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DEVELOPMENTS IN NANOTECHNOLOGY

HEARING

BEFORE THE

COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION UNITED STATES SENATE

ONE HUNDRED NINTH CONGRESS

SECOND SESSION

FEBRUARY 15, 2006

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ONE HUNDRED NINTH CONGRESS

SECOND SESSION

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DEVELOPMENTS IN NANOTECHNOLOGY

WEDNESDAY, FEBRUARY 15, 2006

U.S. SENATE,
COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION,
Washington, DC.

The Committee met, pursuant to notice, at 2:40 p.m. in room SD–562, Dirksen Senate Office Building, Hon. Ted Stevens, Chairman of the Committee, presiding.

OPENING STATEMENT OF HON. TED STEVENS, U.S. SENATOR FROM ALASKA

The CHAIRMAN. I'm sorry to be a little late. We appreciate your being here. I do not know how many others will join us. I am going to put my statement in the record.

[The prepared statements of Senator Stevens and Senator Inouye follow:]

PREPARED STATEMENT OF HON. TED STEVENS, U.S. SENATOR FROM ALASKA

Nanotechnology is a revolutionary science, one that has the potential to change and improve many facets of our lives.

From the creation of more precise methods of targeting and treating cancer, to stronger body armor for our soldiers in the line of attack, to consumer products like straighter flying golf balls or better sunscreen, nanotechnology's potential engenders excitement, intrigue, and substantial benefits to society as a whole.

As with any technological and scientific progress, certain obstacles and challenges abound. For starters, how does one efficiently produce anything in quantity when the raw material is only one one-thousandth the width of a human hair? Or, do nanoparticles differ to such an extent from their larger counterparts in the physical world that their properties exhibit unknown or unstable characteristics? These questions lie at the heart of what we hope to examine today. In other words, what is the status of developments in the nanotech field and how will further progress in this area of science impact our everyday lives?

Because we are here in a Senate hearing room, it is only natural for us also to consider what the proper role of government is in responding to nanotechnology's tremendous promise. We want to avoid stifling this technology before beneficial applications have the opportunity to successfully enter the market. We also want to protect all consumers who are the eventual end-users of these scientific achievements. Because, after all, if a nanoproduct is not safe, all the potential in the world would not justify its use.

We welcome two very distinguished panels of witnesses today. Our witnesses come from diverse backgrounds, and we look forward to hearing their perspectives on developments in the field of nanotechnology. We hope to take away some of their wisdom regarding the most appropriate paths to follow in this area of science.

PREPARED STATEMENT OF HON. DANIEL K. INOUYE, U.S. SENATOR FROM HAWAII

Nanotechnology is the science of very small things that have very big potential. Like information technology, nanotechnology is not an end in itself. Rather, it has the potential to change fundamentally the way we make products from airplanes to pharmaceuticals.

Nanotechnology holds great promise, but to secure that promise, we need to understand the long-term effects of exposure to nano-engineered particles. What, if any, impact do they have on human health? Researchers are trying to answer this question as we speak.

Despite this uncertainty, companies are already marketing a wide range of products that utilize nanotechnology, from stain-resistant clothing to clear sunscreen.

The question is, are we doing enough to learn about the long-term effects of nano-engineered products? Are we making the right decisions about research funding and prudent regulation?

According to Mr. Davies' colleagues at the Wilson Center, the answer is no. Only $39 million of the government's $1.3 billion annual investment in nanotechnology research has been directed toward environmental, health, and safety research and development. Little of that is dedicated to long-term exposure studies.

In what could be a fortuitous coincidence, the Senate is currently considering legislation that addresses the consequences of asbestos exposure. As many of us recall, asbestos was once well-regarded. We knew very little about its effect on human health before its widespread use. We now know it can be deadly to those exposed to it.

With nanotechnology, history must be our guide, and our experience with asbestos provides an important lesson. If we do not learn from it, Congress could very well be considering legislation 30 years from now to address the ill-effects of nano-engineered products.

Like the other members of this committee, I am excited about nanotechnology's enormous potential, and I look forward to hearing about the advancements in this field. I also hope that our witnesses can help us understand how we can make choices that will allow this industry to grow safely and responsibly.

The CHAIRMAN. I think everyone realizes that we are dealing with a very evolutionary science, and we are trying to improve our knowledge of what it is and what is going on and what is the progress—what has the progress been so far, and what obstacles and challenges are involved.

So, I'll yield to my friend here, who was here ahead of me.

Senator Ensign, do you have an opening statement?

