

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Hearing on the President's FY 2024 Funding Request and Budget Justification

for the National Institutes of Health

Witness appearing before the

Senate Appropriations Subcommittee on Labor, HHS, Education, and Related

Agencies

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Good morning, Chair Baldwin, Ranking Member Capito, and distinguished Members of the Subcommittee. I am Lawrence A. Tabak, D.D.S., Ph.D., privileged to be Performing the Duties of the Director of the National Institutes of Health (NIH). Thank you for the invitation to appear before you today so that I may provide you with information about our efforts in pandemic preparedness and our Fiscal Year (FY) 2024 budget request.

I truly appreciate the Committee's ongoing bipartisan support for NIH. As a result of this support, scientific advances have been made that reach people of all ages across the United States. From improving treatment options for substance use disorders to developing vaccines to prevent infectious diseases to discovering novel cancer treatments, the investment Congress continues to make in NIH improves the health of your communities.

The FY 2024 President's Budget builds on the Committee's investment in numerous public health challenges including maternal health, mental health, and health disparities research. In addition, it builds on the Reignited Cancer MoonshotSM, continues efforts to develop a universal influenza vaccine, increases focus on substance use disorders, and prioritizes innovative nutrition research to reduce diet-related diseases.

Steady Progress on Pandemic Response

The COVID-19 global pandemic demonstrated how fundamental research, and early-stage discovery, design, and development of vaccines and therapeutics can yield impactful results in a short amount of time. As we continue to address the effect of the pandemic on the public's health, a sustained investment in biomedical research is necessary to ensure our momentum on current vaccine and treatment options against future emerging infectious agents.

NIH was able to respond efficiently to the COVID-19 pandemic by capitalizing on decades of basic and applied research to facilitate the rapid development of vaccines, therapeutics, and diagnostics. These continue to be important tools to reduce the threat of disease. Over the past three years, NIH established networks and initiatives that are cornerstones in the study of and response to pandemic threats. This includes the Antiviral Program for Pandemics, the Rapid Acceleration of Diagnostics (RADx[®]) initiative, and the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership.

We are also grappling with a new public health challenge as we begin to understand the long-term effects of the COVID-19 pandemic, including Post-Acute Sequelae of SARS-CoV-2 Infection (PASC, also commonly known as “Long COVID”) and the mental health effects of the pandemic. Furthermore, NIH continues to apply lessons learned during the COVID-19 pandemic to address other public health issues, including the recent mpox Public Health Emergency, and to help prepare for future pandemics.

Capitalizing on Vaccine Research for Universal Influenza

Influenza viruses are deadly and costly pathogens that place a substantial health and economic burden on the United States and across the world each year. In the United States, the CDC estimates that the disease burden of influenza has resulted in between 9.2 million and 35.6 million illnesses, between 140,000 and 710,000 hospitalizations, and between 12,000 and 56,000 deaths annually since 2010, all of which results in an estimated \$27 billion in health costs. Pandemic influenza—which occurs when a new, non-human flu virus emerges from an animal source with the capacity to spread readily from person to person—can pose an even greater threat. Current influenza vaccination strategies rely on the development of an annual vaccine targeting the circulating strains that are anticipated to spread in the United States. However, this approach does not always yield high levels of protection against seasonal strains and offers little to no protection against pandemic influenza viruses.

NIH seeks to develop a universal influenza vaccine that would generate robust, long-lasting protection against multiple subtypes of influenza, eliminating the need to update the vaccine each year and protect against newly emerging strains with pandemic potential. In 2022, a Phase 1 clinical trial began enrolling healthy volunteers at the NIH Clinical Center to assess the safety and efficacy of a novel universal flu vaccine candidate.¹ Building upon the success of mRNA vaccines developed during the COVID-19 pandemic, NIH is working to apply this platform to the universal influenza vaccine development. Additionally, NIH-supported researchers are actively identifying and developing novel adjuvants for influenza vaccines to increase their immunogenicity and effectiveness. Continued investment in this research will enable the development of more broadly protective and longer-lasting influenza vaccines. The FY 2024 budget request includes \$270.0 million for universal influenza vaccine research, the same as the FY 2023 Enacted level.

