NATIONAL HEALTH COUNCIL

August 6, 2026

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

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

Submitted electronically via regulations.gov

The National Health Council (NHC) appreciates the opportunity to submit comments to the U.S. Food and Drug Administration (FDA) on the draft Medical Device User Fee Amendments (MDUFA) Performance Goals and Procedures for fiscal years 2028 through 2032 (MDUFA VI). We also value FDA's continued consultation with patient and consumer stakeholders throughout the reauthorization process and the opportunity to provide public remarks at the August 5, 2026, meeting.[1]

Created by and for patient organizations more than 100 years ago, the NHC convenes organizations from across the health ecosystem to forge consensus and drive patient-centered health policy. We promote increased access to affordable, high-value, comprehensive, accessible, equitable, and sustainable health care. Made up of nearly 200 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 representing the provider, research, and family caregiver communities, as well as businesses and organizations representing biopharmaceuticals, medical devices, diagnostics, generics, and payers.

The draft commitment letter reflects the conclusion of an extensive negotiation and stakeholder consultation process and represents a constructive agreement between FDA and the medical device industry on the resources, performance goals, scientific capabilities, and operational improvements that will support the device program during fiscal years 2028 through 2032. The NHC recognizes the substantial work required to reach this stage and appreciates that the agreement maintains a strong focus on FDA capacity, review predictability, timely communication, scientific expertise, and more efficient development pathways, all of which can support more timely patient access to safe and effective medical technologies and greater predictability for developers.[2]

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[1] U.S. Food and Drug Administration, "Draft MDUFA Performance Goals and Procedures, Fiscal Years 2028 Through 2032" (2026), https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa-fees/medical-device-user-fee-amendments-2028-mdufa-vi.

[2] U.S. Food and Drug Administration, "Background on MDUFMA," July 9, 2019, https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa-fees/background-mdufma.

The agreement also includes meaningful commitments related to patient science, real-world evidence, digital health, artificial intelligence, reviewer training, and the Total Product Life Cycle Advisory Program (TAP). These provisions reflect a shared recognition among FDA, industry, and the patient community that an effective medical device review program depends not only on clear timelines and adequate staffing, but also on evidence that reflects patient priorities, regulatory approaches that can keep pace with changing technologies, and early communication that helps sponsors address evidentiary questions before they become sources of delay or unnecessary burden.

The NHC's overall view of the draft agreement is therefore positive. At this stage in the reauthorization process, the NHC's recommendations are intended primarily to support effective implementation of commitments already included in the agreement, identify areas where additional clarification or public reporting may improve accountability, and encourage continued patient-community engagement as FDA develops implementation plans, guidance, training, evaluation methods, and other supporting activities. Consistent with the current stage of the reauthorization process, these recommendations focus on strengthening the negotiated framework's ability to deliver meaningful value for patients rather than substantially revising its core terms.

For patients, the success of MDUFA VI will ultimately be measured by whether the program supports timely access to safe and effective devices, improves the relevance and quality of evidence used in regulatory decision-making, reduces avoidable delays and inconsistencies, strengthens confidence in evolving technologies, and provides understandable information about benefits, risks, uncertainties, and changes in device performance over time. Review predictability and efficient FDA-industry interaction are important components of that success because they can improve development planning, reduce unnecessary rework, and facilitate earlier resolution of questions concerning study populations, patient-relevant outcomes, usability, and evidence needs.

The recommendations below build on the NHC's September 2025 comments at the opening of the MDUFA VI reauthorization process and on preliminary input gathered from NHC patient organization members representing chronic-condition, rare-disease, and cancer communities.[3] That member input identified the consistent integration of patient-focused data as the highest-ranked priority and transparency and public accountability as among the most important opportunities for improvement. Members also emphasized validated real-world and digital measures, patient-centered outcomes, reviewer capacity and consistency, representative study participation, and sustained opportunities for patient engagement during implementation.[4]

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[3] National Health Council, "NHC Comments on Public Meeting on Reauthorization of the Medical Device User Fee Amendments" (September 4, 2025), https://nationalhealthcouncil.org/letters-comments/nhc-comments-on-public-meeting-on-reauthorization-of-the-medical-device-user-fee-amendments/.

[4] National Health Council, "NHC Phase 1 Snapshot: Patient Community Priorities: Prepared for FDA Stakeholder Consultations on PDUFA VIII and MDUFA VI" (preliminary discussion draft, November 2025).

Summary of Recommendations

The NHC encourages FDA to build on the negotiated MDUFA VI framework by:

- Fully implementing and adequately resourcing the patient science and engagement commitments, including continued expertise in patient preference information, patient-reported outcomes, patient-generated health data, clinical outcome assessments, and patient-centered study approaches.
- Using existing reporting requirements, public reports, implementation updates, FDA website materials, and case examples to demonstrate more clearly how patient experience data and other forms of patient input impact study design, benefit-risk assessment, labeling, review, and other regulatory activities.
- Promoting early and fit-for-purpose patient engagement so that patients, caregivers, and patient organizations can help identify meaningful outcomes, study burdens, usability considerations, evidence gaps, and communication needs before development plans become difficult to modify.
- Advancing voluntary use of patient-centered outcome and impact measures to promote greater consistency and comparability of evidence while preserving methodological flexibility and avoiding requiring identical endpoints across all devices or populations.
- Implementing the real-world evidence commitments through dedicated FDA expertise, greater consistency across review offices, fit-for-purpose assessment of data sources, and continued work through the National Evaluation System for health Technology (NEST), with attention to longitudinal questions affecting people with chronic diseases and disabilities, including durability of benefit, cumulative risk, usability, adherence, maintenance and replacement burden, software changes, and variation across populations and stages of disease.
- Ensuring meaningful patient and caregiver participation in NEST activities and other relevant implementation structures, particularly in the selection of clinical areas, research questions, patient-relevant outcomes, and communication of findings.
- Continuing implementation of the digital health and artificial intelligence commitments in ways that support safe and effective use, with attention to usability, accessibility, representativeness, cybersecurity, appropriate human oversight, clear communication of material information and software changes, and real-world performance.
- Using existing early-interaction pathways, including TAP, the Pre-Submission Program, and Breakthrough Device interactions, to support fit-for-purpose consideration of patient perspectives when defining unmet need, meaningful outcomes, usability, study burden, and other patient-relevant evidence questions.
- Supporting sufficient FDA staffing, retention, and training and promoting consistent scientific and regulatory approaches across offices, including in patient science, real-world evidence, digital health, artificial intelligence, cybersecurity, human factors, and patient communication.
- Continuing structured engagement with patient and consumer stakeholders throughout implementation, using existing advisory, public meeting, reporting, and consultation mechanisms wherever feasible to identify emerging issues and share progress.

