August 6, 2026

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Medical Device User Fee Amendments (MDUFA VI); Public Meeting; Request for Comments [FDA-2026-N-6655]

Dear Sir/Madam:

The Personalized Medicine Coalition (PMC), an education and advocacy organization comprised of nearly 160 institutions from across the health care spectrum, appreciates the opportunity to provide insights on the importance of the Medical Device User Fee program to personalized medicine and to highlight priorities for the reauthorization of the Medical Device User Fee Amendments for fiscal years 2028 through 2032.[i]

Personalized medicine is an evolving field in which physicians use diagnostic tests to determine which medical treatments will work best for each patient or use medical interventions to alter molecular mechanisms that impact health. By combining data from diagnostic tests with an individual's medical history, circumstances, and values, health care providers can develop targeted treatment and prevention plans with their patients. Personalized medicine is helping to shift the patient and provider experiences away from trial-and-error toward a more streamlined process for making clinical decisions, which will lead to improved patient outcomes, a reduction in unnecessary treatment costs, and better patient and provider satisfaction.

Personalized medicine-related developments at FDA in 2025 show that scientific innovation continues to move the health system toward the utilization of individual patient information to improve patient outcomes and make clinical care more efficient. A well-resourced, focused, transparent, and flexible U.S. Food and Drug Administration (FDA) is essential to achieving PMC's mission of bringing forward the best treatment and prevention strategies for each patient. User fees supplement the agency's budget authority from Congress and ensure the FDA has the resources and workforce needed to complete the timely evaluation of personalized medicine products while upholding the agency's high standards for ensuring safety and effectiveness. Without this funding, many FDA activities that support personalized medicine would lag the technological progress we are seeing.

Statement of Neutrality

Many of PMC's members will present their own responses to the FDA's request for comments on the sixth reauthorization of MDUFA and will actively advocate for those positions. PMC's comments are designed to provide feedback so that the general concept of personalized medicine can advance, and are not intended to impact adversely the ability of individual PMC members, alone or in combination, to pursue separate comments with respect to MDUFA VI.

Importance of MDUFA to Personalized Medicine

The MDUFA program is a critical mechanism that has helped improve the timeliness of medical device reviews, encourage innovation in medical product development, and promote initiatives at the Center for Devices and Radiological Health (CDRH) that leverage the best science for disease diagnosis and personalized care. In this cycle and in previous reauthorization cycles, PMC has engaged at multiple points throughout the process to ensure that the FDA can continue to review and approve lifesaving products.

Research on the genetic and biological underpinnings of disease have contributed to development of an increasing number of personalized treatments and diagnostic products benefiting patients today. PMC's analyses have shown that personalized medicines account for more than a quarter of all new drugs approved annually by the FDA. An important consideration for personalized medicine is the use of diagnostics to discern biomarker statuses that guide drug use and prevention strategies. In 2025, CDRH approved or cleared several significant new or expanded indications within sixteen companion diagnostic testing platforms that will help inform targeted treatment for patients with various types and stages of cancer, as well as diseases like hemophilia A and B and Duchene Muscular Dystrophy. CDRH also marked a significant step toward earlier and less invasive detection of Alzheimer's disease by clearing or approving two blood-based testing applications that can aid earlier diagnosis. Together these actions represent meaningful progress in personalized medicine by enabling more informed clinical decision-making.[ii]

Initiatives advanced by the FDA in recent years have also fostered many notable regulatory firsts beyond the approval or clearance of new diagnostic testing indications, such as the authorization of Digital Health Technologies (DHTs) including more than 1,000 Artificial Intelligence (AI)/Machine Learning (ML)-enabled medical devices. 2025 brought FDA's first qualification of an AI-based tool under the Drug Development Tool Qualification Program for assessing liver biopsies in metabolic dysfunction-associated steatohepatitis (MASH). Guidance documents developed by CDRH to foster real-world evidence (RWE) for use across a medical device's total product lifecycle and the establishment of FDA-recognized Collaborative Communities, such as the STRIPE in the area of pharmacogenetic testing, have allowed personalized medicine to advance.[iii] The current reauthorization of the MDUFA program (MDUFA VI) will continue yielding benefits for a wide range of patients, including those with unmet medical needs.

Considerations for MDUFA VI

MDUFA VI builds meaningfully on commitments made under previous authorizations, particularly in the areas RWE, DHTs, and patient/stakeholder engagement. PMC's previously proposed considerations for the sixth reauthorization of the MDUFA program are reflected in the draft commitment letter and will bolster the progress already made through MDUFA V.

