U.S. FOOD & DRUG ADMINISTRATION

MDUFA VI
Public Meeting

August 5, 2026

U.S. Food and Drug Administration

Begins at 10:00AM

Welcome & Introductions

Eli Tomar, J.D., M.P.H

Deputy Director, Office of Policy

Center for Devices and Radiological Health (CDRH)

Your Feedback

Docket:

https://www.regulations.gov/

Docket No. FDA-2026-N-6655

Email Address:

MDUFAVIReauthorization@fda.hhs.gov

Opening Remarks

Kyle Diamantas, J.D.

Acting FDA Commissioner

MDUFA VI

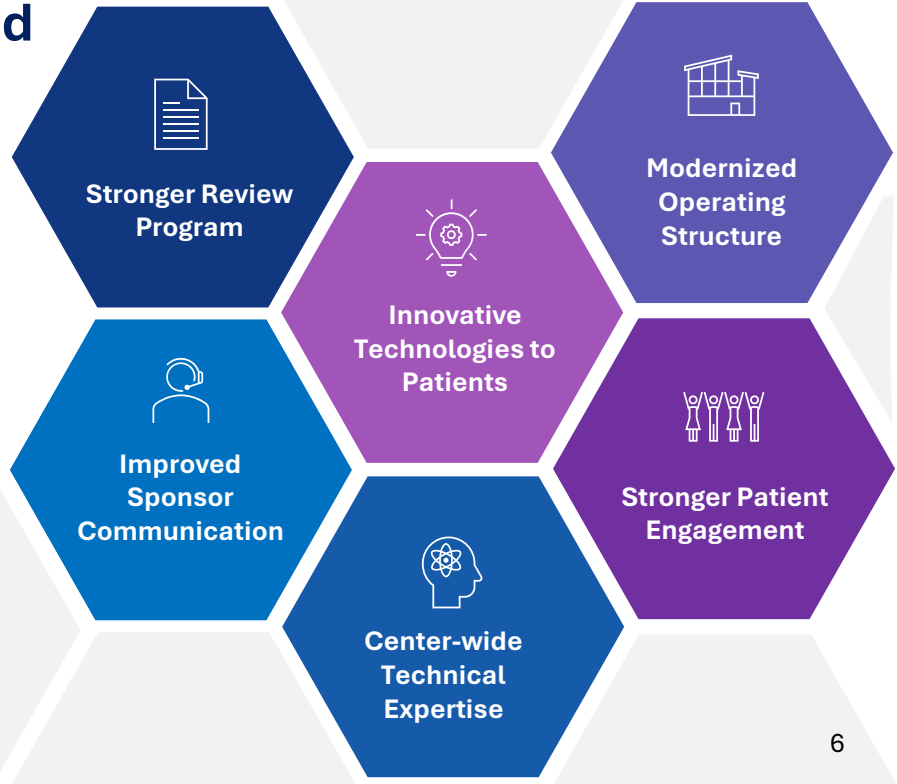
Advancing CDRH's Mission

Michelle Tarver, M.D., Ph.D.

Director, Center for Devices and Radiological Health (CDRH)

MDUFA Program History

The MDUFA program has strengthened every aspect of how CDRH regulates medical devices leading to improved outcomes for patients.



Collaboration

Patient Groups

Industry

Healthcare Providers

Participating Stakeholders

MDUFA VI

Advancing Regulatory Excellence through a proven Total Product Life Cycle approach to safety and innovation for medical devices.

Strengthen Core Review Fundamentals

Elevate the Quality of the Journey

Optimize Transparency & Accountability

Advancing Regulatory Excellence

Strengthen Core Review Fundamentals

- Invest in people, processes, and scientific foundation
- Improve review consistency
- Strengthen pre-submission interactions
- Improve efficiency of De Novo review
- Enhance deficiency communications
- Build and sustain reviewer expertise

