US FDA Update
MDUFA and International Harmonization

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Medical Device User Fee Amendments (MDUFA) Overview

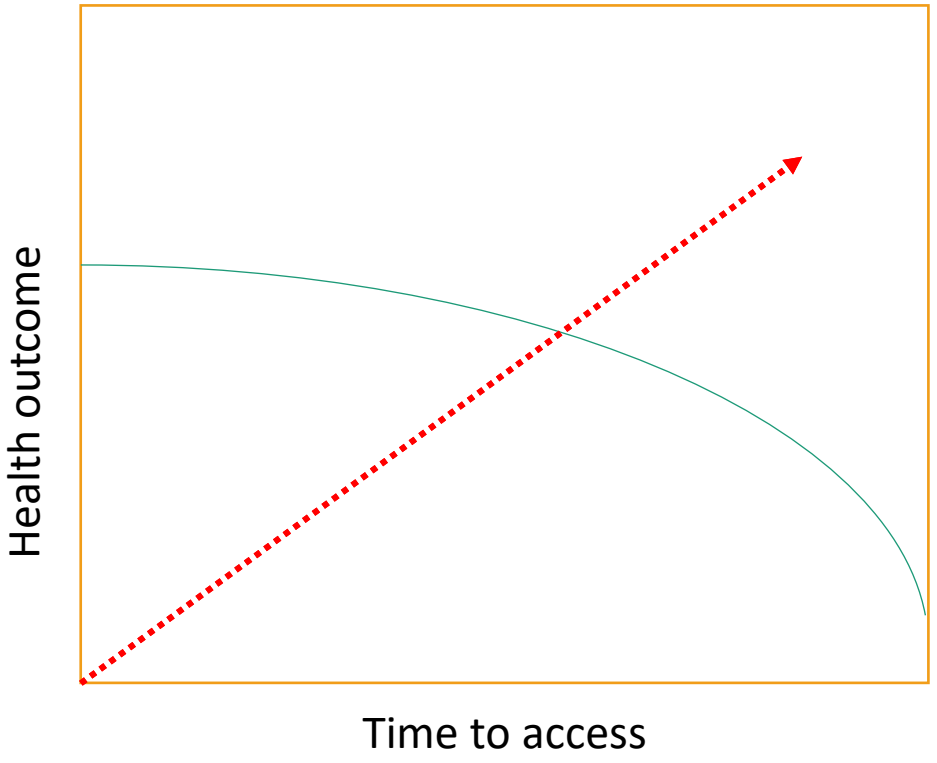
- Program where industry pays **user fees** which the agency uses to increase review capacity to meet performance goals on review timelines and implement targeted process improvements.
- Helps **assure patients have access to safe, effective, high-quality devices in a timely fashion** and there is a clear, predictable path to market for new innovations.
- The user fees authorized by MDUFA are crucial to enabling CDRH to **continue to modernize** our regulatory programs.
- The program is reauthorized every five years based on new negotiated agreements and new legislation:
  - MDUFA I: FY 2003-2007
  - MDUFA II: FY 2008-2012
  - MDUFA III: FY 2013-2017
  - MDUFA IV: FY 2018-2022
  - **MDUFA V: FY 2023-2027**

Themes of the MDUFA V Agreement

- **Review Performance |** Introducing a new goal structure with opportunities for "add-on" payments, as well as improving goals for PMA Total Time to Decision, 510(k) Total Time to Decision, Pre-Submissions, and De Novo decisions
- **Hiring & Retention |** Providing resources and associated goals to enhance hiring and retention of world-class technical and scientific staff
- **Performance Accountability |** Supporting a high-quality program through regular audits by a quality management team and independent assessments
- **Financial Transparency |** Adding new accountability mechanisms and enhanced reporting
- **Program Improvements |** Launching a TPLC Advisory Program Pilot, as well as enhancing programs to support patient science and engagement, real-world evidence, ***consensus standards***, ***digital health***, and ***international harmonization***

International Harmonization

- **International harmonization is essential** to accelerate access to safe and effective medical devices.
- A **delay in diagnosis** and treatment can result in **lower health outcomes** and an increase in overall healthcare spend.
- To achieve harmonization, we have to work together and **keep the patient at the center of our work**.



Delay in access = lower health outcome and higher healthcare spend

MDUFA V International Harmonization Commitments

- There are **five broad commitments** related to international harmonization efforts:
  1. Expand engagement in international harmonization and convergence efforts through participation with international regulators and other key stakeholders in forums, working groups, projects, and committees
  2. Further support regulatory convergence by creating a mechanism for FDA to work with regulatory partners.
  3. Assess the extent of CDRH implementation of IMDRF technical documents and make this information publicly available.
  4. Support the creation of a forum to engage with relevant stakeholders to identify opportunities for regulators to leverage one another's approach to decision making.
  5. Participate in outreach activities to other regulatory authorities that encourage harmonization

- Issuance of a strategic plan with additional details and timelines associated with achieving these international harmonization objectives and publish an annual assessment of our international harmonization activities.

