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How Can NIST Better Serve the Needs of the Biomedical Research Community in the 21st Century?

Chairman Wu, Congresswoman Edwards and Biggert, and Committee Members:

Thank you for this opportunity to testify before the Technology and Innovation sub-committee on *How NIST Can Better Serve the Needs of the Biomedical Research Community in the 21st Century*.

My name is Tom Baer, and I am the Executive Director of the Stanford Photonics Research Center and a Consulting Professor in the Applied Physics Department at Stanford University. Although my early training and scientific research was in Physics, I have spent most of my career working in the fields of biotechnology and biomedicine, primarily in the private sector. I have been a research scientist, founder, CEO, and senior manager in several biomedical companies in Silicon Valley and have developed technology used in the diagnosis of AIDS, quality control of bone marrow transplants, and the molecular analysis and diagnosis of breast and lung cancer.

I have a long association with NIST, having worked with several directors and lab managers, serving six years in the 1990s on the NRC review panels for both the Physics and Chemical Science and Technology Laboratories. I have also served for the past four years on the Visiting Committee for Advanced Technology (VCAT). I want to clearly state that in my testimony today I am presenting my own perspective on the topics being discussed, and I am not speaking on behalf of the VCAT committee. However, my perspective has been influenced by many in-depth discussions held with my colleagues on the VCAT, and we share similar views on many of these issues.

My long association with NIST has instilled in me a deep respect for this government agency, its personnel, and its unique mission. NIST's world class measurement science and standards development activities can form an important framework for innovation, enhancing competitiveness of US industry, and supporting job creation. This is particular true in the area we are discussing today of bioscience and healthcare.

As one of the largest sectors of our economy, estimated at $2.5 trillion, healthcare makes up 20% of the total US gross domestic product and employs approximately ten million Americans. These workers provide services essential to our quality of life in this dynamic,

rapidly growing sector. In spite of the recession, US venture capital firms clearly foresee tremendous growth potential in biomedicine and biotechnology. Venture capital firms in Silicon Valley continue to fund life science startups, creating dozens of companies each year, employing thousands of workers. Startup companies translating scientific advances into important, new therapeutic and diagnostic medical procedures have been one of the largest areas of venture capital investment in Silicon Valley for the last ten years. This area is clearly one of the most important, dynamic sectors of our economy, and one in which NIST can and must play a vital role.

What is causing this tremendous growth? Technology innovation and new product engineering historically have been based on a foundation provided by the quantitative sciences: physics, chemistry and mathematics, strong areas of focus at NIST. However over the past 30 years tremendous advances in instrumentation and new technologies have stimulated extraordinary progress in the life sciences. Innovative instrumentation has opened up unprecedented capabilities for precise measurement of biological macromolecules such as DNA and proteins. Thirty years ago, using an instrument of that era, it would have taken several thousand years to sequence a human genome. The newest generation of high throughput gene sequencing instruments can sequence a human genome in less than one day. Similarly, 3 decades ago measuring the expression level of a single gene in a tumor would have taken several days or weeks in a biomedical research lab. Today we can measure the expression levels of thousands of genes simultaneously in under an hour. These measurements provide the possibility for more precise classification of cancer tumors and much more effective methods for quickly and effectively choosing optimal drug therapy. These advances make possible *personalized medicine* where custom therapies are developed and prescribed based on a patient's individual genetic makeup. Medicine is being transformed by these developments, moving from a primarily observational science to a truly quantitative discipline, hopefully soon to fully join the ranks of physics, chemistry and mathematics.

This progress presents tremendous potential for lowering medical costs by reducing the number of tests necessary to diagnose disease and by helping physicians choose the best therapies and thus helping patients avoid unnecessary medical procedures. However, capitalizing on these therapeutic and diagnostic opportunities presented by recent advances in biotechnology requires the development of standardized procedures, new reference materials, instrument calibration protocols, and a much better understanding of the science underlying these new technologies, areas where NIST can make critical contributions.

Despite the introduction of many new, effective diagnostic tests numerous challenges remain: the lack of standards, cross platform inconsistencies, and lab-to-lab variability are significant barriers to optimizing their impact. Two examples of current problems are illustrated by tests performed millions of times each year in the US: measuring levels of prostate specific antigen (PSA) to diagnose prostate cancer and thyroid stimulating hormone (TSH) essential to diagnose and treat thyroid disease. Results of PSA or TSH tests cannot be reliably compared if they are performed at different diagnostic laboratories using different measurement methods. A recent laboratory report had the

following warning in a footnote “PSA values from different methods cannot be used interchangeably.” Patients are warned to be careful about interpreting TSH laboratory results if they have moved to a new location or change laboratories. This lack of reproducibility in test results confuses patients, causes much concern in medical practitioners, makes appropriate therapeutic intervention much more difficult, and often increases medical costs by creating a demand for multiple, repeated testing. NIST, specializing as it does in measurement science and standards development, could help to vastly improve test consistent and accuracy, substantially reducing medical costs.

Translating the tremendous advances in quantitative biology instrumentation into effective diagnostic tests will require developing standard reference materials, reproducible consensus protocols, and understanding the basic measurement science underlying these new quantitative biomedical instruments. Much of this work has yet to be done and lack of this standards framework is impeding the translation of these new technologies into medical practice, affecting the lives of many critically ill US citizens who could benefit from accelerated introduction of these breakthrough technologies. NIST can play a pivotal role in accelerating deployment of these remarkable new instruments and procedures. Other government agencies, such as the FDA and NIH focus, on different aspects of health care, regulatory affairs and disease research respectively. Both of these agencies have strongly encouraged greater involvement by NIST in supporting the health care industry by developing standards and by expanding its ongoing research efforts bioscience and healthcare.

