American Society of Pediatric Nephrology
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August 16, 2024

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

Submitted via email to NIHReform@mail.house.gov

Dear Chair McMorris Rodgers,

On behalf of the American Society of Pediatric Nephrology (ASPN), thank you for the opportunity to submit these comments on your reform framework for the National Institutes of Health (NIH). Founded in 1969, ASPN is a professional society composed of pediatric nephrologists whose goal is to promote optimal care for children with kidney disease and to disseminate advances in the clinical practice and basic science of pediatric nephrology. ASPN currently has over 700 members, making it the primary representative of the Pediatric Nephrology community in North America.

NIH's support for pediatric nephrology research is critical to support advances in our understanding of the basic science of, and to develop new treatments for, pediatric kidney disease. Because the causes of chronic kidney disease and end-stage kidney disease (ESKD – the need for chronic dialysis or a kidney transplant) in children differ from those in adults, investment in pediatric-specific research is particularly important to improve the health outcomes of this small, vulnerable population of children. ASPN is invested in ensuring that NIH remains the leader in pediatric kidney disease research specifically, and biomedical research generally, in this country. Like you, we believe that the world's largest biomedical research organization should be reauthorized. A reauthorization process is an opportunity to ensure that the NIH is working to its fullest capacity and that its structure and policies are optimized to support its mission.

With this understanding, ASPN supports efforts to reauthorize NIH but has grave concerns about the process being employed. The reauthorization of a $48 billion agency should be a bipartisan and bicameral process that includes a series of hearings, done in consultation with leadership across NIH, and with multiple opportunities for stakeholder input. It is unclear how the framework was developed, but it was not through a thorough bipartisan and bicameral reauthorization process that included hearings and multiple opportunities for public comment.

As you consider launching a more inclusive reauthorization process, ASPN shares your goals of breaking down silos and supporting life course research at NIH, which are particularly important to advance research in general pediatrics and pediatric nephrology. We would like to offer these specific comments about the reforms included in the framework.

Regarding the institute and center organization, ASPN is very concerned that these changes are not grounded in scientific and public health principles. The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) is the home—but not the only funder—for pediatric kidney disease research. In the framework, it is proposed to become part of a new National Institute on Body Systems Research along with the National Heart, Lung, and Blood Institute (NHLBI), and the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS). Under the proposal, this new consolidated institute will still be funded at a lower level than the National Cancer Institute. ESKD is the only condition that automatically qualifies individuals under 65 years of age, including children, for Medicare. In 2020, Medicare spent $37.1 billion on ESKD.[1] This federal investment in care for individuals living with ESKD makes it paramount that a significant federal investment be made in ESKD and other kidney disease research. By including NIDDK in a larger body systems research agency, ASPN is concerned that the needed focus on kidney disease research will be diluted.

Our concern is even greater for pediatric-specific kidney disease research since fewer than 10,000 children and adolescents have ESKD.[2] To continue to advance our understanding of pediatric kidney disease, any new institute must have expertise in this area. In a new, much larger institute, the review process may become a barrier to research investment. The critical depth of subspecialty scientific knowledge required by reviewers to assess grant proposals may be lost. Already potential grantees share that their grants are not being evaluated by reviewers with pediatric expertise. Any further dilution of the expertise by grant reviewers could be catastrophic to the future advancement of the field. ASPN cannot support policies that would discourage early-stage investigators from entering the field of pediatric nephrology, which is already experiencing a workforce shortage. Additionally, NIDDK currently has program officers with expertise in pediatric and adult kidney disease. In a larger, consolidated institute it is unclear whether the deep expertise required to prioritize and administer grant portfolios at the program officer level will be maintained. Retention of this expertise with the associated institutional memory is critical to supporting specialized areas of research like pediatric kidney disease.

ASPN is also concerned that the framework proposal to combine the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) with the National Institute on Deafness and Other Communications Disorders into a new National Institute for Disability Related Research will adversely affect research on child health and life span. When the NICHD was authorized in 1962,[3] it was the first NIH institute to focus on the entire life process rather

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[1] https://usrds-adr.niddk.nih.gov/2023/end-stage-renal-disease/9-healthcare-expenditures-for-persons-with-esrd

[2] https://usrds-adr.niddk.nih.gov/2022/end-stage-renal-disease/8-esrd-among-children-and-adolescents

[3] P.L. 87-838

than a specific disease or body system. This purpose appears consistent with your goal to support life span research.

From the framework, it is not clear how child health-focused research will fit within an institute focused on disabilities research. ASPN cannot stress strongly enough the importance of investing in general pediatric and pediatric subspecialty research to ensure that children grow up to be healthier adults. By understanding and treating chronic conditions manifesting in childhood, there is an opportunity to ensure the future adult population is healthier, with fewer costly health conditions. This is particularly true as it relates to kidney disease as we already have highlighted how ESKD is the only condition that guarantees an individual Medicare coverage regardless of age.

