



Council

Carol L. Beck

President
Thomas Jefferson University

Randy Hall

President-Elect
Emory University School of
Medicine

Namandjé N. Bumpus

Past President
U.S. Food and Drug Administration

Pamela Hornby

Secretary/Treasurer
Drexel University College of
Medicine

John Traynor

Secretary/Treasurer-Elect
University of Michigan

Xinxin Ding

Past Secretary/Treasurer
University of Arizona College of
Pharmacy

Amy Arnold

Councilor
Pennsylvania State University
College of Medicine

Nina Isoherranen

Councilor
University of Washington

Daniela Salvemini

Councilor
Saint Louis University

Kenneth Tew

Chair, Publications Committee
Medical University of South
Carolina

Jerry Madukwe

FASEB Board Representative
Cell Press

Carol Paronis

Chair, Program Committee
McLean Hospital

Ashim Malhotra

Chair, IDEA Committee
California Northstate University
College of Pharmacy

Saranya Radhakrishnan

Chair, Young Scientists Committee
National Institute of Mental Health

David Jackson

Executive Officer

August 16, 2024

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

RE: Request for Feedback and Suggestions from Stakeholders on the Framework for NIH Reform

Submitted electronically via email to NIHReform@mail.house.gov

Dear Honorable Member Rogers,

On behalf of the members of the American Society for Pharmacology and Experimental Therapeutics (ASPET), we appreciate the opportunity to submit feedback on the House Energy and Commerce Framework for National Institutes of Health (NIH) Reform.

ASPET is a 4,000-member scientific society whose members conduct basic and clinical pharmacological research and work in academia, government, industry, and non-profit organizations. ASPET members conduct research leading to the development of new medicines and therapeutic agents to fight existing and emerging diseases. ASPET's mission is to be the professional home for educators, students, researchers, healthcare practitioners, and others working to advance pharmacological sciences and increase the impact and influence of this scientific discipline.

The House Energy and Commerce Framework for NIH Reform (Framework) is commendable on its goal to position the NIH to better succeed moving forward. Along with the Senate Health, Education, Labor & Pension Committee's NIH in the 21st Century plan, ASPET appreciates the focus on the NIH and the desire to cement NIH as the global leader in biomedical research.

ASPET shares its comments in the spirit that this Framework is the beginning of a conversation to engage the science community and NIH stakeholders to work together towards NIH reform. In that vein, ASPET has vast concerns of the Framework's inclusion in the current FY2025 Labor HHS Appropriations bill. It is troubling to see the Framework plans to restructure NIH appear to be concluded and a finality placed in legislative text with very little discussion and transparency. ASPET joined a larger coalition [letter](#) signaling its concern for this matter. Moving forward, we hope that the conversation will continue without the need for such drastic actions.

Transforming Discoveries into Therapies

ASPET · 1801 Rockville Pike, Suite 210 · Rockville, MD 20852 · Office: 301-634-7060 · aspet.org



Structural Reform

ASPET recognizes and appreciates the Framework's end goal, "to build a stronger NIH for the future." It is with that goal in mind that ASPET strongly disagrees with the Framework's structural reorganization of NIH as is. The Framework lacks a timeline for the reorganization and consolidations of the ICs. If taken at face value, the inclusion in the Labor-HHS appropriations bill seems to signify that this would happen overnight and there would be no negative consequence to the nation's premier biomedical research enterprise.

Congress should consider the excessive cost and risk associated with authorizing a new structure for the NIH in an appropriations bill without a bipartisan, bicameral process with input from all relevant stakeholders in the research community. ASPET urges that any plans to restructure and consolidate NIH centers and institutes should go through a formal authorization process, similar to the one that led to the NIH Reform Act of 2006, with adequate opportunity for members of the scientific research community to provide their input.

Structural reform through consolidating institutes and centers as described in the Framework does not detail how the missions and goals of each IC will be combined. Without that information, the current plans to restructure could leave gaps in knowledge needed for pharmacology and toxicology (and biomedical research overall) to advance discoveries and the development of therapies. This includes potential major disruptions in the biomedical research progress, such as creating uncertainty in the recruitment of grant reviewers, the review process of research grants, shared resources, and centralizing services, causing unintended consequences that could negatively affect the biomedical research enterprise. ASPET encourages Congress to consider including language on safeguards to prevent the elimination of entire research fields while supporting structural changes driven by scientific needs.

Pharmacology is a unique field that integrates knowledge from multiple biological and biomedical sciences. As our understanding of science and how interconnected aspects of research are, we encourage congress to consider natural pairings of certain ICs guided by researchers and other specialists in the related field as case studies before drastic changes to all ICs, especially with no implementation plan or clear and transparent descriptions of how the new ICs will absorb the goals and missions of the previous ones. Such large scale, potentially disruptive changes, can be highly costly making this approach counter to the Framework's underlying justification to rein in costs.

Mission and Leadership Reform

ASPET agrees with the Framework's sentiment about "supporting our nation's role as a leader in scientific research and discovery and medical innovation, while remaining fully accountable to the taxpayers." ASPET views NIH funding as the public's investment in its health and future. We offer the following comments for this section's recommendations.