STATEMENT OF HON. JOHN ENSIGN, U.S. SENATOR FROM NEVADA

Senator ENSIGN. Yes, Mr. Chairman. I'll keep it very brief, because I know we have nine witnesses today and we want to hear as much as we can, especially with all the witnesses we had this morning. We did not get nearly as much time to hear from them as we wanted to.

In the second panel, I'm very excited to have a Nevadan here, Dr. Allan Gotcher. Dr. Gotcher will be discussing his efforts to develop a nanotechnology business. He is the President and Chief Executive Officer of Altair Nanotechnologies, in Reno, Nevada. I think the importance of this hearing is that nanotechnology is such an exciting field with so many potential applications. But I know that people have raised a lot of concerns about the safety of nanotechnology. We have to be careful, but we also have to make sure that we do not squelch innovation. In addition, although we must monitor potential health problems related to nanotechnology, I think that we have to proceed very carefully and slowly as we are looking at potentially regulating an incredible field of science and technology. The potential benefits from nanotechnology are so incredible that we have to be careful, exactly what we do as policymakers. With that in mind, I look forward to hearing from the witnesses on both of our panels.

[The prepared statement of Senator Ensign follows:]

PREPARED STATEMENT OF HON. JOHN ENSIGN, U.S. SENATOR FROM NEVADA

Thank you, Chairman Stevens, for holding a hearing on this exciting topic.

With 9 witnesses set to testify, I will try to keep my opening remarks brief. I look forward to hearing from all of our witnesses this afternoon and, in particular, I would like to extend a hearty welcome to a fellow Nevadan, Dr. Alan Gotcher. Dr. Gotcher will be discussing his efforts to develop a nanotechnology business, Altair Nanotechnologies, Inc., out in Reno.

Nanotechnology has the potential to positively impact so many aspects of our lives that it is helpful for this committee to explore where we have been, where we are, and where we are going with nanotechnology.

Nanotechnology can assist humans in very serious ways, from improving the treatment of life-threatening diseases like cancer and diabetes, to assisting our men and women in the armed forces to detect explosive devices.

In addition, nanotechnology can help provide simple pleasures like facilitating the creation of improved sports equipment and chocolate chewing gum.

Nanotechnology has already demonstrated that it will be increasingly relevant in society for a long time to come.

As scientists, universities, and businesses continue their efforts to use nanotechnology in a broad number of fields, we as policymakers in Washington need to be careful as we examine what role we should play.

While nanotechnology has tremendous potential to improve our daily lives, we need to make sure that we are adequately addressing the potential safety concerns that are raised by this dynamic field of development. I look forward to hearing more on this topic from today's witnesses.

At the same time, we need to be cautious about introducing additional regulation that could unintentionally squelch the positive innovation that is occurring in the field.

Thank you again, Mr. Chairman.

The CHAIRMAN. Well, thank you very much.

We have two panels this afternoon. The first panel has three witnesses: Dr. E. Clayton Teague, Director of the National Nanotechnology Coordination Office; Dr. Richard Buckius, Assistant Director for Engineering at the National Science Foundation; and Dr. Jeffrey Schloss, the Co-Chairman of the Nanomedicine Roadmap Initiative at the National Institutes of Health.

We look forward to hearing your testimony. We will print your statements in the record in full. Because of the subject matter, I am not going to place a time limit on you, but I hope you'll realize that there is a second panel behind you of six other people that we would like to listen to this afternoon.

So, Dr. Teague, would you start it off, please?

STATEMENT OF DR. E. CLAYTON TEAGUE, DIRECTOR, NATIONAL NANOTECHNOLOGY COORDINATION OFFICE

Dr. TEAGUE. Good afternoon, and thank you, sir.

Chairman Stevens and other distinguished members of the Committee who are present, I'm honored to have this opportunity to speak with you today about developments in nanotechnology; in particular, the role of the National Nanotechnology Initiative. My primary message today is that, with your support, the NNI has been, and will continue to be, a major driver for the responsible development of nanotechnology in the United States and the world.

The NNI is now in its sixth year, and it is a highly collaborative program among 25 Federal agencies, 13 of which have budgets for nanotechnology R&D. Because of the NNI, Federal agencies have initiated major new nanotechnology R&D activities that support national goals in their agency missions. There is an extensive and growing infrastructure of nanotechnology research centers and

user-facilities that have been put in place. The 25 participating agencies are—and I have emphasized—they are working together very harmoniously to maximize the effectiveness of their individual and collective investments through communication, coordination, and actual joint programs.

