CAPITOL STREET

August 4, 2025

Medical Device User Fee Meeting Highlights

Digital Health, Regulating LDTs, & Expanding Breakthrough Pathway

Relevant Companies

Our Take & Next Up

Policies that could be reflected in the FY28 MDUFA reauthorization package include (1) Promoting the use of digital health & AI (2) Regulating Laboratory Developed Tests, and (3) Expanding the Breakthrough Devices pathway. We attended the first FDA FY 2028 MDUFA reauthorization meeting where Commissioner Makary, CDRH leadership, stakeholders, and industry spoke on priorities for MDUFA 6 (here). Dr. Makary emphasized "common sense" reforms to speed access to innovative devices, while industry prioritized pre-market reviews and adequate staffing. Themes provided by med tech trade associations and their "asks" are always telling and could be key to the policy riders that make it in MDUFA 6.

Key Points

The FDA wants to finalize the MDUFA package by Fall 2026 and transmit to Congress by Jan 2027. The current MDUFA authorization (MDUFA 5) ends Sept 30, 2027. The FDA today heard from stakeholders on items to include in the next reauthorization of the Medical Device User Fee Act (MDUFA 6) for fiscal years (FYs) 2028 through 2032. Similar to the PDUFA reauthorization (here), the FDA will aim to host public stakeholder meetings monthly during negotiations this Fall/Spring 2026.

Potential MDUFA policies include (1) enhancing the role of digital health (2) regulating Laboratory Developed Tests, and (3) expanding the Breakthrough Devices pathway. We note the "must-pass" user fee reauthorization bills typically include a range of FDA-related policy riders.

- **Enhancing the role of digital health.** The FDA and industry recognize the importance & potential for AI and machine learning.
- **Regulating Laboratory Developed Tests (LDTs).** While the lab industry (ACLA) was not present at the meeting, we expect there will be another bipartisan effort to include legislation like the *VALID Act* in MDUFA 6 that gives the FDA authority to regulate LDTs. Recall, the FDA's LDT guidance was recently struck down by the courts, which was good news for the clinical lab industry (our take here).
- **Expanding the Breakthrough Devices pathway.** Both the FDA and industry support this pathway and will likely seek policies to further encourage its use. In 2024, the FDA designated 156 devices as Breakthrough Devices, with 42 being authorized. One possibility is to expand the criteria beyond life-threatening conditions.

Competition from China and the EU is real. Makary suggested there may be ways to improve the application process to make it more user-friendly. Makary encouraged the use of more real world evidence along with Elsa, the FDA's AI tool used by thousands of scientific reviewers every day (our take here).

- Dr. Makary noted the FDA regulates 248,400 devices on the market today.
- Makary emphasized that the US is 40% of the medtech market with two-thirds of devices made domestically and $72B of exports over 2022-2024.
- Makary also noted the five-fold increase in device authorizations since the start of MDUFA.

Dr. Michelle Tarver, Director of the FDA's Center for Devices and Radiological Health, highlighted that the agency has met or exceeded most MDUFA 5 submission timeline goals. Under MDUFA 5, the FDA approved 100 devices using real-world evidence (RWE). The agency exceeded its MDUFA 5 goals on digital health, authorizing ~1,250 AI-powered medical devices. The FDA's Total Product Life Cycle Advisory Program (TAP) also expanded from 15 to 93 devices.

- The TAP pilot is a program that helps medical device makers get early and ongoing feedback from the agency & insurers to speed development.
- The FDA plans to expand the TAP pilot into other clinical areas (to be determined), with up to 225 total devices in FY 2026 and 325 total devices in FY 2027.

Industry wants FDA funding primarily via congressional appropriations vs. user fees, prioritizing pre-market reviews & adequate staffing. Medtech trade associations (AdvaMed, MDMA) shared Makary's goal of improving the efficiency and speed of the device approval process, without sacrificing safety and efficacy. However, the groups called for less reliance on industry-based agency funding, which is a view shared by HHS Secretary RFK Jr. (here). They also want funding to focus more on pre-market vs. post-market, along with adequate agency staffing. We note that devices are considered to have been less decimated by restructuring at FDA.

- According to AdvaMed, MDUFA 3 introduced goals for total time of review, MDUFA 4 advanced digital health technologies, and MDUFA 5 expanded international regulation.
- In FY 2022, user fees funded 35% of the medical devices review program (here).
- For FY 2026, the MDUFA fee for an application requiring clinical data (PMA) is $579,272 (here).

Patient advocates urge increased transparency, accessibility, and post-market analysis. Many of the panelists referenced the success of FDA's Total Product Life Cycle Advisory Program (TAP) as an example. Recommended improvements to MDUFA included promoting patients' access to information and including booklets, Informed Consent Checklists, postmarket surveillance, "Dear Doctor" letters, warning labels, and recall campaigns. Innovation in rare disease was also emphasized as a key area of focus.

Ipsita Smolinski
Managing Director I Capitol Street
ipsita@capitol-street.com

202.250.3741 I www.capitol-street.com

900 19th St NW 6th Fl
Washington, D.C. 20006

CAPITOL STREET