Initiate and Complete a Comprehensive Review of the NIH

ASPET supports a review of NIH and its objectives. We believe that this should be the first step taken before any reorganization should occur and any additional parts of the Framework implemented. Establishing a congressionally mandated commission that is bipartisan and has members of the public, relevant NIH stakeholders including scientists and scientific societies along with experts would be the correct way forward. NIH is a vast organization and as stewards of the public dollar and trust should be reviewed regularly. Congress in turn should also not shy away from its role as overseer of the public's trust and finances and should take an active role to strengthen the NIH and improve upon NIH's mission, objectives, and programs. Stagnation of oversight may have led to the demise of the Science Merit Review Board for nearly a decade. We

Transforming Discoveries into Therapies

ASPET · 1801 Rockville Pike, Suite 210 · Rockville, MD 20852 · Office: 301-634-7060 · aspet.org



encourage Congress to look at this recommendation as their initial step in this process before implementing massive reorganization without relevant stakeholder input and public hearings while also providing the necessary oversight that should occur as matter of public responsibility.

Support Innovation

ASPET is pleased to see and is supportive of the recommendation to support innovation by supporting formal public-private partnerships. As an organization that includes scientists who conduct basic and clinical pharmacological research and work in academia, government, and industry, we believe that without partnerships, NIH would not have the same degree of impact on the advancement of new disease treatments and cures, as well as impact on the US economy. ASPET, however, strongly encourages reconsidering ARPA-H consolidation into the proposed new National Institute on Innovation and Advanced Research. Considering that NIH extramural research programs tend to fund less high-risk grants. The “ARPA model” is designed to have a high degree of autonomy to select and fund research projects using a milestone-based contract approach. Eliminating ARPA-H and combining it with other NIH ICs will undermine its intended purpose to support innovation through high-risk, high-reward biomedical research that may lead to breakthroughs on a faster timeline. This is critical to ensuring U.S. competitiveness. ASPET strongly supports the core of mission of NIH and its research. ASPET has previously submitted [comments](#) on the Department of Commerce’s NIST proposed rule concerning march-in rights.

Introduce Term Limits for IC Leadership

ASPET understands the need for turnover of NIH leadership to promote adapting and evolving expectations in the workplace or to proactively change an existing workplace culture. However, ASPET is unsure how the term limit of 5 years was determined. Research visions and goals take time to execute. Input from relevant stakeholders on appropriate term limits or mandatory retirement age is strongly encouraged.

Eliminate Silos Between ICs

ASPET is supportive of eliminating silos and improving collaboration across ICs, particularly in intramural research programs.

Address Misconduct and Expect Accountability

Training and support of the next generation of scientists is crucial in building the biomedical research workforce and safe research environments are essential. Misconduct of any kind including harassment, bullying and hostile work environments threaten not only the mental and physical health of scientists in training but also their career trajectories as these issues have and still drive many historically excluded populations to leave scientific research. ASPET acknowledges that NIH along with other organizations have taken steps towards this goal already and encourages building on this progress through implementing evidence-based practices.

Funding Reform

ASPET appreciates the bipartisan support NIH has received over the years and we acknowledge that Congress has increased NIH’s budget consistently from 2015 to 2023. This has had a major positive effect on the United States economy. NIH generated nearly \$97 billion in economic activity in 2022 alone. However, for FY 2024, Congress only provided a relatively small percent increase to NIH’s funding, which has barely kept up with inflation rates. This comes at a time when critical technologies, innovation, and the scientific research workforce are needed to help maintain the U.S.’s global competitiveness. Robust and consistent funding for NIH is essential for advancing biomedical research and promoting the next generation of treatments and cures. Therefore, to ensure that the U.S. maintains

Transforming Discoveries into Therapies

ASPET · 1801 Rockville Pike, Suite 210 · Rockville, MD 20852 · Office: 301-634-7060 · aspet.org



its global competitiveness in biomedical research, ASPET urges Congress to also focus on providing stable and predictable funding for research with yearly increases that adjust for the inflation rate, to sustain critical infrastructure of NIH and to allow the agency to address emerging research priorities. We offer the following comments for this section's recommendations.

Restore Congress's Role in Directing Funding

ASPET is confused by this recommendation as the "PHS Evaluation Tap" routinely has had appropriations language that raises the allowed set aside [beyond the statutory 1% and included additional requirements](#). Congress already has a role in directing funding and does so regularly through the appropriations process. As previously mentioned, Congress could provide oversight on the accounting of these set asides that would then show an accurate picture of NIH funding and that of HHS.

Reexamine Indirect Costs

The recommendations to provide incentives or preferences to those institutions with established and proven lower indirect costs would be a devastating blow to biomedical research in the US. These preferences or incentives would likely decrease or eliminate some institutions from receiving NIH funding, even though the grants from the individual researchers at these institutions could be the most innovative, novel, and most likely to push biomedical research forward. Providing these incentives or preferences would effectively punish individual researchers, even though they are not responsible for how their institutions' indirect cost rates are negotiated, nor do they profit from their institution receiving a greater percentage of these funds. Alternatives should be considered and examined by various stakeholders, but these alternatives should be in line with methods that other federal funding agencies are currently using. The NIH is not the only federal funding agency that pays indirect costs, thus any reexamination of these costs would need to include multiple stakeholders from all funding agencies that pay these negotiated rates. ASPET is supportive of transparency of grant indirect costs but cautions against reexamining them.

Grant Reform

ASPET is overall supportive of reducing the complexity of the NIH grant system and promoting career pathways for early-stage investigators. However, focusing grants to primary investigators limits trainees and collaborators in scientific labs. We offer the following comments for this section's recommendations.

Ensure Appropriate Oversight of Animal Research

ASPET is also supportive of the concerns and recommendation for oversight of use of animals in research. However, this oversight already exists at NIH through OLAW and through IACUC at each grant-receiving institution.

In conclusion, ASPET appreciates the opportunity to provide feedback on this Framework and looks forward to continuing dialogue on these critical issues. If you have any questions about our comments or would like to continue this dialogue, please contact Carter Alleman, Director, Government Affairs & Science Policy at calleman@aspet.org.