

# United States Senate

WASHINGTON, DC 20510

December 13, 2023

The Honorable Gene Dodaro  
Comptroller General of the United States  
U.S. Government Accountability Office  
441 G Street NW  
Washington, D.C. 20548

Dear Mr. Dodaro:

We are writing to request that the Government Accountability Office (GAO) update its 2011 report entitled “Medical Devices: FDA Should Enhance Its Oversight of Recalls” (GAO-11-468).

From contact lenses and catheters to prosthetics and pacemakers, medical devices improve and save lives. Health care providers use them to diagnose and treat illnesses and injuries. Tens of millions of patients have implanted medical devices or use them in their homes to live healthier, more productive lives. But, there can be major risks. Due to unforeseen safety or manufacturing issues, medical devices can cause harm to patients, which can lead to a recall.

In Fiscal Year (FY) 2022, the Food and Drug Administration (FDA) oversaw 898 medical device recalls, impacting tens of millions of medical devices. This figure represents a 125 percent increase compared to FY 2012, when there were 399 medical device recalls. It also includes 70 class I recalls—FDA’s highest recall classification—a 15-year high. Medical device-related adverse event reports submitted to FDA have increased as well. In FY 2012, FDA received 486,986 adverse event reports, but it received 2,946,889 adverse event reports in FY 2022—a 505 percent increase.

Recalls must be conducted in an efficient manner in order to mitigate harm. However, this does not happen all of the time. For example, in 2021, Philips Respironics announced that it had recalled millions of CPAPs, BiPAPs, and mechanical ventilators, which patients with sleep apnea, COPD, and other respiratory conditions use to help them breathe. The company made this decision after it purportedly had learned that the sound abatement foam in some of these medical devices could deteriorate and be inhaled. According to FDA, this issue could cause headaches, vomiting, allergic reactions, and “toxic or cancer-causing effects.” However, recent reporting indicated Philips Respironics—and FDA—knew about this issue for several years before the recall was initiated.

According to the Pittsburgh Post-Gazette and ProPublica, Philips Respironics received an adverse event report about this issue in 2010. Rather than reporting the adverse event report to FDA or initiating a recall, it waited and withheld thousands of additional adverse event reports for more than a decade. Even when Philips Respironics conducted an internal health hazard evaluation, which confirmed that inhaling the chemicals from the sound abatement foam could cause “permanent impairment,” it did nothing, while patients suffered. That is unacceptable.

Additionally, it now appears that FDA missed several opportunities to mitigate the harm done to the millions of patients who have used these recalled medical devices. FDA reportedly also received at least 30 adverse event reports related to degradation of the sound abatement foam significantly prior to the initiation of the recall. FDA has stated that it “reviews all reports of adverse events associated with medical devices.” However, it is not clear whether or not FDA took action to inform hospitals, health care providers, and patients about the potential risks. Further, the Pittsburgh Post-Gazette and ProPublica’s reporting suggests that FDA knew Philips Respironics had a history of withholding adverse event reports from the agency, but still allowed it—and other medical device manufacturers—to submit late adverse event reports without appropriate enforcement for such violations.

In 2011, GAO released a report about FDA’s oversight of medical device recalls that found FDA often failed to conduct recall-related inspections. It also found that FDA’s process to confirm the effectiveness of a recall was “ineffective,” and that its process to terminate a recall increased “the risk that unsafe medical devices [could] continue to be used.” These were important insights that Congress used as the basis for several measures included in the *Food and Drug Administration Safety and Innovation Act* (P.L. 112-144), which reauthorized the FDA User Fee Amendments. But, given recent reporting and the dramatic increase in recalls since then, it is clear that GAO and Congress must examine FDA’s oversight of medical device recalls once again.

We urge GAO to conduct an updated review as soon as possible, taking into consideration the following questions:

1. What is known about the number and characteristics of medical device recalls and the extent to which FDA uses this information to improve its oversight of medical device recalls?
2. What is known about the authorities and actions that FDA has used or taken to ensure that medical device manufacturers initiate medical device recalls?
3. What is known about the authorities and actions that FDA has used or taken when medical device manufacturers have not initiated timely medical device recalls in compliance with federal regulations? Please provide data, including the number of medical device recalls not initiated in a timely manner, as part of this examination.
4. What is known about the factors that could contribute to the likelihood of a medical device recall initiation?
  - a. Section 510(k) of the *Federal Food, Drug, and Cosmetic Act* (P.L. 75-717) allows a medical device to be marketed if it is proven to be “substantially equivalent” to a “predicate device.” How does clearance through the section 510(k) process impact the risk of a recall?

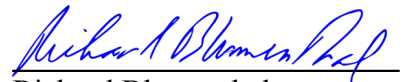
- b. Section 515(a) of the *Federal Food, Drug, and Cosmetic Act* (P.L. 75-717) allows a medical device to be marketed if it is proven to be safe and effective through clinical trials and receives Pre-Market Approval (PMA) from FDA. How does clearance through the PMA process impact the risk of a recall?
5. What additional resources, funding, or legislative authorities would improve FDA's oversight of medical device recalls?
6. What is known about the number and characteristics of adverse event reports submitted to FDA and the extent to which FDA uses this information to improve its oversight of medical device recalls?
7. What is known about the authorities and actions that FDA has used or taken to ensure that medical device manufacturers submit adverse event reports?
8. What known about the authorities and actions that FDA has used or taken when medical device manufacturers have not submitted timely adverse event reports in compliance with federal regulations? Please provide data, including the number of adverse events not submitted in a timely manner, as part of this examination.
9. What is known about the factors that could contribute to the likelihood of an adverse event report submission?
10. What additional resources, funding, or legislative authorities would improve FDA's oversight of adverse event reports?

Thank you for considering this request. We look forward to reading GAO's report on this important topic.

Sincerely,



Richard J. Durbin  
United States Senator



Richard Blumenthal  
United States Senator