

**U.S. HOUSE OF REPRESENTATIVES  
COMMITTEE ON SCIENCE AND TECHNOLOGY  
SUBCOMMITTEE ON TECHNOLOGY AND INNOVATION**

**HEARING CHARTER**

*How Can NIST Better Serve the Needs of the Biomedical Research Community in the 21<sup>st</sup> Century?*

**Wednesday, February 24, 2010  
2:00 – 4:00 pm  
2318 Rayburn House Office Building**

**1. Purpose**

On February 24, 2010, the Subcommittee on Technology and Innovation will hold a hearing to examine ways in which NIST could better serve the needs of the biomedical community. This hearing is a follow-up hearing to the hearing held on September 24, 2009, entitled: *The Need for Measurement Standards To Facilitate Research and Development of Biologic Drugs*.

**2. Witnesses**

**Dr. Thomas M. Baer** is the Executive Director of Stanford Photonics Research Center at Ginzton Lab.

**Sharon F. Terry, MA** is the President and CEO of Genetic Alliance.

**Dr. Daniel Sullivan** is a Professor and Vice Chair for Research in Radiology at Duke University Medical Center and Science Advisor to the Radiologic Society of North America.

**3. Background**

On September 24, 2009, the Science and Technology Committee for the House of Representatives, Subcommittee on Technology and Innovation, held a hearing to examine the need to develop measurements, reference materials, reference standards, standard processes, and validation procedures to improve the research, development and regulatory approval of biologics.<sup>1</sup> In the September 24<sup>th</sup> hearing, industry and the FDA expressed that there is a need for NIST to perform basic measurement science research to support the growth of the biologics industry.

Additional initiatives in the biomedical field have been proposed by NIST, including performing metrology research to support better diagnostic testing and the development of personalized medicine. Developing reference standards and materials in each of these areas could potentially

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<sup>1</sup> Hearing available at: [http://science.house.gov/publications/hearings\\_markups\\_details.aspx?NewsID=2597](http://science.house.gov/publications/hearings_markups_details.aspx?NewsID=2597).

lead to a substantial savings in the cost of healthcare, supporting innovation in the biomedical field, leading to job creation. For example, in the area of personalized medicine, the development of basic measurement science, particularly in the area of proteomics and biomarker discovery, could enable small biotech companies to utilize their more limited resources to develop therapies targeted to specific populations of patients. This, in turn, could lead to the growth of the biotech industry which has traditionally fostered innovation through small and start-up biotechnology companies.

As another example, interpreting the results of diagnostic tests can be inconsistent and inaccurate, leading to the need for multiple testing of the same patient and/or the use of less effective treatment options. In the area of imaging tools, such as x-rays, magnetic resonance imaging (MRI) and positron emission tomography (PET), interpretation of the results is a subjective task; however the treatment of disease is an increasingly objective process given the multiple options available to patients. In addition, medical imaging devices vary from hospital to hospital, thus increasing the likelihood that results obtained from different machines using different standards and methods will not be comparable. Hence, better reference standards are needed to assist doctors in interpreting diagnostic medical imaging results objectively and consistently to improve patient treatment options.

In a third example, as recently as 1980, the measurement uncertainty for cholesterol tests was more than 10 percent. This wide margin of uncertainty meant that large numbers of people were misdiagnosed as needing treatment when they did not, or not needing treatment when they did. After an investigation by the Subcommittee, NIST, in collaboration with the Centers for Disease Control and Prevention, developed a Standard Reference Material, which reduced the uncertainty level of these tests to 5 percent saving millions of dollars per year in unneeded treatment costs and improving the quality of health care for patients.<sup>2</sup>

All of the initiatives proposed by NIST in the biomedical field will require a substantial investment of resources and funding. As suggested in the September 24<sup>th</sup> hearing, in addition to providing increased funding to NIST for these programs, structural and managerial improvements would also be desirable to help NIST accomplish its goals in the biomedical area.<sup>3</sup> The National Research Council, while approving of the efforts of NIST in the biomedical area, has indicated that improvements may also be made to NIST, and particularly to the Chemical Science and Technology Laboratory (CSTL), in order to maximize the impact of these efforts on the advancement of biomedical science.<sup>4</sup>

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<sup>2</sup> See [http://www.nist.gov/public\\_affairs/techbeat/tb9709.htm](http://www.nist.gov/public_affairs/techbeat/tb9709.htm).

<sup>3</sup> *The Potential Need for Measurement Standards to Facilitate the Research and Development of Biologic Drugs*, Hearing before the Subcommittee on Technology and Innovation, Committee on Science and Technology, House of Representatives, 111<sup>th</sup> Congress, 1<sup>st</sup> Session (September 24, 2009), Ser. No. 111-53 at p. 86.

<sup>4</sup> The National Research Council, for example, suggested that:

The Biochemical Science Division should identify what it considers to be success in the context of NIST. There may be too many small efforts to make a major impact. An overarching strategy should be articulated and priorities set, based on identifying what kinds of activities can best be done in the NIST environment. Many of the groups have done this, but a top-down alignment of research with the division mission is missing. Once this is achieved, the management team will have less difficulty in sifting through the projects to determine which are the most important to pursue going forward.

The Subcommittee will examine ways in which the NIST Director could improve biomedical research at NIST to accurately and effectively reflect the needs of the biomedical community. In particular, biomedical research at NIST should be structured to achieve the following: (1) increase NIST's technical expertise through collaborations with academic institutions, private industry and nonprofits; (2) increase and improve NIST's outreach efforts to industry, academia and nonprofits; and (3) develop mechanisms that allow for NIST to obtain effective and targeted input and feedback from industry, academia and nonprofits.

As examples, the Subcommittee, with input and comments from experts in the biomedical field, will examine whether the following proposals may improve the ability of NIST to serve the needs of the biomedical community:

1. Development of an advisory board or panel of experts, largely from industry, in the biomedical field to provide guidance on focal areas and to discuss CSTL's official activities.
2. Proving for the establishment of joint NIST university centers for biomedical research at universities with strong reputations for their biotechnology programs.
3. The establishment of a user facility at NIST that could be used by industry and academia, similar to the NIST Center for Neutron Research.

Further, the Subcommittee has asked witnesses to provide comments on any additional changes that the NIST Director may implement that would improve NIST's ability to achieve the goal of providing the most effective service to the biomedical community, patients and doctors.

#### **4. Witness Questions**

The following questions were asked of each witness:

- If NIST expands its involvement in performing measurement science to develop measurements, reference materials, reference standards, standard processes, and validation procedures in the biomedical area, what future and nascent areas of biomedicine will be most affected and how?
- Would the following elements assist NIST in ascertaining current and future metrology needs for the biomedical community? If so, how?
  - an advisory board for CSTL.
  - a NIST university center for biomedical research.

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*An Assessment of the National Institute of Standards and Technology Chemical Science and Technology Laboratory, Fiscal Year 2009, Panel on Chemical Science and Technology Laboratory Assessments Board, Division on Engineering and Physical Sciences, National Research Council of the National Academies (p. 17).*

- a user facility at NIST that could be used by industry and academia.
- What other recommendations would you make regarding the implementation of these or other elements?