



COALITION FOR PEDIATRIC MEDICAL RESEARCH



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Ann & Robert H. Lurie Children’s Hospital of Chicago	Connecticut Children’s
Boston Children’s Hospital	Intermountain Primary Children’s Hospital
Cincinnati Children’s Hospital Medical Center	Nationwide Children’s Hospital
Children’s Hospital Colorado	Nemours Children’s Health
Children’s of Alabama	University Hospitals Rainbow Babies & Children’s Hospital
Children’s Healthcare of Atlanta	Seattle Children’s
Children’s Hospital of Los Angeles	Stanford Maternal & Child Health Research Institute
Children’s Hospital of Philadelphia	St. Jude Children’s Research Hospital
Children’s Mercy Kansas City	Texas Children’s Hospital
Children’s Wisconsin	UPMC Children’s Hospital of Pittsburgh
Cleveland Clinic Children’s Hospital	Weill Cornell Medicine Pediatrics
Corewell Health	

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July 26, 2024

The Honorable Diana DeGette  
United States Congress  
2111 Rayburn House Office Building  
Washington, DC 20515

The Honorable Larry Bucshon, M.D.  
United States Congress  
2313 Rayburn House Office Building  
Washington, DC 20515

Dear Congresswoman DeGette and Congressman Bucshon:

On behalf of the Coalition for Pediatric Medical Research, a collaborative of leading children’s hospitals and research institutions deeply committed to advancing child health research, we are writing to provide feedback on your request for input on a next-generation Cures bill. We appreciate both your past and your prospective work on this most important topic. As we approach the 10-year anniversary of the 21<sup>st</sup> Century Cures Act, a milestone we will meet during the next Congress, we believe it is an appropriate time to review both the progress made and the challenges that remain in developing and delivering novel therapies to people in need, especially our nation’s children.

Our institutions are on the frontlines of both caring for sick children – including those impacted by complex medical conditions, rare diseases, and other serious illnesses – as well as discharging vibrant research agendas to achieve research discoveries to develop the next generation of therapies and, ultimately, cures. Our coalition was actively engaged in the efforts

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to develop the Cures Act from 2014 through 2016. We appreciate provisions that were included in the first law including those that:

- Sought to strengthen National Institutes of Health (NIH) implementation of pediatric-focused research activities.
- Authorized and funded the *All of Us* Precision Medicine initiative.
- Recognized the need to support early-career researchers on their journey toward research independence.
- Advanced policies at the Food and Drug Administration (FDA) to strengthen the voice and perspective of the patient in therapy development.

As you contemplate a Cures 2.0 bill, we offer the following recommendations for your consideration.

### **Build upon the Cures Act’s Focus on Early-Stage Researchers and Address Specific Challenges in Child Health**

We applaud that the Cures Act recognized the need for the NIH to better support early-career researchers and included Sec. 2021 focused on next generation researchers. We urge you to ensure a focus on this population as part of any Cures 2.0 bill. Specifically, we recommend that you include a career development section that incorporates the bipartisan [Pediatricians Accelerate Childhood Therapies \(PACT\) Act](#) (H.R. 4714), sponsored by Reps. John Joyce (R-PA) and Kim Schrier (D-WA). This bill would create a new training model focused explicitly on promising early-career researchers focusing on child health, including those from backgrounds under-represented in pediatric research. Including this bill would be a tangible way to infuse training dollars into child health research training programs, helping reverse declines that have occurred over the past several years.

A robust pipeline of research talent is essential to achieving research breakthroughs. Including the PACT Act in a Cures 2.0 would address this need and would also speak to the findings and recommendations made in September 2023 by the National Academies entitled [The Future Pediatric Subspecialty Workforce: Meeting the Needs of Infants, Children, and Adolescents](#). Notably, the report includes recommendation 6-2 that calls for the NIH to “increase the number of career development grants in pediatrics, particularly institutional training awards...with attention to providing such grants to physician-scientists from backgrounds that are underrepresented in the scientific workforce...”<sup>1</sup>

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<sup>1</sup> National Academies of Sciences, Engineering, and Medicine. 2023. *The Future Pediatric Subspecialty Physician Workforce: Meeting the Needs of Infants, Children, and Adolescents*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/27207>.

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If we fail to heed these warnings and recommendations, we will see a further erosion of the pediatric research workforce pipeline. This will result in several consequences not just for child health interests but for research activities more broadly given the well-established Development Origins of Health and Disease (DOHaD) theory that many adult-onset diseases and conditions are rooted in early life. It is also important that the research workforce be reflective of the population being addressed, which is why the PACT Act also includes a provision to support development of highly qualified researchers from populations that have historically been underrepresented in the pediatric researcher community.