The Draft Agreement Represents Constructive and Meaningful Progress

The NHC recognizes the substantial work undertaken by FDA and the medical device industry to reach a negotiated commitment package and appreciates that the draft preserves and strengthens the core purposes of the user fee program by supporting FDA's scientific and operational capacity, improving the predictability and consistency of review, and facilitating timely patient access to safe and effective medical devices. The agreement maintains rigorous performance goals for premarket submissions, expands opportunities for timely communication between FDA and sponsors, and continues investments in information technology, reviewer training, patient science, real-world evidence, digital health, standards, international harmonization, and TAP. These commitments recognize that an effective device review program depends on FDA's ability to maintain specialized expertise, provide clear and consistent scientific feedback, and adapt its regulatory approaches to increasingly complex technologies, rather than solely on the timely completion of individual reviews.[5]

Patients stand to benefit from these commitments because clearer review expectations, earlier identification of evidentiary issues, timely communication, and greater consistency across review teams can reduce avoidable delays and unnecessary rework while supporting stronger development programs.[6] More predictable interactions can also create opportunities for FDA and sponsors to address questions involving study populations, patient-relevant outcomes, usability, patient preference information, and evidence generation earlier in development, when those considerations can be incorporated more effectively and with less disruption to an established development plan. The draft appropriately pairs its performance goals with continued adherence to FDA's standards for safety and effectiveness, and its investments in scientific expertise, patient science, real-world evidence, digital health, and early interaction demonstrate that regulatory efficiency is not being treated solely as a matter of shortening review timelines. These provisions therefore reflect substantial common interests among FDA, industry, and the patient community in identifying and resolving evidentiary questions early to improve development efficiency and evidence quality.

As is appropriate for a negotiated user fee agreement, many of the most detailed commitments and performance measures address review operations, timelines, staffing, and FDA-industry interactions. The NHC's interest at this stage is not in displacing or substantially revising those measures but in encouraging FDA to use the implementation and reporting mechanisms already outlined in the agreement to make the effects of its patient-centered investments more visible. Publicly available aggregate information and practical examples could help patients, sponsors, and other stakeholders understand how patient experience data, patient-science expertise, real-world evidence, and early engagement have informed development planning or regulatory activity, while avoiding disclosure of confidential commercial information,

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[5] U.S. Food and Drug Administration, "Draft MDUFA Performance Goals and Procedures."

[6] U.S. Food and Drug Administration, *Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program: Guidance for Industry and Food and Drug Administration Staff* (May 2025), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program.

unnecessary reporting burdens, or changes to the negotiated performance framework. This type of transparency could also provide useful guidance to developers by illustrating how patient-centered evidence may be incorporated in a fit-for-purpose manner.

The NHC's 2025 comments emphasized that review speed is important but is most meaningful when accompanied by evidence that is relevant to patients and sufficient to support confidence in device safety and effectiveness. Early engagement, fit-for-purpose evidence generation, and meaningful patient input can advance both efficiency and evidence quality by reducing the likelihood that studies assess outcomes that do not reflect patient needs, overlook practical barriers to device use, or require later modification because important questions were not addressed at the outset.[7] The NHC therefore views the draft agreement as a strong foundation for the next user fee cycle, and the recommendations that follow are intended principally to support implementation of commitments already included in the agreement and to help ensure that their benefits are understandable and meaningful to patients, caregivers, sponsors, and other stakeholders. In many instances, these objectives can be advanced through implementation plans, existing public reports, stakeholder engagement, training, case examples, and program evaluations rather than through substantial revision of the negotiated commitment letter.

Patient Science and Engagement Commitments Are a Meaningful Strength of the Agreement

The NHC strongly supports continuation of the patient science and engagement program. The draft commitment letter would maintain FDA expertise and training related to patient preference information, patient-reported outcomes, patient-generated health data, clinical outcome assessments, patient-centered study approaches, and methods intended to reduce participation burden and improve representativeness. These provisions build on progress made under prior user fee cycles and are closely aligned with priorities identified by NHC members. They also reflect an area of alignment among FDA, industry, and the patient community, as consistent consideration of patient experience can improve the relevance of evidence, support clearer development planning, and identify questions that can be addressed more efficiently before a development program or submission strategy is substantially established.[8]

Patient experience can provide context that is not fully captured through traditional clinical or technical measures. People living with chronic and rare conditions can identify symptoms, functional limitations, treatment burdens, risks, tradeoffs, and benefits that may otherwise receive insufficient attention in study design or benefit-risk assessment. Family caregivers can offer additional insight when devices are used by children, people with cognitive or functional limitations, or individuals who rely on assistance with setup, maintenance, monitoring, or troubleshooting. Patient preference information can help

[7] National Health Council, "NHC Comments on Public Meeting on Reauthorization."

[8] National Health Council, "NHC MDUFA V Public Meeting Comments" (April 21, 2022), https://nationalhealthcouncil.org/letters-comments/nhc-mdufa-v-public-meeting-comments/.

explain how affected individuals weigh benefits and risks, while patient-reported outcomes and patient-generated health data can provide insight into how a device affects functioning, quality of life, and daily activities outside the clinical setting.[9,10,11,12] Consideration of these perspectives can therefore strengthen both the scientific relevance of evidence and the usefulness of the resulting device information.

The agreement's continued investment in FDA expertise and training is particularly welcome because the value of patient experience data depends in part on whether sponsors receive clear and reasonably consistent feedback regarding when such information may be useful and how it will be evaluated. The NHC encourages FDA to use the implementation flexibility available within the negotiated framework to promote access to patient-science expertise across review teams and offices through cross-office training, consultation pathways, communities of practice, and access to internal specialists. These mechanisms can support greater consistency while preserving the fit-for-purpose judgment needed for different devices, conditions, populations, and regulatory questions. Greater consistency would benefit patients and developers alike by reducing uncertainty, enabling earlier planning, and limiting the risk that sponsors invest in potentially valuable evidence-generation activities without sufficient clarity regarding their intended regulatory use.[13]

FDA could also use the reporting, educational, and public-engagement activities already presented by the agreement to promote the visibility of progress in patient science. Aggregate information could describe the types of submissions in which patient experience data were considered, the stages of development at which FDA provided patient-science advice, and the regulatory contexts in which patient preference information, patient-reported outcomes, patient-generated health data, or other clinical outcome assessments were relevant. The draft commitment to develop examples showing how patient-generated data affect device development and review is especially

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[9] U.S. Food and Drug Administration, *Patient Preference Information—Voluntary Submission, Review in Premarket Approval Applications, Humanitarian Device Exemption Applications, and De Novo Requests, and Inclusion in Decision Summaries and Device Labeling: Guidance for Industry, FDA Staff, and Other Stakeholders* (August 24, 2016), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-preference-information-voluntary-submission-review-premarket-approval-applications.

[10] American Diabetes Association, *CGM Coverage Report: Patient and Health Care Professional Experience of Access and Choice* (August 2025), https://diabetes.org/sites/default/files/2025-08/ADA-CGM-Covg-Report-Patient-and-HCP-Experience-of-Access-and-Choice-2025-final.pdf.

[11] Parkinson's Foundation, "Work with Research Advocates," accessed July 23, 2026, https://www.parkinson.org/resources-support/professionals/advocates/.

[12] National Organization for Rare Disorders, "NORD Comments to the Food and Drug Administration Regarding a Patient Engagement in Medical Device Clinical Trials Discussion Document" (January 8, 2019), https://rarediseases.org/wp-content/uploads/2019/01/NORD-2018-Comments-on-FDA-Patient-Engagement-in-Medical-Device-Clinical-Trials-Discussion-Document-Final.pdf.

[13] U.S. Food and Drug Administration, *Incorporating Voluntary Patient Preference Information over the Total Product Life Cycle: Guidance for Industry and Food and Drug Administration Staff* (March 2026), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-preference-information-voluntary-submission-review-premarket-approval-applications.

valuable because practical examples can help sponsors, patient organizations, researchers, and review staff understand what high-quality engagement and fit-for-purpose evidence may look like without converting one successful approach into a rigid expectation.[14,15] The NHC encourages FDA to implement this commitment in a manner that reflects the broader range of patient experience data addressed by the program and includes examples across device types, risk classifications, populations, and stages of development. Where feasible, those examples could identify the regulatory question under consideration, explain the relevance and limitations of the information, describe whether additional evidence was needed, and clarify how the input contributed to development planning or review. Even where patient input did not materially alter a decision, a concise explanation of the methodological or evidentiary considerations that affected its use could provide valuable guidance without disclosing confidential commercial information or creating a new evidentiary expectation for every sponsor.

