DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

Hearing on the FY 2025 Budget Request for the National Institutes of Health

Witness appearing before the

House Appropriations Subcommittee on Labor, HHS, Education, and Related Agencies

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Good morning, Chair Aderholt, Ranking Member DeLauro, and distinguished Members of the Subcommittee. I am Monica Bertagnolli, M.D., Director of the National Institutes of Health (NIH). Thank you for the invitation to appear before you today. It is an honor to lead the NIH, guide the work of a remarkable research community and provide stewardship of public resources to enhance the lives of all Americans.

I am grateful for the committee's long-standing support for NIH. NIH research has made significant contributions to improving the health of people in the United States and around the world. NIH's successes would not have been possible without the investment made by this committee. But we still have work to do. Families across the country are grappling with new cancer diagnoses, managing chronic diseases, or struggling with ill health from Long COVID, among many other challenges. To tackle the most persistent and complex problems, and to restore trust in science and the value it brings to society, we need to bring more members of the public into the research enterprise as our partners in discovery. By linking the laboratory to the clinic and to diversity of communities that encompass our country and making sure that the information we collect is used safely and ethically to improve health for all people, we can find solutions to the health challenges facing our communities.

The FY 2025 President's Budget requests $50.1 billion in discretionary and mandatory resources for NIH Institutes, Centers, and Offices. This funding will allow the NIH to continue our vital work to support the Administration's goal to prevent more than four million cancer deaths by 2047, make targeted investments in mental health, women's health research and data science in an environment of tight discretionary spending caps.

A Reinvigorated Cancer Moonshot

In FY 2025, the President's Reignited Cancer Moonshot Initiative[1] will support priority investments to advance the goal of cutting America's cancer death rate by 50 percent by 2047. Since it was established in 2016, the Beau Biden Cancer Moonshot has supported over 300 research projects that pushed the boundaries of discovery and collaboration on behalf of cancer patients. The President's FY 2025 Budget requests $716 million in discretionary funding.

In addition to discretionary resources, the budget also proposes to reauthorize the 21st Century Cures Act Cancer Moonshot program through FY 2026 and provide $2.9 billion in mandatory funding in FY 2025 and FY 2026, $1.448 billion each year. In total, the budget proposes $2.164 billion in combined discretionary and mandatory funding for FY 2025.

To attain the goal of a 50 percent reduction in cancer mortality, funding for the Moonshot will continue to focus on substantially increasing the number and diversity of people who participate in National Cancer Institute-sponsored clinical trials to develop new prevention, diagnosis, and treatment approaches. Additionally, making faster progress is critical against cancers that have proven the most difficult to treat, such as pancreatic cancer, glioblastoma, as well as rare cancers and certain pediatric tumors. The FY 2025 request will build on research supported through the Moonshot that led to foundational advancements in immunotherapy, progress in childhood cancer research, and expanded use of proven strategies for cancer prevention and early detection to reduce cancer risk and disparities.

Revolutionizing Mental Health with Precision Medicine

Scientific and clinical advances are rapidly advancing mental health care in the United

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[1] https://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative

States. Progress in basic science has led to new tools and resources that enable investigators to gain significant insight into the complex interactions between the brain, environment, and disease. This Budget increases funding for NIMH mental health initiatives, including $10 million to support behavioral health prevention implementation science, focusing on sustainable prevention and early intervention approaches. For example, NIMH aims to change the game for precision medicine in psychiatry with a groundbreaking new initiative. NIMH's Individually Measured Phenotypes to Advance Computational Translation in Mental Health (IMPACT-MH) seeks to harness machine learning and other data-driven approaches to integrate data from behavioral assessments with clinically available data, with the goal of generating more precise, objective clinical signatures and improving mental health outcomes by helping mental health providers and their patients make more informed decisions.

Additionally, the President's Unity Agenda for mental health[2] emphasizes strategies for addressing our national mental health crisis, including scalable approaches for prevention and early intervention. In alignment with this agenda, NIMH is focused on building and disseminating a robust evidence base for effective preventive and treatment interventions for mental and behavioral disorders, driving this investment in the FY 2025 Budget.

Women's Health Research Across the Lifespan

Advancing science for women's health requires a multipronged approach to advance a vision in which sex and/or gender influences are integrated into the biomedical research enterprise; every woman receives evidence-based disease prevention and treatment tailored to her own needs, circumstances, and goals; and women in science careers reach their full

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[2] https://www.whitehouse.gov/briefing-room/statements-releases/2024/03/08/fact-sheet-president-bidens-unity-agenda-for-the-nation/

potential. This budget directs $153.9 million in FY 2025 to the NIH Office of Research on Women's Health (ORWH). ORWH plans to use the increase to support a range of new and ongoing activities to enhance research into women's health issues, including increasing the number of hubs in the Maternal and Pediatric Precision in Therapeutics Centers of Excellence (MPRINT) initiative to increase the knowledge, tools, and expertise in maternal therapeutics available to the broader research, regulatory science, and drug development communities; expanding trial capacity for the Maternal-Fetal Medicine Unit Network to advance specific treatment approaches to leading drivers of maternal morbidity and mortality, and establishing clinical trials to test technologies developed through the RADx-Tech Maternal Health Challenge based on levels of readiness of the technology in rural and remote locations. The funds will also support new research into important topics such as the intersection of menopause and diabetes, and ORWH will continue to support cross-NIH initiatives to promote sex and gender equity across all domains of research.