A Reinvigorated Cancer Moonshot

In FY 2024, the President's Reignited Cancer Moonshot Initiative² will support priority investments to advance the goals of the Reignited Cancer Moonshot which includes cutting America's cancer death rate by 50 percent over the next 25 years. Since its establishment in 2016, the Beau Biden Cancer Moonshot has supported over 250 research projects that pushed the boundaries of discovery and collaboration on behalf of cancer patients. The President's Budget includes an increase of \$500.0 million for the Cancer Moonshot from the FY 2023 Enacted level, for a total of \$716.0 million, with further increases proposed in FY 2025 and FY 2026 using mandatory funding.

Clinical trials play a prominent role in evaluating new cancer prevention, screening, and treatment approaches. NIH National Cancer Institute (NCI) funding will focus on doubling the

¹ www.nih.gov/news-events/news-releases/trial-potential-universal-flu-vaccine-opens-nih-clinical-center

² www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative

number and increasing the diversity of people who enter NCI-sponsored clinical trials to develop new prevention, diagnostic, and therapeutic approaches at a more rapid pace. Funding will also support continued work towards increasing the pipeline of new cancer drugs. Additionally, the resources will fund a major trial to evaluate multi-center detection tests, the Cancer Moonshot Scholars program, and the NCI Telehealth Research Centers of Excellence, allowing the agency to sustain progress towards meeting the President's goal to end cancer as we know it. The FY 2024 proposal fully aligns with the following seven pillars of the Reignited Cancer Moonshot, which include diagnosing cancer sooner; preventing cancer; addressing inequities; targeting the right treatments to the right patients; accelerating progress against the most deadly and rare cancers, including childhood cancers; supporting patients, caregivers, and survivors; and learning from all patients.

Enhancing Nutrition Research and Food Security

The Office of Nutrition Research (ONR), within the NIH Office of the Director, focuses on advancing nutrition science to promote health, and to reduce the burden of diet-related diseases and nutrition health disparities. The budget includes an increase of \$120 million to support nutrition research, including investments that will advance the goals of the White House National Strategy on Hunger, Nutrition, and Health. Resources will expand the efforts of the NIH Common Fund Community Partnerships to Advance Science for Society, and help to ensure diversity and inclusion in nutrition, health, and food security research. Funding will also allow NIH to focus on expanding and diversifying the nutrition science workforce and investing in creative new approaches to advance research regarding the prevention and treatment of diet-related diseases, including the Food is Medicine initiative and an Artificial Intelligence for Precision Nutrition program.

ONR is also collaborating with the NIH Institutes and Centers on a transformative research

program examining the role of diet, food environment and related environmental exposures on the Developmental Origins of Health and Diseases. There is increasing concern that food environment, life stress, traumas, medications, health and nutritional status, microbiome ecology, and related environmental exposures are responsible for future diet-related disease risk. This discovery science program will also include a comprehensive study of human milk composition, dietary intake, and nutritional status measures and outcomes, answer mechanistic questions about the developmental origins of disease, and ultimately, lead to an optimized diet for the health of the mother and child.

Revolutionizing Mental Health with Precision Medicine

With the FY 2024 President's Budget Request, NIH intends to direct increased attention towards mental health across all ages. Mental illnesses are the fifth leading cause of disability in the United States, accounting for 6.6 percent of all disability-adjusted life years in 2019. Exacerbated by the pandemic, suicide rates for youth have risen over the past 2 decades in the United States; in 2020, an estimated 6,643 youth ages 10 to 24 died by suicide.³ Despite advances in the treatment of depression and other serious mental illnesses, there remain few evidence-based interventions that rapidly reduce suicide risk within health care settings. Finding the right treatment for a specific individual required a trial-and-error process that can lead to unacceptable delays in receiving effective treatment. The President's Budget includes efforts to apply the concepts of precision medicine to the field of psychiatry through the Precision Psychiatry Initiative. This initiative includes two component parts: 1) an innovation funnel to rapidly identify and assess biomarkers for the treatment for depression with the intent to lead to large-scale clinical trials; and 2) a data-driven refinement of precision diagnostics to study patterns of clinical trajectories and treatment response across large cohorts over time.