Patients and Patient Organizations Should Remain Partners in Implementation

Meaningful patient engagement is most valuable when it occurs early, allowing the identification of unmet needs, intended uses, and concepts of interest and informing development choices such as study populations, meaningful outcomes, acceptable burdens, and evidence gaps. Incorporating patient input before a pivotal study is designed, a product design is finalized, or submission strategy is established can help developers identify issues before they become sources of delay, redesign, or uncertainty, making early engagement can an important complement to the agreement's emphasis on timely FDA-sponsor interaction. Patient engagement also remains useful later in development for interpreting findings, evaluating usability, understanding heterogeneity within the intended population, and determining how evidence and remaining uncertainties can be communicated clearly. The agreement already contemplates patient-science and stakeholder-engagement activities that can provide a foundation for continued patient involvement.[16] The NHC encourages FDA to use those mechanisms at points where patient perspectives can meaningfully improve development and review, rather than creating a separate or duplicative framework.[17]

Depending on the purpose and regulatory question, relevant perspectives may come from individual patients, family caregivers, disease-specific organizations, organizations representing people with disabilities, and cross-cutting patient coalitions. Patient organizations can contribute both community and technical expertise, help identify knowledgeable participants, explain variation in experience within a condition, provide context on the interaction between device use and other treatments or daily

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[14] U.S. Food and Drug Administration, "Draft MDUFA Performance Goals and Procedures."

[15] National Health Council, "Patient-Focused Medical Product Development Case Examples," accessed July 23, 2026, https://nationalhealthcouncil.org/additional-resources/patient-focused-medical-product-case-examples/.

[16] U.S. Food and Drug Administration, "Draft MDUFA Performance Goals and Procedures."

[17] National Organization for Rare Disorders, "NORD Comments Regarding Patient Engagement in Medical Device Clinical Trials."

responsibilities, and support interpretation and dissemination of findings. Patient organizations can also help sponsors and FDA assess whether existing patient-experience data are sufficient or whether additional engagement would add value, allowing the approach to remain proportionate to the device and development question. This flexibility is important because meaningful engagement does not require the same process for every product, nor does it require direct consultation at every stage when credible patient evidence already exists.

In implementing the agreement, FDA should also account for the practical conditions that affect who is able to participate in patient-engagement activities and how effectively they can contribute. Advance notice, plain-language and accessible materials, virtual participation options, sufficient preparation time, and reasonable consideration of compensation, travel, caregiving responsibilities, disability accommodations, and technology access can improve both the quality and reach of engagement, particularly for individual patients and smaller organizations with limited staff or financial capacity. The breadth and composition of patient and caregiver participation should be considered in relation to the purpose of the engagement, the population affected, and the intended use of the information, recognizing that the appropriate approach will vary across devices, conditions, and regulatory questions. Because no single meeting or consultation will capture every perspective, appropriate context regarding the types of participants and experiences included, any important gaps in perspective, and whether additional engagement may be useful can support accurate interpretation of the input received.

Patient-Centered Outcomes Should Advance Through Voluntary, Fit-for-Purpose Approaches

The NHC's 2025 comments encouraged greater use of patient-centered core outcome sets in device trials and registries, informed where appropriate by patient-centered core impact set principles, and preliminary input from NHC members likewise identified greater consistency in patient-meaningful outcomes as an important priority.[18,19,20] Greater consistency in the domains assessed across studies can improve comparability, facilitate evidence synthesis, reduce selective reporting, and help patients, clinicians, developers, and regulators to determine whether a device affects outcomes that are meaningful in daily life.[21] Depending on the device, condition, and intended use, those outcomes may include symptoms, functioning, independence, treatment burden, caregiver burden, maintenance requirements, disruption to work or

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[18] National Health Council, "NHC Comments on Public Meeting on Reauthorization of the Medical Device User Fee Amendments" (September 4, 2025).

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

[20] National Health Council, "NHC Phase 1 Snapshot: Patient Community Priorities" (preliminary discussion draft, November 2025).

[21] Paula R. Williamson et al., "The COMET Handbook: Version 1.0," *Trials* 18, suppl. 3 (2017): 280, https://doi.org/10.1186/s13063-017-1978-4.

education, and the ability to participate in ordinary activities. Technical and clinical performance measures remain essential, but they may not fully describe the benefits, burdens, or practical consequences of living with and relying on a medical device over time.

The patient science program provides an appropriate platform for developing, evaluating, and using of patient-centered outcome and impact measures on a voluntary, fit-for purpose basis. This approach would allow sponsors to select endpoints appropriate to the device, population, and regulatory question while preserving the scientific flexibility needed across different technologies. FDA could use the workshops, pilots, case examples, technical assistance, and stakeholder engagement already contemplated under the patient science program to identify domains that are consistently important within a condition or device category, clarify where suitable measures are available, and illustrate how sponsors may justify alternative or additional outcomes when appropriate. This approach could help sponsors and review teams make earlier and more patient-relevant decisions about evidence generation, improve the usefulness and comparability of resulting data, and preserve the flexibility necessary for innovation and methodological development.

Real-World Evidence Should Reflect the Longitudinal Experience of Chronic Disease Populations

The NHC supports the agreement's continued investment in real-world data and real-world evidence (RWE). The draft would expand internal expertise across the Offices of Health Technology and the Office of Clinical Evidence and Analysis, promote greater coordination and consistency, clarify approaches to evaluating data-source fitness, support sponsor engagement, assess capabilities in selected clinical areas, advance methodological development, and provide public reporting on funded activities. These commitments can improve both the quality and predictability of RWE used in premarket submissions and reflect an important area of shared interest among FDA, developers, and patients. Greater regulatory clarity can help sponsors determine earlier whether a real-world data source is fit for a particular question, what additional validation may be needed, and how RWE may complement evidence generated through more traditional clinical studies. By combining methodological development with opportunities for earlier FDA-sponsor interaction, the agreement can reduce uncertainty and the need for later revisions while expanding the range of populations, settings, and outcomes that may be studied through fit-for-purpose approaches.[22]

The patient community brings an essential longitudinal prospective to this work. Many NHC member organizations represent people who live with chronic diseases and disabilities for years or decades and may use implanted, connected, diagnostic, monitoring, assistive, or therapeutic devices repeatedly or continuously. The benefits, burdens, and risks that matter to these populations may emerge gradually, change as a condition progresses, or become apparent only after a device is used across varied

[22] U.S. Food and Drug Administration, "Draft MDUFA Performance Goals and Procedures."

home, work, educational, and clinical settings.[23,24,25] Premarket studies may not fully capture durability of benefits, cumulative or delayed harms, device reliability over time, adherence, usability, maintenance burden, replacement or revision procedures, interactions with other treatments, caregiver workload, software updates, interoperability challenges, or differences among patient subgroups.[26] Real-world evidence can help address these questions when the research question, follow-up period, data source, and outcomes are selected with the experience of the intended population in mind.

