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August 15, 2024

The Honorable Cathy McMorris Rodgers
Chair
House Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chair McMorris Rodgers:

[The American Association of Immunologists \(AAI\)](#) greatly appreciates this opportunity to submit comments in response to your recently released framework on “Reforming the National Institutes of Health [NIH].” AAI shares your long-held belief in the importance of a strong NIH and frequently takes the opportunity to provide comments directly to the agency to ensure that it is running as efficiently and effectively as possible. While Congress may wish to consider an NIH reauthorization bill in the near future, it is crucial for any NIH reform process to be rigorous, data-driven, and include Congressional hearings with key stakeholders and significant input from the scientific community.

AAI is the nation’s largest organization of immunologists and scientists in related disciplines. Our mission is to improve global health and well-being by advancing immunology and elevating public understanding about the immune system. AAI members, many of whom are funded by the NIH, are responsible for some of the most significant biomedical discoveries of the past century. These include understanding the transmission of infectious diseases, like COVID-19, and developing effective methods (such as vaccines) to prevent and treat them; discovering new defenses against re-emerging and drug-resistant bacterial infections; expanding our understanding of the immunological basis of cancer and developing immunotherapies; regulating debilitating autoimmune diseases; and developing treatments to prevent the rejection of transplanted organs and bone marrow.

AAI believes that a comprehensive NIH reauthorization effort should include a careful review of the agency’s organizational structure. While AAI agrees that optimizing the use of taxpayer dollars is a priority, any reorganization must be rationally designed and scientifically justified. As a first step, AAI encourages Congress to commission a study by a nonpartisan, expert scientific body, and charge this entity with reviewing NIH’s current organizational structure and recommending whether, and how, NIH should be reorganized.

Although AAI is unable to provide detailed comments about every aspect of your proposed reorganization plan in the requested timeframe, we would like to outline some initial concerns, the first of which is about process. AAI is grateful that you strongly encouraged feedback from stakeholders and provided a two-month comment period but was disappointed to see that your proposed



reorganization had already been included in the House Labor, Health and Human Services, Education, and Related Agencies appropriations bill that was approved by the subcommittee less than two weeks after your framework was released. As previously articulated, AAI strongly believes that this kind of broad reform should be handled by the authorizing committees following a rigorous, data-driven process, not via an appropriations bill.

AAI also has concerns about specific elements of the proposed restructuring plan. Dividing the National Institute of Allergy and Infectious Diseases into two institutes (the National Institute on Infectious Diseases and the National Institute on the Immune System and Arthritis) would not only be antithetical to the stated goals of streamlining NIH Institutes and Centers (ICs) and creating new efficiencies, but it would also impede the advancement of scientific research, as immunology and infectious diseases are inextricably linked and there is a natural synergy created by grouping these disciplines together. Further, it is not clear why arthritis would be paired with the immune system in this realignment. While arthritis is one of hundreds of diseases that can be better understood and potentially treated because of immunological research, AAI does not see a scientific justification for singling it out in this way.

AAI is also concerned about changing the name of the National Institute on Aging (NIA) to the National Institute on Dementia. While AAI applauds Congress for prioritizing important research on Alzheimer's disease and related dementias in recent years, this research is just one important part of NIA's [strategic research directions](#). Aging is the most important risk factor of many of the most common chronic diseases, and the most [common conditions](#) of those over age 65 are hypertension, high cholesterol, obesity, and arthritis. NIA-funded fundamental and clinical immunological research on these conditions is crucial, as aging interventions have the potential to prevent, delay, or possibly even cure multiple age-related diseases simultaneously.

AAI is also concerned about the proposed creation of the National Institute on Innovation and Advanced Research, which would include, among other entities, the Advanced Research Projects Agency for Health (ARPA-H). ARPA-H, like the Defense Advanced Research Projects Agency (DARPA) and other "ARPA-agencies," was explicitly created by Congress to operate as an independent entity governed by its own rules and culture. This flexibility allows it to operate differently from NIH, funding high-risk, high-impact research, with the potential to result in accelerated solutions to major health challenges. Grouping ARPA-H with other NIH institutes and programs could pose a threat to the very independence that makes it unique.