As called for by you and your fellow legislators, the President's Council of Advisors on Science and Technology, in its role as the National Nanotechnology Advisory Panel, recently reviewed the first 5 years of the NNI. Overall, they gave the NNI high marks for advancing foundational knowledge, for promoting technology transfer for commercial and public benefit, and taking steps to address societal concerns. They also concluded that the money the U.S. is investing in nanotechnology is money very well spent.

With a Federal investment of over $1 billion a year and over 4,000 active R&D projects, the U.S. is the world leader in nanotechnology development. With only one-quarter of the total international funding in nanotechnology, U.S. researchers are the leading producers of nanotechnology patents and publish over half of the nanotechnology papers in the key high-impact journals worldwide.

The NNI has also been effective in using these funds to support the movement of scientific discoveries from the lab to the marketplace. More than 160 companies supported by Small Business Innovation Research grants are now producing nanotechnology products or providing related commercial services. Since 2001, some 600 new "pure-play"—totally nanotechnology—companies have been formed in the United States.

Technology transfer, in this vein, is also promoted by the creation of a large geographically distributed network of research facilities. The NNI has established more than 50 nanotechnology research and education centers. I've provided a list of these centers along with my written testimony. These include more than a dozen user-facilities that are open to all researchers from academia and from industry.

I'd like now to take just a moment to explain a little bit about why spending a billion dollars of taxpayers' money each year in nanotechnology R&D is justified.

This slide shows some of the major application areas for nanotechnology. In each of the areas that are shown—and this is just a sampling of the many areas that nanotechnology will impact—this transformational technology promises to overcome what people sometimes call "brick walls" to the advancement by conventional approaches. In medicine and health, for example, targeted treatments for cancer with minimal or no side-effects. In information technology, devices that are "beyond silicon," a phrase that's used in the industry, and will allow us to stay on the path of Moore's Law. In energy production, revolutionary high-efficiency, low-cost solar cells. In materials science, achievement of atom-by-atom design of materials. In food, water, and the environment, effective remediation methods for Superfund sites and membranes to produce pure water, free even of viruses. In instrumentation, microscopes that can image the 3D—three dimensional—locations of atoms and the nanostructure on the time-scale of chemical reactions.

Along with all these advances in technology, in line with your comments, the United States has also pioneered environmental health and safety research, leading the world in this area. This research has been directed at implications of engineered nanoscale materials, and the U.S. is the world's leader in funding this work. Another vital element of the NNI is research directed at the societal aspects of nanotechnology development, as well as education and public outreach.

Among the challenges ahead are, certainly, strong competition from other countries, an issue with both economic and national security implications. While recognizing this, we are working to cooperate with other countries on research related to safety and societal impacts and on setting standards for this field.

In these brief remarks today, I hope I've been able to communicate that the NNI has been a major driver for nanotechnology in the U.S. and the world. All the members of the NNI, the agency members and representatives, see tremendous opportunity ahead and realize that we've got much work that remains to be done. We have now in place a vigorous program underway to launch a new era in this science and technology, thanks to the support of this administration and this Congress. With your continued support, the NNI will bring us closer to achieving some of our greatest national and societal goals.

Thank you, and I'll look forward to your questions.

[The prepared statement of Dr. Teague follows:]

PREPARED STATEMENT OF DR. E. CLAYTON TEAGUE, DIRECTOR, NATIONAL NANOTECHNOLOGY COORDINATION OFFICE

Chairman Stevens, Co-Chairman Inouye, and distinguished members of the Committee, I'm honored to have the opportunity to speak with you on behalf of the Nanoscale Science, Engineering, and Technology (NSET) Subcommittee of the President's National Science and Technology Council, which coordinates the National Nanotechnology Initiative (NNI). My subject is developments in nanotechnology—in particular, the role of the National Nanotechnology Initiative (NNI) in driving the responsible development and application of nanotechnology. That is my primary message today—that the NNI has been and continues to be the major driver for developments and applications of nanotechnology in the U.S. and the world.

The NNI—now in its sixth year—is a highly successful, collaborative, cross-cutting program among 25 Federal agencies: 13 agencies involved in the NNI R&D budget and 12 others with missions related to advances in nanotechnology (see list below). For a description of the vision, goals, organization, and management of the initiative, I would direct you to the NNI Strategic Plan provided along with this written testimony. Because of the NNI: (1) Federal agencies have initiated major new programs and efforts in nanotechnology research, development, and applications that expand knowledge and understanding, address broad national goals, and support the agencies' missions; (2) an extensive infrastructure of focused centers of excellence in nanotechnology and nanotechnology user facilities has been established and continues to grow; and (3) the 25 participating agencies are working together to maximize the effectiveness of their individual and collective investment through communication, coordination, and joint programs.

