MILKEN INSTITUTE

August 7, 2026

Kyle A. Diamantas, JD
Acting Commissioner of the Food and Drug Administration
US Department of Health and Human Services
Silver Spring, MD 20993

Re: Medical Device User Fee Amendments; Public Meeting; Request for Comments [Docket No. FDA–2026–N–6655]

Dear Acting Commissioner Diamantas,

The FasterCures team at the Milken Institute appreciates the opportunity to provide comments on the proposed recommendations for the reauthorization of the Medical Device User Fee Amendments (MDUFA VI). FDA has made meaningful progress in fostering patient-focused medical device development, and the proposed MDUFA VI commitments provide an important opportunity to build on that foundation and further strengthen the role of patient perspectives across the total product life cycle.

> *Disclosure Statement: The Milken Institute currently holds an active research contract with the Food and Drug Administration, contract #75F40124C00120, to conduct research and produce resources for a project titled "Defining the Value and Return on Investment of Patient Engagement in Medtech Product Development." The views expressed in this comment letter are solely those of the Milken Institute.*

As a nonprofit, nonpartisan think tank, the Milken Institute believes in the power of capital markets to solve urgent social and economic challenges to improve lives. At the heart of the Institute's work is the idea that societies prosper with an educated, healthy workforce, open and efficient capital markets, and effective social institutions. FasterCures is driven by a singular goal: to save lives by accelerating scientific advancements for all patients.

For more than 15 years, FasterCures has worked to advance patient engagement (PE) in biomedical research and development (R&D) by convening stakeholders, identifying barriers and opportunities to drive progress, and developing practical resources to support the implementation of PE activities. While significant progress has been made across the broader life sciences ecosystem, adoption of patient engagement practices in the medtech sector continues to lag behind the pharma sector. Through our past and current research on medtech patient engagement and collaborations with medtech stakeholders, including ongoing work with the FDA's Center for Devices and Radiological Health, we have identified persistent barriers that limit broader adoption of patient engagement in medtech, including:[1]

- limited organizational resources and uncertainty regarding the return on investment of patient engagement activities;
- compliance, privacy, and legal concerns;
- need for greater regulatory and reimbursement clarity on the use and application of PE data and information;
- difficulty identifying and reaching appropriate patient populations;
- challenges engaging patients early in product development;
- limited adoption of available tools and frameworks; and
- organizational and cultural barriers to leadership and functional team buy-in.

In light of these findings, FasterCures offers four recommendations to strengthen MDUFA VI implementation and maximize the value of patient engagement in medtech development:

1. Build patient organization capacity to support regulatory-relevant patient experience data (PED), patient-generated health data (PGHD), and real-world evidence (RWE) contributions.
2. Increase transparency regarding how PED and PGHD are submitted, reviewed, and used.
3. Report on PE activities, lessons learned, and impacts coming out of the Total Product Life Cycle Advisory Program (TAP).
4. Leverage TAP and Regulatory Alignment for Predictable and Immediate Device (RAPID) to advance FDA-CMS alignment and reduce downstream access barriers.

Recommendation 1: Build Capacity for Patient Organizations Supporting Regulatory-Grade Data and Evidence

A growing set of regulatory guidance documents now address the use of PED and RWE, which has created new opportunities to incorporate patient perspectives into regulatory decision-making.

However, many of the organizations responsible for collecting, stewarding, and generating these data sources are patient organizations with limited financial and technical capacity. Many patient organizations operate patient registries, natural history studies, and data-sharing initiatives that can serve as critical sources of this data for product R&D. With increasing demands for PED and PGHD that may be generated as a result of continued guidance development on these topics, it is essential that patient organization capacity is increased to keep up with the rising demand.

We therefore encourage the FDA to explore mechanisms that support capacity-building for patient organizations serving as contributors of regulatory-relevant patient experience and patient-generated health data. Strengthening organizational readiness, data quality, and evidence-generation capabilities among these trusted partners will help ensure that developers, regulators, and ultimately patients can realize the full potential of these investments.

