

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Hearing on the FY 2023 Budget Request 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 Murray, Ranking Member Blunt, and distinguished Members of the Subcommittee. I am Lawrence A. Tabak, D.D.S., Ph.D, the Acting Director of the National Institutes of Health (NIH). It is an honor to appear before you today.

I am grateful for the committee's long-standing support for NIH. Whether it is cancer immunotherapy or sickle cell therapies or COVID-19 vaccines, NIH's successes would not have been possible without the investment made by this committee.

The FY 2023 President's Budget will support science that helps tackle many critical national challenges: from initiatives to address health disparities, fight the rising tide of addiction, and transform nutrition science. The budget will also build upon the initial investment in the new Advanced Research Projects Agency for Health (ARPA-H).

Advanced Research Projects Agency for Health

The President's Request proposes \$5 billion to fully operationalize ARPA-H¹ in FY 2023. This new agency will be a key component to drive transformational innovation in health research and we are grateful for your support. At the direction of the Secretary, we are working to create an ARPA-H that is free to innovate and take risks, an ARPA-H that leverages NIH infrastructure, and an ARPA-H that has unfettered and frequent access to all of the brightest minds across all research fields – from biomedicine to sociology to mathematics. In alignment with the DARPA model, ARPA-H will recruit term limited, visionary program managers who will use its catalytic platform to take on critical challenges in conjunction with traditional and nontraditional partners across academia, government, and industry. ARPA-H will use directive approaches that will provide quick funding decisions to support projects that are results- and use-driven and time-limited, and identify emergent opportunities through advanced systematic horizon scans of academic and industry efforts.

¹ <https://www.nih.gov/arpa-h>

ARPA-H projects would be bounded in time, typically a few years with longer periods allowed for efforts that are highly complex, and with the understanding that a significant fraction of projects will not reach their goals, a necessary outcome when conducting ambitious, innovative research. To determine which bold questions should be undertaken and to evaluate proposed programs and projects, ARPA-H would adopt approaches similar to those utilized by DARPA, such as the “Heilmeier Catechism,”² a set of principles that assesses the challenge, approach, relevance, risk, duration, and metrics of success. It will be critical for ARPA-H to engage with the broader biomedical community, including patients and their caregivers, researchers, industry, community groups, and others, to understand the full range of problems and the practical considerations that need to be addressed for all groups and populations.

Cancer Moonshot

The President’s Cancer Moonshot^{SM3} aims to accelerate progress in cancer research and make additional therapies available to more patients. Established in 2016, the Beau Biden Cancer Moonshot was a bold action on behalf of cancer patients. The President’s Budget includes \$216 million to the National Cancer Institute for Cancer Moonshot.

Prominent, ongoing Moonshot priorities include immunotherapy, childhood cancer, cancer prevention and early detection, and cancer implementation science. For example, several Moonshot initiatives focus on rare pediatric cancers, including research on the fusion of genes that yield novel “fusion oncoproteins” that drive some childhood cancers. Additionally, federal agencies, led by NIH, will develop a focused program to expeditiously study and evaluate multicancer detection tests, as we did for COVID-19 diagnostics, which could help detect cancers early, when there may be other, more effective, treatment options for patients. Finally,

² <https://www.darpa.mil/work-with-us/heilmeier-catechism>

³ <https://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative>

implementation science strives to maximize the use of proven cancer prevention and early detection strategies and to incorporate them into standards of care, which is an urgent need among underserved, rural, and minority populations.

Health Disparities

A key area where NIH hopes to build upon investments made by this committee in FY 2022 is in the agency-wide effort to reduce health disparities. In the wake of a pandemic that disproportionately affected communities of color, this year's President's Budget will enlist most of our Institutes and Centers (ICs) in developing and testing interventions to reduce health disparities that have been appropriately tailored to the breadth of clinical and community services found in diverse settings and contexts.