<u>Digital Health Technologies (DHTs) Artificial Intelligence (AI)/Machine Learning (ML)</u>

PMC believes that DHTs can enhance trial efficiency, parallel to the delivery of real-world care, and may even provide personalized insights at the point of care. We applauded commitments in MDUFA V that fostered the adoption of DHTs as evidence generation evolves and advanced understanding of how to measure and monitor quality across the total product lifecycle of a medical device. The rapid growth of DHTs and AI-enabled devices

presents opportunities for patients and significant regulatory challenges. The FDA and external stakeholders will benefit from CDRH's continued work to provide expertise in premarket submissions that include software, interoperable devices, wearables, and AI/ML technologies and to ensure that regulatory pathways involving the FDA are predictable, transparent, and patient-centered.

At the start of negotiations PMC expressed that MDUFA VI should support clear and publicly available guidance to help all stakeholders understand evidentiary expectations, approval pathways, and post-market oversight mechanisms for DHTs and AI/ML devices. We are pleased that FDA proposes in Section IV.H of the draft commitment letter to expand technical expertise to address rapidly evolving DHTs, strengthen reviewer training, and engage with stakeholders through formal and informal mechanisms to explore regulatory approaches to emerging DHTs. Public reporting of evidence standards and decision-making rationales would also help ensure that innovation in this space translates into safe, effective, and trustworthy technologies for the patients who depend on them and should be considered when the commitment letter is finalized.

Real-World Evidence (RWE)

Data collected about individuals' lifestyles, disease biology and treatment outcomes made available through the collection of RWE has the potential to transform the future of personalized medicine. Guidance development in MDUFA IV on the use of RWE, along with resources to allow CDRH's participation on the Coordinating Committee for the National Evaluation System for health Technologies (NEST) and the Medical Device Innovation Consortium (MDIC), provided a foundation for understanding how and when RWE may be used to support medical device regulatory decisions.

RWE can strengthen the consistency of safety and effectiveness evaluations across device categories and provide a more complete understanding of device performance in diverse patient populations. Because the impact of CDRH's work in this area of RWE extends beyond industry and industry-supported groups, in our response at the start of MDUFA VI negotiations PMC asked for additional transparency in MDUFA VI on avenues available for researchers, health data organizations, and other non-industry stakeholders like patient groups to interact with the agency on RWE pre-market and post-market data development and analysis. It is encouraging that the MDUFA VI draft commitment letter in Section IV.G proposes to advance the continued development of real-world data and RWE methods and approaches to support regulatory acceptance for premarket submissions and that FDA will make this information available to public stakeholders through two or more open public meetings and published examples of market authorization decisions that relied on real-world data and real-world evidence.

Patient Engagement Activities

Identifying the benefits and risks of medical products that matter to patients is essential to the effective delivery of personalized medicine. In 2019, PMC submitted feedback to CDRH on its draft priority list of patient preference-sensitive areas developed as part of MDUFA IV.[iv] In our comments, we suggested further stakeholder engagement on complicated patient preference sensitive areas such as those individuals living with chronic or rare conditions before CDRH proceeded with implementation of a final patient-preference priority list. Under MDUFA V CDRH made strides in advancing the science of patient engagement, particularly through the issuance of guidance on patient preference information, clinical outcome assessments, and the use of patient-generated health data. At the start of negotiations on MDUFA VI PMC generally supported continued focus on how patient insights can positively impact the design and conduct of premarket clinical studies, benefit-risk assessments, and post-market evaluation of medical devices.

PMC supports FDA's proposed commitments to continue to advance CDRH's Patient Science and Engagement program. The expansion of scientific expertise and staff capacity will help the Agency respond to the growing

volume and complexity of patient data submissions. Additional internal and external training detailed in Section IV.F of the draft commitment letter along with published case examples of the generation and use of patient-generated health data have the potential to support further adoption of innovative technologies to capture patient perspectives and reduce patient burden.

Total Product Life Cycle (TPLC) Advisory Program (TAP)

PMC has strongly supported legislative solutions and a Medicare access pathway that would extend coverage for breakthrough devices immediately upon the date of FDA approval for up to four years.[vvi] For devices addressing areas of unmet medical need, which may include some diagnostic and screening tests underpinning personalized medicine, the newness of the device, and in some cases small patient population sizes, can create challenges to gathering the clinical evidence needed for coverage and reimbursement determinations, including age- and disability-related outcomes, subsequently increasing the time between introduction to the market and patient access.

PMC understands that under MDUFA VI the FDA intends to transition to a voluntary TAP program covering all eligible CDRH-regulated breakthrough devices by October 1, 2027, and that CDRH will add a new feature focused on enhanced collaboration between the FDA and the Centers for Medicare and Medicaid Services (CMS). The purpose of FDA and CMS engagement would be to align evidentiary requirements for regulatory approval and coverage. Facilitating regular, solutions-focused engagement between FDA review teams, TAP program participants, and other stakeholders such as patients, providers, and payers, may be beneficial to align expectations regarding evidence generation, however, if a developer has to meet CMS coverage requirements to obtain FDA clearance or approval, it will add time and cost to bring products to market which may inadvertently impact patient access. If this aspect of the TAP program is finalized participation should remain voluntary and the separate and distinct remits of FDA and CMS should be maintained to appropriately inform approval and coverage decisions.

