NATIONAL HEALTH COUNCIL

September 4, 2025

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

RE: Reauthorization of the Medical Device User Fee Amendments; Public Meeting; Request for Comments [FDA-2025-N-1157]

To Whom It May Concern:

The National Health Council (NHC) appreciates the opportunity to submit comments to the U.S. Food and Drug Administration (FDA) following its August 4, 2025, public meeting on the reauthorization of the Medical Device User Fee Amendments (MDUFA) for fiscal years 2028 through 2032 (MDUFA VI).

Created by and for patient organizations over 100 years ago, the NHC brings diverse organizations together to forge consensus and drive patient-centered health policy. We promote increased access to affordable, high-value, equitable, and sustainable health care. Made up of more than 180 national health-related organizations and businesses, the NHC's core membership includes the nation's leading patient organizations. Other members include health-related associations and nonprofit organizations including the provider, research, and family caregiver communities; and businesses and organizations representing biopharmaceuticals, devices, diagnostics, generics, and payers.

Assessment of MDUFA V Overall Performance

At the outset of the MDUFA VI reauthorization process, it is necessary for a comprehensive examination of the FDA's reported progress under MDUFA V and the perspectives of the broader stakeholder community. FDA data indicate that the program has met most review performance goals, enhanced staff capacity, and advanced critical initiatives, including the Total Product Life Cycle Advisory Program and digital health oversight.[1] These achievements have increased the predictability of device reviews and facilitated earlier access to innovative technologies.

However, stakeholders emphasize that review speed, while crucial, should not be the sole metric for program effectiveness. Persistent concerns exist regarding the adequacy of post-market surveillance, particularly for devices entering the market with limited premarket data. Stakeholders have also highlighted the need for the systematic

[1] U.S. Food and Drug Administration, *Medical Device User Fee Performance Reports*, updated June 12, 2025, https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa-fees/mdufa-reports

integration of patient perspectives, expanded use of real-world data to capture long-term outcomes, and more transparent communication of safety information.

An additional concern involves the sustainability and transparency of user fee funding. While user fees have undeniably enabled significant enhancements in review capacity, questions remain about the long-term trajectory of fee levels and the clarity with which expenditures are reported. Stakeholders have also emphasized the importance of preserving programs that support small businesses and promote international harmonization.

MDUFA V has delivered measurable progress while also revealing areas where additional attention is warranted. To build upon this progress, MDUFA VI must sustain timely review performance, strengthen oversight across the device life cycle, ensure meaningful patient engagement, and provide greater transparency in the use of resources. A balanced approach that integrates these priorities—and refines existing initiatives to avoid duplication—will best serve patients, caregivers, innovators, and the health system as a whole.

Sustaining FDA Capacity and Expertise

FDA's ability to fulfill its mission depends on its sustained capacity to recruit and retain expert staff and to invest in regulatory science. For medical devices, this includes developing expertise in critical areas such as cybersecurity, biocompatibility, digital health, and artificial intelligence. User fees are essential for maintaining this capacity, enabling FDA to meet its performance commitments and provide oversight across the total product life cycle.

To fulfill these responsibilities, user fees must be set at levels sufficient to support thorough premarket reviews, robust post-market surveillance, and timely safety communications that patients and providers can trust. However, concerns regarding the long-term sustainability of fee growth and the clarity of resource allocation must be addressed. While adequate funding is indispensable to patient safety, unsustainable increases could hinder innovation and erode confidence in the program.

MDUFA VI should achieve an appropriate balance. The program should ensure that fee levels provide FDA with the necessary expertise and infrastructure to protect patients, while simultaneously enhancing transparency in resource utilization and provide predictability for all stakeholders. Mechanisms such as small business fee waivers and targeted support programs must be maintained to preserve pathways for emerging innovators, thereby guaranteeing that patients continue to benefit from rigorous oversight and timely access to safe and effective technologies.

