ENERGY & COMMERCE
CHAIR RODGERS

MEMORANDUM

To: Subcommittee on Health Members and Staff
From: Committee on Energy and Commerce Majority Staff
Re: Health Subcommittee Hearing on May 22, 2024

The Subcommittee on Health will hold a hearing on Wednesday, May 22, 2024, at 10:30 a.m. (ET) in 2322 Rayburn House Office Building. The title of the hearing is "Check Up: Examining FDA Regulation of Drugs, Biologics, and Devices."

I. Witnesses

- **Dr. Patrizia Cavazzoni, M.D.,** Director, Center for Drug Evaluation and Research
- **Dr. Peter Marks, M.D., Ph.D.,** Director, Center for Biologics Evaluation and Research
- **Dr. Jeff Shuren, M.D., J.D.,** Director, Center for Devices and Radiological Health

II. Background

FDA Mission and Structure

First established in 1906, the U.S. Food and Drug Administration (FDA) was created to promote and protect the public health through the regulation of human and veterinary drugs, biological products, tobacco, cosmetics, medical devices, food, and electronic products that emit radiation. FDA-regulated products account for about 21 cents of every dollar spent by U.S. consumers.[1] In total, the FDA oversees more than $3.6 trillion worth of food, tobacco, and medical products produced in the U.S. and abroad.[2]

The FDA currently employs more than 18,000 people in all 50 states and in international outposts.[3] It is made up of nine centers and 13 offices.[4] Each center plays a unique role in carrying out the Agency's regulatory responsibilities. This hearing will focus on (1) the Center for Drug Evaluation and Research, (2) the Center for Biologics Evaluation and Research, and (3) the Center for Devices and Radiological Health.

Center for Drug Evaluation and Research:

[1] "FDA at a Glance." https://www.fda.gov/media/175664/download
[2] "FDA at a Glance." https://www.fda.gov/media/175664/download
[3] "About FDA." https://www.fda.gov/about-fda#:~:text=Each%20day%20in%20America%2C%20you,%2C%20biologics%2C%20and%20medical%20devices
4 "FDA Organization Charts," https://www.fda.gov/about-fda/fda-organization/fda-organization-charts

The Center for Drug Evaluation and Research (CDER) is the largest Center at the FDA.[5] It is responsible for ensuring the safety and efficacy of prescription and over-the-counter (OTC) drug products, including generic drugs, therapeutic biological products, and biosimilars. CDER is comprised of 12 offices, including those responsible for providing guidance to industry, reviewing applications, and making approval decisions for each respective product category.[6] The Office of New Drugs (OND) approved 55 novel drugs in 2023.[7] The Office of Generic Drugs (OGD) approved or tentatively approved 956 generic drug applications in 2023.[8]

The President's FY2025 Budget request for the Human Drugs Program is $2,403,402,000, of which $754,049,000 is budget authority and $1,649,353,000 is user fees.[9] The CDER amount in the request is $2,110,936,000. The total requested increase was $34 million and includes requests for shortages and supply chain authorities, enterprise transformation, information technology (IT) stabilization and modernization, and employee compensation. The request constitutes a decrease of $7,445,000 compared to the FY 2023 Final Level while user fees increase by $127,100,000.

Center for Biologics Evaluation and Research:

The Center for Biologics Evaluation and Research (CBER) is responsible for ensuring the safety, purity, potency, and effectiveness of biological products including vaccines, allergenics, blood and blood products, cells, tissues, and gene therapies for the prevention, diagnosis, and treatment of human diseases, conditions, or injury.[10] Several offices within CBER are responsible for reviewing these products, including the Office of Vaccines Research and Review (OVRR), the Office of Therapeutic Products (OTP) and the Office of Blood Research and Review (OBRR).[11]

There are about 900 FDA-licensed biologics products, with nearly 5,900 FDA-registered facilities.[12] In 2023, CBER approved 23 biologics device applications, 20 biologics license applications, and 17 biologics license application supplements.[13] In 2024, CBER plans to build upon advancements in gene and cell therapy to expedite the

[5] "FDA at a Glance." https://www.fda.gov/media/175664/download.
[6] "Center for Drug Evaluation and Research Organization Chart." https://www.fda.gov/about-fda/fda-organization-charts/center-drug-evaluation-and-research-organization-chart
[7] "Center for Drug Evaluation and Research: 2023 OND Annual Report." https://www.fda.gov/media/178111/download?attachment
[8] "Office of Generic Drugs 2023 Annual Report." https://www.fda.gov/media/176440/download?attachment
[9] "Department of Health and Human Services Fiscal Year 2025; Food and Drug Administration: Justification of Estimates for Appropriations Committees." https://www.fda.gov/media/176925/download?attachment
[10] "Center for Biologics Evaluation and Research." https://www.fda.gov/about-fda/fda-organization/center-biologics-evaluation-and-research-cber
[11] "Center for Biologics Evaluation and Research." https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/center-biologics-evaluation-and-research
[12] "FDA at a Glance." https://www.fda.gov/media/175664/download
[13] "CY 2023 Report from the Director." https://www.fda.gov/vaccines-blood-biologics/cy-2023-report-director

development and regulation of innovative, safe and effective treatments for patients. So far, 8 biologics license applications have been approved in 2024.[14]

The President's FY2025 Budget request for the Biologics Program is $589,682,000, of which $279,986,000 is budget authority and $309,696,000 is user fees.[15] The CBER amount in the request is $536,798,000. The total requested increase in the President's FY2025 Budget for the Biologics Program was $12.7 million and includes requests for shortages and supply chain authorities, enterprise transformation, IT stabilization and modernization, and employee compensation. The request constitutes a $7,771,000 increase compared to the FY 2023 Final Level, with a $91,446,000 increase in user fees.