Resources for Expertise and Infrastructure

Finally, in previous comments to the FDA, PMC highlighted that progress made under past MDUFA reauthorizations enabled CDRH to reduce the total time it takes to return a decision on a product submission while maintaining high standards for device safety and effectiveness.[vii] This has been possible because of the dedication of CDRH's leadership and staff. It has also been achieved through additional opportunities for engagement between industry and CDRH during the device review process. These interactions allow product sponsors to better understand FDA's data needs. User fees are essential for maintaining CDRH's capacity, enabling FDA to meet its performance commitments for medical device review and oversight.

We understand that user fees must be set at levels sufficient to support CDRH's responsibilities across the total product life cycle of medical devices. However, medical device user fees were first collected in FY2003 and have comprised an increasing proportion of FDA's budget that is focused on device regulation. In FY2003, medical device user fees accounted for 11 percent of the MDUFA program total costs, compared with 44 percent in FY2023.[viii] Concerns regarding the long-term sustainability of fee growth and the clarity of resource allocation must be addressed.

While adequate funding for recruitment, retention and infrastructure is indispensable to patient health, unsustainable increases could hinder innovation and erode confidence in the MDUFA program. MDUFA VI strikes a reasonable balance between activities funded through user fees and those supported with appropriated resources. PMC is represented on the Board of the Alliance for a Stronger FDA and is prepared to advocate for annual Budget Authority (BA) levels that supplement MDUFA VI fees that provide FDA with the necessary expertise and infrastructure to uphold CDRH's core pillars of safety and innovation.

Conclusion

Thank you for your commitment to ensuring that patients have timely access to safe and effective medical devices so that every patient may have the opportunity to benefit from a personalized approach to health care. PMC looks forward to working with your colleagues at the FDA and Congress as the reauthorization process advances. If you have any questions about the content of this letter, please contact me at 202-499-0986 or cbens@personalizedmedicinecoalition.org.

Sincerely,

Cynthia A. Bens
Senior Vice President, Public Policy

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[i] U.S. Food and Drug Association. Draft MDUFA Goals and Procedures, Fiscal Years 2028 through 2032. July 8, 2026. https://www.fda.gov/media/193465/download?attachment (accessed August 3, 2026)

[ii] Personalized Medicine Coalition. Personalized Medicine at the FDA: The Scope and Significance of progress in 2025. May 2026. https://www.personalizedmedicinecoalition.org/wp-content/uploads/2026/05/9920-PMC_PM_at_FDA_The_Scope__Significance_of_Progress_2025_v8_Digital.pdf (accessed August 3, 2026).

[iii] Personalized Medicine Coalition. Comments on the Medical Device User Fee Act (MDUFA VI); Public Meeting. September 4, 2025. https://www.personalizedmedicinecoalition.org/wp-content/uploads/2025/09/MDUFA_VI_Public_Meeting_Comment_FINAL_09042025.pdf (accessed August 3, 2026).

[iv] Personalized Medicine Coalition. Comments on Center for Devices and Radiological Health (CDRH) List of Patient Preference-Sensitive Priorities. July 12, 2019. https://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/PMC_Comments_Patient-Preference-Sensitive-Areas-for-Medical-Device-Review.pdf (accessed August 3, 2026).

[v] Personalized Medicine Coalition. Feedback on H.R. 6000 *Cures 2.0 Act*. February 28, 2022. https://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/PMC_Cures_2.0_Comments_2.28.2022.pdf (accessed August 5, 2026).

[vi] Personalized Medicine Coalition. Comments on Centers for Medicare and Medicaid Services Public Comment Period on Medicare Coverage of Innovative Technology (MCIT) and Definition of ''Reasonable and Necessary'' (CMS–3372–IFC) April 16, 2021. https://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/PMC-Comments_MCIT-Interim-Final-Rule_2021.04.16.pdf (accessed August 5, 2026).

[vii] Personalized Medicine Coalition. Comments on the Fifth Reauthorization of the Medical Device User Fee Act (MDUFA V). https://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/MDUFA_V_comments_4.21.22.pdf (accessed August 3, 2026).

[viii] Congressional Research Service. FDA Human Medical Products User Fee Programs. April 26, 2024. https://www.congress.gov/crs_external_products/R/PDF/R44750/R44750.11.pdf (accessed August 3, 2026).