Patient Engagement in Device Development and Regulation

The NHC acknowledges the progress made under MDUFA V 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. These initiatives represent important steps toward ensuring that regulatory decisions reflect patient experiences and perspectives, providing critical context on

unmet needs, tolerable risk, and meaningful benefits for those living with chronic and rare conditions.

For MDUFA VI, it is critical to build on these achievements by further integrating patient input into all phases of device development and regulatory decision-making. The use of patient-reported outcomes and patient preference information should become a more systematic, rather than voluntary or exceptional, feature of regulatory submissions. FDA should also invest in infrastructure that reduces barriers to trial participation, including developing digital and remote data collection tools that enable broader, more inclusive participation. Reducing burdens on patients and caregivers not only supports recruitment and retention but also ensures that study populations better reflect the diversity of those who will ultimately use these devices.

Effective patient engagement also requires a strong focus on public education. The continued development of accessible, patient-friendly educational modules on device trials, real-world data, and regulatory frameworks will empower patients and caregivers to engage more confidently. These resources should be written in plain language and tailored to reach diverse communities, including those historically underrepresented in clinical research.

Finally, the details of implementation are critical. Patients and patient organizations must be meaningfully involved at every stage of translating commitments into practice. The NHC and its members stand ready to assist as FDA and stakeholders codify these commitments into MDUFA VI, ensuring that engagement processes are designed with patient input from the outset to make them more effective, trustworthy, and sustainable.

Real World Evidence and Post-Market Surveillance

The NHC supports the continued advancement of real-world evidence (RWE) as a critical complement to premarket data in device regulation. When appropriately applied, 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. Given that premarket evidence for medical devices may be limited, this approach is particularly important as post-market data provide critical insights into long-term safety and real-world use.

Strengthening post-market systems must be a central priority for MDUFA VI. User fees should be structured to ensure FDA has the resources to enforce the use of unique device identifiers in order to improve traceability throughout the health system. Additionally, adverse event reporting systems must be enhanced to support more complete and accurate data collection, and the resulting information should be made accessible in a manner that is transparent and meaningful to patients, caregivers, and providers.

Collaboration with professional registries and integration with electronic health record systems can also improve the ability to monitor device performance longitudinally. These mechanisms support a life-cycle approach to regulation that aligns with both patient safety and clinical utility. Finally, timely communication of safety information is

essential; FDA must be equipped to translate data into clear, accessible updates for patients and caregivers, enabling them to make informed decisions.

Embedding these commitments into MDUFA VI will ensure that RWE and post-market surveillance serve as robust, patient-centered safeguards that complement FDA's premarket review responsibilities and strengthen public confidence in the medical device ecosystem.

Digital Health and Artificial Intelligence

The rapid growth of digital health technologies and AI-enabled devices presents both opportunities for patients and significant regulatory challenges. These technologies hold the potential to transform care delivery, expand access, and generate new forms of evidence. However, their complexity necessitates dedicated expertise within FDA to ensure that regulatory pathways are predictable, transparent, and patient-centered.

MDUFA VI should support the continued expansion of FDA's capacity to evaluate digital and AI-based technologies, including tools that evolve through continuous learning. Clear and publicly available guidance is necessary to help stakeholders understand evidentiary expectations, approval pathways, and post-market oversight mechanisms. Public reporting of evidence standards and decision-making rationales will be essential to sustaining confidence in these products.

Finally, the oversight of digital health and AI-enabled technologies should be approached through a total product life-cycle lens. FDA must be equipped to monitor performance post-market, communicate safety and effectiveness information in clear and accessible terms, and coordinate across its Centers to ensure regulatory consistency. These efforts will help ensure that innovation in this space translates into safe, effective, and trustworthy technologies for the patients who depend on them.

Transparency, Accountability, and Sustainability

To maintain public confidence in the MDUFA program, transparency and accountability in the use of user fees are essential. The NHC urges FDA to provide clearer financial and programmatic reporting, detailing how fee revenues are allocated, the staff positions they support, and how expenditures translate into measurable outcomes for patients.

