Testimony at the FDA Public Meeting on the Reauthorization of the Medical Device User Fee Amendments

U.S. Food and Drug Administration, via webinar (recorded)

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Michael T. Abrams, M.P.H., Ph.D.

I'm Dr. Michael Abrams, a senior health researcher with Public Citizen. Public Citizen is a nonprofit consumer advocacy organization with over one million members. We have no financial conflicts of interest related to medical device regulation, including today's topic: the Food and Drug Administration's (FDA's) draft commitment language regarding the future of the Medical Device User Fee Amendments (MDUFA) program.[1]

Public Citizen is concerned that the draft commitment language for 2028-2032 focuses on advancing the interests of device manufacturers at the expense of consumer interests and expectations. Accordingly, we recommend these changes to the proposed language.

The FDA should…

1. … ask Congress for more direct appropriations to evaluate medical devices *before* they are approved or cleared for marketing in the United States.
2. … give consumers and public interest organizations more meaningful input into the medical device review process. Presently, patient stakeholder groups, ironically, are "second class" compared to device manufacturers, who have a financial interest in marketing new devices. Increased transparency through more public advisory committee meetings would be valuable as well.
3. … add program performance measures that quantify health improvements or spared morbidity for newly cleared or approved devices. At present, "performance" under MDUFA is focused on how quickly the FDA responds to device-maker (companies the agency often refers to as their "customers") applications and related requests.
4. …advance efforts to optimize diversity in premarket clinical trials for medical devices. For example, the FDA should add performance measures that benchmark the accuracy of wearable technologies, such as pulse oximeters, to detect physiological signs in persons across the skin pigmentation spectrum.
5. … be far more cautious about using "real-world" rather than higher-quality evidence to support regulatory decision-making. Per a 2025 FDA report, real-world evidence

[1] U.S. Food and Drug Administration. MDUFA performance goals and procedures, fiscal years 2028 through 2032. *Undated*. https://www.fda.gov/media/193465/download?attachment. Accessed August 3, 2026.

is defined as routinely collected health care information from questionable sources that include electronic billing records.[2] The FDA has stated that such information can be used as the main evidence in support of high-risk devices, including implantable spinal cord stimulators. Review of the report, however, suggests that reliance on "real-world evidence," rather than randomized clinical trials with contemporary, comparator arms, is often a fool's errand.

6. Finally, the language should be more proactive and detailed than it currently is regarding the FDA's pledge to bolster its capacity to regulate artificial intelligence (AI)-enabled and related devices. Recent reporting suggests that AI-enabled medical technologies of many types (including diagnostic software and mental health therapy chatbots) are flooding the market, many without FDA oversight.[3][4] At this critical moment for regulation of AI technologies, the commitment language should reflect the FDA's distinctive obligation to protect public health.

Thank you.

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[2] U.S. Food and Drug Administration. Report: Examples of Real-World Evidence Used in Medical Device Regulatory Decisions (Fiscal Years 2020–2025). April 2026. https://www.fda.gov/media/191805/download. Accessed August 3, 2026.

[3] Abrams MT. Testimony to the FDA's Digital Health Advisory Committee regarding generative artificial intelligence (AI)-enabled digital mental heath medical devices. November 6, 2025. https://www.citizen.org/article/testimony-to-fdas-digital-health-advisory-committee-regarding-generative-artificial-intelligence-ai-enabled-digital-mental-health-medical-devices/. Accessed August 4, 2026.

[4] American Psychological Association. Psychologists say patients are turning to chatbots as mental health professionals. June 16, 2025. https://www.apa.org/news/press/releases/2026/06/patients-chatbots-mental-health. Accessed August 4, 2026.