

August 16, 2024

The Honorable Cathy McMorris Rodgers
Chair
Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, D.C. 20515

Re: National Institutes of Health Structural Reform

Dear Chair McMorris Rodgers:

Thank you for the opportunity to provide input on the National Institutes of Health's (NIH's) proposed framework for structural reform.

The American Lung Association is the oldest voluntary public health association in the United States, representing the more than 34 million individuals living with lung disease. The Lung Association is the leading organization working to save lives by improving lung health and preventing lung disease through research, education and advocacy.

The Lung Association is pleased to share our perspective on the proposed structural and policy reform to the NIH. We consistently work to fulfill our mission of saving lives through advocacy and support collaboration across multiple NIH institutes and centers, including the National Heart, Lung, and Blood Institute (NHLBI), the National Cancer Institute (NCI), the National Institute of Allergy and Infectious Diseases (NIAID), the National Institute on Minority Health and Health Disparities (NIMHD), the National Institute on Drug Abuse (NIDA) and the National Institute of Environmental Health Sciences (NIEHS).

The Lung Association's role in improving lung health spans across all factors that contribute to lung disease, including air quality, commercial tobacco use, and access to care, uniquely qualifying our organization to comment on the large impact of the proposed NIH reform. We urge the Committee to make the best use of the recommendations, knowledge and experience our organization offers here and to also move forward in a bipartisan, bicameral manner, including holding hearings.

General Principles for Reforming the NIH

The NIH has provided significant funding for research into lung disease including lung cancer, asthma, chronic obstructive pulmonary disease (COPD), and pulmonary fibrosis. This research has directly contributed to a better understanding of these diseases, allowing for the development of new detection, treatment and prevention strategies. By funding and conducting research that focuses on preventing or treating the leading drivers of death and disease, NIH research can help reduce our nation's healthcare costs. This makes the success of the NIH incredibly important to the Lung Association and the millions of people living with lung disease in the U.S.

NIH is a beacon of hope and a pathway to cures. Any changes to NIH's structure must be carefully and thoroughly evaluated to ensure that such changes work to improve health and accelerate results. We recognize that there could be ways to change the structure or activities of the NIH to strengthen its ability to fund impactful research that benefits people's health. However, these changes must carefully respect the need to not harm NIH's current work, which will likely have cascading effects in the future. For example, in the 1980s, NIH spent significant funding on research related to immunology and HIV/AIDS and today, that research is being translated into immunology for cancer treatments. Sixty new treatments for lung cancer have been approved since 2016 and many of these tremendous advances rely on the research done in the 1980s. We hope that any potential NIH reforms not only support this investigative spirit and collaboration but make it even more efficient so that it doesn't take 30 years for the discoveries of today to benefit additional patient communities in the future.

As you consider structural reforms to the NIH, we ask that you employ these general principles to guide your work:

Proposed reforms must improve the ability of NIH to support investigator-initiated research to impact human health. Reforms cannot jeopardize the ability of NIH to support research that seeks fundamental scientific knowledge and improvement of human health. People with or at risk for lung disease need NIH research to be consistent with the understanding of the science and address pressing public health challenges, including commercial tobacco use, addiction, air pollution and other lung diseases. All individuals in the U.S. need NIH to focus on drivers of disease and death to ensure that scientific discoveries are translated into affordable medical advancements at the bedside as quickly as possible.

Proposed reforms must continue to allow NIH to continue to fund research that no one else will. Basic research is fundamental to the mission of the NIH, as well as foundational for the scientific discoveries that follow. But there are also large multi-center studies that require NIH support. For example, from 2002-2010, the NIH-supported National Lung Screening Trial (NLST) enrolled more than 50,000 people who either currently or formerly smoked heavily to compare two ways of detecting lung cancer: low-dose computed tomography (LDCT) and standard chest X-ray. The study found that participants who received LDCT scans had a 15 to 20 percent lower risk of dying from lung cancer than participants who received standard chest X-rays. This study changed medical practice and is saving lives today.

Proposed reforms must be considered in a transparent process that allows for the NIH stakeholder community to provide input. We encourage you to go beyond this comment opportunity to meaningfully engage with a diverse group of experts, including NIH staff, researchers and scientists, and patient and science advocates, to hear their perspectives on how to optimize NIH and prevent any unintended consequences from reform. We also encourage you to use the existing NIH advisory committees to provide input. Furthermore, Congress should hold hearings to gather comprehensive testimonies from all relevant stakeholders, including research institutes, patient advocacy and public health groups. A more comprehensive, inclusive and transparent approach will help safeguard the integrity and effectiveness of NIH funding and support across all areas of biomedical research.

