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"Investing in Public Health Legislation to Support Patients, Workers, and Research"
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Good morning Chairwoman Eshoo, Ranking Member Guthrie and members of the Subcommittee and thank you for convening this hearing on this most important topic and for inviting me as a witness.

I am Leslie Walker-Harding and I presently serve as Chair of the University of Washington School of Medicine Department of Pediatrics and as Senior Vice President and Chief Academic Officer of Seattle Children's Hospital. I am an adolescent medicine pediatrician by training and have worked extensively in the field as well as in the field of adolescent substance use disorders. In addition to my roles at the University of Washington and Seattle Children's, I serve as an executive committee member of the Pediatric Scientist Development Program (PSDP) run by the national Association of Medical School Pediatric Department Chairs (AMSPDC), in which I am also an elected board member. Additionally, I serve as a member of the steering committee of the Coalition for Pediatric Medical Research, which is an alliance of more than two dozen of the country's most research-intensive children's hospitals.

I will focus my opening remarks primarily on H.R. 3773, the Pediatricians Accelerate Childhood Therapies Act which is led by Dr. John Joyce and my good friend – and the only pediatrician serving in Congress today, Dr. Kim Schrier – and that was co-led led by another health policy leader from the Washington State delegation, ranking Member McMorris Rodgers, last Congress. I will also speak to the importance of H.R. 7845 to enhance the diversity of clinical trial participation.

The PACT Act and the NIH Clinical Trial Diversity Act focus on three core principals that are needed to achieve more research breakthroughs for children and other populations:

- First, the PACT Act recognizes that a robust Pediatric research workforce – particularly a pipeline that includes early-career researchers – is fundamental to achieving breakthroughs that will lead us to new therapies, treatments and cures for children and adolescents. Simply put, if we don't attract and retain the next generation of pediatric scientists to the field, we won't realize the scientific discoveries that benefit the health of all of us. Children and adolescents will continue to suffer the effects of diseases and syndromes that impact them into adulthood that might otherwise have been treated or cured.
- The PACT Act also recognizes that our pediatric research workforce needs to better reflect the diversity of our nation's children. The current research workforce has not adequately been available to groups currently underrepresented in pediatric science. This imbalance

limits the diversity of questions asked and studied, resulting in fewer solutions to be applied to improve the health of all children.

- And the NIH Clinical Trial Diversity Act recognizes that our clinical trials need to better reflect our nation's population, particularly when it comes to the very patients the candidate therapies are intended to treat.

The core of the PACT Act is simple: it would authorize the National Institutes of Health (NIH) to create a career development award that focuses on developing early-career researchers who are focusing their careers in pediatrics, particularly those researchers from populations that have been historically under-represented in the field. It seeks to leverage and codify the existing Trans-NIH Pediatric Research Consortium or N-PerC to support this award across all NIH Institutes and Centers and is modeled upon other training programs authorized by Congress as well as the Next Generation Researchers initiative created by the 21st Century Cures Act. Before I speak to more of the details of the PACT Act, I want to focus on the problems we are trying to solve.

Developing our next generation of researchers is a top priority of my institution, and we have several programs focused on this objective. At Seattle Children's Research Institute, we conduct research that spans basic laboratory and preclinical science to clinical trials and community participatory research. To attract a wide range of early career research scientists with diverse lived experience, we created internally funded career development 3-year awards to support a MD, MD/PhD or PhD just after the completion of their post-doctoral or medical fellowship training so they can benefit from 3 years of mentorship and funding in order to be successful in acquiring NIH career award funding. This program has helped center directors and principal investigators look for promising recent trainees that can come and flourish in the Institute.

We also have developed an intentional program identifying the principal investigators who are eligible for a diversity supplement award from their NIH grant and to help them complete the application process. This has resulted in more than a dozen diversity supplement awards over the last three years. This Children's program has been presented and shared nationally as a way to leverage resources already available to diversify and engage pediatric research scientists in their very early years. This funding has resulted in Seattle Children's Research Institute employing our college research summer internship participants in long-term research projects of their own and helping to launch their research careers. It has also helped provide key funding at the early entry level to help post-doctoral students prepare to submit for career award funding. Ultimately, this strategy has been successful and resulted in new faculty members joining our institution.

Unfortunately, these types of programs that develop promising pediatric researchers into impactful scientists are not sustainable or feasible for most academic or children's hospital programs to fund indefinitely. At the current rate of recruitment of diverse underrepresented researchers, it would take decades to achieve gender equity and centuries to realize racial and ethnic equity. We cannot afford to wait that long. A federal solution will be important to ensure

that all potential scientists have access to support regardless of where they live in this country including particularly rural or remote locations.

As several of my colleagues noted in a recent *Nature* piece, the structure of pediatrics places our field at a disadvantage. The smaller proportion of the overall population represented by children as compared with adults and the relatively smaller pediatric fields of discovery compared to fields focused on adults means the majority of funding is directed toward adult disease. Departments of pediatrics are typically smaller than our peer adult departments, and our clinician-researchers often have to spend more time on clinical service, which means that they have less time available to spend in the lab or community on research pursuit.

Additionally, children's hospitals rely heavily on Medicaid and Children's Health Insurance Programs (CHIP) as payors. These programs pay not only less than commercial payers and Medicare, they also do not cover the actual cost of care. At Seattle Children's, Medicaid covers about 60 percent of the true cost of care we provide our patients. This means our systems are stretched to keep the clinical system running and do not have sufficient funds to invest in research.