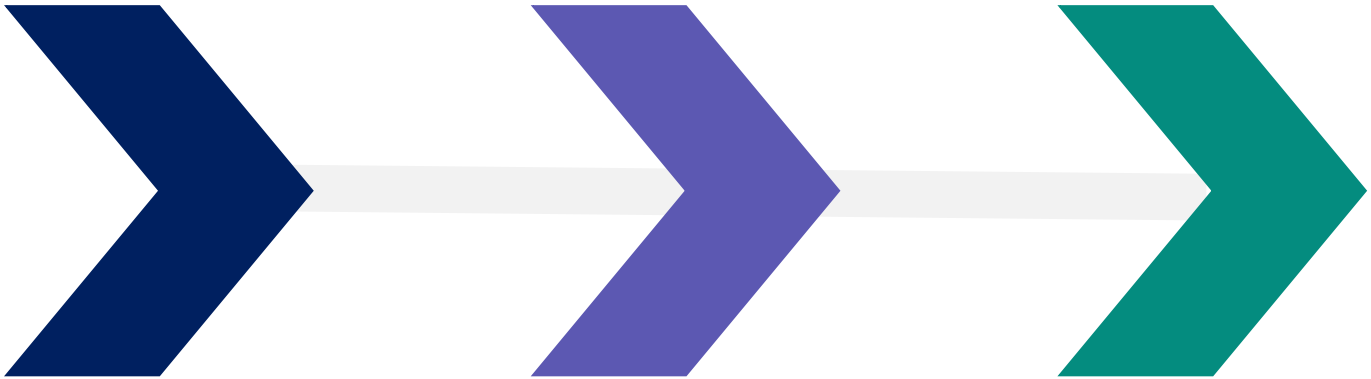
Elevate the Quality of the Journey

- Advance Real World Evidence
- Expand Digital Health capabilities
- Strengthen Patient Science
- Invest in Consensus Standards
- Evolve and optimize TAP
- Deepen International Harmonization

Optimize Transparency & Accountability

- Increase clarity through review
- Strengthen communication with sponsors
- Improve customer-facing tools
- Enhance resource and workforce planning
- Ensure long-term program sustainability

MDUFA VI Agreement



TODAY

Drafted and posted MDUFA VI proposed agreement

NEXT

Congressional Authorization

MOVING FORWARD

Continued Partnership & Stakeholder Engagement

Thank You!

This agreement reflects the dedication and partnership of many.

