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May 11, 2022

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

Dear Comptroller General Dodaro:

The Food and Drug Administration (FDA) in the Department of Health and Human Services (HHS) is primarily responsible for protecting and promoting public health through the control and supervision of a variety of products, including medical devices. Within the FDA, the Center for Devices and Radiological Health (CDRH) is responsible for the premarket approval of medical devices, as well as oversight of manufacturing, performance and safety of these devices. However, the number of adverse events associated with medical devices in the United States has continued to increase in recent years.[1] According to an investigation by the International Consortium of Investigative Journalists, almost 2 million injuries and over 80,000 deaths were associated with medical devices between 2008 and 2017.[2] Improved post-market surveillance of these devices is critical to the agency's stated mission to protect public health and safety.

FDA relies on a variety of databases and reporting mechanisms for post-market surveillance of medical devices. This includes the Manufacturer and User Facility Device Experience (MAUDE), which contains reports of adverse events involving medical devices known as MDRs. However, the FDA acknowledges that "this passive surveillance system has limitations"[3] and that "the incidence, prevalence, or cause of an event cannot be determined from this reporting system alone due to under-reporting of events, inaccuracies in reports, lack of verification that the device caused the reported event, and lack of information about frequency of device use"[4]. Additionally, "reporting under this system is voluntary for patients and physicians, and reports – if filed at all – are frequently logged several months after the incident has occurred". Previous investigations, including by HHS OIG, have uncovered that a significant

[1] https://www.fda.gov/media/144083/download
[2] https://www.icij.org/investigations/implant-files/medical-devices-harm-patients-worldwide-as-governments-fail-on-safety/
[3] https://www.fda.gov/medical-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities/about-manufacturer-and-user-facility-device-experience-maude
[4] Ibid.

number of these reports contain deficiencies in the information provided, including incomplete and sometimes inaccurate data.[5]

The FDA also requires that manufacturers assign unique device identifiers (UDIs) to medical devices, which can help support post-market surveillance, including better identification of devices slated for recall, as well as identification of adverse events associated with a specific device. However, the FDA lacks the authority to mandate the inclusion of UDIs in electronic health records. Consequently, UDI use and uptake in existing health systems is generally lacking and varies substantially, limiting its usefulness in post-market surveillance.

Since 2016, FDA has also operated the National Evaluation System for health Technology (NEST), which is intended to collect real-world evidence to better inform decisions about medical devices across their life cycles, including assessing the safety of medical devices on the market. This system's active surveillance approach is currently limited to 21 pilot projects, or Test-Cases. An interim report by the RAND Corporation found that the Test-Cases "as valuable in helping to identify lessons about the use of RWD that could generalize across devices and clinical conditions"[6] but also "revealed several challenges facing manufacturers who seek to use RWE for regulatory purposes, including reliably capturing UDIs, and ensuring adequate sample sizes, sufficient follow-up, and valid measures of patient and device characteristics and endpoints"[7].

Strengthening post-market surveillance of medical devices by improving these systems is critical to addressing adverse events and protecting patient health and safety which is a core part of FDA's mission. GAO last issued a report on FDA's post-market safety efforts in April 2011 – more than a decade ago. Since that time, significant changes have been made to FDA's post-market surveillance efforts, but continued work remains. Given this, I am requesting that GAO review existing FDA efforts on post-market surveillance of medical devices and provide an evaluation of their effectiveness, as well as provide recommendations to address gaps in current systems to better identify adverse events and safety issues in a timely manner. This includes evaluating the process and potential barriers for notifying patients of an implanted device recall, and the accessibility of adverse event reporting systems for people with disabilities.

Thank you for your consideration of this request.

Sincerely,

Debbie Dingell

Debbie Dingell
Member of Congress

[5] https://oig.hhs.gov/oei/reports/oei-01-08-00110.pdf
[6] https://nestcc.org/independent-assessment-of-the-nestcc-test-cases-rand-interim-report/
[7] Ibid.