugs marketed in the U.S. are safe and effective. The agency also plays a role in supporting manufacturing innovation. GAO has previously reported on challenges FDA has faced in its oversight of the drug supply chain and deficiencies in FDA and other HHS entities' preparation for and response to public health emergencies. As such, GAO has designated both as high-risk areas.

The CARES Act includes a provision for GAO to report on the federal pandemic response. This report (1) examines FDA's efforts to support advanced manufacturing, including in response to the COVID-19 pandemic. In addition, it (2) describes stakeholders' perspectives on the regulatory challenges to increasing the use of advanced manufacturing for drugs and (3) describes FDA actions to address challenges to increasing the use of advanced manufacturing. For this work, GAO reviewed FDA documents, national supply chain resiliency strategies, and interviewed FDA and 15 drug industry stakeholders, including companies with approved drugs and those seeking approval.

What GAO Recommends

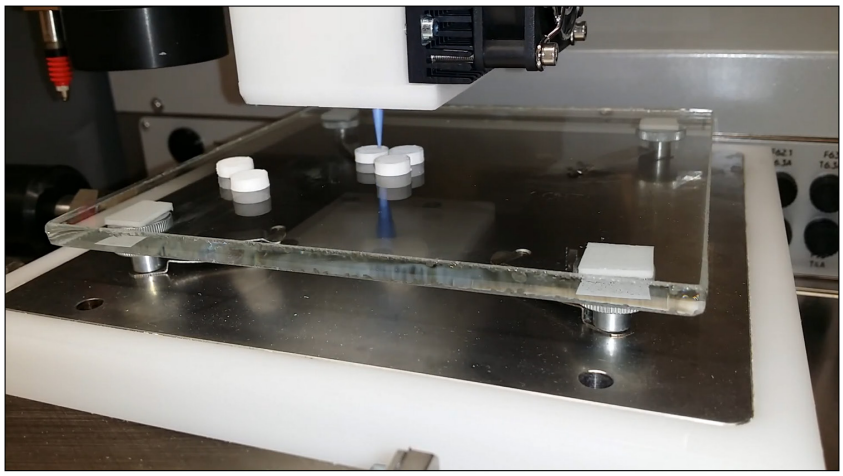
GAO is recommending that FDA document and finalize performance goals and measures related to its advanced manufacturing program efforts and regularly assess program progress. HHS concurred with this recommendation.

View GAO-23-105650. For more information, contact Mary Denigan-Macauley at (202) 512-7114 or deniganmacauleym@gao.gov.

What GAO Found

The COVID-19 pandemic revealed vulnerabilities in the medical supply chain that led to drug shortages. The Food and Drug Administration (FDA) has highlighted advanced manufacturing—innovative technologies that improve product quality and process performance—as a way to enhance supply chain resiliency. However, at the time of this report, few drugs had been made using advanced manufacturing (see figure).

3D printing of drugs, an example of advanced manufacturing



Source: Food and Drug Administration. | GAO-23-105650

FDA has three efforts focused on increasing advanced manufacturing for drugs related to (1) industry engagement, (2) policy and guidance, and (3) research. During the COVID-19 pandemic, FDA leveraged its industry engagement effort to approve two drugs for the treatment of a COVID-19 complication, which are made using advanced manufacturing technology. GAO found, however, that FDA lacks information on the extent to which its industry engagement and policy and guidance efforts encourage adoption of advanced manufacturing. This is because FDA has not documented and finalized performance goals—defining what it expects these efforts to achieve and performance measures—to regularly assess progress the agency is making in achieving these goals. Taking these steps would help FDA make informed program management decisions, including the allocation of finite resources.

The 15 industry stakeholders GAO interviewed reported that regulatory challenges contributed to uncertainty about when and whether a drug manufactured using advanced manufacturing will be approved. This uncertainty weakens the business case for, and contributes to slow adoption of, advanced manufacturing. For example, according to stakeholders, the unfamiliarly of FDA application review staff with advanced manufacturing may lead to delays in approval. FDA has taken steps to address regulatory challenges, including using its industry engagement program to provide opportunities for companies to discuss new technologies with FDA and its research program to familiarize staff with advanced technologies, such as through a yearly training on 3D printing.