FDA Negotiation Team

Industry Partners

Patients & Participating Stakeholders

FDA Staff

FDA Presentation

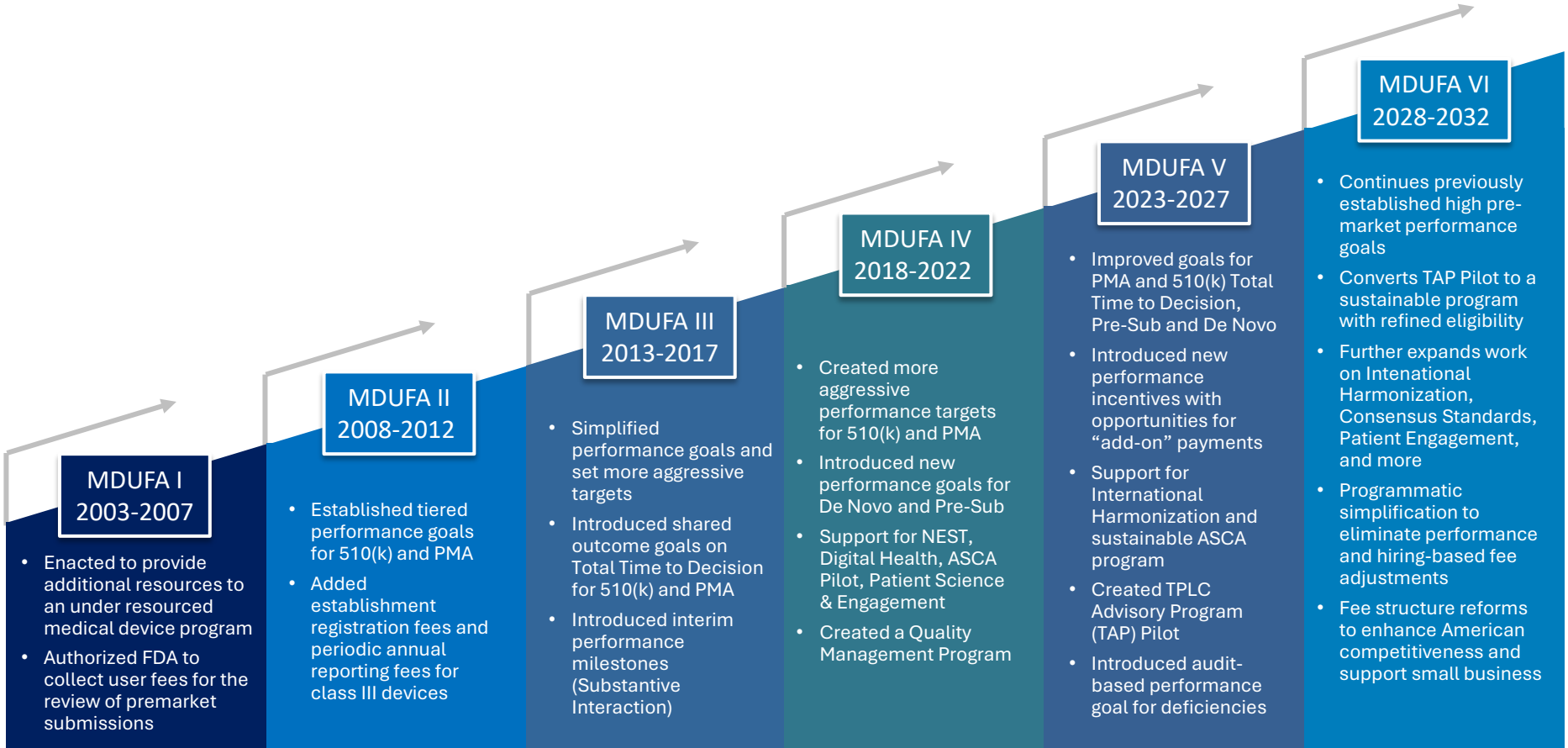
MDUFA VI Overview

Eli Tomar, J.D., M.P.H

Deputy Director, Office of Policy

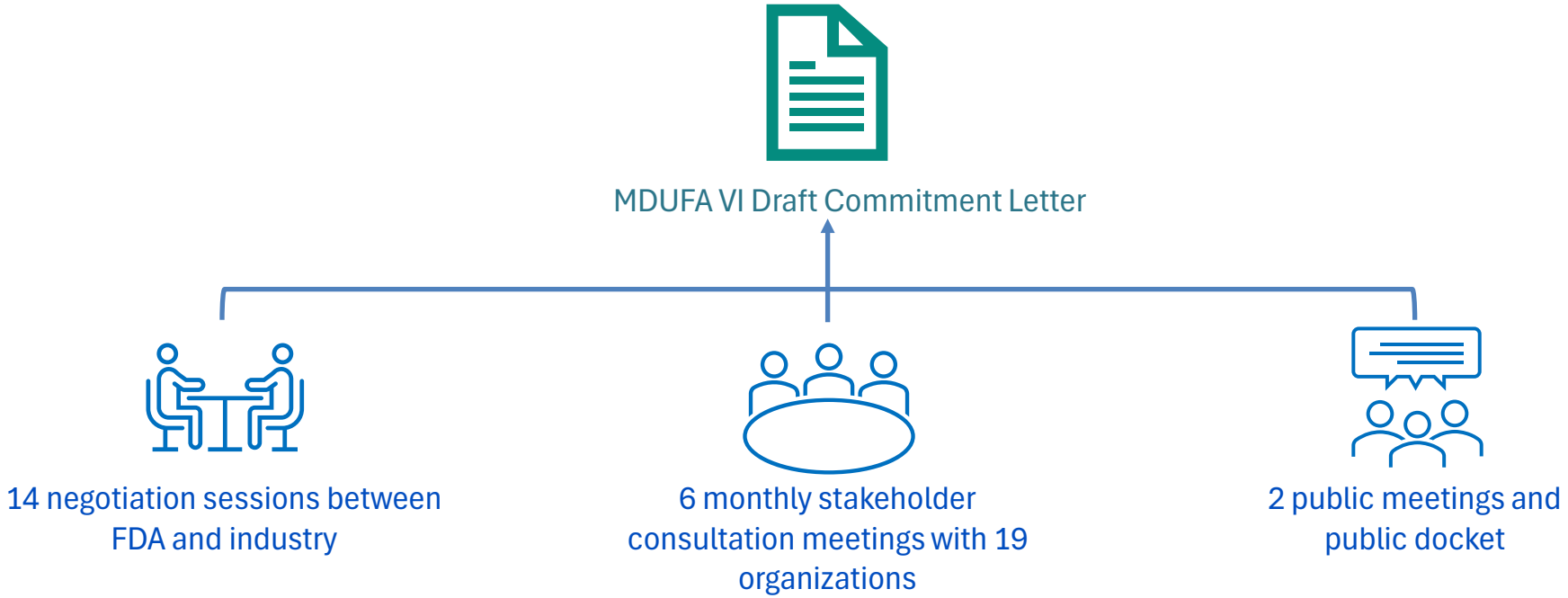
Center for Devices and Radiological Health

MDUFA Program History



MDUFA VI Reauthorization

MDUFA VI negotiations incorporated inputs and priorities from the Agency, industry and our other stakeholders.



MDUFA VI Agreement Overview

- Nearly flat financial footprint in MDUFA VI compared to FY2027 (with focus on staffing needs)
- Maintain high performance across all review goals
- Advances U.S. interests and agency standardization priorities
- Alignment on impactful programmatic enhancements in key areas (e.g., Pre-Submissions, Real-World Evidence, continuous improvement)

FDA Review Goals will remain steady

Review-Time Goals

Submission Type*	Goal	MDUFA V (FY27)	MDUFA VI (FY28-FY32)
Original PMAs, PDPs, Panel-Track PMA Supplements, and Premarket Reports			
Substantive Interaction	90 calendar days	95%	95%
Decision (No Advisory Committee Input)	180 FDA days	90%	90%
180-Day PMA Supplements			
Substantive Interaction	90 calendar days	95%	95%
Decision	180 FDA days	95%	95%
Real-Time PMA Supplements			
Decision	90 FDA days	95%	95%
De Novo Classification Requests			
Decision	150 FDA days	90%	90%
510(k) Premarket Notifications			
Substantive Interaction	60 calendar days	95%	95%
Decision	90 FDA days	95%	95%
Pre-Submissions			
Written Feedback	70 calendar days (or 5 days prior to meeting)	90%	90%
		No Max	Up to 5,000 Pre-Subs
Deficiencies	include a “statement of basis”	95%	95%

*Not all Review Goals cited; MDUFA goals for CLIA Waivers and BLAs not listed but will also remain same as in MDUFA V

MDUFA VI Goal: Strengthen Core Review Fundamentals

FDA and Industry have reached agreement-in-principle on several initiatives aimed at strengthening the core elements of the medical device review process.

