

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

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Witness appearing before the

House 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

Norman E. Sharpless, M.D.

Director, National Cancer Institute

Nora D. Volkow, M.D.

Director, National Institute on Drug Abuse

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Good morning, Chairwoman DeLauro, Ranking Member Cole, 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 to present the Administration's fiscal year (FY) 2021 budget request for the NIH and provide an overview of our critical role in enhancing our nation's health through scientific discovery. Before I discuss NIH's Budget request for the upcoming fiscal year and some exciting scientific opportunities on the horizon, I want to express my gratitude to each of you for your commitment to ensure that our nation remains the global leader in the life sciences and advances in human health. Thanks to your support, we are at a remarkable moment in biomedical science that I am privileged to shepherd.

As the nation's premier biomedical research agency, NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and to apply that knowledge to enhance human health, lengthen life, and reduce illness and disability. As some of you have witnessed first-hand on your visits to NIH, our leadership and employees believe passionately in our mission. This extends equally to the tens of thousands of individuals whose research and training we support, located in every state of this great country, and where more than 80 percent of our budget is distributed.

The FY 2021 President's Budget provides \$38.7 billion for NIH's biomedical research efforts. NIH has been advancing our understanding of health and disease for over a century. Scientific and technological breakthroughs generated by NIH-supported research are behind much of the gains our country has enjoyed in health and longevity.

The Budget will support NIH's ability to fund the highest priority scientific discoveries while also maintaining fiscal stewardship of Federal resources. The Budget prioritizes

biomedical research to confront our nation's greatest medical challenges and opportunities, including precision medicine, the opioid crisis, and HIV/AIDS.

As in previous years, the Budget proposes to streamline federal research by consolidating activities of the Agency for Healthcare Research and Quality (AHRQ) into a new National Institute for Research on Safety and Quality (NIRSQ) within the NIH. The Budget provides NIRSQ \$355 million to support its activities to improve the quality, safety, effectiveness, and efficiency of health care.

America's continuing leadership in biomedical research requires infrastructure and facilities that are safe and conducive to cutting-edge research. NIH buildings include inpatient hospital beds, intensive care facilities, operating rooms, biosafety containment facilities, biomedical research laboratories, animal holding facilities, and even a utility plant. NIH's backlog of maintenance and repair (BMAR) is now approximately \$2.1 billion. An independent review of the facility needs of NIH's main campus by the National Academies of Sciences, Engineering, and Medicine that was released last August substantiates the need for an increase in NIH facilities funding and additional flexibilities to reduce BMAR as requested in the FY 2021 Budget.

NIH is using FY 2020 funding to address some of this backlog and ensure our facilities are both safe for patients and conducive to cutting-edge research and research support. The FY 2021 Budget invests in NIH's facilities by providing \$300 million to support multiple biomedical research infrastructure priorities at NIH-owned sites and limit the deterioration of its facilities. The Budget also proposes a general provision to allow NIH to address facility needs through a new transfer authority.

This is an historic moment in biomedical science where truly exciting, world class science is taking place through NIH support. I would like to provide just a few examples of the depth and breadth of the amazing research the FY 2021 Budget supports.

The Budget prioritizes America's youngest patients by providing \$100 million over FY 2020 and FY 2021 to advance research and care for premature babies. Almost 1 of every 10 infants born in the United States are premature. There is a critical need for rigorous research to improve the treatment and health outcomes of critically ill pre-term babies. NIH will also support clinical trials to determine the best treatment strategies for opioid-exposed infants, the smallest victims of the current opioid crisis. In addition, we want pre-term infants to have the best possible start in life. NIH will explore the most scientifically innovative ways to support multi-site clinical trials in pregnancy and lactation, which will lay the foundation for optimal clinical care for these infants.

Millions of Americans across the Nation have been devastated by opioid misuse, addiction and overdose. To help bring scientific solutions to this crisis, and to provide safe and effective options for the more than 50 million Americans who suffer from chronic pain, NIH launched the Helping to End Addiction Long-term (HEAL) Initiative. HEAL will also help establish evidence-based guidelines for treating pain with non-opioid therapies to reduce the use of prescription opioid medications and possible subsequent addiction. Through HEAL, NIH is driving towards breakthroughs in opioids and pain research to develop long lasting preventive and therapeutic solutions. The FY 2021 Budget dedicates \$533 million to HEAL and supports a total investment of \$1.4 billion for opioids and pain research across NIH, ensuring that we continue to respond aggressively to the crisis of pain and addiction in our communities.