As called for by you and your fellow legislators, the President's Council of Advisors on Science and Technology (PCAST), in its role as the National Nanotechnology Advisory Panel, recently reviewed the first 5 years of the NNI. In its report, which is provided along with this written testimony, PCAST concludes that our activities already have paid significant dividends, such as "advancing foundational knowledge, promoting technology transfer for commercial and public benefit, developing an infrastructure of user facilities and instrumentation, and taking steps to address societal concerns." PCAST members believe the NNI "appears well positioned to maintain United States leadership going forward," that "the money the U.S. is investing

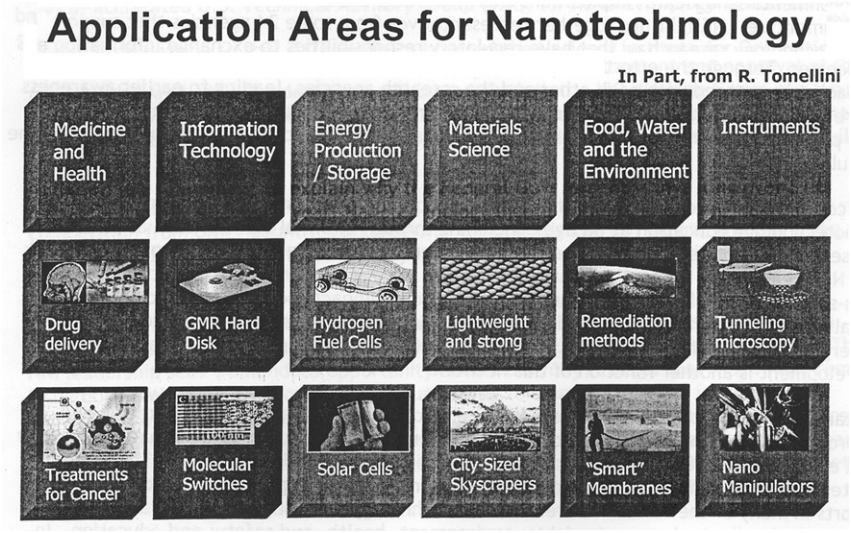
in nanotechnology is money very well spent," and that "continued robust funding is important for the Nation's long-term economic well-being and national security."

With a total Federal investment of more than $1 billion per year, the U.S. is the acknowledged world leader in nanotechnology R&D as evidenced by research output measured by patents and publications. With only one quarter of the total international funding in nanotechnology, U.S. researchers are the leading producers of nanotechnology patents and publish over half of the nanotechnology papers in high-impact journals worldwide.

The investment of such funds must lead to commercialization, however, in order to contribute to our economy. The NNI has also been effective in moving science from the bench to products in the marketplace. The U.S. leads in the number of nanotechnology-based start-up companies, many of which have received Federal support. More than 160 companies supported by Small Business Innovation Research grants are now producing nanotechnology-based products or providing related commercial services. Many of these are among the 600 "pure play" nanotechnology companies formed in the United States since 2001, identified in a recent survey by *Small Times Media*.

Technology transfer is also promoted by the creation of a large, geographically distributed network of research facilities. The NNI has established more than 50 nanotechnology research and education centers at universities and government laboratories, including more than a dozen user-facilities that are open to all researchers, including those from industry. Such broad access facilitates collaborations between government, business, and university partners. (See the attached list of all centers and user facilities established by the agencies participating in the NNI.)

I'd like to take a moment to explain why the Federal Government is investing over $1 billion in nanotechnology R&D each year. Nanotechnology incorporates science, engineering, and technology at the nanometer scale. Technically, a nanometer is a millionth of a millimeter; I find it useful to think of a nanometer in terms of the thickness of a sheet of paper—100,000 nanometers. At this scale, properties of materials can differ markedly from those of individual atoms and molecules or of bulk matter. By putting these unique properties to work, scientists are developing highly beneficial products in medicine, energy, electronics, materials, and other areas. Nanoscale control over the structure of materials and their properties is already leading to a variety of innovative technologies and is expected to impact virtually all industry sectors as an "enabling" or "key" technology. Some examples of impact areas are shown in the figure below.



