

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Hearing on National Institutes of Health's FY22 Budget and the State
of Medical Research

Witness appearing before the

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

Francis S. Collins, M.D., Ph.D.

Director, National Institutes of Health

Accompanied by

Diana W. Bianchi, M.D.

Director, *Eunice Kennedy Shriver* National Institute of Child Health and Human Development

Anthony S. Fauci, M.D.

Director, National Institute of Allergy and Infectious Diseases

Gary H. Gibbons, M.D.

Director, National Heart, Lung, and Blood Institute

Eliseo J. Pérez-Stable, M.D.

Director, National Institute on Minority Health and Health Disparities Institute

Norman E. Sharpless, M.D.

Director, National Cancer Institute

Bruce J. Tromberg, Ph.D.

Director, National Institute of Biomedical Imaging and Bioengineering

May 26, 2021

Good morning, Chairwoman Murray, Ranking Member Blunt, and distinguished Members of the Subcommittee. I am Francis S. Collins, M.D., Ph.D., and I have served as the Director of the National Institutes of Health (NIH) since 2009. It is an honor to appear before you today.

First, I want to thank this Subcommittee for your commitment to NIH, which allowed the biomedical research enterprise to respond quickly to the greatest public health crisis in our generation over the past year. We mounted vigorous research efforts to understand the viral biology and pathogenesis of the coronavirus disease 2019 (COVID-19), develop vaccines in record time, support and commercialize diagnostics at the point of care, and test therapeutics for both outpatient and inpatient settings. This work is far from finished.

The President's Discretionary Request proposes budget authority of \$51 billion for NIH in fiscal year (FY) 2022. The Biden Administration places great emphasis on research and development in general. At NIH in particular, the Request proposes to build on the successes of pandemic era research and to put the research enterprise to work on some of our Nation's most persistent and perplexing health challenges, including cancer, Alzheimer's disease, opioid use disorder, health disparities, maternal mortality, HIV/AIDS, gun violence, climate change, and other areas with major implications for our Nation's health.

First and foremost, the President's Request proposes \$6.5 billion to establish the Advanced Research Projects Agency for Health – ARPA-H to drive transformational innovation in health research and speed application and implementation of health breakthroughs. ARPA-H will tackle bold challenges requiring large scale, cross-sector coordination, employing a non-traditional and nimble approach to high risk research, modeled after DARPA in the Department of Defense. To achieve this, ARPA-H will invest

in emergent opportunities by conducting advanced systematic horizon scans of academic and industry efforts, leveraging novel public-private partnerships, recruiting visionary program managers, and using directive approaches that provide quick funding decisions to support projects that are results-driven and time-limited. Potential areas of transformative research driven by ARPA-H include: the use of the mRNA vaccines to teach the immune system to recognize any of the 50 common genetic mutations that drive cancer; development of a universal vaccine that protects against the 10 most common infectious diseases in a single shot; development of wearable sensors to measure blood pressure accurately 24/7; and leveraging of artificial intelligence technology to advance care for individual patients and improve detection of early predictors of disease.

ARPA-H represents the kind of transformative idea for biomedical research that only comes along once in a long while. Our confidence that NIH is ready has been greatly advanced by our experience in addressing the COVID-19 pandemic – developing vaccines in record time, establishing an unprecedented public-private partnership on therapeutics that has made it possible to test more than a dozen possible therapeutics in rigorous trials, and building a venture capital model for assessing SARS-CoV-2 diagnostic technologies that has yielded millions of daily tests in just months.

But while we begin to imagine a life after COVID-19, we must acknowledge that there are COVID-related impacts that we have yet to understand and address, including the full impact of the pandemic on children. Children were largely spared from COVID-19 but for some children, exposure to the COVID-19 virus led to Multisystem Inflammatory Syndrome in Children (MIS-C), a severe and sometimes fatal inflammation of organs and tissues. The *Eunice Kennedy Shriver* National Institute of Child Health and Human

Development (NICHD) is leading a multi-institute initiative known as the Collaboration to Assess Risk and Identify loNG-term outcomes for Children with COVID (CARING for Children with COVID), which will assess both short-term and long-term effects of MIS-C and other severe illness related to COVID-19 in children, including cardiovascular and neurodevelopmental complications.

For many Americans, this pandemic and its related socioeconomic effects have had an overwhelming impact on their mental health. Prior research on disasters and epidemics has shown that in the immediate wake of a traumatic experience, large numbers of affected people report distress, including new or worsening symptoms of depression, anxiety, and insomnia. To aid in mental health recovery from the COVID-19 pandemic, NIH will continue to focus on research in this area. This will be done, in part, by utilizing participants in existing cohort studies, who will be surveyed on the effect of the pandemic and various mitigation measures on their physical and mental health.