The reduction in opioid availability has led some people to seek alternative drugs like methamphetamines and other stimulants. The Budget provides an additional \$50 million to develop medication-assisted treatment and evidence-based psychosocial treatment to support the Department's strategy for reducing methamphetamine and other stimulant use. NIH will increase support for this critical area of research, and is currently soliciting research to develop medications and devices for the treatment of substance use disorders, and emphasizing the urgent need for medications or devices treating stimulant use disorders in particular.

The Budget provides \$50 million for the Childhood Cancer Data Initiative to help change the course of childhood cancer, the leading cause of death from disease among children and adolescents in the United States. This Initiative will continue to build connections to childhood cancer data repositories, healthcare systems, and registries; establish an interactive data commons with pediatric preclinical models and clinical data to enhance the development of novel precision therapies; and advance and support creation of new research grant opportunities that focus on rare and hard-to-treat pediatric, adolescent and young adult tumors.

First identified in 1981, AIDS is one of humanity's deadliest and most persistent epidemics. Although significant progress has been made in the fight against new infections and AIDS deaths, the HIV/AIDS pandemic continues around the world. NIH-supported basic research has allowed us to gain a deep understanding of the biology of HIV. The Budget provides \$16 million for NIH-funded Centers for AIDS Research to design and evaluate integrated delivery of prevention and treatment across multiple locations and settings, including the areas where most new HIV infections occur. The NIH-wide HIV research program will continue to sustain the accomplishments already made and secure future

advances to prevent the spread of HIV, improve health outcomes, and ultimately to find a cure for HIV.

Circulating and emerging influenza viruses present a public health threat and affect health in the United States and worldwide. Each year, seasonal influenza infection causes nearly 650,000 deaths worldwide and up to 56,000 deaths in the United States. The Budget prioritizes the development of improved vaccines by providing \$423 million for innovative research to diagnose, treat, and prevent influenza infection and protect against future pandemics. Within the total, the Budget dedicates \$200 million to develop a universal vaccine to protect adults and children by eliminating the need to update and administer the seasonal flu vaccine each year. Several universal vaccine strategies are currently being tested in NIH-supported clinical trials.

The Budget provides \$115 million to address the public health challenge posed by the rising numbers of tick-borne diseases (including Lyme disease) in the United States. The number of reported cases reached a record high of more than 59,000 cases in 2018. Current strategies to address these types of diseases are limited by challenges with diagnostics, treatment options, and the lack of vaccines. This funding will help NIH to accelerate its progress towards the development of effective tools that advance treatment through basic, translational, and clinical research to better understand the complex interplay between ticks, hosts impacted by ticks and their defenses against ticks.

In support of the Administration's Industries of the Future initiative, the Budget provides \$50 million to build a bridge between the biomedical and computer science communities to maximize the promise of Artificial Intelligence (AI), in order to gain a deeper understanding of the underlying causes of chronic diseases and identify successful early treatments. We are excited about the potential to employ AI, Machine Learning, and Deep

Learning to enhance the collection, integration, analyses, and interpretation of data related to the onset and progression of chronic diseases. This initiative will also support new career pathways for investigators who can work at the interface of medicine and computational science and will jumpstart new efforts by articulating bold, scalable challenges for the community.

In recent years, transformative advances have emerged in the use of gene therapy and gene editing. These approaches are some of the most promising treatment modalities for a growing number of disease conditions. Vectors are the delivery vehicles by which a gene can be ferried to a targeted location in the body. Adeno-Associated Viruses (AAVs) are currently the most prevalent type of vector used in both gene therapy and gene editing studies.

Unfortunately, AAV production is resource-intensive, and wait times to produce vector therapies that meet the manufacturing standards necessary for clinical trials are often one to two years. The Budget provides \$30 million to create a consortium to address this production bottleneck, to help ensure gene-based clinical trials can get underway without manufacturing delays.

We have never witnessed a time of greater promise for advances in medicine than right now. Thanks to your support, the future of medicine is very bright. This concludes my testimony. We look forward to answering your questions.