Congress of the United States

Washington, DC 20515

September 19, 2024

VIA ELECTRONIC SUBMISSION

Dr. Michelle Tarver
Acting Director
Center for Devices and Radiological Health
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Tarver,

We share your interest in advancing access to medical innovation and write regarding your recent comments on the 510(k) Third-Party Review program. Specifically, we write regarding the "Medical Devices; Laboratory Developed Tests," 88 Fed. Reg. 32,786 (May 6, 2024) (the "LDT Final Rule"), the preamble to which states that the Food and Drug Administration (FDA) "is currently working to enhance its Third-Party Review Program to handle the review of low- and moderate-risk devices by [third-party review organizations accredited under FDA's third-party review program ("3P510k Review Organizations")]. Our hope is that this will free up Agency staff time to review more complex, innovative, high-risk devices. In fact, the FDA estimates that half of the IVDs offered as LDTs subject to 510(k) requirements will be reviewed under the Third-Party Review Program." 88 Fed. Reg. at 37,311.

As required by the Federal Food, Drug, and Cosmetic Act, we understand that the FDA applies a risk-based regulatory framework where devices are classified into one of three classes based on the degree of risk associated with the device and the extent of regulation necessary to provide reasonable assurance of safety and effectiveness. Most Class I devices – considered low risk and well understood – are subject to General Controls like quality system practice requirements and registration of manufacturing facilities and listing of devices and may be subject to premarket notification (510(k) (unless the device type is exempt from 510(k)). Most Class II devices – considered of moderate risk – are subject to Special Controls in addition to the General Controls – and require premarket clearance by the FDA through the 510(k) process before commercialization. Class III devices – the highest risk category, like pacemakers – generally require Premarket Approval. Within this device classification system, the 510(k) Third-Party Review Program was designed to offload the review of certain Class I and Class II classified type devices, as determined by the FDA, allowing the FDA to focus its resources on higher-risk

devices. Under the program, FDA recognizes qualified Third-Party Review organizations on 510(k) device statutory, regulatory, guidance, and policies.

We agree that the principles of the Third-Party Review Program have great promise for increasing efficiency in device regulation. In particular, we see the promise of this program to streamline the review of well-understood device types, which can, in turn, maximize the FDA's capability to address higher-risk devices. At the same time, we recognize that the Third-Party Review Program has struggled. Utilization declined from a peak of 9.3% in 2008 to 2.4% in 2020, and the number of reviewing organizations declined to 7.[1]

With this in mind, we suggest that the agency consider potential solutions and answer the following questions regarding its intentions expressed in the LDT Final Rule:

1. What specific improvements does the agency intend to make to the Third-Party Review Program? This will be further compounded by the increasing intricacy and uncertainty of devices in emerging areas such as AI/ML and device types that have not been classified into Class I or II.
2. How does the agency plan to address re-review in the Third-Party Review Program?
    a) Please provide an update on the commitment to audit for agency re-review and re-training, something that was enumerated in both the 2017 FDARA Act (MDUFA IV) and the Food and Drug Omnibus Reform Act of 2022 ("FDORA"; MDUFA V).
3. Does the agency believe that any statutory changes are needed to modify program capacity?
4. Given the changes in the medical device landscape since the onset of the COVID-19 pandemic, does the agency intend to update its March 2020 guidance to reflect newly classified device types that might utilize third-party review?
5. Does the agency believe that there is a need to expand the FDA-recognized Third-Party Organizations, given the agency's acknowledgment that certain Clinical Laboratory Improvement Amendments (*CLIA*) accredited organizations might participate in the FDA's Third-Party Review Program?
6. How does the FDA plan to approach accreditation for organizations already accredited under CLIA?
7. Does the agency intend to provide specific Third-Party Review guidance for down-classified IVDs?
8. Could the agency give Third-Party Organizations limited access to 510(k) submissions for predicate devices identified in new 510(k) submissions and, if not, could the agency

[1] Current List of FDA-Recognized 510(k) Third Party Review Organizations. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfthirdparty/accredit.cfm. Accessed September 10, 2024.

provide access to documentation of the FDA's review of prior 510(k) submissions for such predicate devices?

We look forward to working with you and share your commitment to expanding access to safe and effective medical innovation for all Americans.

Sincerely,

Dan Crenshaw
Member of Congress

Angie Craig
Member of Congress