At the same time, the sustainability of fee growth must also be addressed. While user fees must remain adequate to fund rigorous oversight and advance regulatory science, their long-term trajectory should be calibrated to avoid unsustainable increases. MDUFA VI should ensure sufficient funding while providing transparency and predictability for all stakeholders.

Finally, mechanisms that safeguard innovation—such as small business waivers and targeted support programs—should be maintained. These measures help ensure that start-ups and smaller firms, which are often key drivers of breakthrough technologies, are not disproportionately burdened. These mechanisms ensure the resources necessary for robust patient protections and regulatory capacity.

New Features for Consideration in MDUFA VI

The NHC supports the inclusion of new features in the MDUFA VI performance goals to further embed patient-centeredness, strengthen scientific capacity, and enhance regulatory transparency.

The NHC recommends that FDA support the development and use of patient-centered core outcome sets in device trials and registries. This initiative should align with broader efforts to define patient-centered core impact sets (PC-CIS), such as those developed by the NHC.[2] Establishing consistent, clinically valid, and meaningful outcomes will promote comparability across studies, facilitate pooled analyses, and ensure endpoints reflect what matters most to patients and caregivers. Participation in such initiatives should remain voluntary, serving as a complementary resource for sponsors.

The NHC also recommends that FDA expand its capacity and issue guidance on the regulatory use of externally controlled studies and RWE in device contexts. These approaches are particularly valuable for small populations and rare conditions where traditional randomized trials may be impractical. Clear methodological guidance, coupled with earlier opportunities for sponsor engagement on study design, would strengthen predictability and ensure scientific rigor. When validated and appropriately applied, these methods can improve trial feasibility while upholding evidentiary standards that protect patients.

The NHC further recommends that FDA explore mechanisms to publish non-proprietary, aggregate-level metrics on patient input in regulatory decisions. Providing information on the types and frequency of patient experience data submitted, and how such data are incorporated, would enhance transparency and demonstrate the value of patient contributions without imposing additional burdens on sponsors or compromising proprietary information.

Finally, the NHC supports further investment in FDA reviewer training and staffing related to patient-focused device development, digital health technologies, and real-world evidence. Expanding reviewer expertise in these areas will ensure the consistent application of patient-centered methodologies, strengthen the integration of patient experience and post-market data, and reinforce the evidentiary standards that support timely and efficient reviews.

Conclusion

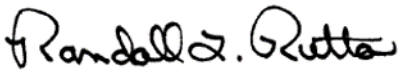
The MDUFA program has played a central role in strengthening the efficiency and predictability of medical device review, while also supporting FDA's growing capacity to integrate patient perspectives and advance regulatory science. As FDA and stakeholders begin negotiations on MDUFA VI, the NHC urges the agency to prioritize the institutionalization of patient-focused device development, the expansion of real-world evidence and other novel evidence tools, the continued development of patient-

[2] National Health Council, *A Blueprint for Developing Patient-Centered Core Impact Sets (PC-CIS)* (2022), https://nationalhealthcouncil.org/a-blueprint-for-developing-patient-centered-core-impact-sets-pc-cis/.

centered outcome measures, and the safeguarding of FDA's review capacity through sustainable user fee structures. These efforts are vital to ensuring that future medical technologies are developed, reviewed, and monitored in ways that reflect rigorous scientific standards as well as the perspectives and priorities of the patients who rely on them.

The NHC remains committed to advancing a regulatory system that is transparent, evidence-driven, and accountable to the public it serves. We thank FDA for its continued leadership and the opportunity to provide input into this process. The NHC looks forward to participating in the upcoming stakeholder consultation meetings and remains committed to working collaboratively to advance a regulatory system for devices that is scientifically rigorous, transparent, and responsive to patient needs. Please contact Kimberly Beer, Senior Vice President, Policy & External Affairs at kbeer@nhcouncil.org or Shion Chang, Senior Director, Policy & Regulatory Affairs at schang@nhcouncil.org, if you would like to discuss our recommendations in greater detail.

Sincerely,



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