Fiscal Year 2027 Senate Appropriations Committee Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies

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Food and Drug Administration Fiscal Year 2027 Appropriations

Chairman Hoeven, Ranking Member Shaheen and distinguished members of the subcommittee, the Personalized Medicine Coalition (PMC) appreciates the opportunity to submit testimony on the Food and Drug Administration (FDA)'s fiscal year (FY) 2027 appropriations. PMC is a nonprofit education and advocacy organization comprised of nearly 200 institutions from across the health care spectrum who support a growing field that depends on the FDA. As the subcommittee begins work on the FY 2027 Agriculture, Rural Development, FDA, and Related Agencies Appropriations bill, we respectfully ask that you maintain a minimum of funding for the FDA at the FY 2026 enacted level of $6.96 billion. Congress should ensure that increases in FY 2027 funding come in the form of budget authority and not increases in the percentage of user fee funding as proposed in the President's FY 2027 Budget Request. Prioritizing budget authority is necessary for the FDA to support innovative human drug, biologic, and medical device developments that are the foundation for the future of personalized medicine. An adequately resourced FDA also helps ensure that breakthrough discoveries, clinical development, and manufacturing investment remain rooted in the United States.

Personalized medicine, also called precision or individualized medicine, is an evolving field in which physicians use diagnostic tests to determine which medical treatments will work best for each patient or use medical interventions to alter molecular mechanisms that impact health. By combining data from diagnostic tests with an individual's medical history, circumstances, and values, health care providers can develop targeted treatment and prevention plans with their patients. Personalized medicine promises to detect the onset of disease, pre-empt its progression, and improve the quality, accessibility, and affordability of health care.[i]

Budget authority provides FDA with the broadest and most flexible means of meeting all of its responsibilities.[ii] Previous increases in budget authority have enabled the FDA to implement multiple programs facilitating the development of personalized medicine products, which require greater sophistication and expertise to review. The FDA has recently experienced significant staff losses. Remaining staff have limited bandwidth to manage many of these programs. Maintaining high levels of budget authority for the FDA in FY 2027 will allow the agency to rebuild capacity for these initiatives with a highly skilled workforce equipped with modernized data infrastructure and analytical tools, capable of evaluating complex technologies across the total product lifecycle, to support evidence-based decision-making. By providing funding for FDA activities that foster the development of cutting-edge medical products, Congress can help usher in a new

era of personalized medicine at a pivotal moment and enable the United States to remain a leader in health care innovation.

Facilitating the Development of Personalized Medicine Products

The FDA is the gateway for many personalized medicine breakthroughs entering the market. FDA's Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), and Center for Devices and Radiological Health (CDRH) each have responsibilities for evaluating medical products. To date, more than 300 personalized treatments and over 140,000 diagnostic products have been made available to patients.[iii] These numbers continue to grow, with personalized medicines accounting for more than a quarter of all new drugs approved by the FDA since 2015.[iv] In 2025, the FDA approved 16 personalized medicines representing approximately 36 percent of all newly approved therapeutic molecular entities last year.

As a byproduct of scientific breakthroughs, the number of cell and gene therapy submissions to the FDA is rising sharply — and this increase is expected to continue. Cell and gene therapies have potential to treat serious diseases and conditions, including cancer and rare genetic diseases, with many such products being developed to address unmet medical needs. FDA's CBER has been supporting products in clinical development by providing extensive scientific and regulatory advice to product manufacturers throughout the medical product lifecycle, including feedback on manufacturing, preclinical, and clinical topic areas. Of the 16 personalized medicine approvals in 2025, five are new cell and gene therapies offering personalized treatment approaches to patients with rare genetic diseases, as well as to those with certain hematological cancers. [v]

CDRH handles more than 20,000 medical device submissions each year, while promoting access to innovation. CDRH has authorized 46 designated breakthrough devices, which provide more effective treatment or diagnosis of life-threatening or irreversible debilitating human diseases where few of no alternatives exist for patients.[vi] Last year, the FDA approved or cleared new or expanded indications for 12 diagnostic testing systems that underpin personalized medicine strategies, including a new non-invasive blood-based early detection cancer test for primary colorectal cancer (CRC) screening, expanding its approved uses for adults ages 45 and older who are at average risk for CRC, and two new blood-based biomarker tests for Alzheimer's disease, which extend the benefits of personalized medicine to patients with cognitive decline to help rule out Alzheimer's pathology or to measure biomarkers in plasma for early, less invasive Alzheimer's disease.[vii]

These new approvals and expanded uses of already approved drugs, biologics, and diagnostics are helping transform care for molecularly selected subsets of patients with cancer as well as rare, common, and infectious diseases. To keep pace with scientific and technological advancements and remain a responsive regulatory agency, Congress must provide the FDA with sustained budget authority.