The NHC encourages FDA to use clinical-area assessments, stakeholder engagement, and other implementation activities already contemplated in the agreement to obtain input from relevant patient and disability organizations. These groups can help identify the questions of greatest importance to patients, assess whether proposed follow-up periods are meaningful, identify outcomes that may not be well captured in claims or electronic health records, and provide context for patterns of discontinuation, nonuse, or changing device performance. This engagement can also benefit developers by helping sponsors identify patient-relevant evidence gaps earlier, select appropriate data sources, and distinguish limitations of a device from barriers associated with training, coverage, clinical workflow, or the environment in which the device is used. Patient organizations can therefore improve the relevance and interpretation of RWE without displacing FDA's scientific judgment or creating the expectation that every project follows an identical engagement model. Early RWE planning can also help identify remaining uncertainties, relevant populations, meaningful outcomes, and follow-up needs that may warrant continued evaluation through separately supported activities after authorization.

Patient-generated health data may be particularly useful in this area because information collected through devices, applications, surveys, registries, remote monitoring tools, and direct patient reports can illuminate symptoms, functioning, quality of life, use patterns, adherence, and burden between clinical encounters. At the same time, the ability to collect a data element does not by itself establish that the information is useful, necessary, or appropriate for a particular regulatory purpose. Fit-for-purpose approaches should account for patient burden, privacy, missing or incomplete data, differences in access to technology, data quality, representativeness, and the intended use of the evidence. The NHC's recommendations for patient-centered RWE methods emphasize engagement in formulating research questions, selecting outcomes and data sources, designing and conducting studies, interpreting findings, and disseminating results. These principles are well suited to implementation of the MDUFA VI RWE

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[23] American Diabetes Association, *CGM Coverage Report.*

[24] Muscular Dystrophy Association, *Highlights of the MDA U.S. Neuromuscular Disease Registry: Duchenne and Becker Muscular Dystrophy* (Chicago: Muscular Dystrophy Association, 2018), https://www.mda.org/sites/default/files/MDA-Registry-Report-Highlights-Digital_9-2018.pdf.

[25] Parkinson's Foundation, *Care Innovation: A Patient-Centered Agenda for Parkinson's Disease* (2026), https://www.parkinson.org/sites/default/files/documents/Care-Innovation-Patient-Centered-Agenda.pdf.

[26] U.S. Food and Drug Administration, "FDA Facts: Postmarket Patient Registry Ensures Access to Safe and Effective Devices," December 21, 2017, https://www.fda.gov/about-fda/innovation-fda/fda-facts-postmarket-patient-registry-ensures-access-safe-and-effective-devices.

commitments. Patient-centeredness in this context does not mean that patients direct every methodological decision; rather, it means that the evidence-generation process remains connected to the questions, outcomes, and burdens that are relevant to the population expected to use the device.[27,28]

Premarket RWE Investments and Implementation to Promote Consistency and Total-Product-Lifecycle Learning

The NHC encourages FDA to describe how methodological lessons from MDUFA-funded RWE activities may inform greater consistency across the device program. Even when an individual project is premarket-focused, greater clarity regarding data quality, validation, representativeness, device identification, and regulatory relevance can strengthen the broader evidence environment and improve the usefulness of both premarket and postmarket data. NEST contributes to this objective by supporting more efficient generation and use of real-world evidence across the medical device ecosystem, and reporting on implementation could help stakeholders understand how methods and infrastructure developed through premarket projects contribute to longer-term learning without exceeding the negotiated scope of MDUFA VI.[29]

NEST Governance and Priority Setting Should Support Meaningful Patient Participation

The NHC supports the agreement's continued investment in NEST and appreciates the detailed conditions intended to promote accountability, measurable outputs, and alignment with FDA's premarket review needs. A well-functioning NEST can provide value to patients, FDA, developers, clinicians, and researchers by improving access to fit-for-purpose real-world data, advancing common methods, and supporting more efficient evidence generation for medical devices.[30] The draft appropriately recognizes the importance of meaningful industry participation in NEST governance, as medical device manufacturers contribute substantial technical, regulatory, and operational expertise and can help ensure that NEST activities address practical questions relevant to product development and premarket submissions. Clear industry representation can

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[27] Elisabeth Oehrlein, Jennifer Graff, Jason Harris, and Eleanor Perfetto, *Patient-Centered Real-World Evidence: Methods Recommendations from an Evidence-Based Consensus Process* (Washington, DC: National Health Council, May 2021), https://nationalhealthcouncil.org/wp-content/uploads/2021/06/NHC-Patient-Centered-Real-World-Evidence-White-Paper-1.pdf.

[28] Elisabeth Oehrlein, Mehmet Burcu, Silke Schoch, and Laura Gressler, "Enhancing Patient Centricity of Real-World Data Research: An Exploratory Analysis Using the Patient Experience Mapping Toolbox," *Value in Health* 26, no. 1 (January 2023): 10–17, https://doi.org/10.1016/j.jval.2022.10.002.

[29] U.S. Food and Drug Administration, "National Evaluation System for health Technology (NEST)," accessed July 23, 2026, https://www.fda.gov/about-fda/cdrh-reports/national-evaluation-system-health-technology-nest.

[30] U.S. Food and Drug Administration, "National Evaluation System for health Technology (NEST)."

also support alignment among data infrastructure, methodological development, sponsor evidence needs, and the questions encountered by FDA review teams.[31]

Patient and caregiver participation can complement this expertise by helping ensure that research priorities and evidence-development activities remain connected to the outcomes, burdens, and uncertainties that matter to people who use medical devices. Patients and patient organizations can offer insight into which questions warrant longitudinal study, which outcomes are meaningful in daily life, whether available data adequately represent the intended population, and how findings and limitations can be communicated in clear, accessible language. Consistent with the governance and implementation structure allowed by the agreement, the NHC encourages NEST to maintain meaningful opportunities for patient and caregiver input in the selection of clinical priorities, identification of relevant outcomes, assessment of data-source representativeness, interpretation of findings, and communication of results. The objective is not to displace the technical, regulatory, or operational expertise contributed by industry and other stakeholders, but to ensure that the resulting evidence is both methodologically useful and responsive to the needs of affected patient populations.

At this stage of the reauthorization process, the NHC's recommendations focus on transparent and meaningful patient participation within the negotiated governance structure rather than changes to the representational formula contained in the commitment letter. As implementation proceeds, NEST could publicly report on how patient and caregiver perspectives are incorporated into its governing bodies, advisory structures, clinical-area assessments, and project development activities. Such reporting could describe the types of patient expertise sought, the processes used to identify participants, and the ways in which patient input informed priorities, research questions, outcome selection, or project design. Effective participation will also require accessible and understandable materials, sufficient preparation time, reasonable support for participants, and selection processes that recognize the value of disease-specific and cross-cutting perspectives involving chronic conditions, disability, caregiving, and long-term device use. Conflict of interest policies can protect the integrity and independence of NEST while remaining sufficiently nuanced to recognize the experience of patient advocates who routinely engage with multiple stakeholders.

The annual public reporting required for MDUFA-funded NEST activities provides a practical opportunity to demonstrate the program's value without establishing a separate reporting structure. In addition to describing expenditures, projects, and measurable outcomes, the report could explain how stakeholder input informed clinical-area selection and project design, identify the patient-relevant outcomes evaluated, summarize the populations represented in the underlying data, and describe important limitations or remaining evidence gaps.[32] Accessible summaries of significant projects would also help patients, clinicians, developers, and smaller organizations understand how NEST-supported evidence is being used and where additional registries, research programs, or community expertise may contribute to future work. The NHC views NEST

[31] U.S. Food and Drug Administration, "Draft MDUFA Performance Goals and Procedures."

