

August 13, 2024

The Honorable Cathy McMorris Rodgers
Chair, House Energy and Commerce Committee
United States House of Representatives
Washington, D.C. 20515

Dear Chair Rodgers:

The Endocrine Society appreciates the opportunity to provide feedback on the proposed framework for *Reforming the National Institutes of Health* (NIH). Founded in 1916, the Endocrine Society is the world's oldest, largest, and most active organization dedicated to research on hormones and the clinical practice of endocrinology. Our membership consists of over 18,000 scientists, physicians, educators, and students in more than 100 countries. Many of our members conduct biomedical research funded by the NIH; collectively, our members are funded by as many as 18 Institutes and Centers (ICs) at NIH.

It has been nearly a decade since the last public review of NIH's organizational structure, and we agree that a thorough review of the NIH's organizational and operational structure could help identify opportunities to streamline NIH's operations, missions, and goals. While the framework for reorganization introduces important ideas and concepts, any changes will directly affect over 18,000 NIH employees and additional researchers at more than 2500 institutions across the country and must be done with caution. After a careful review of the framework, we have strong concerns about the proposed restructuring and the potential for unintended effects. We agree, on principle, that breaking down silos between ICs is important to coordinate "overarching research goals" and "constituencies;" however, we do not understand how the proposed framework will achieve these and other goals such as a "holistic life stage approach." It is imperative that critical research priorities, strategies, and approaches are maintained in any future state for the NIH, and it is unclear how public health priorities, including endocrine-related research areas such as diabetes, obesity, developmental biology, environmental health, women's health, and reproductive health will be integrated into the proposed restructuring. If implemented as currently described, the framework will have a disruptive impact on biomedical research, the economy, and US competitiveness. **As an overarching suggestion, we urge the Committee to gather additional input from NIH leadership, scientific experts, patients, universities, patient advocacy groups, and scientific societies through a formal, bicameral authorization process.**

We are eager to collaborate with you and your staff to work through a formal authorization process that involves constructive feedback from public health experts and scientists familiar with NIH processes. In the following comments, we focus on issues that are most relevant to our members and propose recommendations that would improve the framework for the reauthorization of NIH.



Structural Reform

The framework proposes massive structural changes to NIH that, without careful and informed deliberation, will severely disrupt the US biomedical research enterprise. Each of NIH's 27 ICs operates with unique missions, priorities, budgets, and staff to drive research on critical areas of health that advance our knowledge of biology and improve the quality of life for all Americans and those across the globe. Realization of the benefits of medical research often takes years or even decades. Collapsing these ICs from 27 to 15 without additional input from the research community to ensure the maintenance of productive research programs and strategic priorities has the potential to create disorder and uncertainty, delaying research progress to the detriment of the health of US citizens and reduce the country's ability to rapidly address emerging threats and other human health issues.

We identify below several critical research areas that may be lost in terms of priority and investment at each IC under the proposed restructuring:

- *National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)*: NIDDK plays a unique role within NIH to understand the biological underpinnings of many endocrine-related diseases leading to novel therapies that can improve a patient's quality of life. Diabetes, for example, is a significant public health crisis necessitating an intense basic and clinical research focus. It will therefore be necessary for any reform proposal to clearly describe how research programs on diabetes and other metabolic diseases will be maintained and led in the future. The Special Diabetes Program (SDP) in particular has a successful track record of scientific research through distinct funding opportunity announcements targeted to Type 1 Diabetes. Research funded through this program has yielded new therapies that allow patients to better manage the disease. Highly successful programs like the SDP must be preserved and supported irrespective of IC organization.
- *Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)*: NICHD plays a unique role within NIH to investigate human development across the life course with reproductive health and pediatric cognitive and neurological development as important areas of focus. It is unclear how these research priorities that were central to NICHD's founding and have been developed throughout its history will be preserved in the new structure.
- *National Institute of Aging (NIA)*: We are concerned that the framework proposes to refocus the NIA by renaming it the National Institute on Dementia. This would seem to exclude important research on developmental trajectories such as the effects of problematic transitions from pediatric to adult health care, the evolution of chronic disease throughout the life course, and how adverse childhood experiences impact women's health later in life. Dementia, in contrast, is a neurological disorder with many causes.
- *National Institute of Environmental Health Sciences (NIEHS)*: NIEHS plays an important role within NIH in understanding how endocrine disrupting chemicals and other environmental



exposures, climate change, and societal equity affect human health. This approach to research is critical, as environmental exposures impact the development of endocrine diseases including infertility, obesity, birth defects, and neurological disorders. In addition to affecting the incidence and progression of disease, environmental exposures contribute to racial, ethnic, and socioeconomic disparities, further highlighting the unique approach of this institute. NIEHS also funds important longitudinal studies utilizing a life course approach, for example as part of the Environmental Exposure and Child Health Outcomes (ECHO) cohorts, that help us understand how the environment contributes to development. It is unclear how environmental health science and health disparities will be preserved in the new structure as presented in the discussion framework.