Any funding created by proposed reforms should be reinvested into the research enterprise. Some proposals could lead to reductions in current spending, and we emphasize the importance of ensuring that any new or recovered dollars are spent on research. It is crucial

that these funds are used to strengthen and expand critical research initiatives, enhance support for ongoing studies and accelerate the development of new treatments and interventions.

Specific Comments on Questions in the RFI

Reorganization of Institutes and Centers: The Framework for NIH Reform proposes a significant restructuring to combine a number of existing institutes and centers and change the focus of others. We have several concerns with this approach. First, it would be challenging to have a leader of what are now multiple institutes who would have sufficient training and insights to support all of the research below them. Additionally, the institutes have varied funding levels and funding rates, and it is not clear that lung disease projects would continue to be prioritized. While we recognize that there could be efficiencies, we are concerned that this reorganization would disrupt the research process.

The framework suggests consolidating NHLBI, the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) into the National Institute on Body Systems Research. The framework also recommends separating allergy activities from NIEHS. These specific consolidations and others could undermine specialized research and treatment strategies that are crucial for each distinct area, such as lung health, arthritis, diabetes and environmental allergies. Each of these institutes developed unique expertise and focus areas that could be diluted in a broader, combined entity.

We also note that while the framework proposes to consolidate a number of institutes, it proposes to break apart NIAID and separate allergy from infectious disease. The Lung Association opposes such a separation, recognizing how vital NIAID were in quickly addressing the COVID-19 pandemic. Our nation's ability to respond to emerging infectious threats would be significantly weakened if this were to occur.

Ultimately, it is not clear that an extensive reorganization is necessary, especially if administrative functions could be further centralized. Today, meaningful and collaborative research happens at NIH at nearly every institute and center, despite them being different entities. For instance, NIMHD and NCI are jointly sponsoring a study to look at the underlying causal factors that result in lung cancer disparities in the U.S. including the causes for screening and treatment disparities for lung cancer. We remain concerned that the consolidation proposal as stated may make it harder to address emerging public health issues and could slow progress and diminish the effectiveness of research and patient care.

Supporting Early Career Researchers and Limiting Researchers to Only Three Awards:

We are concerned that the proposal to limit researchers to no more than three awards will be problematic for clinical researchers who participate in multiple research networks. These networks are often critical to new discoveries, such as the Lung Screening Study group mentioned above. The Lung Association is strongly supportive of process changes that make it easier for early career investigators to be successful, but we are concerned that arbitrary caps on awards could limit scientific advancement.

Instead, we would encourage you to consider a novel funding mechanism specifically designed for early-stage and new investigators to support their entry into the field without unnecessary limitations.

Proposed Funding Levels: The Framework for NIH Reform proposes a significant increase in cancer research funding to NCI, though this would come at the detriment of funding for innovative research institutes such as Advanced Research Projects Agency for Health, Common Fund, National Center for Advancing Translational Sciences and NIBIB. These institutes are crucial for pioneering new techniques and technologies that have the potential to transform the entire biomedical research landscape. The Lung Association advocates for all people in the U.S. at risk for or living with lung disease and we are concerned that this approach could stifle cross-disciplinary innovation and the development of novel approaches that could benefit a wide range of medical fields, including lung disease. Balancing funding to ensure robust support for both targeted cancer research and broader, innovative research initiatives is essential to a more integrated and comprehensive approach to improving the public's health.

Reports on Inter-Institutional Collaboration: We support that you would receive reports from each NIH institute and center on inter-institutional collaboration. These reports would provide data to support a potential broader reorganization, and we believe that this should be implemented first, before there are any other changes to the existing NIH structure. As noted above, there is already significant collaboration on lung disease research across NIH.

Conclusion: The American Lung Association appreciates the opportunity to provide input on the NIH structural reform proposal and looks forward to working with the. For further questions, please reach out to Erika Sward, Nationwide Advocacy Assistant Vice President, at Erika.Sward@Lung.org.

Sincerely,



Harold P. Wimmer
CEO & President