Recommendation 2: Increase Transparency Regarding the Use and Impact of PED and PGHD

Medtech developers have told us they need more examples and greater transparency on how PED is used by FDA—information that helps them justify allocating resources to these activities in the first place.[1]

The proposed MDUFA VI letter commitments include efforts to expand training and share examples related to PGHD and RWE. We support these commitments and encourage the FDA to build upon them through more systematic reporting regarding the submission, utilization, and impact of PED and PGHD in device regulatory activities.

Such reporting could help stakeholders better understand:

- how PED and PGHD are being incorporated into submissions;
- how FDA reviewers are considering these data during review;
- common use cases and lessons learned;
- areas where additional guidance or stakeholder education may be beneficial; and
- the measurable impact of patient-informed evidence on regulatory decision-making.

Greater transparency would help address persistent uncertainty among developers while also encouraging broader adoption of meaningful patient engagement practices.

Recommendation 3: Report on PE Activities, Lessons Learned, and Impacts Coming Out of TAP

FasterCures supports TAP's role in facilitating early engagement among developers, patient organizations, providers, payers, and other stakeholders, and supports the FDA's efforts to continue and expand that program.[2]

We encourage the FDA to track and publicly report lessons learned from patient engagement activities conducted through TAP, including the types of engagement pursued, the purpose of engagement, barriers encountered, and the impact such activities have on product development and regulatory activities. Sharing these insights broadly would help strengthen the evidence base to help justify patient engagement and provide practical examples for developers seeking to implement similar approaches.

Recommendation 4: Leverage TAP and RAPID to Advance FDA-CMS Alignment and Improve Patient Access

We are also encouraged by the emergence of the RAPID coverage pathway, which creates new opportunities for earlier collaboration between the FDA and the Centers for Medicare & Medicaid Services (CMS) and aligns regulatory and coverage considerations earlier in device development. The RAPID coverage pathway is now available for certain Class II devices participating in TAP and Class III devices, regardless of TAP participation.[3]

As TAP and RAPID continue to evolve, the FDA should work with CMS to identify and disseminate promising practices, lessons learned, and measurable outcomes from dual-agency engagement. Particular attention should be paid to how earlier coordination influences evidence planning within medtech companies, review efficiency, coverage determinations, and ultimately patient access to innovative technologies, and draw upon learnings from the FDA, CMS, and participating TAP companies. These programs have the potential to demonstrate how more coordinated regulatory and reimbursement pathways can reduce uncertainty for developers and streamline evidence-generation strategies, while accelerating access to important technologies for patients.

Conclusion

FasterCures and the broader Milken Institute Health community look forward to partnering with the FDA, CMS, medtech developers, and patient organizations to implement these recommendations to support more robust PE in the medtech space and encourage more streamlined and efficient regulatory and coverage activities to ensure both patient voices and needs are fully heard and incorporated, and that those needs are addressed as quickly as possible.

Sincerely,

Esther Krofah
Executive Vice President, Health
Milken Institute

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[1] Raymond Puerini et al., *Defining and Demonstrating the Value of Patient Engagement in Medtech Research and Product Development* (Milken Institute, October 17, 2024), https://milkeninstitute.org/content-hub/research-and-reports/reports/defining-and-demonstrating-value-patient-engagement-medtech-research-and-product-development.

[2] "TAP Overview," Center for Devices and Radiological Health, US Food and Drug Administration, accessed August 3, 2026, https://www.fda.gov/medical-devices/total-product-life-cycle-advisory-program-tap/tap-overview.

[3] "TAP Pilot Enrollment & Expansion," US Food and Drug Administration, accessed August 4, 2026, https://www.fda.gov/medical-devices/total-product-life-cycle-advisory-program-tap/tap-pilot-enrollment-expansion.