Center for Devices and Radiological Health:

The Center for Devices and Radiological Health (CDRH) is responsible for regulating medical devices and radiation-emitting products.[16] These devices range from simple tongue depressors to complex instruments, such as heart valves, programmable pacemakers, in vitro diagnostic products, and MRI machines. The Office of Product Evaluation and Quality (OPEQ) at CDRH is responsible for evaluating or clearing medical devices for clinical investigations and marketing.[17] The Office of Strategic Partnerships and Technology Innovation collaborates with OPEQ on emerging technology related activities, such as cybersecurity, software, and digital health technologies.[18]

There are 255,000 different types of medical devices on the U.S. market, manufactured in more than 27,000 facilities worldwide.[19] In 2023, CDRH received over 19,000 submissions and gave marketing authorization to 124 novel devices.[20] To date, CDRH has authorized nearly 900 Artificial Intelligence and Machine Learning (AI/ML)-enabled medical devices, in coordination with the Digital Health Center of Excellence.[21]

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[14] "2024 Biological License Applications Approvals." https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/2024-biological-license-application-approvals
[14] "Department of Health and Human Services Fiscal Year 2025; Food and Drug Administration: Justification of Estimates for Appropriations Committees." https://www.fda.gov/media/176925/download?attachment
[16] "Center for Devices and Radiological Health." https://www.fda.gov/about-fda/fda-organization/center-devices-and-radiological-health
[17] "Office of Product Evaluation and Quality," https://www.fda.gov/about-fda/cdrh-offices/office-product-evaluation-and-quality
[18] "Office of Strategic Partnerships and Technology Innovation," https://www.fda.gov/about-fda/cdrh-offices/office-strategic-partnerships-and-technology-innovation
[19] "Department of Health and Human Services Fiscal Year 2025; Food and Drug Administration: Justification of Estimates for Appropriations Committees." https://www.fda.gov/media/176925/download?attachment
[20] "2023 Annual Report: Center for Devices and Radiological Health," https://www.fda.gov/media/175479/download?attachment
[21] "Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices," https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices

The President's FY2025 Budget request for the Devices Program is $818,659,000, of which $465,778,000 is budget authority and $352,881,000 is user fees.[22] The amount for CDRH in the request is $704,452,000. The total requested increase in the President's FY2025 Budget for the Devices Program was $20.9 million and includes requests for employee compensation, enterprise transformation, IT stabilization and modernization, and capabilities to identify and respond to shortage threats and vulnerabilities. The request constitutes a $16,181,000 increase compared to the FY 2023 Final Level, with a $56,229,000 increase in user fees.

User Fee Performance

Prescription Drug User Fee Performance

According to the Fiscal Year 2023 Prescription Drug User Fee Performance Report, CDER did not meet its hiring goals for FY23, with 36 remaining vacancies.[23] CBER also did not meet its hiring goals for FY23, with 23 remaining vacancies. For the FY 2023 cohort[24], the FDA is currently meeting or exceeding nine of the 10 review performance goals for FY 2023 and is currently meeting or exceeding 15 of the 29 procedural and processing goals. For the final FY 2022 cohort, the FDA missed several procedural goals related to response to clinical holds and formal meetings, notably responding on time to only 65 percent of Type B and 76 percent of Type B(EOP) written responses, or responses to outreach regarding major clinical and scientific development decisions.

Medical Device User Fee Performance

According to the FY2023 Medical Device User Fee Performance Report, CDRH met its hiring goals for FY 2023. For the FY 2023 cohort, the FDA received submissions to calculate performance results for 16 of the 25 Medical Device User Fee Amendments (MDUFA) V review goals, two of which were sufficiently complete to determine the outcome and were met, no review goals were sufficiently complete to determine the outcome and were missed, and 14 review goals were pending.[25] For the FY 2023 cohort, the FDA had 16 performance-enhancement goals due in FY 2023, all but one of which were completed on time. Two additional goals due at the end of MDUFA V were met ahead of schedule. For the FY2022 cohort, the FDA missed nine review goals, notably

[22] "Department of Health and Human Services Fiscal Year 2025; Food and Drug Administration: Justification of Estimates for Appropriations Committees." https://www.fda.gov/media/176925/download?attachment
[23] "Performance Report to Congress: Prescription Drug User Fee Act FY 2023." https://www.fda.gov/media/177976/download?attachment
[24] FDA annually reports performance data for each fiscal year receipt cohort, defined as submissions filed from October 1 to September 30 of the following year.
[25] "Performance Report to Congress: Medical Device User Fee Act FY 2023." https://www.fda.gov/media/177975/download?attachment

responding to 79 percent of substantive interactions regarding original premarket approvals (PMAs) on time.

III. Staff Contacts

If you have questions regarding this hearing, please contact Emma Schultheis of the Committee on Energy and Commerce Majority staff at 202-225-3641.