Freestanding children's hospitals also are frequently excluded from applying to NIH funding proposals leaving higher education institutions as the only eligible recipients allowed to apply for NIH grants. This further limits any potential to attain federal funding for pediatric research for the institutions whose sole focus is the health and well-being of children and adolescents. Given that many pediatric diseases and conditions are rare, many research initiatives need to include collaborations of multiple institutions, particularly those programs in the translational and clinical stages, to obtain adequate study populations. But barriers to participation by certain institutions as well as the minimization or outright exclusion of pediatrics in larger initiatives impede this endeavor. For example, though we are several years into recruitment of the NIH's precision medicine or *All of Us* program, the program has yet to implement a child recruitment strategy.

Pediatrics also faces significant demographics challenges given that the field has tended to attract a larger share of women than other fields of medicine. This should give pediatrics the ability to realize gender equity in research faster, but unfortunately this is not the case as the systems are not in place to fully account for and accommodate the women that have joined the field of medicine. The COVID-19 pandemic and shuttering of research activities was particularly challenging for early-career researchers working to establish themselves and was especially difficult for women researchers who navigate pauses in their careers to have children and to raise their children.

Typical educational institutions have a timeline by which a researcher must achieve independent research funding; if they are not successful, they are considered unable to meet the responsibilities of a researcher and leave before they reach a full state of maturity in their field. This is also a significant challenge for researchers from underrepresented communities who have the additional burden of overcoming bias in many areas, such as in applying for research funding. NIH has documented that all other things being equal, it takes more years for African American

researchers to get their first grant funded compared to White early-career researchers. There are many hurdles to climb to make sure our country's potential Nobel prize winners in pediatric discovery are cultivated and supported to success.

To add to these challenges, we have unfortunately seen sharp reductions in recent years to several longstanding NIH-supported pediatric-focused career development awards, such as a more than 60 percent reduction during the past decade to the number of training slots supported by the highly successful Child Health Research Career Development Award.

All of these challenges come at a time when advancements in research, including precision medicine, are making it abundantly clear that many diseases and illnesses with onset during adulthood are actually rooted in the pediatric development period, meaning that better supporting pediatric research has widespread implications for both healthier children and healthier adults. So, what should we do to solve the problem?

As noted earlier, the PACT Act seeks to address these challenges by creating a career development award program to support outstanding early-career researchers focusing their career on pediatric research. Awards would go to individual researchers and could also support training programs involving research entities and minority-serving institutions to help develop more researchers from under-represented populations. By focusing awards on individual researchers, the program would not favor only those researchers at the largest institutions and would cast a broad net for talent.

Award funds could be used by recipients to support laboratory operations and scientific pursuits, obtain mentorships, publish research findings and engage in other activities that are fundamental for moving into mature research careers. The goal is similar to what Congress has undertaken through by the Cures Act and other more targeted career development and training programs – to better support and develop the next generation of research talent, the people we need in our labs to obtain the research breakthroughs to improve our knowledge of illness and to develop new therapies and treatments for children and beyond.

I will also note that in addition to authorizing this award program, the bill would codify the Trans-NIH Pediatric Research Consortium, N-PeRC that was established by NIH and the *Eunice Kennedy Shriver* National Institute for Child Health and Human Development in spring 2018. This is an important action to give the N-PeRC permanence and will also require some reporting on its efficacy and impact.

I thank you for including the PACT Act on this agenda and urge you to advance the bill forward so it can be enacted into law this Congress.

I will now turn to H.R. 7845. As I mentioned earlier, just as we need a pediatric research workforce that reflects the demographics of our nation, so to do we need to ensure our clinical trials look like the people the medications are intended to treat. At Seattle Children's we have increasing diverse research participants as an organization goal, measuring and accounting for

changes on a monthly basis. This is hard work and takes having diverse research teams, access to language translation and interpretation other than English and cultural understanding and it takes a better understanding of priorities of families from different lived experience. We are currently focusing on our new language lab as a core service to researchers so they can recruit anyone who is seen in the hospital system without regard to language spoken. It is one of the most highly subscribed services despite opening only a few months ago. I have sat on study sections and observed how many people exclude participants that speak languages other than English due to lack of resources, this is one barrier to having diverse research participants in Pediatrics. There are many solutions to these barriers.

H.R. 7845 will require clinical trials sponsors funded by the NIH to have detailed plans for implementing trials that reflect diverse participation, including plans to reduce burdens on participation to help capture participants who may not be able to meet typical trials requirements such as only in-person follow-up visits or appointments limited to the working day. Importantly, it gives guidance on the importance of including community partners in reviewing and advising on research plans. It also requires sponsors who fall short of their goals to implement a remediation plan and authorizes both a study to explore ways to eliminate barriers that hinder recruitment of more diverse participants as well as a public awareness campaign to enhance participation, including through promotion of best practices.

I support the intent of the legislation to improve diversity of clinical trials funded by the NIH and appreciate the recognition of the barriers that make this difficult today.

Lastly, I was very happy to see legislation to authorize the Advanced Research Projects Agency-Health or ARPA-H pass the House last week. ARPA-H is another opportunity to make sure that big ideas and bold answers to biomedical questions can encompass research that includes outcomes for all ages. We must make sure developmental and pediatric age approaches and concerns are included intentionally to help us create a new future with science for everyone.

Thank you again for inviting me to testify, and I look forward to your questions and to the discussion.