MDUFA V Digital Health Commitments

The FDA will continue to build its digital health expertise and continue working to streamline and align FDA review processes with software lifecycles for digital health products.

1. **Continue to develop software and digital health technical expertise** to provide assistance for premarket submissions that include digital health.
2. **Strengthen efforts to expand staff understanding** of digital health topics and enhance consistent evaluation in submissions
3. **Continue to participate in international harmonization efforts** related to digital health.
4. **Finalize the draft guidance**, "Content of Premarket Submissions for Device Software Functions," by 18 months from close of the comment period.
5. **Publish draft guidance** describing a process to evaluate a predetermined change control plan for digital health devices.
6. **Engage with stakeholders**, including patients, users, and industry, through roundtables, informal meetings, and teleconferences to explore regulatory approaches to digital health technologies.

Benefits of International Harmonization

- Patients gain accelerated access to safe and effective medical products
- Faster diagnosis leads to faster treatment, better health outcomes and lower overall healthcare spend
- Regulators avoid technical barriers to trade and preforming unnecessary, redundant work
- Manufacturers can streamline their processes and deliver products faster
- Elevates regulatory frameworks and builds global competency to international best practice
- Stimulates innovation

US FDA/CDRH Approach

- Collaboration with global regulatory partners
- Use of international consensus standards
- Use of internationally harmonized documents such as those created by the International Medical Device Regulators Forum (IMDRF)
- Use of minimal country specific deviations, if any
- Build confidence and trust with other regulators through multilateral and bilateral efforts
- Use of Least Burdensome Principles

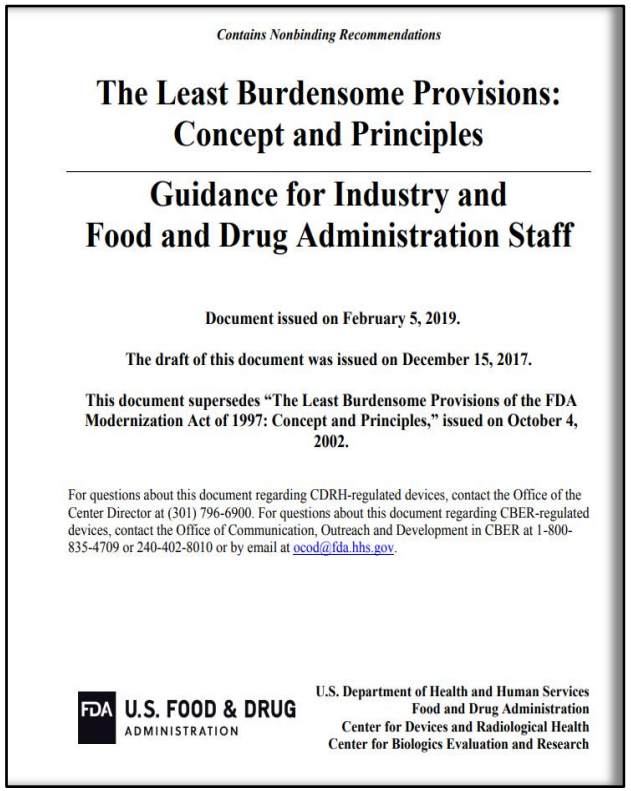
US FDA/CDRH Approach
Least Burdensome

By streamlining regulatory processes and removing or reducing unnecessary burdens associated with US FDA regulatory activities, patients can have earlier and continued access to beneficial products.

Least Burdensome Approach

The minimum amount of information necessary to adequately address a relevant regulatory question or issue through the most efficient manner at the right time.

- This considers the type of information, different approaches to generating or providing information, and when during the total product lifecycle information should be generated or provided to FDA.
- This concept applies to all products that meet the statutory definition of a device and throughout the total product lifecycle (premarket and postmarket).



Contains Nonbinding Recommendations

The Least Burdensome Provisions: Concept and Principles

Guidance for Industry and Food and Drug Administration Staff

Document issued on February 5, 2019.

The draft of this document was issued on December 15, 2017.

This document supersedes "The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles," issued on October 4, 2002.

For questions about this document regarding CDRH-regulated devices, contact the Office of the Center Director at (301) 796-6900. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach and Development in CBER at 1-800-835-4709 or 240-402-8010 or by email at ocod@fda.hhs.gov.

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