Pre-Submissions

- New $2k fee for certain initial Pre-Submissions credited toward future marketing submission fee
- New focused follow-up option with 45-day timeline (for eligible supplements)
- Option to request supervisory review for inconsistent feedback
- Clarifications on informal communications

De Novo

- Introduction meeting within first 30 days
- “Not grantable” decision option
- Fee waiver/ reduction for ineligible devices
- De Novo specific Pre-submission template (including clinical study)

IT Modernization & Continuous Improvement

- Interactive Navigator tool for FDA and external stakeholders
- Improved Customer Collaboration Portal (real-time tracking & two-way communication)
- Automated submission intake and routing
- Strengthen existing deficiency improvement program & improve review consistency

MDUFA VI Goal:
Optimize Transparency & Accountability

MDUFA VI will encompass clearer expectations and meaningful engagement, ensuring all stakeholders understand our mechanisms, resourcing, and processes.

Fee Structure Changes

- Change in small business fee waivers and reductions
- New foreign establishment registration fee premium

Operating Reserve and Carryover

- Refining reserve levels to ensure program stability

Appropriations & Spending Trigger

- Optimizing mechanisms that ensure appropriate federal appropriations relative to user fee funding

Resource Capacity Planning and Management

- Identifying staffing needs to ensure adequate capacity to meet performance goals given workload

Estimated Fee Tables ($FY27)

	MDUFA V		MDUFA VI	
	Estimated (FY27 in $FY27)		Estimated (FY28 in $FY27)	
TOTAL Revenue Target	**$571 M**		**$580 M**	
	Standard Fee	**Small Business Fee**	**Standard Fee**	**Small Business Fee**
Domestic Registration Fee	**$13,785**	**[See Note 1]**	**$12,043**	**[See Note 2]**
Foreign Registration Fee	**$13,785**	**[See Note 1]**	**$17,043**	**[Not Applicable]**
Original PMA (Full fee)	**$636,732**	**$159,183**	**$635,429**	**$158,857**
PMA Panel-Track	$509,386	$127,347	$508,344	$127,086
De Novo	$191,020	$47,755	$190,629	$47,657
PMA 180 Day	$95,510	$23,878	$95,314	$23,829
PMA Real-Time	$44,571	$11,143	$44,480	$11,120
510(k)	**$28,653**	**$7,163**	**$28,594**	**$7,149**
PMA 30-Day Notice	$10,188	$5,094	$10,167	$5,083
513(g)	$8,596	$4,298	$8,578	$4,289
Annual Fee for Periodic Reporting	$22,286	$5,572	$22,240	$5,560

Total Registration Fee Revenue: ~ $406 M (~70%)

Total Submission Fee Revenue: ~ $174 M (~30%)

Note 1: Registration fee waiver applies to small business entities and their affiliates with ≤$1 million gross receipts or sales, can demonstrate payment would represent a financial hardship, and have proof of a prior year's registration fee payment.

Note 2: Registration fee waiver would apply to very small (≤$500k gross receipts or sales) domestic business entities with no foreign affiliates that do not manufacture devices subject to GMP requirements.

MDUFA VI Goal:
Elevate the Quality of the Journey

Several initiatives focus on improving the broader regulatory infrastructure that supports device innovation and regulatory predictability across the total product lifecycle

Real World Evidence

- Advance how real-world data can appropriately support regulatory decision-making
- Develop new premarket data sources through NEST

Digital Health

- Continued support for innovative digital medical technologies and investment in the Center of Excellence

Consensus Standards

- Greater recognition and use of consensus standards to support efficient device review
- Public-private collaboration

International Harmonization

- Strengthen U.S. global leadership in device regulation
- Support development of common submission forms
- Promote and expand bilateral partnerships

Patient Science

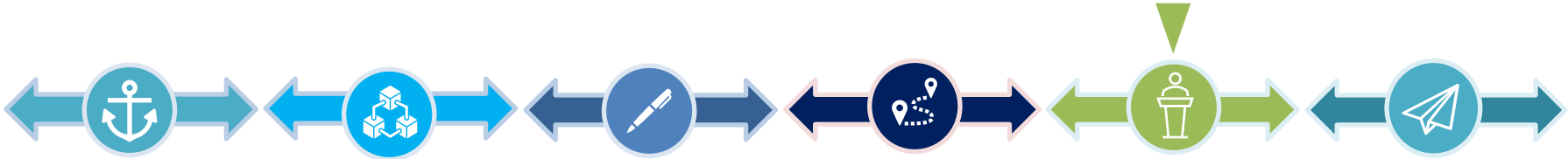
- Further integrate patient perspectives into regulatory decision-making
- Continue capacity building with patient organizations through

