COMMITTEE ON
ENERGY & COMMERCE
CHAIRMAN FRANK PALLONE, JR.

MEMORANDUM

March 28, 2022

To: Subcommittee on Health Members and Staff

Fr: Committee on Energy and Commerce Staff

Re: Hearing on "FDA User Fee Reauthorization: Ensuring Safe and Effective Medical Devices"

On **Wednesday, March 30, 2022, at 9 a.m. (EDT), in the John D. Dingell Room, 2123 of the Rayburn House Office Building, and via Cisco WebEx online video conferencing**, the Subcommittee on Health will hold a legislative hearing entitled, "FDA User Fee Reauthorization: Ensuring Safe and Effective Medical Devices."

I. MEDICAL DEVICE USER FEE AMENDMENTS

A. Background

The Medical Device User Fee Amendments (MDUFA), first established in 2002 and reauthorized three times since then, authorizes the Food and Drug Administration (FDA) to collect user fees from companies producing medical devices. These fees supplement funds appropriated to FDA to support timely review of device applications, facility registrations, and other activities. The most recent MDUFA reauthorization was enacted as part of the FDA Reauthorization Act of 2017 and expires on September 30, 2022.[1] Prior to every user fee reauthorization, FDA and industry representatives negotiate proposed user fees and performance goals, which may include new initiatives to facilitate medical device development, new guidance the agency will provide, modified practices, and other proposals. Although the statutory deadline for transmitting a final performance goals letter for MDUFA V was January 15, 2022, the final performance goals letter has not yet been transmitted to Congress. Instead, the Department of Health and Human Services (HHS) provided a draft performance goals letter to the Committee on March 22, 2022.[2]

The draft performance goals letter contains FDA's commitments on review timelines, hiring estimates, and program enhancements for MDUFA V. Substantial changes to the review programs and new initiatives are described below.

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[1] Pub. L. No. 115–52.

[2] Food and Drug Administration, *Draft: MDUFA Performance Goals and Procedures, Fiscal Years 2023 Through 2027* (www.fda.gov/media/157074/download) (Mar. 22, 2022).

B. Review Timelines

The table below describes the review timelines proposed by FDA and industry in the draft performance goals letter. Agreed upon timelines and fees may be adjusted in later years if Performance Improvement Adjustments are triggered.

Category	Timeline
Pre-Submissions	• Pre-Submissions provide the applicant an opportunity for FDA feedback prior to an intended submission for an investigational device exemption or marketing application. Pre-Submissions include a written request from an applicant for feedback from FDA that is provided in the form of a formal written response, which may be followed by a meeting or teleconference. • Within 15 calendar days of receipt of a Pre-Submission, FDA will communicate with the applicant whether the application has been accepted and, if applicable, discuss the scheduling of a meeting or teleconference. • FDA intends to reach agreement with the applicant regarding a meeting date within 30 days from receipt of accepted submission. • FDA will provide written feedback addressing any issues raised in the Pre-Submission request within 70 calendar days of receipt or five calendar days prior to a scheduled meeting as follows: o For Fiscal Year (FY) 2023, 90 percent of Pre-Submissions if the number of MDUFA cohort submissions is fewer than 3,585 or 75 percent of Pre-Submissions if the number of MDUFA cohort submissions is 3,585 or more, up to 4,300 submissions; o For FY 2024, 90 percent of Pre-Submissions if the number of MDUFA cohort submissions is fewer than 4,060 or 80 percent of Pre-Submissions if the MDUFA cohort submissions is 4,060 or more, up to 4,300 submissions; and o For FY 2025 through FY 2027, 90 percent of pre-submissions in the number of MDUFA cohort, up to 4,300 submissions
Original Premarket Approval Applications (PMAs), Panel-Track Supplements, and Premarket Reports	• PMAs are applications submitted pursuant to section 515(c) of the Federal Food, Drug, and Cosmetic Act (FFDCA). PMA approval is required for Class III devices, which are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury, and for which general and special controls are insufficient. Premarket Reports are for approval of re-processed single-use devices. Panel-Track Supplements are a type of supplement to Original PMAs and Premarket Reports. • Within 15 calendar days of receipt, FDA will communicate with the applicant whether the application has been accepted for filing review. If the application is not accepted for review, FDA will notify the applicant of items necessary for filing review. Filing status of accepted.