³ wisqars.cdc.gov/data/explore-data/explore

Serious Mental Illness (SMI) is a major, albeit less known, risk factor for COVID-19,⁴ and people with SMI are more prone to SARS-CoV-2 infection and are more likely to require hospitalization and die from severe COVID-19. NIH supports research on many facets of mental health including rapid interventions to reduce severe suicide risk, funding adaptive interventions to optimize adolescent mental health treatments, and aggregating data to address mental health disparities research gaps. In response to the pandemic, NIH launched a project to support research focused on the social, behavioral, and economic impacts of COVID-19. The project supports research on the secondary effects of the pandemic, such as financial hardship, reduced access to health care, and school closures.⁵ This initiative includes NIMH-supported research on: the impact of COVID-19 mitigation efforts on socioeconomic disparities in mental health and health care utilization; the effectiveness of digital health apps like Headspace as a just-in-time approach to immediate, personalized behavioral health care; the effectiveness of a digital platform on depression/anxiety symptoms of healthcare workers during the COVID-19 pandemic; and effectiveness, barriers, and facilitators to the implementation of a gold standard exposure treatment for post-traumatic stress disorder in healthcare system employee assistance programs serving frontline healthcare workers.

Making Progress on Health Disparities and Inequities in Research

Building on investments made by this committee over the past several years, NIH hopes to continue the agency-wide effort to reduce health disparities across racial and ethnic minority, rural, low-income, and other underrepresented and marginalized populations. The President's Budget requests \$95 million to sustain health disparities research across the Institutes and Centers that are developing and testing interventions appropriately tailored to the breadth of clinical and community services found in diverse settings and contexts.

⁴ nimh.nih.gov/health/statistics/mental-illness

⁵ covid19.nih.gov/news-and-stories/covid19-ripple-effects

UNITE, launched in February 2021, is an NIH-wide, collaborative effort comprised of five workstreams with distinct but coordinated objectives to tackle the problem of racial and ethnic equity in science while developing data-driven methods to promote diversity, equity, and inclusion across the biomedical and behavioral enterprise. To thoroughly address structural racism that may exist within the enterprise, UNITE works across three domains—Health Disparities and Minority Health Research, the internal NIH workforce, and the external biomedical and behavioral research workforce. Data gathering and analysis are central to all activities, and therefore evidence drives the work of UNITE. UNITE goals and charges are aligned with fundamental tenets of the NIH-Wide Strategic Plan for 2021–2025,⁶ the NIH Minority Health and Health Disparities Strategic Plan 2021–2025,⁷ and the NIH-Wide DEIA Strategic Plan for 2022–2026, released in March 2023.⁸

Combating Overdose and Addiction

Opioid misuse, addiction, and overdose are among several widespread public health crises that were exacerbated by the pandemic. Since the pandemic, studies have found increases in the use of illicit drugs including fentanyl, cocaine, heroin, methamphetamine, cannabis⁹, and most recently xylazine. Founded in 2018, the Helping to End Addiction Long-term (HEAL) initiative strives to address opioid addiction by developing new treatments and strategies to address both pain and opioid use disorder as well as advance healthy equity by acknowledging the environmental factors that contribute to drug use and chronic pain. In FY 2024, HEAL will focus on the health effects of taking multiple drugs together, find tailored treatment approaches, such as combination therapies, for different environments, and continue research on health disparities

⁶ www.nih.gov/sites/default/files/about-nih/strategic-plan-fy2021-2025-508.pdf

⁷ www.nimhd.nih.gov/docs/nimhd-strategic-plan-2021-2025.pdf

⁸ diversity.nih.gov/about-us/strategic-plan

⁹ <https://nida.nih.gov/research-topics/comorbidity/covid-19-substance-use>

in treatment for opioid use disorder, neonatal opioid exposure and maternal health, and integrated pain and mental health treatments.