[32] U.S. Food and Drug Administration, "Draft MDUFA Performance Goals and Procedures."

as an area in which patient and industry perspectives are complementary rather than competing as industry participation can improve the feasibility and regulatory relevance of projects, while patient participation can strengthen the relevance of research questions, outcome selection, interpretation, and communication. A transparent, multi-stakeholder approach can therefore enhance the quality, credibility, and practical usefulness of the evidence generated while supporting the shared goal of timely access to safe and effective devices.

Digital Health and Artificial Intelligence Require Patient-Centered Lifecycle Oversight

The NHC supports continued investment in FDA's digital health expertise and the agreement's efforts to align regulatory processes with the development and life cycles of software-enabled technologies. Digital health tools and artificial intelligence-enabled devices may expand access, support earlier detection and intervention, facilitate remote monitoring, reduce travel and administrative burden, and generate new forms of evidence, while regulatory clarity and more consistent interaction with FDA can help developers address technical and clinical questions earlier and reduce avoidable rework. These technologies also raise questions involving usability, accessibility, cybersecurity, privacy, changing performance, representativeness, and the appropriate role of human judgment. The NHC appreciates that the draft addresses scientific expertise, regulatory predictability, coordination, stakeholder engagement, and efficient review.[33] These commitments are important to responsible innovation and to patient confidence in technologies that may change more rapidly than traditional hardware-based devices.[34,35]

As FDA implements these commitments, the NHC encourages continued attention to the real-world circumstances in which patients and caregivers will use digital and AI-enabled technologies. A device may demonstrate strong technical performance while still creating practical barriers if it is difficult to operate, inaccessible to people with disabilities, dependent on broadband or newer hardware, poorly integrated into clinical workflows, or unclear about when users should seek assistance from a clinician or other qualified professional. Patient and caregiver input can help identify these concerns early, when they may be addressed more efficiently through product design, evidence development, training, labeling, or other communication efforts. Implementation of digital and AI-enabled technologies in particular should remain attentive to accessibility, connectivity, interface design, alert burden, caregiver involvement, and the consequences of interrupted connectivity or system failure in the settings where the device is expected to be used.

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[33] U.S. Food and Drug Administration, "Draft MDUFA Performance Goals and Procedures."

[34] National Health Council, "NHC Submits Comments on FDA Draft Guidance for AI/ML-Enabled Medical Devices" (April 7, 2025), https://nationalhealthcouncil.org/letters-comments/nhc-submits-comments-on-fda-draft-guidance-for-ai-ml-enabled-medical-devices/.

[35] World Health Organization, *Ethics and Governance of Artificial Intelligence for Health: Guidance on Large Multi-Modal Models* (Geneva: World Health Organization, 2024), https://iris.who.int/bitstream/handle/10665/375579/9789240084759-eng.pdf.

Representativeness remains important to confidence in digital health and AI-enabled devices because the populations reflected in development and validation data may affect how reliably a technology performs in broader use. Performance evaluations and validation activities should support meaningful assessment across relevant clinical, demographic, and functional populations, with the appropriate scope and form of analysis determined by the device, intended use, risk, feasibility, available data, and specific scientific questions. Where evidence regarding a relevant population is limited, FDA and sponsors can consider proportionate approaches to additional evaluation and communication sufficient to support the safe and effective use of the device. This issue may warrant particular attention where access to devices, smartphones, broadband, specialty care, or interoperable health systems affects which patients are included in the data used to develop and validate these technologies.[36,37]

Patients and clinicians also need clear, accessible information about the role, intended uses, and known limitations of AI-enabled functions as well as the level of human oversight required for safe and effective use.[38] The NHC recognizes that the appropriate content and level of disclosure will vary by device, risk, and intended user and therefore favors a flexible approach to labeling and communication. FDA's implementation activities could help ensure that patients and clinicians understand how the technology is intended to inform or support decision-making, what degree of reliance is appropriate, and what actions may be needed when performance is uncertain or the technology does not function as expected. The NHC's prior comments on AI-enabled medical devices emphasized patient safety, consistent performance, transparency, privacy, accountability, appropriate human oversight, cybersecurity, data integrity, and total-product-lifecycle monitoring, and these principles remain compatible with industry's interest in clear, predictable, and workable expectations that support responsible development and adoption.[39]

Predetermined change control plans and related approaches intended to accommodate iterative software modifications can improve regulatory efficiency and support timely product improvements. Their patient value will be greatest when material changes are communicated in a manner proportionate to their significance and post-deployment performance is monitored according to risk. Product modifications affect how patients, caregivers, or clinicians interact with, interpret, or rely on a device even when its name does not change. Clear communication about material updates is therefore important to

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[36] James Cross, Michael Choma, and John Onofrey, "Bias in Medical AI: Implications for Clinical Decision-Making," *PLOS Digital Health* 3, no. 11 (2024): e0000651, https://doi.org/10.1371/journal.pdig.0000651.

[37] Richard Chen et al., "Algorithm Fairness in Artificial Intelligence for Medicine and Healthcare," *Nature Biomedical Engineering* 7, no. 6 (2023): 719–42, https://doi.org/10.1038/s41551-023-01056-8.

[38] U.S. Food and Drug Administration, Health Canada, and Medicines and Healthcare Products Regulatory Agency, "Good Machine Learning Practice for Medical Device Development: Guiding Principles" (October 2021), https://www.fda.gov/medical-devices/software-medical-device-samd/good-machine-learning-practice-medical-device-development-guiding-principles.

[39] National Health Council, "NHC Comments on AI/ML-Enabled Medical Devices."

the device's continued safe and effective use. FDA's guidance, public meetings, educational materials, case examples, and other implementation activities can help developers understand when and how such changes should be communicated and how patient perspectives may inform usability, accessibility, representativeness, and ongoing evaluation without creating a separate layer of performance obligations or delaying access to beneficial technologies.[40]

TAP Offers an Opportunity to Integrate Patient Input Earlier in Development

The NHC supports continuation of TAP and its objective of improving coordination, predictability, and early problem-solving for innovative medical devices. By bringing FDA, developers, payers, providers, and other relevant experts into the development process earlier, TAP can help sponsors identify evidentiary, operational, reimbursement, and implementation considerations before they become more difficult or costly to address. This coordinated approach may be particularly valuable for smaller and emerging companies with more limited regulatory infrastructure, as earlier access to FDA and external expertise can support more efficient development planning without lowering evidentiary expectations.[41] Patients may benefit when avoidable development delays are reduced and evidence programs are better positioned to meet the needs of FDA, clinicians, payers, and other decision-makers.[42]

Patient input can add distinct value within this framework when it is incorporated at a stage when product design and evidence plans remain flexible. Questions involving unmet need, meaningful benefit, acceptable tradeoffs, study burden, usability, intended-use settings, and patient-relevant outcomes are often most consequential before pivotal studies are designed or major product features are fixed. Early engagement can help sponsors identify concerns that might otherwise emerge later through recruitment difficulties, usability problems, evidence gaps, or limited adoption, while also providing context on how a device is likely to interact with other treatments, caregiving responsibilities, and daily-life demands. In this respect, patient engagement can reinforce TAP's emphasis on early problem-solving by helping developers address relevant issues before they require substantial redesign or changes to an established development strategy.

Patient engagement will not be necessary in every TAP interaction, and the negotiated structure provides sufficient flexibility to incorporate patient perspectives where they are most likely to add value. FDA could use TAP operating procedures, implementation

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[40] U.S. Food and Drug Administration, *Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions: Guidance for Industry and Food and Drug Administration Staff* (December 2024), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/marketing-submission-recommendations-predetermined-change-control-plan-artificial-intelligence.