### **Addressing Gaps in NIH Support for Child Health Research Activities**

We also encourage you to consider as part of any Cures 2.0 legislation policies to strengthen how the NIH focuses on child health and lifespan research. One ongoing concern has been the exclusion or minimization of the role of pediatrics in many signature NIH undertakings over the past decade plus. Examples of this include:

- Underrepresentation of child health interests in initiatives such as the Cancer Moonshot, the Clinical and Translational Science Awards (CTSAs) and the *All of Us* Precision Medicine Initiative.
- Grant application structure and process issues that make it difficult, if not impossible, for children's hospitals, as non-degree-granting institutions, to apply for certain funding opportunities.
- An overall climate that minimizes funding and support for child health and lifespan research activities despite the increased recognition that health or ill-health later in life is rooted in the childhood years.

To address these concerns, we encourage Congress to require that NIH include an adequate focus on child health as part of any major undertakings such as the Cancer Moonshot, *All of Us* initiative, Common Fund programs and the like. This should include a clear statement as to how the agency will incorporate a child health component as part of each program or, if there is no such plan to do so, a clear explanation as to why. We also encourage you to require the NIH to conduct a comprehensive assessment of its grantmaking policies to identify gaps that inhibit academic children's hospitals or other institutions from competing and to identify solutions to address the problem. Finally, we encourage you to authorize an NIH review of its process for indexing research projects in its Research Portfolio Online Reporting Tools (RePORT) and Research Condition, and Disease Categorization (RCDC) databases to determine if such reporting accurately reflects the focus of a research project. This indexing impacts how research activity is reported and categorized. It is essential that such indexing be as accurate as possible to present the most accurate reporting of NIH spending.

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## Improving NIH Management and Prioritization of Child Health Research Activities

Our coalition supported the establishment of the NIH Pediatric Research Consortium (N-PeRC), which was launched in 2018 to “improve child health research coordination and collaboration across the agency’s 27 institutes and centers and offices.”<sup>2</sup> We support this intent but are concerned that N-PeRC has not lived up to its expectations and believe it could be strengthened further. We encourage you to include within Cures 2.0 legislative text, also included in the PACT Act, that would strengthen N-PeRC by:

- Enabling regular engagement with outside experts to help inform the work and ensure the NIH is hearing from key external partners.
- Requiring reporting on outcomes associated with N-PeRC, particularly multi-institute research initiatives and the inclusion of child health components within larger NIH initiatives.

We also request that you give consideration to other structural issues that could improve how the NIH discharges its pediatric research agenda. Specifically, we believe there is value in establishing an Office of Child Health Research within the Office of the Director that would be tasked with managing the pan-NIH child health research agenda. Such an office would build upon N-PeRC but provide a greater level of accountability. Should Cures 2.0 explore larger structural issues within the NIH, we encourage you to consider establishing such a cross-cutting office.

## Reauthorization of the *All of Us* Initiative

The 21<sup>st</sup> Century Cures Act authorized the *All of Us* Precision Medicine Initiative and appropriated funding for the program for 10 years. Unfortunately, the program has yet to move forward in recruiting children. While a pediatric director was hired in late 2022 and plans to recruit children have been in the works, resource limitations are now threatening the ability to recruit children. Failure to recruit children into the program in numbers that reflect their percentage of the nation’s population will miss significant scientific opportunities, not only for children but for lifespan research.

We encourage that you include within Cures 2.0, reauthorization of the *All of Us* program. Such a reauthorization should focus on the future vision and next stage of this initiative, including ensuring adequate funding for child recruitment and ongoing research activities. Additionally, reauthorization language should address other needs associated with fully leveraging the data collected, including longitudinal studies and other research activities. The *All of Us* program was initially proposed nearly a decade ago, in September 2015. Given the time that has elapsed, we

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<sup>2</sup> See <https://www.nichd.nih.gov/research/supported/nperc>.

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believe the time is now for Congress to assess the current and future needs associated with the *All of Us* Program and its intended goals and objectives.

### **Conclusion**

Thank you, again, for your leadership on a Cures 2.0 initiative and for soliciting this feedback. We appreciate your commitment to this work and hope that we can collaborate with you to ensure that any Cures 2.0 legislation includes robust pediatric research provisions. If you have any questions or if you would like to discuss any of our thoughts further, please reach out to Nick Manetto at 202.312.7499 or [Nicholas.manetto@faegredrinker.com](mailto:Nicholas.manetto@faegredrinker.com) who can facilitate a meeting or call.

Sincerely,

### **The Coalition for Pediatric Medical Research Steering Committee**

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