GAO Highlights

MEDICAL DEVICE RECALLS

HHS and FDA Should Address Limitations in Oversight of Recall Process

GAO-26-107619 DECEMBER 2025

Highlights of GAO-26-107619, a report to congressional requesters.

Why This Matters

The Food and Drug Administration (FDA) oversees recalls of medical devices that may present a risk to the health of users. The ramifications of using recalled devices—such as defective ventilators or pacemakers—include the potential for serious injury or death.

FDA's oversight of medical products, including devices, has been on GAO's high-risk list since 2009.

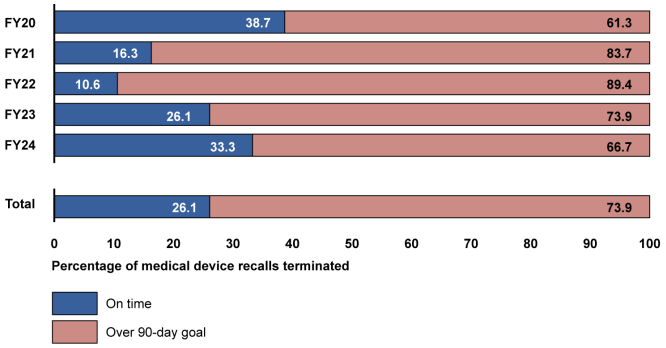
GAO Key Takeaways

From fiscal years 2020 to 2024, FDA oversaw the recall of 3,934 medical devices. All were voluntarily recalled by manufacturers. FDA can mandate a recall, although it rarely does so.

Insufficient staff limit FDA's ability to conduct oversight activities, according to officials. For example, from fiscal years 2020 to 2024, FDA couldn't meet its 3-month goal of terminating recalls (meaning FDA determines all reasonable efforts were made by the manufacturer to remove or correct the device) due to resource constraints. Some stakeholders said delays can affect patient care. The Department of Health and Human Services (HHS) oversees FDA and is currently undergoing reforms. Conducting workforce planning to determine the staffing and skills FDA needs for oversight would help HHS keep unsafe devices from continued use.

According to officials, FDA cannot require manufacturers to adopt its recommendations for how to carry out certain recalls. Some stakeholders said manufacturers and FDA communicating different information can be confusing. FDA officials said it can also result in inefficient use of resources. By working with FDA to assess if additional authorities are needed, and seeking them if beneficial, HHS may be better positioned to address current recall process inefficiencies.

Medical Device Recalls that Exceeded FDA's 3-Month Termination Goal



Source: GAO analysis of Food and Drug Administration (FDA) data. | GAO-26-107619

Note: Termination means FDA determines all reasonable efforts were made by the manufacturer to remove or correct the device.

How GAO Did This Study

We reviewed FDA policies and guidance on the recall process and analyzed data from FDA's Recall Enterprise System. We also interviewed FDA officials and 10 stakeholder groups representing providers, patients, and the medical device industry to get their perspectives on challenges FDA faces in overseeing recalls.

What GAO Recommends

We recommend HHS work with FDA: 1) to conduct workforce planning for device recalls, and 2) assess and seek, if needed, additional authority for manufacturer-initiated recall strategies. HHS concurred with the first recommendation and is taking the second under consideration.

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