As part of my VCAT responsibilities I chaired the Subcommittee on Bioscience and Healthcare. This Subcommittee included fellow VCAT members Lou Ann Heimbrook and James Serum, two highly experienced senior executives from the pharmaceutical and biotechnology industries. We have been working with several of the laboratory directors at NIST to help guide formation of a strategic plan to address the wide ranging needs of the Biomedical Health Care industry and research communities, as well as coordinate this program with the ongoing efforts at NIST to develop electronic medical records standards. I have found working with NIST senior management to formulate a roadmap for NIST in biomedical and healthcare to be a challenging but rewarding task, and it is still a work in process. NIST does not have a completely conceptualized and articulated a vision for how to best serve US industry needs in this area. I do feel strongly, however, that NIST management recognizes that there is an urgent need to complete this process and that there is a very exciting, critical role for NIST to play in the rapidly expanding arenas of healthcare and bioscience. One of the results of this planning was a conference designed to initiate a dialogue between NIST and stakeholders in the Biomedical Industry. The proceedings of this conference have been published in a document summarizing the opinions of the participants

NIST is at present organized by discipline with very strong laboratories in the traditional quantitative sciences. The Physics, Chemical Science and Technology, and Information Technology laboratories provide essential support to many US industries. Unfortunately NIST does not have a laboratory devoted specifically to supporting the biomedical and healthcare industry. In my opinion, NIST currently needs to add more staff familiar with

the challenges facing the pharmaceutical, diagnostic and medical device industries. NIST also needs additional resources for expanding its facilities and acquiring the equipment to develop the research programs necessary to meet the needs of these industries. Currently there are several excellent groups within NIST making very important contributions, focused on research impacting significant, specific biomedical problems. However, the VCAT has commented in past annual reports that these groups are often isolated from one another in different NIST laboratories, their efforts are not well coordinated, and they often lack sufficient resources to optimize their impact. I believe that to be truly effective NIST needs to be provided with additional resources to expand efforts in this area and establish an operating unit or laboratory specifically focused on servicing the needs of the US Biomedical/Healthcare industry.

For over a century NIST has played a very important role in many areas of quantitative science and technology providing standards and world-leading measurement science for precise reproducible measurement of many physical constants, chemical analytes, and important information on material properties. The standards and technologies developed by NIST have led to many very important and diverse advances such as GPS navigation, microelectronics and software standards, and critical standards for building materials which are integral parts of US fire codes. It is thus very appropriate for NIST to develop the expertise and facilities to play a comparable pivotal role in the 21st century in this new era of quantitative biomedicine.

Let me close my remarks by commenting on the strong leadership provided by the current director of NIST, Dr. Patrick Gallagher. Dr. Gallagher indicated at the last VCAT meeting in February, 2010 that he is working with NIST lab directories and senior managers to develop a new NIST structure that will improve NIST's ability to address the pressing needs of US industry and fellow government agencies. He is formulating a significant, exciting new vision for how NIST can best be organized to service its many, diverse stake holders. I believe that this is a great opportunity to reorganize and expand the NIST resources supporting the US biomedical and healthcare industry, and I look forward to working with him to bring about these changes.

In my testimony, Mr. Chairman you asked me to address several specific questions:

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 are the current, future and nascent areas of biomedicine that could be best served by NIST and how?

The areas where I see NIST providing the greatest service are:

1. Diagnostic medicine

    - In particular developing standards, consistent protocols, and advancing measurement science in applying quantitative molecular analysis technology to diagnostic tests
    - Supporting the application of the newest generation of quantitative imaging instruments (CT, MRI, ultrasound)
2. Working with the drug development industry to accelerate the drug development process
    - Improving our understanding of the technology needed to perform the measurements necessary to provide accurate assessment of the safety and efficacy of new drugs.
3. Working with universities and private industry to development methods for new classes of therapy enabled by advances in stem cell science. With applications, in diseases such as diabetes and organ replacement
4. Providing a sound basis for measurement science in the area of neuroscience and neuromedicine. With applications in Parkinson's disease and Alzheimer's disease.

Would the following elements assist NIST in ascertaining current and future metrology needs for the biomedical community? If so, how?

- **An advisory board made up of industry experts.**

I recommend that NIST develop several advisory boards comprised of experts from the private sector and other government agencies representing different sectors of the biomedical industry. For example, separate panels could be formed with experts from molecular diagnostics, imaging diagnostics, drug development, medical devices and biomedical materials. These advisory panels should meet regularly with NIST personnel working in these areas to help identify the critical problems that need to be addressed and to establish the most effective strategic and tactical focus for biomedical programs at NIST.

- **A university center for biomedical research**

University collaborations and joint institutes have played an important and very successful role in other NIST programs, and I believe this approach would work extremely well in the biomedical healthcare area. Specifically a university center focused on research into the fundamental measurement science underlying biomedical instrumentation and a joint institute studying the measurement science challenges inherent in the measurement of complex biological systems.

- **A user facility that could be used by industry and academia**

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A separate operating unit or laboratory would provide a critical central focus for research at NIST in biomedicine. Such a facility could support visiting scientists from industry to provide input to NIST research activities, as well as physical location for NIST researchers, postdocs, and graduate students to associate with multidisciplinary teams working in similar or related biomedical areas.