[41] U.S. Food and Drug Administration, *Total Product Lifecycle Advisory Program Pilot: FY 2025 Performance Report* (2025), https://www.fda.gov/media/190057/download.

[42] U.S. Food and Drug Administration, "Total Product Life Cycle Advisory Program (TAP)," accessed July 23, 2026, https://www.fda.gov/medical-devices/medical-device-development-tools-mddt/total-product-life-cycle-advisory-program-tap.

materials, technical assistance, and case examples to clarify the circumstances in which such input may be especially useful. Relevant considerations may include whether a product is intended for long-term or home use, substantially affects daily functioning, involves significant benefit-risk tradeoffs, depends heavily on patient or caregiver operation, or serves a population with substantial unmet need or heterogeneous experiences. The appropriate form of engagement should remain proportionate to the development and regulatory question, recognizing that existing patient-experience data, preference studies, registries, or published reports may provide sufficient insight in some circumstances, while direct consultation may be more valuable in others.

Existing TAP evaluations and public reports could extend the program's value beyond participating sponsors by describing, at an aggregate level, how early coordination helped participants identify meaningful outcomes, reduce avoidable study burden, improve usability planning, or address evidence needs before pivotal development decisions were made. Practical examples of patient engagement, fit-for-purpose use of patient-experience data, and coordination among FDA, sponsors, payers, providers, and patient organizations could help other developers apply similar approaches outside the formal TAP program. The NHC views TAP as a constructive area of alignment among FDA, industry, and the patient community: sponsors benefit from earlier clarity and reduced uncertainty, FDA benefits from more fully developed evidence plans, and patients benefit when promising technologies are designed and evaluated with greater attention to real-world needs. FDA's implementation of TAP can preserve the flexibility and efficiency that make the program valuable while incorporating patient perspectives where they are likely to materially improve development planning and evidence generation.

Reviewer Capacity, Training, and Consistency Remain Foundational

The NHC strongly supports the draft agreement's continued emphasis on recruiting, hiring, retaining, and training the scientific, technical, and operational staff needed to carry out FDA's medical device responsibilities. The patient science, real-world evidence, digital health, artificial intelligence, cybersecurity, standards, and TAP commitments all depend on a sufficiently staffed agency with stable expertise and the ability to provide timely, consistent, and scientifically grounded feedback. The NHC also appreciates that the draft addresses retention, training, management capacity, and review consistency rather than focusing only on the number of positions filled, because institutional knowledge, effective onboarding, supervisory support, mentoring, and cross-office collaboration are essential to converting additional resources into sustained program performance. These considerations are particularly important in rapidly evolving areas where specialized expertise is scarce and where scientific and regulatory expectations may continue to develop throughout the MDUFA VI period.[43]

Adequate staffing and retention are important to both patients and developers. Review delays, frequent reviewer transitions, and inconsistent interpretation can create uncertainty, require unnecessary rework, and interrupt continuity across a development program, while stable review teams with access to specialized expertise can improve

[43] U.S. Food and Drug Administration, "Draft MDUFA Performance Goals and Procedures."

communication, support more efficient resolution of questions, and help sponsors plan studies and submissions with greater confidence.[44] The review-consistency commitments can therefore improve predictability and promote more consistent treatment of similar evidentiary or regulatory questions while preserving scientifically justified differences among devices and review contexts. The NHC recognizes the value of FDA-industry performance discussions in identifying recurring operational concerns and high-impact areas for improvement, as industry experience across multiple submissions can provide FDA with useful information about patterns that may not be apparent within an individual review. These improvements can ultimately support more timely patient access without compromising FDA's standards for safety and effectiveness.[45]

Patient and consumer stakeholders may identify a complementary set of implementation issues, particularly where inconsistency affects the consideration of patient experience data, clinical outcome assessments, usability, accessibility, representativeness, or patient-facing communication. Rather than establishing a separate review-consistency structure, FDA could use existing public meetings, Patient Engagement Advisory Committee (PEAC) activities, stakeholder consultations, or other established channels to gather this input and determine whether recurring concerns warrant broader training, clarification, or internal coordination. This approach would preserve the negotiated FDA-industry mechanisms while allowing FDA to benefit from additional perspectives relevant to patient-centered implementation. Outside stakeholders would not be involved in individual submission reviews or create competing standards but would instead provide input to help FDA identify cross-cutting issues that may affect the consistency and practical impact of its policies across device areas.

Patient science training should equip FDA reviewers and other relevant staff to evaluate and use patient experience data appropriately. This includes assessing whether the data are fit for purpose, identifying when internal consultation is needed, documenting how data informed the review, communicating evidentiary limitations, and providing constructive feedback to sponsors. Training in RWE, digital health, and AI should likewise address the fitness and representativeness of data sources, missing data, patient burden, accessibility, real-world usability, and communication of uncertainty. The NHC also encourages FDA to continue developing mechanisms through which specialized expertise can be shared across offices, including centralized experts, consultation pathways, communities of practice, shared review resources, and cross-office training, all of which can promote consistency while preserving the device-specific judgment necessary for individual reviews. Public reporting on staffing and training can remain appropriately aggregated and rely on the metrics already contemplated by the agreement, while existing reports and implementation updates could provide useful information on progress in priority expertise areas, major training initiatives, and efforts to address recurring consistency concerns. Reviewer capacity and consistency create benefits across stakeholder groups: FDA retains a stable and capable workforce,

[44] National Health Council, "NHC Phase 1 Snapshot."

[45] U.S. Food and Drug Administration, "Draft MDUFA Performance Goals and Procedures."

developers receive predictable and timely scientific feedback, and patients are better served by rigorous and efficient reviews of high-quality evidence.

Transparency and Accountability Should Build on Existing MDUFA Reporting

Transparency emerged as a leading priority in preliminary input form NHC members. Patient organizations want to understand what opportunities for patient engagement were available and how patient experience data, real-world evidence, and other patient-centered inputs contributed to development planning and regulatory activity. Clear information about the evidence supporting device decisions, important limitations or remaining uncertainties, and material changes in device performance or functionality over time help patient organizations inform and support the communities they represent. Greater visibility into these issues can strengthen confidence in the device program and help patient organizations determine where additional evidence, education, or engagement may be useful.[46]

The NHC appreciates that the draft agreement contains substantial financial, operational, and program-specific reporting commitments, including a five-year financial plan, annual updates, carryover reporting, quarterly performance information, and public reporting on certain MDUFA-funded RWE activities. These provisions can strengthen accountability and help stakeholders understand how user fee resources support FDA capacity, implementation of negotiated commitments, and overall program performance. They also reflect a shared interest among FDA, industry, and the broader stakeholder community in maintaining a financially sustainable and operationally effective program capable of responding to changing workload and scientific needs. FDA's existing MDUFA reporting infrastructure provides a practical foundation for this transparency and reduces the need to create a separate reporting system for each patient-centered initiative.[47,48]

At this stage in the reauthorization process, the NHC encourages FDA to build on the reporting and performance framework already included in the agreement rather than create a separate reporting structure. Existing reporting requirements, public reports, implementation updates, FDA website materials, public meetings, educational activities, and case examples provide practical mechanisms for making the patient-centered effects of MDUFA VI more visible. Where feasible, those materials could distinguish measures of activity from measures of impact, recognizing that the number of meetings held, staff trained, or projects initiated provides useful implementation information but does not fully demonstrate whether those activities affected development planning or regulatory practice. Aggregate examples might describe how patient input informed the selection of study outcomes, how RWE helped address a premarket evidence question, how early interaction reduced avoidable rework, or how usability concerns were reflected in product design, study planning, labeling, or other communication.