The COVID-19 pandemic has brought into sharp focus the dramatic health disparities that exist across the American population. In addition, the Nation has been shaken by the killing of George Floyd and other attacks on people of color, forcing a recognition that our country is still suffering the consequences of centuries of racism. NIH will continue to address these disparities, specifically through research managed by the National Institute on Minority Health and Health Disparities (NIMHD), the National Heart, Lung, and Blood Institute (NHLBI), the National Institute of Nursing Research (NINR) and the Fogarty International Center (Fogarty).

NIMHD looks to better understand the human biological and behavioral mechanisms and pathways that affect disparity populations, better understand the long-term effects of

disasters on health care systems caring for populations with health disparities and research focusing on the societal-level mechanisms and pathways that influence disease risk, resilience, morbidity and mortality. NINR and Fogarty both look to better understand and reduce rural health disparities in low-income counties in the southern United States, support nursing science focused on racial, ethnic, and socioeconomic health disparities, with the goal of closing the gap in health inequities and increase health disparity research in low and middle income countries.

In addition to the core health disparities research, the President's Request puts an additional specific focus on maternal morbidity and mortality (MMM), which disproportionately affect specific racial and ethnic minority populations. Black and American Indian/Alaska Native individuals are two to four times more likely to die from pregnancy-related or pregnancy-associated causes compared to white individuals. Furthermore, Black, Hispanic and Latina Americans, Asian, Pacific Islander, and American Indian/Alaska Native individuals all have higher incidence of severe maternal morbidity (SMM) compared to white individuals. The Implementing a Maternal Health and Pregnancy Outcomes Vision for Everyone (IMPROVE) initiative supports research on how to mitigate preventable MMM, decrease SMM, and promote health equity in maternal health in the United States.

As the climate continues to change, the risks to human health will grow, exacerbating existing health threats and creating new public health challenges. Major scientific assessments document a wide range of human health outcomes associated with climate change. While all Americans will be affected by climate change, underserved populations are disproportionately vulnerable. These populations of concern include children, the elderly, outdoor workers, and those living in disadvantaged communities. NIH is poised to lead new

research efforts to investigate the impact of climate on human health, with the goal to understand all aspects of health-related climate vulnerability. Therefore, the President's Request includes a \$100 million increase for research on the human health impacts of climate change.

The FY 2022 President's Discretionary Request makes a major additional investment to address the opioid crisis. The crisis of opioid misuse, addiction, and overdose in the United States is a rapidly evolving and urgent public health emergency that has been exacerbated by the coronavirus pandemic. Since the declaration of a public health emergency for COVID, illicit fentanyl use and heroin use have increased, and overdoses in May 2020 were 42 percent higher than in May 2019.

The use of opioids together with stimulants, such as methamphetamine, is increasing; and deaths attributed to using these combinations are likewise increasing. Taking note of these trends, FY 2021 appropriation language expanded allowable use of Helping to End Addiction Long-term (HEAL) funds to include research related to stimulant misuse and addiction. Identifying how opioids and stimulants interact in combination to produce increased toxicity will enhance our ability to develop medications to prevent and treat comorbid opioid and stimulant use disorders and overdoses associated with this combination of drugs.

Finally, I'd like to take a moment to thank this Subcommittee for its recognition over the last two years that America's continuing leadership in biomedical research requires infrastructure and facilities that are conducive to cutting-edge research. With your support, we will break ground in the near future on a new Surgical, Radiological, and Laboratory Medicine division of our Clinical Center, which will replace severely outdated and deteriorating operating suites and lab space with state-of-the-art facilities. NIH

continuously works to ensure that the buildings and infrastructure on its campuses are safe and reliable and that these real property assets evolve in support of science – but NIH’s backlog of maintenance and repair is now nearly \$2.5 billion. The President’s FY 2022 Discretionary Request includes \$250 million to make progress on reducing this backlog and requests flexibility for Institutes and Centers to fund construction, repair, and improvement projects.

COVID-19 compelled us to perform a stress test on biomedical research enterprise. The enterprise performed nobly. We found what worked, and also identified barriers we hadn’t fully appreciated before, and invented new ways around them. The President’s FY 2022 Discretionary Request is a roadmap for how to build on the successes of research, address our gaps, and apply our insights to the most important problems we face as a nation. With your support, the future is filled with opportunity. My colleagues and I look forward to answering your questions.