AAI would also like to draw attention to the gain-of-function (GOF) research proposals in the framework. AAI fully agrees that research security is of the utmost importance, requiring careful monitoring of research using the most dangerous pathogens. As you know, gain-of-function research can be very broadly defined and encompasses a wide range of research that is crucial to



understanding infectious disease mechanisms and processes. A subset of GOF research, including research on pathogens with enhanced pandemic potential (PEPP), rightfully requires additional oversight. Therefore, it is important to carefully define “risky GOF research” to limit it to experiments that could pose significant threats to public health or national security. AAI has been encouraged by recent federal government actions to address research security concerns. For example, in 2022, the National Science Advisory Board for Biosecurity (NSABB), a federal advisory committee that provides guidance and recommendations to the U.S. government on biosecurity matters, was asked by NIH and the Department of Health and Human Services to review the major U.S. government frameworks for biosecurity. The NSABB produced a report with detailed, evidence-based recommendations in 2023. This report led to an [updated policy](#), issued by the White House Office of Science and Technology Policy in May 2024, that serves as a “unified federal oversight framework” for dual use research of concern and PEPP. This science-based policy is an important reflection of the seriousness with which scientific agencies are handling research security concerns and should serve as a guidepost for future policy decisions.

While Congress should seek to maximize efficiency, transparency, and accountability within NIH, it is also vital to continue to prioritize robust investment in biomedical research. Following sequestration, the NIH budget steadily increased for eight years, helping to address years of insufficient funding and bringing the inflation-adjusted NIH funding level back to its peak 2003 fiscal year (FY) funding level. Investment in NIH has led to myriad recent breakthroughs, including utilizing immunotherapies to combat cancer, multiple FDA-approved interventions against respiratory syncytial virus (RSV), and rapidly developed vaccines against COVID-19 that changed the course of the pandemic. But the benefits of NIH investment go well beyond human health. In FY 2023, NIH funding supported the creation of [412,041 jobs across the country and generated nearly \\$93 billion in economic activity](#). NIH funding has flowed to every U.S. state and nearly every congressional district, serving as a catalyst for innovation and economic progress across the entire nation.

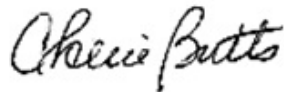
Enacted in December 2016, the bipartisan 21st Century Cures Act provided NIH with \$4.8 billion in supplemental funding over a decade for four specific programs through a new NIH Innovation Account: the Precision Medicine Initiative (now the All of Us Research Program), the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative, the National Cancer Moonshot, and a small project on regenerative medicine. This funding was intended to supplement the regular NIH budget and provide additional resources for these specific initiatives, and in many ways has been a boon to medical research. However, major fluctuations in annual funding levels for these programs have caused challenges and Innovation Account funding has depleted or is winding down for many of these projects. AAI encourages Congress to consider reauthorizing and reinvesting in the NIH Innovation Account, and to provide consistent, stable support for any programs funded through it.



Investment in NIH is also crucial to enabling the U.S. to maintain its international preeminence in biomedical research. A critical component of this is supporting the next generation of U.S. researchers. For too many years, graduate students and postdoctoral fellows have been underpaid and under-supported, problems that NIH recently identified in a report on [“Re-Envisioning NIH-Supported Postdoctoral Training.”](#) NIH has since [announced](#) that it will increase pay for pre- and postdoctoral scholars; however, without increased funding for NIH, this will inevitably lead to supporting fewer trainees or less innovative and cutting-edge research. In addition, some international competitors have dramatically increased spending on research & development in recent years; [according to the National Science Board](#), China has now surpassed the U.S. in key metrics, including total patents and total number of scientific publications each year. If America wants to be the leader in the innovations of tomorrow, robust investment in biomedical research is crucial.

AAI thanks you again for your commitment to supporting and strengthening NIH and looks forward to working with you on this and other issues of importance to the biomedical research community. Because any effort to reauthorize or reform NIH will require bipartisan, bicameral deliberations, we look forward to engaging with the Senate, Health, Education, Labor, and Pensions Committee. If AAI can provide additional information about this or any other issue, please do not hesitate to contact AAI Director of Government Affairs Jake Schumacher (jschumacher@aai.org).

Sincerely,

A handwritten signature in black ink that reads 'Cherié Butts'.

Cherié Butts, Ph.D.
Chair, AAI Committee on Public Affairs