	applications will be communicated within 45 calendar days of receipt of the application. • FDA will communicate with the applicant through a Substantive Interaction within 90 calendar days of the filing date of the application for 95 percent of submissions. • If FDA issues a major deficiency letter to the applicant, it will include all deficiencies and a basis for the deficiencies. • For those submissions that do not require Advisory Committee input, FDA will issue a decision within 180 FDA days for 90 percent of submissions. • For those submissions that require Advisory Committee input, FDA will issue a decision within 320 FDA days for 90 percent of submissions, and within 60 days of an Advisory Committee recommendation as resources permit.
De Novo Submissions	• De Novo requests are those requests made under section 513(f)(2) of the FFDCA with respect to a device classification. • FDA will issue a MDUFA decision within 150 FDA days for 70 percent of De Novo requests. • As resources permit, if a final decision for a De Novo request is not rendered within 180 FDA days, FDA will discuss with the applicant all outstanding issues with the submission preventing FDA from reaching a decision.
510(k)	• A 510(k) is a premarket submission made to FDA to demonstrate that a device is substantially equivalent to a legally marketed device. • Within 15 calendar days of receipt, FDA will notify the applicant regarding whether the application has been accepted for review. • FDA will communicate with the applicant through a Substantive Interaction within 60 calendar days of receipt of the submission for 95 percent of submissions. • FDA will issue a MDUFA decision within 90 FDA days for 95 percent of 510(k) submissions. • For all 510(k) submissions that do not reach a MDUFA decision within 100 FDA days, FDA will provide written feedback to the applicant to be discussed in a meeting or teleconference.

C. Opportunity for Performance Improvement Adjustments

FDA and industry have proposed increasing fee revenue for FY 2025 through FY 2027 if initial goals are met in 2023, 2024, and 2025, which is new to the user fee program in this performance goals letter. The corresponding goals for FDA in FY 2025 through FY 2027 will also escalate if fee revenues are increased. For example, if FDA meets initial goals for Pre-Submissions in FY 2023, the agency will receive increased fees, and the maximum number of Pre-Submissions subject to the written feedback goal will increase from 4,300 submissions to 4,700 submissions in FY 2025 through FY 2027. The full list of performance improvement adjustments is located in Section III of the performance goals letter.

D. Financial Transparency and Hiring

No later than the second quarter of FY 2023, FDA will publish a five-year financial plan for the MDUFA program, which will include hiring targets. That plan will be updated annually with an accounting of user fee funds and the number of new hires, among other information.

The performance goals letter limits FDA to 13 weeks of operating reserves that can be kept in a carryover balance. If FDA has more than 13 weeks of operating reserves in a carryover balance, registration fees will be decreased.

FDA will establish hiring goals throughout the FY 2023 through FY 2027 period for MDUFA V. According to the performance goals letter, the minimums are: 144 hires in FY 2023, 42 hires in FY 2024, and 24 hires in FY 2025. FY 2026 and FY 2027 hiring goals will be calculated and published in the Federal Register. If initial performance improvement adjustments described above are triggered, hiring goals will correspondingly increase for FY 2025 through FY 2027.

Additionally, if hiring goals are not met, registration fees may be reduced. For example, if FDA misses its hiring goal by more than 15 precent in FY 2023, registration fees for FY 2025 will be decreased. Similarly, if the FY 2024 or 2025 hiring goal is missed by more than 10 percent, registration fees will be reduced in FY 2026 and FY 2027, respectively.

E. Process Improvements and Program Continuations

1. Deficiency Letters

No later than January 1, 2023, FDA will update its guidance on deficiency letters, including a requirement that FDA provide a statement of the basis for the deficiencies and the letters will undergo supervisory review before they go out. New in this performance goals letter, FDA has committed to metrics for providing the basis of deficiency. FDA will provide a basis of deficiency for 75 percent of deficiencies in FY 2023, and the metric will increase steadily to 95 percent of deficiencies by FY 2027. This commitment will be audited.

