PUBLIC CITIZEN 50
People • Power • Progress YEARS

April 21, 2022

Comments regarding the MDUFA V – Draft Commitment Letter, Performance Goals and Procedures for Fiscal Years 2023 Through 2027
Document No. FDA-2020-N-0907-0040

Public Citizen, a consumer advocacy organization with more than 500,000 members and supporters nationwide, respectfully submits the following comments regarding the Food and Drug Administration's (FDA's) draft commitment letter regarding the Medical Device User Fee Amendments for fiscal years 2023 to 2027 (MDUFA V).

Since October 2020, Public Citizen has participated in the FDA's public stakeholder consultation meetings with patient and consumer advocacy groups regarding MDUFA V. Based on our involvement in these meetings and our deep knowledge of the FDA's medical-device regulatory processes, we have serious concerns regarding the draft commitment letter's substance as well as the process leading to the creation of that draft. Specifically, regarding this latter point, we have observed first-hand that the stakeholder process is strongly biased by nonpublic negotiations between the FDA and the medical-device industry.

As a result of the regulatory capture that has been fostered by the FDA's heavy reliance on user fees, the MDUFA V reauthorization proceedings once again have been skewed heavily towards placating the interests of the medical-device industry with ever-faster reviews of marketing applications. In contrast, the agency has ignored recommendations from Public Citizen and other consumer advocacy groups for improving the premarket and postmarket regulatory oversight of medical devices to better ensure that these products are safe and effective.

On June 10, 2020, we released a detailed report documenting the FDA's dangerously lax regulatory oversight of high-risk implanted spinal cord stimulators for pain relief that had resulted in unacceptable risk to patients.[1] Our report illustrated that the FDA's regulatory oversight of implanted spinal cord stimulators for pain relief had serious, wide-ranging deficiencies since the enactment of the Medical Device Amendments of 1976 and was emblematic of what's wrong with the agency's oversight of medical devices and the serious harm to patients that can result. Our 2020 report concluded with a series of recommendations to better ensure the safety and effectiveness of high-risk, permanently implanted devices.

On April 16, 2019, the FDA banned dangerous transvaginal surgical meshes, but only after thousands of women experienced preventable, serious life-altering harms because these faulty devices were cleared by the agency for marketing, and several years after the agency denied a petition submitted by Public Citizen in August 2011 to ban these devices.[2]

---

[1] Carome MA. Implanted Spinal Cord Stimulators for Pain Relief. June 10, 2020. https://www.citizen.org/wpcontent/uploads/2526_200610_Spinal-Cord-Stimulator-Report_FINAL.pdf. Accessed April 22, 2022.

[2] Public Citizen. Press statement: FDA bans dangerous surgical mesh for pelvic repair, following Public Citizen

These two examples — implantable spinal cord stimulators and transvaginal surgical meshes — typify the consequences of lax FDA medical device oversight that has expanded along with industry capture of the agency, and yet, these fundamental concerns are completely disregarded by the draft commitment letter despite persistent suggestions from many non-industry stakeholders including Public Citizen.

Accordingly, we again offer the following ideas to improve the FDA's medical device approval process, especially as it pertains to efficient reviews that require and demonstrate reasonable standards for the safety and effectiveness of marketed devices. Specifically, the FDA should:

(1) Require submission of premarket approval applications (PMAs) for all high-risk, permanently implanted medical devices and the inclusion of data from well-designed, randomized controlled trials in such PMA submissions.

(2) Require the FDA to make publicly available (a) summary review memoranda for all PMA supplements for all Class III medical devices, and (b) summary and safety and effectiveness data for any approved PMA supplements for which the device is modified in ways that could alter its safety or effectiveness.

(3) Require the FDA to perform and publish comprehensive analyses and assessments of adverse events from all approved PMAs and PMA supplements, PMA annual reports, and the agency's Manufacturer and User Facility Device Experience (MAUDE) database.

(4) Require the FDA to revamp its online MAUDE database to make it more user friendly.