Expediting Personalized Medicine Product Development

Personalized approaches to treatment and prevention have grown to include companion diagnostics, advanced therapies, and AI-enabled devices. Regulatory activities often span multiple FDA centers. Sustained budget authority enables the coordination, consistency, and scientific alignment necessary to support timely and predictable regulatory decisions.
The FDA has taken a number of steps to modernize its regulatory processes, including the issuance of 36 guidance documents in 2025 pertaining to important aspects of drug development such as the use of artificial intelligence (AI) technologies for regulatory decision making. To help establish a risk-based framework for integrating AI into drug development and ensure AI tools used for personalized medicine technology development and clinical implementation are validated, transparent, and maintain consistent performance throughout their lifecycle, FDA released a draft guidance document focusing on model credibility, data quality, and human oversight. The FDA also released the third in a series of four methodological patient-centered drug development guidance documents that describe how patients, researchers, medical product developers, and others can acquire and submit patient experience and other relevant patient information to be used for personalized medicine product development and regulatory decision-making.

To speed up progress against deadly adult and pediatric cancers, in January 2017 CDER established the Oncology Center of Excellence (OCE), which unites experts across the FDA to expedite the review of medical products for oncologic and hematologic malignancies. OCE leads a variety of research and educational outreach projects and programs to advance the development and regulation of medical products for patients with cancer. Real-Time Oncology Review (RTOR) by OCE provides FDA reviewers with earlier data access allowing the identification of data quality issues and facilitating early applicant feedback. RTOR allows submission of topline efficacy and safety results before a complete application, supporting earlier FDA evaluation to ensure safe and effective treatments reach patients sooner while upholding standards for review quality. OCE approved 10 RTOR applications in 2025.[viii]

Like OCE the FDA created the Rare Disease Innovation Hub (RDIH) in 2024 to serve as a point of collaboration and connectivity across CDER, CBER, and CDRH. The RDIH aims to address common scientific, clinical, and policy issues related to rare disease product development. The RDIH works across all rare diseases and has dedicated workstreams that can help advance personalized medicines by considering novel endpoints, biomarker development and assays, innovative trial design, real world evidence, and statistical methods. CDER and CBER released an FDA Rare Disease Hub Strategic Agenda in 2025 which outlines actions the RDIH would take to support rare disease drug development. Additionally, in September 2025, FDA introduced the Rare Disease Evidence Principles to provide greater speed and predictability in the review of therapies intended to treat rare diseases with very small patient populations with significant unmet medical need and that are driven by a known genetic defect.[ix]

There are approximately 248,000 different types of medical devices on the U.S. market.[x] Over the past 10 years FDA approvals of AI/ML enabled medical devices has increased significantly with more than 1,000 authorized as of January 2025.[xi] FDA's Digital Health Center of Excellence supports CDRH reviews of medical devices by convening the Digital Health Advisory Committee to discuss generative AI-enabled digital health devices and issuing draft guidance on management and marketing of AI-enabled device software functions. CDRH also updated guidance on the use of real-world evidence to support regulatory decision making for medical devices. That guidance explains how a least burdensome approach applies to assessing whether real-world data are relevant and reliable for expanding indications for use of a device or for clearance/approval of a new device. FDA has identified 73 examples of marketing authorizations between FY 2020 and 2025 that have utilized real-world evidence, highlighting the growing use of real-world data to validate device software functions, including AI/ML-enabled technologies.[xii] FDA's ongoing efforts to establish risk-based, lifecycle regulatory frameworks for AI-enabled technologies are foundational to both patient safety and sustained innovation. Appropriate levels of budget authority and user fee funding in FY 2027 will be essential for patients to fully realize the benefits of technological advances.

Conclusion

PMC appreciates the opportunity to highlight the FDA's importance to the continued success of personalized medicine in the United States. Maintaining a minimum of funding for the FDA at the FY 2026 enacted level of $6.96 billion and strategically increasing funding through budget authority appropriations in FY 2027 will help the agency advance innovative human drug, biologic, and medical device development and bring us closer to a future in which every patient benefits from a personalized approach to health care.

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[i] http://www.personalizedmedicinecoalition.org/Userfiles/PMCCorporate/file/PMC_The_Personalized_Medicine_Report_Opportunity_Challenges_and_the_Future.pdf

[ii] https://acrobat.adobe.com/link/track?uri=urn:aaid:scds:US:fbda0765-44c4-47d2-aa11-71a4721a4d3f#pageNum=2

[iii] https://doi.org/10.1002/ajmg.c.31881

[iv] https://www.personalizedmedicinecoalition.org/wp-content/uploads/2024/02/report-3.pdf

[v] https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm

[vi] https://www.fda.gov/media/191778/download?attachment

[vii] https://www.fda.gov/medical-devices/products-and-medical-procedures/device-approvals-and-clearances

[viii] https://www.fda.gov/media/191778/download?attachment

[ix] https://www.fda.gov/media/191778/download?attachment

[x] https://www.fda.gov/media/191778/download?attachment

[xi] https://www.fda.gov/news-events/press-announcements/fda-issues-comprehensive-draft-guidance-developers-artificial-intelligence-enabled-medical-devices

[xii] https://www.fda.gov/news-events/fda-voices/real-world-evidence-advancing-regulatory-decision-making-medical-devices