Grant Reform and Oversight Requires Specific Expertise

Our members are funded by as many as 18 different ICs and we appreciate the importance of fair and knowledgeable grant review panels across ICs that recruit individuals with expertise in hormone biology and endocrinology to evaluate grant applications. We support efforts to improve NIH's grant review process to ensure that meritorious research is supported and reviewed by individuals with appropriate expertise. We are concerned about major disruptions to the grant review process that a substantial and ill-defined restructuring would introduce and urge for the solicitation of feedback from experts with experience in all aspects of the grant review process. This would include staff from NIH's Center for Scientific Review, funded scientists, patients and patient advocates, scientific societies, etc. to inform any plans to consolidate ICs and change grant review structures.

The responsible and ethical use of animals in research remains indispensable to advance research and develop therapies for many endocrine diseases and conditions. We support oversight for the use of animals in research through the NIH Office of Laboratory Animal Welfare (OLAW), which provides guidance on the interpretation of the Public Health Service Policy to ensure the health and welfare of all laboratory animals as mandated by law. Before any modifications to the oversight of the use of animals in research are made, relevant staff from OLAW, university animal care staff, and scientists should inform the development of those plans.

Additional Points for Inclusion in Reform Efforts

NIH, as it operates today, is leading the world's biomedical research efforts and there is much that NIH does well and should be preserved. However, as Congress considers reform and reauthorization, we identify several areas that should be emphasized and prioritized in the future state for NIH:

Build and support the next generation of scientists: Innovative and competitive research is driven by a steady progression of scientists through career stages. Policy changes and reforms should support the next generation of scientists to ensure a steady stream of innovative and competitive researchers. We recommend that graduate students and



postdoctoral researchers, especially, have a voice in any proposed changes as their career paths and progression will be directly impacted by any restructuring. We also recommend that particular attention be paid to scientists who have not been historically represented in the scientific workforce to ensure that any future state for the NIH is able to include and support scientists from underrepresented communities as active members of the biomedical research enterprise.

Prioritize women's health: Women's health research has historically not been adequately supported. Research strategies must prioritize the needs of women across their lifespan and proposed structural reforms should address women's health in a comprehensive way that goes beyond reproductive health.

Reduce administrative burden: Researchers and institutions are burdened with significant administrative tasks including paperwork and reporting requirements that take time away from managing laboratories, teaching, mentoring, and discovering the next set of research questions. As part of reform efforts, we suggest a comprehensive review of NIH be conducted to identify opportunities for streamlining administrative processes to re-focus responsibilities on conducting scientific work.

Improve research by addressing sexual harassment and misconduct: Creating productive, safe environments for the next generation of scientists is critical for maintaining the country's competitiveness in science. In principle, we support efforts to monitor, respond to, and reduce the prevalence of sexual harassment and misconduct in research environments. We recommend that input be solicited from graduate students, postdoctoral researchers, principal investigators, NIH staff, and university staff to develop a structured plan to address issues of harassment and misconduct.

Beyond ethical and public health considerations, NIH-funded research bolsters the US economy in all 50 states, drives innovation, and is essential for maintaining our competitiveness in technology, research, and development. In fact, for FY 2022, NIH reported a return on investment of \$2.64 of economic activity for every \$1 of NIH funding spent. Furthermore, each IC is required to allocate a portion of its funding to support small businesses through the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs. These provide startup funding for promising entrepreneurial endeavors that create employment opportunities and advance innovative new technologies and solutions.

Conclusion

NIH is the crown jewel of human health research agencies in the United States and must be protected. Furthermore, maintaining the US' leadership in biomedical research and discovery will ensure that the US is able to influence the ethical standards by which research is conducted and translated into effective interventions that meet patients' needs.



Long-term support for research priorities reduces the costly burden of disease, further strengthening the economy, and improves our overall quality of life. Most importantly, NIH-funded research saves lives. Failing to fund NIH research at levels that account for inflation combined with incomprehensible restructuring plans that lack informed feedback will directly affect our economy, reduce our standing in the global biomedical research arena, and endanger the lives of Americans. The Endocrine Society urges that the NIH reform process goes through a formal bicameral authorization process. We are eager to collaborate with you and provide valuable recommendations that support the important hormone-related research that our members conduct. If we can be of further assistance, please contact Sophia Kaska, Ph.D., Manager of Science Policy and Research Affairs at skaska@endocrine.org.

Sincerely,

A handwritten signature in blue ink, reading "John Newell-Price".

John Newell-Price, MD, PhD, FRCP
President, Endocrine Society