



Responding to the Draft Commitment Letter for the Medical Device User Fee Amendments Reauthorization for Fiscal Years 2023 Through 2027

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During this most recent user-fee reauthorization cycle, I have represented Public Citizen's views at the FDA-convened consumer/patient stakeholder meetings for both the prescription drug user fee amendments (PDUFA) and medical device user fee amendments (MDUFA). That experience has left my colleagues and I deeply concerned that existing regulatory review programs for these critical components of health care are increasingly compromised by substantial regulatory capture by industry and concomitant undue pressure.

The recently released MDUFA draft commitment letter expands a program that gives device-makers too much influence over their federal regulators.

The draft commitment language may well please industry, but certainly does not advance the best interests of consumers, especially for patients who rely on the FDA to protect them from ineffective or unsafe medical devices.

Accordingly, my brief testimony today offers a list of reforms that should be appended to the goals and procedures of the medical device review program.

As two examples that evoke the need for such reforms, consider implanted spinal cord stimulators for pain and transvaginal meshes for surgical repair. Past studies by our group have revealed that the FDA's lax approval and subsequently inadequate oversight of these high-risk implantable devices resulted in serious harms, including fatalities, to large numbers of patients.^{1,2}

¹ Carome MA. Implanted Spinal Cord Stimulators for Pain Relief. July 10, 2020. https://www.citizen.org/wp-content/uploads/2526_200610_Spinal-Cord-Stimulator-Report_FINAL.pdf. Accessed April 18, 2020.

² Public Citizen. Press statement: FDA bans dangerous surgical mesh for pelvic repair, following Public Citizen urging. April 16, 2019. <https://www.citizen.org/news/press-statement-fda-bans-dangerous-surgical-mesh-for-pelvic-repair-following-public-citizen-urging/>. Accessed April 18, 2022.

Here are several reforms that can reduce such morbidity and mortality. I strongly encourage the FDA to carefully consider each of them and to include these proposals in the medical device commitment letter packet submitted to Congress.

To advance FDA/Center for Devices and Radiological Health's (CDRH's) key mission of efficiently managing a safe and effective medical device pipeline, they should:

- Require high-risk, permanently implanted medical device sponsors to submit premarket approval applications (PMAs) with data from well-designed randomized trials.
- Make publicly available:
 - Review summaries for all PMA supplements for Class III medical devices.
 - Comprehensive assessments of adverse events from all approved PMAs and supplements, and the agency's Manufacturer and User Facility Device Experience (MAUDE) database.
 - A list of all Class III devices for which approval was granted based solely on literature reviews (rather than empirical trials) of studies assessing devices other than the one for which PMA approval was sought.
 - PMA annual report information (required for approvals since August 1, 2009) that reveals the number of devices sold, shipped, and implanted.
- Designate other staff, who are not involved in providing advice and guidance to sponsors prior to the submission of a PMA or 510(k) premarket submission for a medical device, to review and make decisions on any subsequent premarket submission related to that device. To ensure the integrity of these reviews and decisions, a fire-wall should be created between the FDA staff involved in any presubmission interactions and those involved in the formal evaluation of the PMA or 510(k) premarket submissions.
- Create a 510(k)-predicate database that is used to issue annual performance reports examining the quality and appropriateness of legacy devices as a foundation for premarket clearance decisions.
- Establish annual public health performance measures that quantify the benefits and harms of medical devices that have been cleared, approved, recalled, or rejected.

These proposals all aim to strengthen the FDA's independence from the industry it regulates and its commitment to safeguard the medical device pipeline by careful, transparent monitoring of regulatory decisions — especially as they pertain to the safety and effectiveness of high-risk devices like implantable stimulators, surgical meshes, stents, artificial valves, catheters and countless other invasive technologies.

Remarkably, the draft commitment letter contains none of these common-sense, patient-centered suggestions, instead yielding to industry's obvious desire to bring devices to market as quickly and cheaply as possible. Accordingly, we strongly encourage the FDA/CDRH to revise the commitment letter by aiming assertively towards the following two justifiable goals:

- (1) Establish and expand efforts that explicitly promote a regulatory pipeline that yields safe and effective devices.

- (2) Most importantly, press Congress to provide the FDA with taxpayer-funded resources to achieve that first goal independent of pernicious financial influences from the industry it regulates.

This last point is essential. If Congress truly desires a sound regulatory system, it must give the FDA direct financial appropriations and authorities to maintain and adapt that system. For its critical part, the FDA must not be shy in asking for those monies and mandates.

A recent scholarly analysis of PDUFA concluded that the program

...raises enough serious questions about PDUFA's overall impact on US drug regulatory policy that policymakers should reconsider perpetuating this system... and reallocate the necessary funds to relieve FDA of its financial reliance on industry.³

This is similarly applicable to MDUFA.

³ Mitchell AP, Trivedi NU, Bach PB. The prescription drug user fee act: much more than user fees. *Med Care*. 2022;60(4):287-293.