PUBLIC CITIZEN 50
People • Power • Progress YEARS

March 29, 2022

The Honorable Anna G. Eshoo
Chair, Subcommittee on Health
Committee on Energy & Commerce
United States House of Representatives
Washington, D.C. 20515

The Honorable Brett Guthrie
Ranking Member, Subcommittee on Health
Committee on Energy & Commerce
United States House of Representatives
Washington, D.C. 20515

RE: Comments Regarding Reauthorization of the Medical Device User Fee Amendments

Dear Chairperson Eshoo and Ranking Member Guthrie:

Public Citizen, a consumer advocacy organization with more than 500,000 members and supporters nationwide, respectfully submits the following comments regarding pending legislation that would reauthorize the Medical Device User Fee Amendments for fiscal years 2023 to 2027 (MDUFA V).

Since October 2020, Public Citizen has participated in the Food and Drug Administration's (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 protracted, nonpublic negotiations that occurred between the FDA and the medical-device industry prior to the agency's belated release of the draft MDUFA V commitment letter last week.

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 forwarded to your subcommittee our 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 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.

[1] https://www.citizen.org/wp-content/uploads/2526_200610_Spinal-Cord-Stimulator-Report_FINAL.pdf.

As your subcommittee deliberates on the MDUFA V legislation, we recommend that you consider including provisions in the legislation that would do the following:

(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 take the following steps:

   (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.

(7) Nullify the Supreme Court's 2008 decision in *Riegel v. Medtronic*, which held that the existing law preempts the right of patients to bring damages claims against medical-device manufacturers for injuries caused by high-risk medical devices marketed pursuant to a PMA. The Riegel decision ended a period of more than 30 years in which federal and state laws had worked hand in hand to strengthen device safety. The multiple dangerous weaknesses in the FDA's regulatory oversight of medical devices make the preemption decision in Riegel a dangerous outcome for patients.

(8) 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.

(9) 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.

(10) 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.

(11) 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.

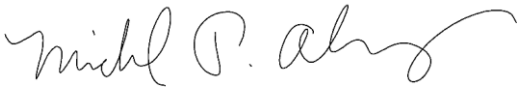
(12) Establish MDUFA performance measures that assess long-term (three or more years) public health impacts of medical devices that have been approved or cleared for marketing.

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

(14) Provide the FDA with the 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.

We encourage your subcommittee to take our recommendations into consideration when crafting legislation for MDUFA V.

Sincerely,



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

cc: Members, Subcommittee on Health, Committee on Energy & Commerce