Instead of collapsing the institutes and centers as outlined, ASPN recommends that you consider other policy options to accomplish the goals of breaking down silos and promoting innovation. One alternative is to require the existing institutes and centers to devote a certain portion of their budgets to fund collaborative research with other institutes using U-grants and other existing and yet-to-be developed mechanisms to foster cross-cutting research. The Chronic Kidney Disease in Children (CKiD)[4] study funded by NIDDK, NICHD, and NHLBI is a strong example of how this collaborative work can be supported. CKiD has been funded for over 23 years and utilizes two types of U mechanisms: U01, the Research Project Cooperative Agreement, and U24, the Milestone Driven Cooperative Agreement. Other mechanisms that support would support your goals include Program Project Grants, which support collaborative thematic grants to address big health programs, and R21s, which are high risk, high reward projects that support innovation. These NIH funding mechanisms have supported significant clinical breakthroughs. By supporting more interdisciplinary research, there is an opportunity to collect organ-specific information that can be used to inform future studies and increase our knowledge of the life course of certain conditions. An NIH reform framework should differentiate between programs that have been productive and those that have not, and should use successful existing collaborations to model how institutes and centers can be shaped and interdisciplinary work promoted going forward.

ASPN also recommends that any reauthorization process examine how interdisciplinary collaboration is being supported in the research community both within and outside of NIH. Some good examples include the Federal Hypertension Leadership Council and the Kidney Interagency Coordinating Committee, which is run by NIDDK.[5,6] Much of the collaboration that the committee wishes to encourage is already happening at research institutions and in the private sector. NIH should harness some of this existing infrastructure supporting multi-institute workshops that would include diverse stakeholders and result in solicitations for new U-grants or other mechanisms that support interdisciplinary research.

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[4] https://www.niddk.nih.gov/about-niddk/research-areas/kidney-disease/chronic-kidney-disease-children-study-ckid
[5] https://www.cdc.gov/high-blood-pressure/php/fhclc/index.html
[6] https://www.niddk.nih.gov/about-niddk/advisory-coordinating-committees/kuh-icc/kicc#:~:text=The%20Kidney%20Interagency%20Coordinating%20Committee,coordinated%20Federal%20response%20to%20CKD

Additionally, ASPN urges the committee to consider policies to reduce the administrative burden associated with the NIH grant award process. The grant application process has grown increasingly complex over time, requiring more resources and time to complete and longer wait times to receive scores and funding decisions. This part of the process does not foster innovation in grant applications. We recommend looking at other groups, like the Patient-Centered Outcomes Research Institute (PCORI), that have less burdensome applications processes and faster turnaround times.

ASPN shares your goal to get more researchers into the biomedical research pathway but believes that the policy to cap the number of awards a primary investigator can receive at three may have unintended consequences as written. It is important to recognize that an investigator's grants may not all be running on the same timeline, and they may start applying for new grants while serving as primary investigator on three or more projects to ensure that they continue to receive enough funding to continue their research and support their position at their institution We urge you reconsider this proposal and explore concepts like limiting primary investigators to no more than three grants for which they serve as the sole primary investigator. This policy should not limit researchers' ability to serve as co-primary investigators. To support more multi-disciplinary research, individuals must be able to serve as co-investigator on several grants and support colleagues in collaborative research.

As you consider policies to support a robust biomedical research pipeline, ASPN would like to highlight the important role that physician-scientists play. The policies that support their participation in the biomedical research workforce will differ from those that support PhD scientists. Physician-scientists are still required to perform clinical duties, and it is becoming more challenging for them to receive enough research support to protect the time needed to support their research. Therefore, we request that the NIH institutes and centers be required to set aside funding for K and R awards for physician-scientists and for pediatric-focused grants when appropriate.

Additionally, ASPN would like to request more information on how the operation of NIH's scientific review and study sections (the groups that review grant applications for scientific merit and rank them for receipt of funding) would change under the proposed reorganization. In our meetings with NIH, we have repeatedly emphasized the need for pediatric representation, including pediatric nephrologists, on study sections. By increasing the number of pediatric specialist reviewers, pediatric nephrology researchers have had more success in the peer review process. It is critical that this not change. Our members report that the more diversity in study section participants in terms of basic, translational, and clinical researchers, gender, and racial diversity, the richer the discussion and feedback that is provided to successful and unsuccessful applicants. We urge the committee to support this diversity in any policy changes. Grant reviews also take a significant amount of time, and reviewers are compensated very little for this time and effort. This policy should be revisited to support robust grant reviews.

Finally, ASPN was pleased that your reform framework explored reforms to the allocation of indirect costs. If money saved on indirect costs would allow more grant awards to be made, we

recommend that the committee carefully explore how best to revise this system and potentially directing any savings to underfunded areas of study, like pediatric nephrology.

Thank you for the opportunity to submit these comments. Should you have any questions or require additional information, please contact Erika Miller, ASPN's Washington representative, at emiller@dc-crd.com.

Sincerely,

Meredith Atkinson, MD
President