Importantly, the health disparities research agenda will be aided and informed by the NIH UNITE Initiative,⁴ composed of actively engaged representatives from across all 27 NIH ICs and the Office of the Director. This initiative was launched with the goal of identifying and addressing structural racism within the NIH-supported and the greater biomedical research community through development and implementation of new policies, procedures, and practices. To gain a better understanding of stakeholders' concerns, NIH issued a public Request for Information in March 2021, which captured over 1,100 responses from researchers, external partners, and members of the public. Responses will inform efforts to improve the culture and advance structural change in biomedical research.

NIH has recently launched several more initiatives to improve the health of racial and ethnic minorities and other populations who experience health disparities. One of the funding opportunities will commit \$60 million over the next five years to support transformative research

⁴ <https://www.nih.gov/ending-structural-racism/unite>

to address health disparities and advance health equity.⁵ NIH will also commit \$30 million from 25 Institutes, Centers, and offices to support observational research that will define the role of structural racism and discrimination (SDR) in causing and sustaining health disparities, and intervention research that will address SDR to improve minority health or reduce health disparities.⁶ Finally, NIH will provide approximately \$24 million for the Transformative Research to Address Health Disparities and Advance Health Equity at Minority Serving Institutions initiative, which is designed to support research projects with the strongest potential to have a profound effect on health disparities research.⁷

Mental Health

With the FY 2023 President’s Budget Request, NIH intends to direct increased attention towards mental health. 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. In addition, suicide rates for youth have risen over the past 2 decades in the United States; in 2019, an estimated 6,488 youth ages 10 to 24 died by suicide. 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. NIH is supporting research projects that focus on testing the safety, efficacy, and feasibility of several of the newest antidepressant interventions – intravenous ketamine and intranasal esketamine (medications known to rapidly reduce depressive symptoms in hours or days) as well as transcranial magnetic stimulation (TMS; a noninvasive treatment that uses magnets to activate specific parts of the brain) – to

⁵ <https://grants.nih.gov/grants/guide/rfa-files/RFA-RM-21-021.html>; <https://grants.nih.gov/grants/guide/rfa-files/RFA-RM-21-022.html>

⁶ <https://grants.nih.gov/grants/guide/rfa-files/RFA-MD-21-004.html>

⁷ <https://grants.nih.gov/grants/guide/rfa-files/RFA-RM-21-022.html>

rapidly reduce suicidal thoughts and behaviors in adults and adolescents.^{8,9}

In response to the pandemic, which exacerbated mental illness throughout the country, NIH launched a project to support research focused on the social, behavioral, and economic impacts of COVID-19, which supports research on the secondary effects of the pandemic, such as financial hardship, reduced access to health care, and school closures.¹⁰ The FY 2023 President's Budget requests \$2.2 billion for the National Institute of Mental Health (NIMH), that includes targeted increases of \$25 million to expand research on the impact of the COVID-19 pandemic on mental health, \$5 million to undertake studies of the impact of social media on mental health, and \$5 million to inform mental health treatment approaches, service delivery, and system transformation in support of the Administration's mental health initiatives.

Maternal Morbidity and Mortality

Even during a global pandemic, NIH has continued to focus on other long-standing yet urgent public health needs. The Centers for Disease Control and Prevention estimates 700 women die each year in the United States of pregnancy-related deaths, 60 percent of which are preventable, and over 50,000 experience severe pregnancy-related morbidity each year.

To address this alarming trend, NIH established the Maternal Morbidity and Mortality Task Force,¹¹ an NIH-wide collaboration. The Task Force coordinates the Implementing a Maternal health and Pregnancy Outcomes Vision for Everyone (IMPROVE) Initiative¹², which invests in studies to promote an integrated understanding of biological, behavioral, sociocultural, and structural factors that contribute to maternal morbidity and mortality and engages

⁸ <https://www.fda.gov/news-events/press-announcements/fda-approves-new-nasal-spray-medication-treatment-resistant-depression-available-only-certified>