Opioid use is not the only alarming trend in addiction and overdose. The misuse of stimulants, such as methamphetamine, is also increasing, as are deaths attributed to combining opioids and stimulants. Improved prevention and treatment strategies are needed for both opioid use disorder and co-occurring conditions such as mental health conditions and polysubstance use for a range of at-risk populations and in various settings. Recently launched HEAL programs aim to develop safe and effective treatments, as well as define approaches to improve treatment access and retention in various settings.

Preventing Maternal Morbidity and Mortality

Even during a global pandemic, NIH continued to focus on other long-standing yet urgent public health needs. The CDC estimates 1,200 women die each year in the United States of maternal causes, 80 percent of which are preventable, and thousands more experience severe pregnancy-related morbidity.^{10,11}

To address this alarming trend, NIH established an agency-wide collaboration called the Implementing a Maternal health and Pregnancy Outcomes Vision for Everyone (IMPROVE) Initiative¹² which is an evidence-based approach to reduce preventable maternal and pregnancy-related deaths and associated health disparities for women at all stages of pregnancy. To build on the momentum made by the committee's previous investments, the FY 2024 President's Budget requests \$30 million to continue the IMPROVE Initiative. In addition, the request also includes \$3 million for the *Eunice Kennedy Shriver* National Institute of Child Health and Human

¹⁰ www.cdc.gov/nchs/data/hestat/maternal-mortality/2021/maternal-mortality-rates-2021.htm

¹¹ www.cdc.gov/reproductivehealth/maternal-mortality/erase-mm/data-mmrc.html

¹² www.nih.gov/research-training/medical-research-initiatives/improve-initiative

Development to support research on mitigating the effects of COVID-19 on pregnancies, lactation, and post-partum health with a focus on individuals from racial and ethnic minority groups.

In summer 2023, IMPROVE will implement a national network of Maternal Health Research Centers of Excellence to support research projects that build on previous research and take innovative, community tailored approaches to address health disparities and risk factors for maternal morbidity and mortality. This research supports the development of earlier interventions to decrease or prevent negative maternal outcomes and promote maternal health equity.

NIH Buildings and Facilities

Facilities must co-evolve with science for NIH to achieve its full potential. A major component of the NIH Building and Facilities (B&F) program is the Repair & Improvement (R&I) program, which enables NIH to maintain and improve the performance of existing facilities throughout their life cycle. A key aspect of NIH's strategy is to sustain the condition of existing facilities to prevent premature deterioration and the curtailment of research. These investments help reduce the likelihood and consequences of building emergencies associated with NIH's Backlog of Maintenance and Repairs (BMAR) of nearly \$3.8 billion across all campuses as of the end of FY 2022. NIH requests a funding level for B&F of \$350.0 million, maintaining the FY 2023 Enacted level. This level is designed to address the pressing campus-wide infrastructure needs identified in the independent review of the facility needs of NIH's main campus in 2019 by the National Academies of Sciences, Engineering, and Medicine (NASEM). 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). In FY 2024, NIH is requesting a total of \$120.1 million in NEF funding for five critical infrastructure projects on the Bethesda campus.

NIH plans to execute various modernization and repair projects to NIH's research hospital, replace research animal facilities with a centralized and more efficient facility, improve facilities that advance computational and data science, replace temporary and obsolete administrative support facilities with permanent buildings, improve the energy and water efficiency of buildings, and support the co-evolution of science and buildings.

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. The NIH research community is fervently working on all fronts – from individualized medicine to societal level pandemic response – to foster new discoveries and catalyze breakthroughs in research. With the support of this Committee, NIH looks forward to tackling timely public health challenges through rigorous and innovative science in FY 2024. I look forward to answering your questions.