NIH is also playing a major role in the new White House Initiative on Women's Health Research, led by First Lady Jill Biden, who has long championed women's health, and the White House Gender Policy Council. In announcing this Initiative, President Biden stated: "I have always believed in the power of research to save lives and to ensure that Americans get the high-quality health care they need. To achieve scientific breakthroughs and strengthen our ability to prevent, detect, and treat diseases, we have to be bold. That's why today, we're establishing a new White House Initiative on Women's Health Research so that my Administration—from the National Institutes of Health to the Department of Defense—does everything we can to drive innovation in women's health and close research gaps."   The goal is to fundamentally change how our government approaches and funds women's health research, to improve how it is

conducted and to maximize the impact of our investments.

Long COVID

For many, symptoms of COVID-19 persist long after the initial, acute phase of COVID-19 infection has ended. To address this growing public health concern, NIH's National Heart, Lung, and Blood Institute (NHLBI), the National Institute of Allergy and Infectious Diseases (NIAID), and the National Institute of Neurological Disorders and Stroke (NINDS), along with several other NIH Institutes and the Office of the Director (OD), are leading NIH's Researching COVID to Enhance Recovery (RECOVER) initiative,[3] a national research program to understand post-acute sequelae of SARS-CoV-2 (PASC), commonly known as Long COVID. In 2023, the NIH RECOVER initiative launched and opened enrollment for phase II clinical trials to evaluate at least four potential treatments for Long COVID, with additional clinical trials planned. These trials were informed by findings from earlier RECOVER research and focus on several of the symptoms described as most burdensome by people experiencing Long COVID. With its complementary research efforts, RECOVER has positioned NIH to design and conduct trials that have the potential to provide Long COVID patients who experience varying symptoms with relief sooner than any individual study can alone. The Administration has dedicated an additional $662 million of COVID supplemental appropriations to RECOVER over the past year, on top of the original $1.15 billion, to support a second wave of clinical trial activity, long-term patient follow-up, and further pathobiology and mechanistic studies, as well as electronic health record research and overall research infrastructure.

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[3] https://recovercovid.org/research

Data Sharing Across the Research Ecosystem

The lifeblood of a research-driven Agency is its data, and for NIH, this includes data spanning fundamental research (basic science) generated in laboratories, large health care systems, and individual communities. The FY 2025 Budget includes $30 million for the National Library of Medicine to serve as a focal point to support data sharing and use for biomedical, behavioral, and social sciences research across the Nation. NIH is committed to harnessing the power of artificial intelligence and machine learning to maximize benefits from this wealth of data to advance research across diverse fields, diseases, and scientific communities. Looking ahead, advanced scientific methods, new data analytics, and technologies are unlocking possibilities to leverage data in ways that achieve faster and more definitive results. These approaches are only as good as the data used to train them. For research extending to the clinic, this requires data that are comprehensive and include all communities that we serve. For example, NIH's AIM-AHEAD program seeks to promote broad researcher participation and increase the variety of data in the AI/machine learning field. NIH has launched innovative and ambitious initiatives to propel the fusion of biomedicine and artificial intelligence and machine learning, such as the Bridge2AI program, which aims to generate new flagship data sets and best practices for machine learning analysis.

The NIH Office of Data Science Strategy will work with NLM to increase capacity for data hosting, development of programs, and infrastructure to deliver minimal cost access to open-industry data standards, support for broad access to advanced analytics and computational power, and support for education and workforce development, including promoting participation by population groups not currently represented.

These efforts are informed by the NIH Strategic Plan for Data Science[4] and the NIH Policy for Data Management and Sharing[5] which aim to promote responsible sharing and management of data collected from NIH-supported research. Implemented in January 2023, the data management and sharing policy reflects NIH's longstanding commitment to making the results of the research it supports with public funds available to the public by expecting that NIH-supported researchers maximize appropriate data sharing.

Strengthening Biodefense

The FY 2025 budget will support biodefense activities across HHS with mandatory funding of $20.0 billion, including $2.7 billion for NIH research and development of vaccines, diagnostics, and therapeutics against high-priority viral families, biosafety and biosecurity, and expanding laboratory capacity and clinical trial infrastructure. NIH will conduct and support preclinical and clinical research on vaccines and vaccine platforms, monoclonal antibodies, and novel adjuvants to provide protection against prototype or representative pathogens. It will support the development and clinical trials of additional therapeutic candidates, including host-tissue-directed therapies, and develop next-generation diagnostics to fill critical gaps, such as the need for affordable and accessible at-home tests that are as reliable as lab-based PCR tests.

Buildings and Facilities

Safe, reliable infrastructure and facilities are essential to pursue the cutting-edge research within the NIH intramural research program. The FY 2025 request of $350 million enables NIH to continue to address the Backlog of Maintenance and Repairs (BMAR) which was estimated at $4.1 billion as of the end of FY 2024. This request enables NIH to continue to

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[4] https://datascience.nih.gov/sites/default/files/NIH_Strategic_Plan_for_Data_Science_Final_508.pdf
[5] https://sharing.nih.gov/data-management-and-sharing-policy

implement recommendations from the National Academies of Sciences, Engineering, and Medicine 2019 report. In addition to the B&F appropriation, NIH has received support for critical infrastructure projects in recent years from targeted allocations from the Nonrecurring Expenses Fund (NEF).

Conclusion

Turning discovery into health remains the central goal and mission of NIH. Improving health across the lifespan is essential to maintaining our country's greatest asset: its people. My life experiences have given me a powerful sense of the transformative potential of research, and of the critical importance of equity and access for all people to research and its benefits. One of my guiding principles is that our work is not finished when we deliver scientific discoveries; our work is finished only when all people are living long and healthy lives. We should celebrate our successes but remain humble in the face of human suffering and approach our work with great urgency. With your support, NIH looks forward to tackling timely public health challenges through rigorous and innovative science in FY 2025. I look forward to answering your questions.