⁹ <https://www.nimh.nih.gov/news/research-highlights/2021/nimh-addresses-critical-need-for-rapid-acting-interventions-for-severe-suicide-risk>

¹⁰ <https://covid19.nih.gov/news-and-stories/covid19-ripple-effects>

¹¹ <https://www.nih.gov/research-training/medical-research-initiatives/improve-initiative/trans-nih>

¹² <https://www.nih.gov/research-training/medical-research-initiatives/improve-initiative>

communities in the development of solutions to address the needs of pregnant and postpartum individuals. IMPROVE plans to launch a national network of Maternal Health Research Centers of Excellence that will incorporate local community needs and perspectives to expand and complement existing research efforts by developing, implement and evaluating community tailored interventions to address health disparities in severe maternal morbidity (SMM) and maternal mortality (MM). Through this strategy, IMPROVE will build an evidence-based approach to reducing SMM/MM and its associated health disparities. To support this key initiative, the FY 2023 President’s Budget requests \$30 million for IMPROVE. In addition, the request also includes \$3 million for the *Eunice Kennedy Shriver* National Institute of Child Health and Human 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.

Opioids and Pain Research

Since early in the pandemic, studies have found increases in the use of many kinds of illicit drugs, including fentanyl, cocaine, heroin, methamphetamine, and cannabis. The NIH Helping to End Addiction Longterm (HEAL) Initiative,¹³ launched in 2018, is a cross-agency program spanning basic, translational, and clinical research on opioid and stimulant misuse and addiction, and pain. HEAL Initiative funds are being used to accelerate the development and availability of longer-acting formulations of existing opioid use disorder (OUD) therapies (e.g., buprenorphine and methadone) and novel immunotherapies (e.g., vaccines) that could block the effect of opioids in the brain to help people with OUD and decrease the incidence of overdose. The HEAL Initiative is building the Integrative Management of chronic Pain and OUD for

¹³ <https://heal.nih.gov/>

Whole Recovery (IMPOWR) network¹⁴ to develop effective treatment interventions for people who experience both chronic pain and OUD. The IMPOWR network consists of clinical research centers that collaborate to develop effective interventions, best models of care for delivery of services, and sustainable implementation strategies for a variety of patients with co-occurring chronic pain and OUD or opioid misuse, with an emphasis on highly vulnerable groups.

In 2020, this committee directed NIH to expand HEAL to address methamphetamine use and we are making progress toward this goal. For example, NIH-funded research on immunotherapies for stimulant use disorders led to the development of a monoclonal antibody called IXT-m200 that targets methamphetamine.¹⁵ This treatment has received Fast Track designation from the Food and Drug Administration and is now being studied in emergency department settings in people with methamphetamine overdose.¹⁶ It is the first novel, investigational treatment for methamphetamine addiction ever to advance in the medication development process to a Phase 2 clinical trial. In order to continue to respond to these evolving challenges, the FY 2023 President's Budget includes total funding of \$2.6 billion in this research area across NIH's ICs.

Importantly, NIH seeks to involve many more of our ICs in this initiative, particularly with respect to research addressing pain. The FY 2023 President's Budget Request will expand research into effective therapies that don't involve the brain or the central nervous system by involving researchers from many Institutes and Centers like the National Institute on Dental and Craniofacial Research (NIDCR),¹⁷ which I led for a decade prior to becoming the Principal

¹⁴ <https://heal.nih.gov/research/clinical-research/integrative-management-chronic-pain>

¹⁵ <https://nida.nih.gov/news-events/nida-notes/2020/02/part-2-immunotherapies-new-tool-to-treat-methamphetamine-addiction>

¹⁶ <http://intervexion.com/2016/01/intervexion-therapeutics-announces-fast-track-designation-of-ixt-m200-for-treatment-of-methamphetamine-addiction/>

¹⁷ <https://www.nidcr.nih.gov/>

Deputy Director of NIH. As a dentist, I know that there is no group of clinicians who have more to contribute or more to gain from identifying better pain management approaches. For example, researchers have identified clinical signs and symptoms that can help predict whether temporomandibular disorder pain will linger and turn into chronic pain. Research at the National Center on Complementary and Integrative Health¹⁸ proposes to investigate the role of the brain in pain processing and control, and how factors such as emotion, attention, environment, and genetics affect pain perception.