Total Product Life Cycle Advisory Program (TAP 2.0)

- Refined eligibility criteria, including U.S. presence
- Expanding opportunities for novel technology developers to engage early with FDA and CMS

MDUFA Reauthorization Timeline

We are here



June 2025 – September 2025	October 2025 - April 2026	March 2026 – April 2026	May 2026 – July 2026	August 2026 – December 2026	January 2027 – September 2027
Process Initiation & Initial Public Input	Negotiations & Consultations	Draft Commitment Letter	Obtain Clearance & Publish	Brief Congress & Consider Public Feedback	Submit for Reauthorization & Legislative Process

FDA Panel

Eli Tomar, J.D., M.P.H - Moderator
Deputy Director, Office of Policy (CDRH)

Kathryn Capanna, M.B.A.
Associate Director, Office of Strategic Partnerships & Technology Innovation (CDRH)

Barbara Marsden
Director, Office of Regulatory Programs, Office of Product Evaluation and Quality (CDRH)

Jonathan Sauer, M.B.A.
Associate Director, Office of Finance, Budget, and Acquisition (FDA)

Industry Perspectives

Mark Leahey, J.D., M.B.A.

Medical Device Manufacturers Association (MDMA)

Zach Rothstein, J.D.

Advanced Medical Technology Association (AdvaMed)

Break

Please return by 12:45 PM

Patient & Consumer Perspectives Panel Discussion

Eli Tomar, J.D., M.P.H - Moderator
Deputy Director, Office of Policy (CDRH)

Cynthia Bens
Personalized Medicine Coalition

Shion Chang, M.P.A., M.S.P.H.
National Health Council

Jen French, M.B.A.
American Brain Coalition

Paul Melmeyer, M.P.P.
Muscular Dystrophy Association

Diana Zuckerman, Ph.D
National Center for Health Research

Health Care Professional, Scientific, & Innovation Perspectives Panel Discussion

Eli Tomar, J.D., M.P.H - Moderator
Deputy Director, Office of Policy (CDRH)

Amanda Benedict, M.A.
Association for the Advancement of Medical Instrumentation

Andrew Fish, J.D.
Medical Device Innovation Consortium

Zachary Hochstetler, M. B. A.
American Medical Association

Samuel Jones, M.D., M.P.H., F.A.C.C.
American College of Cardiology

Benjamin Vandendriessche, Ph.D.
Digital Medicine Society

Open Public Comment Period

Public Comment About the Draft MDUFA "Commitment" Language for 2028-2032

August 5, 2026 (virtually via a FDA-hosted hybrid meeting)

Michael T. Abrams, M.P.H., Ph.D. (he/him)
Senior Health Researcher
Health Research Group
Public Citizen

American Association of Kidney Patients
aakp.org

American Association of Kidney Patients

Formal Public Comment for:

U.S. FDA Medical Device User Fee Amendments (MDUFA VI) Public Meeting

Presented by:

Paul T. Conway

Vice President & Chair of Policy and Global Affairs

August 5, 2026

FDA TAP: Patient Insights & Product Development Lifecycle

2022

MDUFA V + TAP announced

AAKP has participated since TAP inception as the first organization representing individuals affected by kidney diseases.

Independent kidney patient voice

Kidney patient and care partner communities fully engaged – provide industry and FDA with wholistic view of disease burdens among patients as well as patient preferences.

MDUFA VI decision point: preserve and strengthen TAP as a mechanism for early, substantive and effective patient engagement.

Enhanced ability to inform and educate industry, CMS and FDA on unmet patient needs and patient preferences.

Expand FDA role as a national and global thought leader in patient-centered device development, collaboration, regulatory reviews and consensus standards.

AAKP Center for Patient Research & Education: Core Capacities

The AAKP Center for Patient Research and Education is a national hub for integrating the kidney patient voice into medical research, innovation, and education. Through national patient engagement, research partnerships, and evidence-based educational programs, the Center ensures that the unique insights, lived experiences, preferences and risk tolerances of kidney patients inform the development, evaluation, and adoption of new diagnostics, medical devices, and drugs.

Research & Patient Insight

- **AAKP Constituent Database** (continual data collection)
- **Patient Advisory Panels/Councils**
- **Patient Roundtables**
- **Focus Groups** (web-based/in-person)
- **Direct patient interviews** (one-on-one)
- **Patient surveys** (web-based/telephone)
- **Clinical Trial Awareness Campaigns**
- **Market Research Recruitment**
- **Geographic targeting of patients for specific engagement efforts**
- **Demographic targeting of patients for specific engagement efforts**
- **Post Market Research – Patient Consumers**

American Association of Kidney Patients
aakp.org

Impact: TAP is Central to Patient-Centered Innovations

TAP moved patient input from a late-stage "check the box" exercise to a substantive driver of device design, evidence strategy, and real-world adoption.

