



August 14, 2024

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

Dear Chairwoman McMorris Rodgers:

On behalf of the Society for Women's Health Research (SWHR)—a more than 30-year-old national nonprofit working to advance women's health through science, policy, and education while promoting research on sex differences to optimize women's health—I would like to thank you for the opportunity to provide comments on the discussion framework *Reforming the National Institutes of Health*. As a science-based organization committed to advancing the health of women and closing the gender health gap through research, this process is one of tremendous importance to SWHR.

Given the value SWHR places on science and good governance, we appreciate your efforts to examine how the National Institutes of Health (NIH) is structured and how a revitalized configuration could "position the NIH to better succeed moving forward." With the last comprehensive reauthorization of the NIH happening in 2006 and a new authorization needed, this is an appropriate time to review the NIH's operations, structures, and programming to ensure the agency is meeting the ever-evolving research landscape and is best positioned to achieve its mission to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.

SWHR supports a bipartisan, bicameral process that includes public hearings and multiple opportunities for stakeholder input throughout the process. Because of the breadth of this endeavor, we urge the Committee to take a comprehensive and procedurally-oriented approach to reauthorization or restructuring that involves a thorough portfolio and budget analysis and input from key stakeholders across the public health and scientific communities along with federal government officials. Researchers who are and are not NIH-funded, patients who benefit from NIH research, organizations representing disease states, conditions, and populations that engage with the NIH, and importantly, the NIH Director and director and staff of each of the Institute, Center, and Office (ICO) to gauge their suggestions and leverage their expertise about agency operations and how any structural changes might benefit or hinder scientific progress. Our hope is that this comment opportunity represents a first step in this more comprehensive process that includes many touchpoints and public opportunities to address this issue.

As you continue to consider potential reforms to the NIH and review stakeholder feedback, SWHR raises the following points for your consideration, and we look forward to the opportunity to have further conversations on them:

Call for Lifespan and Population Approach to Research

SWHR was pleased to see this framework express interest in having each Institute consider “the whole individual and all populations across the entire lifespan.” As an organization that focuses broadly on the health of women, who have been historically underrepresented in and actively excluded from clinical research for decades, SWHR has advocated for the integration and elevation of this research across NIH since our founding in 1990. During that time, we have seen the passage of the NIH Revitalization Act of 1993, which required the inclusion of women in clinical research for the first time and established the Office of Research on Women’s Health (ORWH) at the NIH, and the implementations of policies within the NIH that ensure considerations of sex differences. That is, that men and women are different, and that different conditions, symptoms, and treatments may be different. We strongly believe that to improve accountability and outcomes for all women across the lifespan, as well as to accelerate knowledge, treatment and cures, women’s health research must be a core principle of each of the Institutes and that data sharing and tracking surrounding women’s health should be improved.

While SWHR appreciates the desire to have NIH Institutes incorporate more of a lifespan approach to research, the framework as written does not make clear how it will promote this focus and break down silos between the various Institutes and Centers. Further clarification on how this would be implemented would be helpful, in addition to the role of the Centers and Offices throughout the NIH as they currently exist.

NIH Restructuring

Reiterating our comment at the outset of this letter, SWHR recognizes the value in examining the current NIH structure to determine whether the NIH is well-positioned to keep the United States in its role as a scientific world leader. While we recognize the framework is intended to serve as an entry point for discussion, SWHR urges the Committee to consider that a restructuring of this magnitude does not simply represent a corporate structure consolidation; there are key considerations for the conduct of its science. Said differently, the NIH cannot be restructured without understanding the full implications that such a restructuring would have on the scientific rigor of the institution, as well as on the implementation of the science itself.

Specifically, SWHR raises the following items for consideration related to the restructuring:

- **Implications for Active Research and Research Portfolios.** First, how would the NIH consolidation, as proposed, affect research that is currently being funded? Would the research remain active through the end of its funding cycle and be placed into the most appropriate new Institute, or would those grants and awards be terminated? Further guidance on this would be greatly appreciated and should be considered.

Additionally, before proceeding with any type of consolidation, SWHR encourages

Congress to work with NIH to conduct a thorough portfolio analysis to determine what research is active and where it would live under a new structure, in addition to identifying gaps in research that may need to be addressed and could better inform the framework proposal. There are critical areas of research pertaining to women's health being funded within the NIH that crosses Institutes that need to continue to further advance the health of women – from menopause research to bone health, and research inclusive of pregnant and lactating populations.

- **Scientific Expertise and Program Administration Implications.** A critical component of the NIH's success is the unique expertise that exists within each of its Institutes. These subject-matter experts have unparalleled knowledge over very particular research focus areas and often provide invaluable information to grantees, NIH staff, and other stakeholders. We are concerned that consolidation may result in an unintended consequence of the loss of specific expertise that exists within NIH and its workforce. There is value to having nuanced and diverse skill sets within NIH; having those with more general, high-level research knowledge presiding over grants and programs could affect the kinds of grants that are funded and the advice given to prospective grantees. Further unintended consequences resulting from this lack of diverse expertise could be the creation of risk-averse practices. That is, if reviewers and the individuals who serve on study sections have broader expertise, they may choose to fund "safe" research as opposed to innovative research—not recognizing the true value of a given research proposal. We urge the Committee to consider structures that ensure that the NIH is staffed by those with unique skill sets and backgrounds to be able to understand the nuances of research proposals to fund the best science within areas of need.