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[46] National Health Council, "NHC Phase 1 Snapshot."

[47] U.S. Food and Drug Administration, "Draft MDUFA Performance Goals and Procedures."

[48] U.S. Food and Drug Administration, "MDUFA Reports."

This type of reporting could benefit developers as well as patients because practical examples can clarify FDA's expectations, identify appropriate points for early engagement, and illustrate how patient experience data or RWE may be used in a fit-for-purpose manner. Greater clarity can reduce uncertainty without creating a prescriptive template or suggesting that every submission must include the same type of evidence. The NHC recognizes that confidential commercial information and the integrity of individual submission reviews must be protected, and aggregate reporting, anonymized examples, and carefully selected case studies can provide meaningful transparency without disclosing proprietary information or creating unnecessary burdens for sponsors.

Implementation should continue to include patient-facing communications through decision summaries, safety communications, educational materials, and public reports designed to help patients and caregivers understand the intended use of a device, the evidence supporting its authorization, important uncertainties, and any actions they may need to take. Technical detail will remain necessary for expert audiences, but plain-language and accessible materials can complement that information and strengthen trust without oversimplifying the underlying evidence. The NHC encourages FDA to consider whether existing MDUFA reports and public updates can be organized so that stakeholders can follow progress across the agreement's major patient-centered commitments over time, whether through a consolidated section within current reports, a recurring implementation update, or clearer links among related program materials. The objective is not to expand reporting for its own sake, but to help patients, developers, and other stakeholders understand whether the resources and programs supported through MDUFA VI are contributing to stronger scientific capacity, more predictable development and review, better use of patient-centered evidence, and timely access to safe and effective devices.

Study Design, Participation, and Representativeness Should Be Addressed Through Early, Fit-for-Purpose Planning

NHC members have emphasized the importance of study designs that are scientifically sound, feasible for participants, and reasonably reflective of the populations expected to use a device. To answer certain research questions or protect participant safety, device studies may require repeated site visits, specialized centers, complex procedures, caregiver participation, travel, or the use of unfamiliar technology. At the same time, avoidable burdens that are not identified early can affect recruitment, retention, data completeness, and the relevance of the resulting evidence. Patient organizations can provide context that may not be apparent from protocol review alone, including transportation challenges, time away from work or caregiving, accessibility needs, technology requirements, disease-related fatigue, and the cumulative burden of repeated assessments. Their input can help sponsors distinguish research

requirements that are essential from those that may be modified without reducing scientific rigor.[49,50,51]

The NHC appreciates that several commitments in the draft, including patient science, digital health, Pre-Submission interactions, and TAP, create opportunities for FDA and sponsors to consider study feasibility earlier in development. Early discussion can help determine whether decentralized elements, remote data collection, local testing, electronic consent, flexible scheduling, or caregiver support are appropriate for the device, population, and regulatory question. These approaches will not be suitable in every study, but fit-for-purpose planning can reduce unnecessary burden without compromising evidence quality. It can also support development efficiency, as studies that are workable for participants may recruit more effectively, retain participants longer, and generate more complete data, thereby reducing the likelihood of later protocol amendments, enrollment delays, or evidence gaps.[52] The interests of patients and developers are therefore often aligned in designing studies that are both rigorous and feasible.

Representativeness should be considered in relation to the intended use of the device and the populations for whom performance, usability, risks, or benefits may differ. Factors to consider may include age, sex, race and ethnicity, disability, disease severity, comorbidities, language, geography, socioeconomic circumstances, and access to technology or specialty care. The importance of these factors will vary across device types, risk profiles, and clinical contexts, limiting the usefulness of a single enrollment formula and instead requiring a flexible and proportionate approach to patient recruitment. FDA's early-interaction programs and implementation materials could encourage sponsors to identify the populations most relevant to the regulatory question, explain how the evidence plan addresses those populations, and describe remaining limitations when full representation is not feasible. Clear and proportionate expectations can improve evidence relevance while preserving flexibility for small populations, rare conditions, novel technologies, and studies in which certain recruitment challenges cannot be fully resolved before authorization.[53]

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[49] National Health Council, "NHC Phase 1 Snapshot."

[50] U.S. Food and Drug Administration, *Patient Engagement in the Design and Conduct of Medical Device Clinical Studies: Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders* (January 2022), 4–6, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-engagement-design-and-conduct-medical-device-clinical-studies.

[51] U.S. Food and Drug Administration, *Conducting Clinical Trials with Decentralized Elements: Guidance for Industry, Investigators, and Other Interested Parties* (October 2025), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/conducting-clinical-trials-decentralized-elements.

[52] U.S. Food and Drug Administration, *Patient Engagement in the Design and Conduct of Medical Device Clinical Studies*.

[53] U.S. Food and Drug Administration, *Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies: Draft Guidance for Industry* (June 2024), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/diversity-action-plans-improve-enrollment-participants-underrepresented-populations-clinical-studies.

Where evidence gaps remain, transparent communication regarding those limitations and any proportionate plans for continued evaluation can help clinicians and patients interpret the available evidence appropriately. This is particularly important for devices whose usability or performance may be influenced by the setting of use, access to supporting technology, caregiver involvement, or differences not fully captured during premarket development. FDA could also use existing case examples, educational materials, and implementation updates to illustrate how early patient input has helped sponsors improve study feasibility, select meaningful outcomes, or address recruitment and retention challenges. Such examples could provide practical value to developers without creating prescriptive requirements or suggesting that every study must use the same design features. The NHC encourages FDA to preserve a flexible, risk-based approach that supports innovation while promoting evidence that is sufficiently relevant to the intended population, recognizing that early consideration of participant burden and representativeness can strengthen study quality, improve development efficiency, and increase confidence in how authorized devices will perform in real-world use.

Financial Sustainability and Resource Allocation

The NHC supports user fee levels and financial-management practices sufficient to sustain rigorous review, scientific expertise, information technology, and the programmatic commitments described in the agreement. A stable and adequately resourced medical device program benefits patients, FDA, and developers by supporting timely review, consistent communication, and access to the specialized expertise needed to evaluate increasingly complex technologies. Predictable resources are particularly important for patient science, real-world evidence, digital health, artificial intelligence, cybersecurity, statistics, and human factors, where recruitment and retention may be challenging and where scientific expectations may continue to evolve throughout the MDUFA VI period.[54]

The draft agreement's five-year financial plan, annual updates, carryover reporting, and related transparency provisions are constructive because they can help FDA plan hiring, training, contracting, and information-technology investments across the full user fee cycle rather than responding primarily to short-term fluctuations. The NHC also recognizes the value of continued FDA-industry dialogue regarding workload, fee collections, carryover balances, and planned resource allocation. Because industry provides the user fee revenue that supports a substantial portion of the device review program, regular consultation can help identify operational pressures early, support responsible stewardship, and reduce the risk that unexpected financial or staffing constraints disrupt implementation or undermine review predictability.

Public transparency remains an important complement to those discussions. Existing financial plans and reports could continue to describe, at an appropriate aggregate level, how resources support major commitments and whether implementation remains on schedule, particularly where staffing or financial conditions materially affect patient science, RWE, digital health, TAP, or other cross-cutting activities. Existing financial plans and reporting mechanisms provide a practical means of connecting resources,

[54] National Health Council, "NHC Comments on Public Meeting on Reauthorization."

implementation milestones, and patient-centered program outputs at this stage. These materials could present that information in a manner understandable to patient organizations and other stakeholders, thereby reinforcing confidence that the negotiated commitments remain adequately supported throughout the five-year cycle.