1. **Substantive lived experience** — Captures treatment burden, device usability, training needs, caregiver realities, mobility, work and quality-of-life priorities.
2. **Better evidence and endpoints** — Helps align protocols, outcomes, and data collection with what patients experience and value.
3. **Real-world insight earlier** — Surfaces recruitment, retention, adherence, access and health equity issues before they become commercialization barriers.
4. **Stronger ecosystem alignment** — Connects FDA, innovators, clinicians, and patient advocates around patient access from concept to coverage.
5. **Reduced innovation risk** — Improves the odds that safe and effective devices are practical, acceptable, and meaningful to the people they are intended to serve.

AAKP recommendation: retain and expand TAP - with patient organizations as independent, strategic partners in every stage of the product lifecycle.

MDUFA VI Commitment Letter Comments

Milken Institute

Raymond Puerini, Director, FasterCures

August 5, 2026

Disclosures

I am speaking on behalf of FasterCures, which is part of the Milken Institute Health pillar within the Milken Institute, a 501(c)(3) nonprofit organization.

Our organization currently holds an active research contract (#[75F40124C00120) with the Food and Drug Administration to conduct research and produce resources as part of a project entitled “Defining the Value and Return on Investment of Patient Engagement in Medtech Product Development,” though the views expressed here are strictly our own.

MILKEN INSTITUTE

FasterCures: Patient Needs Above All Else

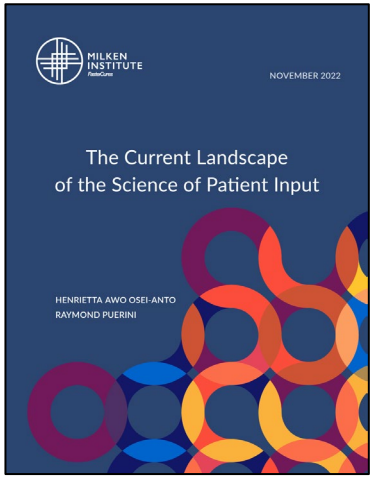
FasterCures is working to build a system that is effective, efficient, and driven by a clear vision:

Working with our partners to build a patient-centric system where science is accelerated, unnecessary barriers are overcome, and lifesaving and life-enhancing treatments get to those who need them as rapidly as possible.

Background

Over the past decade, integrating patient perspectives into biomedical research has gained significant traction

FasterCures has led initiatives and produced resources aimed at advancing the science of patient input and expanding the role of the patient and patient engagement (PE) in biomedical R&D



Explore our [Patient Engagement Resources:]

MILKEN INSTITUTE

A Foundation Already in Motion

The medtech (i.e. device, diagnostic, and digital health) sector has lagged behind the pharma space in terms of uptake of PE practices

To explore why and create solutions, FasterCures has worked directly with CDRH to understand and characterize the challenges that prevent robust PE in medtech R&D and develop resources to help address those challenges.

This work directly reinforces the FDA's commitment to share case examples and identify high-impact opportunities to bring the patient voice into device development.

Barriers and Challenges to Medtech PE:

- Resource constraints
- Lack of clear ROI
- Reaching patient populations
- Compliance concerns
- Adoption of tools

Our Latest Resources on Medtech PE:

Medtech PE Value Framework

Live today — identifies key decision points across the total product life cycle where PE can be used to inform medtech R&D activities

Medtech PE Toolkit

Coming soon — FAQ-style toolkit that provides a curated listing of resources for the planning, conduct, and evaluation of medtech PE activities

Medtech PE Case Study Library

Coming soon — repository of real examples showing PE impact across the medtech R&D lifecycle.

More case examples needed!
Email medtech@milkeninstitute.org for details on submitting one

MILKEN INSTITUTE

The Capacity Gap Behind the Growth

- A growing set of regulatory guidance documents now address the use of Patient Experience Data (PED) and real-world evidence (RWE), and MDUFA VI commits to more training on RWE and patient-generated health data (PGHD).
- Many patient organizations have developed and maintain registries, natural history studies, and data sharing platforms that serve as sources of PED, real-world data, and PDGH, all of which have the potential to be leveraged for product R&D activities.

RECOMMENDATION

Build dedicated capacity-building support for patient organizations — the key contributors of PED and PGHD — to meet rising demand to leverage these data in medtech regulatory activities.

MILKEN INSTITUTE

From Sharing Examples to Greater Transparency

MEDTECH DEVELOPERS NEED EXAMPLES & TRANSPARENCY

Medtech developers have expressed a need for more examples and greater transparency on how PED is used to justify the allocation of resources

MDUFA LETTER TODAY

Commits to sharing examples on the use and impact of PGHD, and identifying high-impact opportunities to bring patient perspectives and experiences into device development.

RECOMMENDATION

A broader, systematic report on how PED and PGHD is submitted by medtech developers, how it is used by FDA, and its measurable impact across submissions — beyond just illustrative examples.

