



May 14, 2015

The Honorable Joe Pitts  
Chair  
The Honorable Gene Green  
Ranking Member  
Subcommittee on Health  
2125 Rayburn House Office Building  
Washington, D.C. 20515

Dear Chairman Pitts and Ranking Member Green:

On behalf of the National Down Syndrome Society (NDSS) and the more than 400,000 people living with Down syndrome in the United States, I am writing to express our support for the bipartisan 21<sup>st</sup> Century Cures Initiative, which will significantly improve the process for developing new treatments, diagnostics and tools for effective clinical trials. We appreciate your efforts to refine and improve the legislation, and encourage you to continue doing so as the legislative process advances.

NDSS's mission is to be the national advocate for people with Down syndrome and their families. The organization is at the forefront of supporting initiatives that advance the biomedical research field in Down syndrome and related conditions. NDSS is working with other national Down syndrome groups, biomedical and clinical researchers, the National Institutes of Health (NIH) and local service providers to cooperatively develop the infrastructure for sustainable and continuous multi-institutional and state-of-the-art clinical trials in an effort to improve health outcomes and the quality of life for all people with Down syndrome.

Biomedical research has advanced to the point where scientists now have a much better understanding of the genetic basis for cognitive and medical impairments associated with Down syndrome, and they have made unprecedented progress towards identifying effective treatments. The advances in clinical research infrastructure support that will come about as a result of the 21<sup>st</sup> Century Cures Initiative are vital to our efforts to translate research achievements into real treatments and therapies. However, as you move forward with this legislation, we urge you to consider additional concepts that have the potential to significantly improve our understanding of related psychiatric and medical conditions.

Specifically, a lack of research on individuals who have numerous co-occurring and/or simultaneous psychiatric and medical conditions has, in many instances, been an impediment to the development of clinical and behavioral treatments and interventions. A clear and compelling example relates to the cognitive function of individuals with Down syndrome. According to the NIH, at least one-half of all children with Down syndrome also have one or more comorbid conditions. During the early years of life and across their lifespan, these comorbid conditions could have the potential to significantly affect cognitive function and overall health.

For many rare or near-rare diseases and conditions, the scientific and biomedical research community lacks sufficient tools and resources to develop coordinated and integrated systems for measuring, for purposes of clinical outcomes, the differences in variability related to co-occurring psychiatric or medical conditions and genetic differences among individuals. Authorizing NIH to develop classification and measurement tools for comorbid conditions would significantly expedite ongoing efforts in the scientific research and medical community to develop effective clinical and behavioral treatments and interventions. Psychiatric and medical conditions that could benefit from NIH's partnership in the development of such tools include, in addition to Down syndrome, Alzheimer's disease, childhood leukemia, congenital heart disease, autism spectrum disorders, sleep apnea and epilepsy, to name a few.

We welcome the opportunity to work with you on appropriate and effective ways to improve our understanding of comorbid conditions and the health outcomes of people with those conditions. Thank you for your leadership and commitment to this important initiative.

Sincerely,

A handwritten signature in cursive script, appearing to read "Sara Weir".

Sara Weir  
President  
National Down Syndrome Society