



Archived Policy Statement

House Committee on Science and Technology Subcommittee on Technology and Innovation

Written Public Testimony
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Chairman Wu, Congresswomen Edwards and Biggert, and Committee Members. Thank you for this opportunity to testify at this hearing on the National Institute of Standards and Technology.

I ask that my written testimony be accepted into the record.

Today you will hear from accomplished researchers and leaders in their fields of study from Duke University and Stanford. These individuals are scientists, entrepreneurs, and biotechnology innovators.

I come here primarily as a mom. I am here today to address the critical link between my experience as a mother striving for treatments, for my kids and millions of others, and the question before this Committee: *How our National Institute of Standards and Technology can more effectively influence innovation in life sciences.*

I begin with a plain statement about NIST and its activities—it can appear to be boring, non-interesting, and terribly esoteric. NIST suffers from being hidden, embedded into the foundational infrastructure of the scientific and early commercial enterprise of innovation, as well as having the thankless task of creating measurement standards for a whole array of scientific disciplines. However, it is precisely because of these elements that this Committee needs to champion a more active role for NIST in the life sciences.

Some have argued quite convincingly that the next century of scientific and technological innovations will be most profound in the life sciences. NIST is critical to a robust biomedical enterprise and must contribute high-quality materials, methods, and expertise for the field to advance on a platform of certainty and high-quality measurements.

My two children were diagnosed with a genetic disease 15 years ago. As a result, I chose to leave my career as a college chaplain and become involved with the life sciences and biotechnology in a search for a solution for their disease. I started a research foundation called PXE International, organized patient populations around the world, created a biobank, isolated

the disease gene, developed a commercial diagnostic, created animal models, and have supported clinical inventions for adults living with the more severe forms of the disease. We still do not have a treatment intervention for my children. We are still hard at work.

We have been stymied by a number of measurement and experimental roadblocks in advancing clear understanding of the disease and the function of the altered protein that causes my children's condition. We have smacked into the wall of both scientific and technological limitations.

My foundation's research work has been written about in prestigious journals as a model of innovation and an example of the power of patient-driven translational research. Some have said that our work will change the future of biomedical research and medical practice in this country. But I am telling you today we are now limping toward the finish line of our objective because of the current limitations in measurement science. This science has real-world impact on patients, families, and communities.

At this time, each provider of biomedical tests and therapies is creating its own system, leading to widespread inconsistencies between these practices. Americans believe that they are receiving healthcare that is high-quality, accurate, valid, useful, and consistent. They do not realize that a PSA test from one lab cannot be compared to another lab. They have no idea that the 4 million newborns who received screening at birth this year are subjected to different screening cutoffs in each of the state programs for the somewhere between 29 and 54 tests. States count the number of screens they conduct differently from one another because there are no standards. The 2,700 genetic tests listed in *Gene Tests* (<http://www.ncbi.nlm.nih.gov/sites/GeneTests/?db=GeneTests>) are purported to be actually hundreds of thousands of tests because of the variability across the labs performing these tests in the U.S. and beyond. No one knows how many tests there are, and there are only standards for 35 analytes.

Every technology manufacturer applies relevant measurement technology with its own standard references and controls, in housekeeping genes and general control reagents, for example. The Food and Drug Administration, as a regulatory agency, is challenged with ascertaining the accuracy and precision of these technologies based on the manufacturers' supplied standards. Ultimately, they must trust the manufacturers.

NIST must take a leadership role in creating the standards necessary to integrate new technologies into medicine. These technologies, in genetics, genomics, laboratory science, and imaging, are migrating into healthcare, sometimes to point-of-care. It is critical that patients know that these healthcare services are based on the certitude that only standards can bring.

With Congress's increased support, NIST should:

- 1.) Create a life sciences infrastructure, catalog, and distribution system for reference materials and standards for quality assurance for all clinical diagnostic tests.
- 2.) Integrate measurement standards and technologies into the FDA regulatory regime.

- 3.) Partner with the National Institutes of Health on resolving the measurement challenges at the intersection of patient care.
- 4.) Conduct a comprehensive analysis of the life sciences to determine the highest needs for measurement science.

In this age of emerging personalized medicine, delivered through new technologies to patients today, we cannot wait any longer, having far outstripped the standards available to biomedical enterprises. Leading Genetic Alliance, and feeling the urgency of the hundreds of millions of people who need answers today, I know we need excellent leadership in an exceptional age. Let us take this charge seriously. Every one of us has a role to play, and NIST is poised to do great things. Thank you for the opportunity to contribute to the important work of this committee.

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