MILKEN INSTITUTE

TAP: A Conduit for Deeper and Streamlined Engagement

TAP HELPS CONNECT KEY STAKEHOLDERS

We support TAP's role as a conduit connecting medtech developers with patient organizations, providers, and payers — and support FDA's efforts to continue and expand that program

RECOMMENDATION

Encourage FDA to track and report metrics on patient engagement from TAP participants — and share the learnings broadly.

These metrics build the value proposition for PE and help overcome a real barrier: gaining leadership support and resources for PE activities.

WHAT ELSE SHOULD BE REPORTED:

1. How patient organizations and patients were engaged
2. Reasons for engagement
3. Impact of engagement
4. Barriers encountered

Aligning FDA and CMS Through TAP and RAPID

Using progress from both TAP and the newer RAPID program as signals of deepening FDA–CMS alignment, there may be opportunities for FDA and CMS to keep building within the programs and across both agencies— and to report on what's working.

Understanding how to engage earlier with both FDA and CMS can help medtech developers create more streamlined, efficient, and potentially more effective strategies to get products approved and covered - helping lower barriers to access later on.

RECCOMENDATION

Encourage FDA to report on promising approaches, lessons learned, and impacts from dual FDA/CMS participation — drawing learnings from FDA, CMS, and participating TAP companies.

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THREE RECOMMENDATION AREAS FOR FDA

Moving From Commitment to Impact

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1

Build patient org capacity

Support patient organizations — key PED/PGHD contributors — with resources to meet rising demand.

2

Report on PED impact

Move beyond examples to systematic reporting on how PED is submitted, used, and its measurable impact.

3

Strengthen FDA-CMS Alignment

Through TAP and RAPID engagement, track and share engagement metrics, and report on FDA–CMS alignment and lessons learned.

Thank you — Raymond Puerini, FasterCures

Email: rpuerini@milkeninstitute.org

milkeninstitute.org

MDUFA VI Public Comments

Yuri Quintana, PhD
Chief of the Division of Clinical Informatics
Beth Israel Deaconess Medical Center
Harvard Medical School

July 31, 2026

yquintan@bidmc.harvard.edu

Beth Israel Deaconess Medical Center | HARVARD MEDICAL SCHOOL TEACHING HOSPITAL

50 YEARS 1970 – 2020 Division of Clinical Informatics

Overall Perspective

DISCLOSURE: Yuri Quintana, PhD has no financial disclosures to report

Purpose

- Provide views on the proposed recommendations for the reauthorized program (MDUFA VI).

Opportunity

- Prepare FDA for next generation AI-enabled medical devices
- strengthen AI and digital health evaluation
- Support timely innovation while maintaining patient safety

Major Innovations Compared with MDUFA V

- Focused Follow-Up Pre-Submissions.
- Digital Health emphasis explicitly expanded to include **generative AI** and **agentic AI**.
- **Greater reliance on Real-World Evidence.**
- Enhanced reviewer consistency and quality management.
- More sophisticated Customer Collaboration Portal.
- Stronger international harmonization.
- Increased transparency in financial planning and resource allocation.
- Greater use of regulatory-ready consensus standards.

Strengths of MDUFA V

- **Recognizes AI and software as central components of future medical device regulation.**
- Continues modernization of FDA review processes.
- Expands opportunities for early interaction with sponsors.
- Invests in reviewer training and technical expertise.
- Strengthens quality management and consistency.
- **Places greater emphasis on patient-centered evidence and real-world data.**
- Supports global regulatory convergence while maintaining FDA authority.

Major Proposed Changes Under MDUFA VI (FY 2028–2032) - Key Enhancements

Accelerated & More Predictable Reviews

- Faster shared outcome goals for PMAs and 510(k)s
- Continued emphasis on timely, high quality reviews

Expanded Sponsor Engagement

- New **Focused Follow Up Pre-Submission** pathway
- Earlier FDA interactions and improved communication

Modernized Regulatory Infrastructure

- Enhanced Customer Collaboration Portal
- Interactive communication tools and resource planning

Strengthened Regulatory Science

- Expanded use of Real World Evidence (RWE)
- Greater emphasis on Patient Science and Patient Generated Health Data
- Increased use of regulatory ready consensus standards

Digital Health & AI

- Expanded Digital Health Center of Excellence
- **Greater expertise in software, AI, and emerging technologies**
- **Enhanced reviewer training and stakeholder engagement**

Improved Review Quality

- New review consistency initiative
- Better deficiency letters and quality management

Global Collaboration

- International harmonization pilot
- Coordinated reviews with trusted regulatory authorities
- Expanded participation in IMDRF

Total Product Life Cycle (TAP)

- Expansion from pilot to permanent program
- Earlier collaboration throughout device development

Recommendation 1: AI Evaluation

Strengthen AI Review

- Standardized evidence expectations
- External validation across diverse populations
- Bias and fairness assessment
- Explainability and transparency
- Post-market performance monitoring