Nutrition Research

The complexity of human nutrition, combined with the impact of diet on chronic diseases that were a contributing factor to the excess deaths of the pandemic, demands that cutting-edge data science and system science methods be employed to move nutrition science into the 21st century. To reflect the high priority NIH places on innovative, multidisciplinary nutrition research, in 2021 the NIH Director moved the Office of Nutrition Research (ONR)¹⁹ to the Office of the Director. Dedicated funding is critical to ensure that the ONR can operate effectively as a cross-cutting NIH entity and to accomplish the goals of the plan. The FY 2023 President's Budget requests \$97.2 million for the NIH Office of the Director to support ONR.²⁰

Within this amount, one new collaborative project proposed is Reducing Nutrition Health Disparities through Food Insecurity and Neighborhood Food Environment Research. This research will use precision regional implementation science and pragmatic research approaches to test strategies to ensure food security and access to healthy food, which are intended to prevent disparities in a variety of diet-related diseases and conditions, such as cardiovascular disease, obesity, diabetes, and cancer. Elucidating the role of these social conditions on diet and

¹⁸ <https://www.nccih.nih.gov/>

¹⁹ <https://dpcpsi.nih.gov/onr>

²⁰ <https://officeofbudget.od.nih.gov/pdfs/FY23/ics/27%20-OD%20FY%202023%20CJ%20Chapter.pdf>

nutritional status could help address and prevent diet-related health disparities and promote health equity.

This kind of population and system science will be an important complement to the Nutrition for Precision Health program²¹ (awarded in January 2022 to recruit 10,000 diverse participants to study how a person’s nutritional status, metabolism, microbiome, genetics, and environment affect health) and the \$50 million Artificial Intelligence for Chronic Disease initiative (first funded in FY 2021, the initiative leverages machine learning and data science tools to untangle the complex underlying causes of chronic diseases and look for early treatments).

NIH Buildings and Facilities

NIH strives to ensure that its facilities are safe and enable scientists to discover new diagnostics, therapies, and cures. As part of this effort, the President’s Budget proposes \$300 million for NIH’s Buildings and Facilities appropriation. These funds are meant to begin addressing the backlog of life and safety repairs that totaled over \$1 billion in the 2019 report by the National Academies of Science, Engineering and Medicine on the condition of NIH’s facilities on the Bethesda Campus. A key aspect of NIH’s strategy is to sustain the condition of existing facilities to prevent premature deterioration and the curtailment of research, including the physical plant, building structures, utility systems, roads, and grounds at all NIH sites. These projects will help to ensure the continued efficient and effective performance of NIH’s real property assets to meet ongoing and projected research requirements and to offset the deterioration and obsolescence caused by age and use.

The President’s Budget request also proposes a modification to the language governing

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<https://commonfund.nih.gov/nutritionforprecisionhealth#:~:text=The%20goal%20of%20the%20NIH,prevention%20and%20treatment%20of%20disease.>

repairs, which is intended to move NIH's property stewardship beyond maintenance and repairs to more proactive efforts like the modernization at NIH's research hospital, replacement of obsolete, temporary, and fragmented research facilities, improvement of facilities that advance computational and data science, and improvement of the energy and water efficiency of buildings. To achieve this will take time, so NIH looks to leverage prioritization processes currently in place to focus on the projects that are of the most need to our organization.

Conclusion

A healthier nation is a more productive nation and a vibrant research community is a pillar of an economically sound nation. With your support, NIH looks forward in FY 2023 to continue the tradition of catalyzing major break throughs over decades, bettering the human condition through rigorous and innovative science. My colleagues and I look forward to answering your questions.