Overarching Questions

Beyond the questions of how a restructuring of NIH could affect scientific rigor and implementation, SWHR identified several questions that would help provide greater insight into how Congress envisions this new structure operating on behalf of the American people. The questions SWHR would appreciate answers to include the following:

- Under the proposed framework, what is the plan for NIH Offices, including the Office of Research on Women's Health (ORWH) and the Office of AIDS Research? Would these Offices continue in their current form, or would changes be made to how these entities operate and their respective research and programmatic portfolios?
- Who will serve on the congressionally mandated commission to lead the review of NIH's performance, mission, objectives, and programs? Are the appointees going to be political officials, scientists, non-governmental representatives (e.g., representatives from associations, medical or professional societies), or a combination? We urge the Committee to ensure that such a commission include representatives of all types to ensure that that a multitude of perspectives and expertise are reflected in the conversation.

- The framework includes language that grants and awards should be given “only to primary investigators that do not have more than three ongoing concurrent NIH engagements.” Does this apply to grants or awards of any level, or to investigators that receive grants or awards at a certain threshold? SWHR agrees that we not only need more active grant recipients in the research pipeline, but also that the grantees be more representative of the populations that they are researching, including those from non-traditional research institutions. NIH continues to make efforts to diversify our nation’s research pathways, and an analysis of their current initiatives may help inform whether attempts have been successful and what changes are most worth pursuing.

Calls for Greater Efficiency Within NIH

SWHR recognizes that indirect costs should be evaluated as part of an overall review of NIH structures, operations, and procedures. As part of this review process, SWHR encourages the Committee to keep in mind that these indirect costs are not only used by universities and research institutions, but that indirect costs are also part of grants at smaller entities, such as non-profit associations, small businesses, and non-traditional research organizations. Any changes to the indirect cost funding structure should consider how those changes might impact the research pipeline for smaller entities and whether it could hinder their ability to manage overhead costs and activities that are necessitated for meaningful research.

Recognizing the Value of NIH in Society

Within the framework, it is noted that “central to achieving the NIH’s mission is the role of public-private partnerships,” especially given factors such as rising costs, scientific complexity, workforce training, and the time needed for research and development of pharmaceutical and medical products. There is also a recommendation to encourage these partnerships and collaboration. SWHR strongly agrees that public-private partnerships have an important role to play as part of NIH’s efforts to achieve its mission. These collaborations can leverage the strengths of each entity and spur development and innovation. SWHR would also caution against relying too heavily on industry as our nation’s primary research and development entity.

The NIH serves a unique purpose in that it funds a vast array of research that may not be financially profitable in the short term, but significantly contributes to our understanding of the biological mechanisms of disease, risk factors across different populations, and potential prevention and treatment of disease. Advancements in one area of research can benefit other areas of research. Taking away these funding streams could have negative downstream effects for our overall understanding of certain diseases and conditions. Industry partners, while invaluable to our nation’s research and development efforts, are ultimately for-profit entities. Industry, for example, has not historically invested in women’s health research. According to a 2022 report by McKinsey,¹ just 1% of health care research and innovation is invested in female-specific conditions beyond oncology, and just 4% of health care-related research and

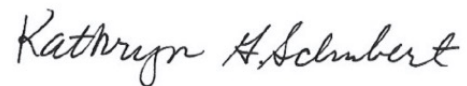
¹ McKinsey & Company. Unlocking opportunities in women's healthcare. 2022. Available from: <https://www.mckinsey.com/industries/healthcare/our-insights/unlocking-opportunities-in-womens-healthcare>

development issues in the United States are targeted specifically at women's health issues.² An overreliance on pharmaceutical and other industry partners could also impact other research areas, including research into rare diseases.

Ultimately, SWHR appreciates that a comprehensive review of the NIH structure is an important component of NIH reauthorization and that ensuring accountability, transparency, and efficiency within the agency is core to good governance, and supports a thorough and transparent process in doing so. We also strongly believe in the NIH's role in advancing knowledge, spurring innovation, and in keeping Americans safe and healthy by curbing the toll of disease and improving longevity. As any review of the NIH is undertaken and new proposals related to its structure are considered, SWHR strongly urges that the Committee take every possible precaution to safeguard the agency from policy changes that could jeopardize its mission, stability, or core infrastructure.

Thank you for your time and consideration. We would welcome the opportunity to discuss this and more specific ways in which the NIH can better integrate the role of sex and gender differences across the research enterprise to further advance the health of women. Should you have questions or need additional information, please contact SWHR's Public Policy & Advocacy Manager Madelyn Adams at madelyn@swhr.org or me directly at kathryn@swhr.org.

Sincerely,



Kathryn G. Schubert, MPP, CAE
President and Chief Executive Officer
Society for Women's Health Research

² McKinsey & Company. Closing the women's health gap: A \$1 trillion opportunity to improve lives and economies. 2024. Available from: <https://www.mckinsey.com/mhi/our-insights/closing-the-womens-health-gap-a-1-trillion-dollar-opportunity-to-improve-lives-and-economies>.