(5) Require the FDA to compile and make publicly available a list of all Class III devices for which PMA approval was granted based on literature reviews of studies assessing devices other than the one for which PMA approval was sought, rather than well-designed prospective clinical trials of the actual devices for which PMA approval was sought.

(6) To provide an essential context for understanding numbers of medical-device adverse-event reports submitted to the FDA for each type of medical device, require the FDA to assume the following activities:

   (a) Make available to the public the PMA annual report information (required for approvals since August 1, 2009) that reveals the number of devices shipped or sold, as well as the number of devices actually implanted, if available.

   (b) Implement a regulation requiring that each permanent implantation of a medical device be reported by device-user facilities to a publicly accessible database maintained by the FDA.

---

urging. April 16, 2019. https://www.citizen.org/news/press-statement-fda-bans-dangerous-surgical-mesh-for-pelvicrepair-following-public-citizen-urging/. Accessed April 21, 2022.

(7) Require the FDA to 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 PMA or 510(k) premarket submission related to that device. To ensure the integrity of these reviews and decisions, an operational firewall should be created between the FDA staff involved in any presubmission interactions and those involved in the postsubmission PMA or 510(k) premarket submission review and decision-making.

(8) Require the creation of a database of predicate devices for 510(k) premarket submission that is to be used by the FDA to issue annual performance reports revealing the quality and appropriateness of legacy predicate devices as a foundation for 510(k) premarket clearance decisions.

(9) Establish MDUFA performance measures that capture public health indicators related to the benefits and harms of medical devices that have been cleared, approved, recalled, and rejected.

Industry may be uninterested in these kinds of measures that expose the true successes and failures of the FDA to promote and safeguard public health, but consumers and especially patients have a deep interest in such performance indicators.

(10) Establish MDUFA performance measures that offer year-over-year indicators regarding advisory committee members' and agency reviewers' perceptions regarding medical-device regulatory decisions made by the FDA.

(11) Establish MDUFA performance measures that assess long-term (three or more years) public health impacts of medical devices that have been approved or cleared for marketing.

(12) Request budgetary resources to strengthen postmarket activities, including timely monitoring of postmarket clinical trials, adverse-event monitoring, and the device recall system (including consumer notification).

(13) Request budgetary resources to strengthen and reaffirm the agency's commitment to timely, rigorous, in-person inspections of manufacturing facilities to ensure the safety and quality of medical devices.

Last month, Mitchell and colleagues published an analysis of all available documents (including public comments and meeting minutes) and resulting reauthorization bills leading up to this year's renewal of the original FDA user-fee program, the Prescription Drug User Fee Amendments (PDUFA), which were first enacted in 1992.[3] Based on their review, these authors concluded that:

[3] Mitchell AP, Trivedi NU, Bach PB. The Prescription Drug User Fee Act: much more than user fees. *Med Care.* 2022 Apr 1;60(4):287-293.

> The majority of policy changes enacted through PDUFA legislation have favored industry through decreasing regulatory standards, shortening approval times, and increasing industry involvement in FDA decision-making…
>
> The analysis of PDUFA's history 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.

Having been directly involved in the reauthorization process for both MDUFA and PDUFA during this most recent reauthorization cycle, we concur with Mitchell et al's critical assessment of user fees, and we believe it pertains to both the current and future regulatory oversight of both drugs and medical devices.

Accordingly, we strongly encourage the FDA to incorporate our suggestions into the commitment letter to Congress with the following two primary goals in mind:

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

(2) 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. An effective regulatory system for medical devices requires direct financial appropriations and authorities to maintain and adapt that system. For its part, the FDA must not be shy in asking for greater appropriations and mandates.

Thank you for the opportunity to comment on these important public health issues.

Michael T. Abrams, M.P.H., Ph.D.
Senior Health Researcher
Public Citizen's Health Research Group

Michael A. Carome, M.D.
Director
Public Citizen's Health Research Group