Benefits

- Greater consistency
- Improved public trust
- Higher quality submissions

Recommendation 2: Real World Evidence

Expand RWE

- Common data models
- Interoperable health data
- Multicenter evidence generation
- Patient-generated health data
- Learning health systems

Impact

Better evidence for AI

Continuous safety assessment

Recommendation 3: Consensus Standards

Advance Regulatory Science

- Consensus standards for AI
- Cybersecurity
- Interoperability
- Human factors
- Software lifecycle evaluation

Outcome

- Predictable reviews
- Reduced duplication
- Higher quality submissions

Recommendation 4: Collaboration

Strategic Partners

- IEEE - Engineering, AI, software, cybersecurity standards
- AMIA - Clinical informatics and implementation science
- Multidisciplinary expertise

Potential Activities

- Joint workshops
- Consensus development
- Reviewer education
- Regulatory science research

Recommendation 5: Patient-Centered Evaluation

Goal

- Technology that improves real-world patient outcomes at scale

Patient Perspective

- Patient-reported outcomes
- Wearables
- Remote monitoring
- Usability

Key Message

- Innovation and safety are complementary
- Evidence throughout the product lifecycle
- Trustworthy AI requires collaboration
- MDUFA VI positions FDA for the future

Brian Scarpelli

Connected Health Initiative

Madris Kinard

MDUFA VI Public Meeting, August 5, 2026

Patient Safety Action Network

Patient Driven, Patient Led

https://www.patientsafetyaction.org/

Patient Safety Action Network (PSAN)

PSAN is a non-profit coalition of individuals and organizations consisting of patients who have been medically harmed, their loved ones, and concerned data advocates and patient safety advocates.

Medical harm affects people of all political affiliations and has always been a bipartisan issue. It affects the rich and the poor, the old and the young, the sick and the well. Regulations and policies can potentially enhance or threaten patient safety and strengthen or compromise transparency and accountability.

MDUFA IV, V, and VI

PSAN's message hasn't wavered because the numbers indicate we are reaching a critical mass.

In 2016 and 2021, PSAN pushed for greater transparency and a stronger voice for patients.

Although patients are now invited to the table for discussions and updates, we sit at a different table—isolated from Industries' negotiations with CDRH.

What is Data Advocacy?

Firestone Tire Recall in the year 2000

When I managed the broadcast outreach for the Firestone tire recall 26 years ago, my job was to make sure that vehicle owners knew that there had been injuries and fatalities so they would get them replaced. I made sure that the news story ran on every major network every single day for as long as possible so no one continued driving on tires that were unsafe.

Consumer safety depended on transparency, once a problem was identified.

238 consumers were killed and 500 were injured in the U.S.

Medical Devices: Outcome Attributed to Adverse Event (2022 – June 2026)

- ☑ Required Intervention (3,998,157)
- ☑ Other Serious/Important Medical Events (552,580)
- ☑ Hospitalization (416,542)
- ☑ Life Threatening (80,724)
- ☑ Death (58,282)
- ☑ Disability (27,359)
- ☑ Congenital Anomaly (1,695)

Note: More than one outcome can be selected, but 623,390 reports did not include a single outcome listed above even when there was a serious outcome in the report narrative.

2025 GAO Report on Medical Device Recalls

According to FDA officials, the agency faces several challenges in the device recall process. Three challenges affect the agency's oversight of recalls. The first is the large number of recalls, officials told us. In any given year, there are more device recalls than biologics and drug recalls combined. FDA's publicly available data show that, in fiscal year 2024, there were 1,017 medical device recalls compared to 333 biologics recalls and 318 drug recalls. 37. FDA Oll officials explained that they must process a large volume of medical device recalls with limited time, insufficient staffing levels, and information technology database systems that require extensive manual data entry.

https://www.gao.gov/assets/gao-26-107619.pdf

The GAO report on Recalls found that only 4% of Recalls were initiated by FDA due to vast under-staffing issues

Breakdown of Recall Initiation

- **Manufacturer-identified**: Manufacturers themselves found the issue and voluntarily started 96% (3,788 out of 3,934) of the recalls.

- **FDA-identified**: The FDA found a violation and told the manufacturer, leading the manufacturer to voluntarily recall the device, accounting for the remaining 4% (145 out of 3,934).

PDUFA Funds Postmarket Surveillance for Drugs, but MDUFA won't fund Postmarket Surveillance for Devices

If medical devices are truly innovative, safe and effective, then why isn't industry willing to help fund post-market activities?

Luis Gil Abinader

Generation Patient

Namrata Pujara

American Academy of Pediatrics

Your Feedback

Docket:

https://www.regulations.gov/

Docket No. FDA-2026-N-6655

Email Address:

MDUFAVIReauthorization@fda.hhs.gov

Closing Remarks

Owen Faris, Ph.D.

Deputy Center Director for Regulatory Operations
Center for Devices and Radiological Health


FDA
U.S. FOOD & DRUG
ADMINISTRATION