The NHC also appreciates the agreement's continued attention to small businesses and emerging developers. Innovative devices may originate in companies with limited regulatory staff or experience, and clear guidance, timely communication, and accessible support can help those sponsors navigate FDA requirements more efficiently while preserving the evidentiary standards necessary to protect patients. This support may be particularly important where the intended population is small, the condition is rare, or the commercial market may not sustain a large development infrastructure, because regulatory predictability and early feedback can affect whether a promising technology advances through development.[55,56] The NHC encourages implementation that maintains meaningful assistance for smaller companies while applying consistent standards for safety, effectiveness, and evidence quality regardless of sponsor size.

The NHC views financial sustainability as foundational to patient-centered implementation. Adequate and predictable resources allow FDA to retain expert staff, provide consistent scientific advice, evaluate complex evidence, and meet negotiated review commitments, while responsible financial stewardship and transparent reporting support both industry confidence in the user fee program and patient trust in the device review process.

Implementation Should Include Continued Patient-Community Engagement

The NHC appreciates the opportunities FDA provided for patient and consumer input throughout the MDUFA VI reauthorization process, including stakeholder consultations, the August 5 public meeting, and the written-comment period. These opportunities helped ensure that patient perspectives were considered alongside the operational, scientific, and resource issues addressed through the FDA-industry negotiations. Patient engagement should continue as MDUFA VI moves into implementation as the program's practical effect will depend on decisions involving guidance and educational materials, allocation of staff and expertise, pilot activities, selection of real-world evidence priorities, operation of TAP, evaluation of patient-science initiatives, and preparation of public reports. Many of these activities can benefit from patient and caregiver input without reopening the negotiated commitment package or creating a new formal consultation process for every initiative.

The NHC therefore encourages FDA to continue using established and proportionate patient engagement mechanisms throughout the MDUFA VI period, including public meetings, listening sessions, requests for information, workshops, advisory committee

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[55] U.S. Food and Drug Administration, "Activities to Support Medical Device Innovators," July 28, 2023, https://www.fda.gov/about-fda/cdrh-innovation/activities-support-medical-device-innovators

[56] U.S. Food and Drug Administration, "Humanitarian Device Exemption," updated January 13, 2025, https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/humanitarian-device-exemption.

discussions, targeted consultations, and opportunities to comment on guidance or implementation materials. In many cases, existing mechanisms may provide a more appropriate, efficient, and effective means of obtaining input than establishing a separate structure. Continued engagement can improve implementation by helping FDA identify practical concerns, clarify communication needs, select meaningful outcomes, and determine whether proposed activities are accessible to affected communities before substantial resources have been committed.[57,58] Early input can thereby reduce the need for later revision and complement the emphasis on early problem-solving, regulatory predictability, and efficient use of resources reflected throughout the agreement.

The PEAC remains an important source of advice on cross-cutting device issues, and the NHC supports continued use of PEAC where its expertise and public deliberative process are well suited to the question under consideration.[59] At the same time, PEAC is most effective as one component of a broader engagement strategy that incorporates appropriate input when an issue concerns a particular disease, disability, device category, data source, outcome measure, or setting of use. Disease-specific patient organizations can provide detailed knowledge of the affected population, cross-cutting organizations can identify themes that extend across conditions and device types, and family caregivers may provide essential perspectives when patients depend on others for device operation, monitoring, maintenance, or decision-making. FDA could provide reasonable advance notice of significant patient-facing implementation activities and periodic updates on major patient-science, RWE, TAP, and digital-health initiatives so that stakeholders can identify where more focused engagement would be useful.

Engagement opportunities should also account for the practical barriers that affect who is able to participate and how effectively they can contribute. Accessible materials, plain-language explanations, virtual participation when appropriate, sufficient preparation time, and reasonable attention to disability, caregiving, travel, and technology needs can broaden participation and improve the quality of the input received, particularly for individual patients and smaller organizations with limited staff capacity. The NHC and its members are prepared to support FDA's implementation efforts by identifying knowledgeable participants, convening relevant communities, providing context regarding longitudinal experience, interpreting patient-generated evidence, and disseminating information to affected populations.[60] These contributions complement the scientific, technical, manufacturing, regulatory, and operational expertise provided by FDA, industry, clinicians, researchers, and other stakeholders. Continued multi-stakeholder engagement can therefore reinforce confidence in the

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[57] U.S. Food and Drug Administration, *Patient Engagement in the Design and Conduct of Medical Device Clinical Studies*.

[58] Oehrlein et al., *Patient-Centered Real-World Evidence*.

[59] U.S. Food and Drug Administration, "Patient Engagement Advisory Committee," accessed July 23, 2026, https://www.fda.gov/advisory-committees/medical-devices-advisory-committee/patient-engagement-advisory-committee.

[60] Oehrlein et al., *Patient-Centered Real-World Evidence.*

program and help FDA implement the negotiated commitments in a manner that supports innovation, evidence quality, regulatory predictability, and patient trust.

Conclusion

The draft MDUFA VI commitment letter reflects the conclusion of a substantial negotiation and stakeholder consultation process and provides a constructive framework for the next user fee cycle. The NHC supports the agreement's continued investments in FDA capacity, review predictability, patient science, real-world evidence, digital health, artificial intelligence, reviewer training, and TAP. Taken together, these commitments can strengthen the quality and efficiency of device development and review while supporting timely patient access to safe and effective medical technologies.

The NHC's recommendations are intended primarily to support implementation of the negotiated framework rather than to reopen the agreement. In many instances, the patient-centered potential of MDUFA VI can be advanced through implementation plans, training, guidance, stakeholder engagement, public reporting, case examples, and program evaluation. These mechanisms can help ensure that commitments related to patient experience data, longitudinal evidence, digital health, and early interaction translate into clearer development pathways and more relevant evidence without creating unnecessary new burdens or reducing the flexibility needed for innovation.

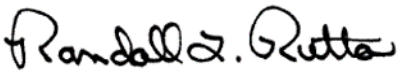
Effective implementation will require continued collaboration among FDA, the medical device industry, patients, caregivers, clinicians, researchers, and other stakeholders. Industry brings essential scientific, technical, manufacturing, and development expertise and provides user fee resources that are central to FDA's device-review capacity. Patients and caregivers contribute direct knowledge of the benefits, risks, burdens, usability considerations, and uncertainties associated with living with and relying on medical devices. FDA's scientific judgment and regulatory oversight provide the foundation for integrating these perspectives in a manner that protects patients while supporting innovation. By combining these contributions through the implementation mechanisms already contemplated in the agreement, MDUFA VI can strengthen evidence quality, regulatory predictability and consistency, development efficiency, and confidence in the medical device program while supporting timely access to safe and effective technologies.

For patients, the success of MDUFA VI will ultimately be reflected in whether devices are developed and reviewed efficiently, evidence addresses outcomes and questions that matter in real-world use, FDA maintains the expertise and consistency necessary for rigorous oversight, and patients and clinicians receive understandable information about benefits, risks, limitations, and material changes over time. The draft agreement provides a strong foundation for advancing those objectives.

Please do not hesitate to contact Kimberly Beer, Senior Vice President, Policy & External Affairs, at kbeer@nhcouncil.org, or Shion Chang, Assistant Vice President, Policy & Regulatory Affairs, at schang@nhcouncil.org, if you or your staff would like to discuss these comments in greater detail. The NHC appreciates FDA's consideration of

these comments and looks forward to continued engagement as the MDUFA VI recommendations are finalized and implemented.

Sincerely,



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