2. Consensus Standards

FDA and industry propose that the voluntary Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program be completed by September 30, 2023, and that FDA be authorized to continue operating a program consistent with the pilot beyond that date. This pilot program was designed to encourage medical device sponsors to use voluntary consensus standards in product submissions, which can then decrease the burden of individual premarket submissions and increase submission quality. Under current law, the ASCA Pilot Program is set to expire on October 1, 2022.[3] While FDA and industry agree that this program should be extended as part of the performance goals letter, extending it beyond this date would require

[3] 21 U.S.C. § 360d(d)(4).

authorization from Congress separate and apart from what was agreed to in the performance goals letter.

3. Third Party Review

FDA and industry agreed to continue to support the Third Party Review program, under which FDA accredits entities to review 510(k)s for certain devices and provides training for third parties seeking accreditation. In the performance goals letter, FDA states that it will use funding from the user fee carryover balance to fund Third Party Review. However, like the ASCA pilot program, the Third Party Review program is set to expire on October 1, 2022,[4] and an extension of the program requires authorization from Congress separate and apart from what was agreed to in the performance goals letter.

4. Patient Science and Engagement

FDA will take several steps to improve patient engagement, including issuing draft guidance on incorporating patient and provider feedback on clinical outcomes as primary or co-primary endpoints in premarket studies. Additionally, by the end of FY 2024, FDA will hold a public meeting to explore ways to use patient-generated health data to advance remote clinical trial data collection and support clinical outcome assessments.

5. Real World Evidence (RWE)

FDA will update its 2017 guidance document on RWE, including more information on previously used and accepted RWE methodologies and best practices for RWE review.

6. Digital Health

FDA will continue efforts to support digital health technology development, including finalizing a guidance document on Content of Premarket Submissions for Device Software Functions by 18 months after the comment period closes and publishing draft guidance describing a process to evaluate a predetermined change control plan for digital health devices.

7. Total Product Life Cycle (TPLC) Advisory Program (TAP)

MDUFA V would establish the TAP Pilot program. This program will facilitate earlier interaction between FDA and industry participants to improve the experience of participants; identify risks earlier in development; facilitate regular engagements between FDA review teams, participants, patients, providers, and payers; and collaborate to align expectations, improve submission quality, and increase efficiency in the premarket review process. The TAP Pilot will begin in FY 2023 with up to 15 products and will eventually enroll up to 325 products through FY 2027. Initial participants will include those that have received Breakthrough designation that are early in the development process and have not submitted a Pre-Submission for their product.

[4] 21 U.S.C. § 360m(c).

II. OTHER LEGISLATION

A. H.R. 7084, the "Protecting and Transforming Cyber Health Care Act of 2022" or the "Patch Act of 2022"

H.R. 7084, the "PATCH Act of 2022," introduced by Rep. Burgess (R-TX), would require premarket submissions to include certain information related to cybersecurity and authorize FDA to require additional cybersecurity information. Manufacturers of cyber devices would be required to monitor, identify, and address in a reasonable time postmarket cybersecurity vulnerabilities and exploits; have a plan and procedures for a Coordinated Vulnerability Disclosure to be part of submissions to FDA; and design, develop, and maintain processes and procedures to update and patch cyber devices and related systems to address vulnerabilities. Cyber devices include all devices that include software or connect to the internet.

B. H.R. 7192, the "Diagnostic Device Advisory Committee Act"

H.R. 7192, the "Diagnostic Device Advisory Committee Act," introduced by Rep. Schrier (D-WA), would establish a panel of experts on diagnostic devices within the Medical Devices Advisory Committee at FDA. The panel would consist of 15 members, four of whom would be non-voting members representing consumer interests, the device industry, and public health or population health-specific representatives. The panel would provide FDA advice and recommendations on the real-world impact of the clearance, classification, approval, and authorization of diagnostic devices; the risk assessment posed by the use of these devices; and the need such devices would fill.

III. WITNESSES

The following witnesses have been invited to testify:

Panel I

Jeff Shuren, M.D.
Director, Center for Devices and Radiological Health
Food and Drug Administration

Panel II

Richard J. Kovacs, M.D.
Q.E. and Sally Russell Professor of Medicine
Indiana University School of Medicine
Chief Medical Officer, American College of Cardiology

Mark Leahey
President & CEO
Medical Device Manufacturers Association

Janet Trunzo
Senior Executive Vice President, Technology and Regulatory Affairs
Advanced Medical Technology Association (AdvaMed)

Diane Wurzburger
Executive of Regulatory Affairs
GE Healthcare