To focus on one of these areas, consider an example of how nanotechnology could transform our economy and enhance our national security. Sunlight is by far the largest of all carbon-neutral energy sources. More energy from sunlight strikes the Earth in 1 hour than all the energy consumed on the planet in a year. Sunlight has long been seen as a compelling solution to our need for clean, abundant sources of energy in the future. It is readily available, secure from geopolitical tension, and can

reduce the impact of energy use on our environment. This great promise has long been recognized. But cost and low-efficiency issues have stood in the way of harnessing this energy—problems that are largely due to materials limitations. Nanotechnology allows us to design materials with combinations of properties not found in previously available materials. Photovoltaic cells formed from quantum dots—nanometer-sized particles of semiconductor materials—have been engineered to absorb and convert energy from multiple parts of sunlight's spectrum to electricity, yielding devices with significantly higher efficiency than those currently in use.

Today, the cost of producing electricity from photovoltaic cells is between two and five times that from conventional systems. With new materials and devices for energy conversion, transmission, and storage, this price differential could be bridged and make photovoltaic cell production of electricity competitive with that of conventional systems.

Another vital element of the NNI is research directed at environmental, health, and safety (EHS) impacts. The U.S. is the world leader in funding EHS research on the implications of engineered nanoscale materials. Further, the Federal Government has been coordinating research activity in this area since 2003, when the National Toxicology Program began a new program on several engineered nanoscale materials and the Nanotechnology Environmental and Health Implications (NEHI) Working Group was formed within the NSET Subcommittee. NEHI brings together representatives from some 24 agencies that support nanotechnology research or that have regulatory responsibilities to exchange information and to identify, prioritize, and implement research needed to support regulatory decisionmaking processes. Through the efforts of the NEHI Working Group, regulatory agencies have been proactively engaged with each other and the research agencies, leading to earlier awareness of relevant issues and expedited activities to address them. In addition, those agencies that are primarily focused on research have a greater appreciation for the issues confronted by the regulatory bodies.

My colleague Dr. Buckius will report on NSF's support of programs aimed at improving nanotechnology education at all ages, including through informal venues, such as science museums. NSF is also to be commended for the creation, in the Fall of 2005, of the Network for Nanotechnology in Society. That network will engage economists, social scientists, and non-scientists in looking at how nanotechnology could impact society economically, socially, legally, and how nanotechnology fits into the ethical dialogue on potential outcomes of emerging technologies. Engaging various publics in discussions regarding nanotechnology development is another function of this network.

Because technological innovation is a global phenomenon, international cooperation and coordination on many of the pre-competitive and noncompetitive aspects of nanotechnology will encourage development to occur in a responsible and beneficial manner. The United States takes the position that all countries will benefit from cooperating and coordinating efforts in many of the formative areas of nanotechnology R&D, such as technical norms and standards; intellectual property rights; environment, health, and safety; and education. In 2005, the NSET Subcommittee created an informal working group on Global Issues in Nanotechnology, whose purpose is to develop, coordinate, and support U.S. Government international activities related to nanotechnology.

The GIN working group has supported numerous international activities in the past year, including those involving the Organization for Economic Co-operation and Development (OECD). At an October 2005 meeting of the OECD Committee for Scientific and Technological Policy (CSTP, within the Science, Technology and Industry Directorate), the U.S. proposed the creation of a Working Party on Nanotechnology. This new Working Party would provide an international governmental forum to help OECD Member States and Observers more effectively utilize their nanotechnology R&D investments in furtherance of the CSTP goals of stimulating science and innovation, enhancing economic growth, providing societal benefits, and promoting innovation through international science and technology cooperation. In parallel, following a workshop hosted by the United States on the safety of manufactured nanomaterials, a proposal has been made to create within the OECD Environmental Directorate a working group focused on EHS risk assessment and management of nanomaterials.

A critical aspect of protecting health and the environment are standardized tools and methods for measuring and monitoring exposure; developing standardized methods for characterizing properties of personal protective equipment, *etc.* Accordingly, the International Organization for Standardization (ISO) established in late 2005 the Nanotechnologies Technical Committee. The Working Group on Health, Safety, and Environmental Aspects of Nanotechnologies under the Technical Committee will be led by the U.S. I was privileged to lead the U.S. delegation to the

ISO inaugural nanotechnology-related meeting and also chair the American National Standards Institute (ANSI)-accredited U.S. Technical Advisory Group (TAG) for nanotechnology standards.

The U.S. delegation to that ISO meeting submitted the National Institute for Occupational Safety and Health document on "*Approaches to Safe Nanotechnology*" to the ANSI TAG for consideration as a possible work item. Following further development and approval of the draft by the ANSI TAG, the document will be put forth to the ISO Working Group as a draft work item toward an ISO Technical Report. Once approved by the ISO Technical Committee, the document will be issued as an ISO Technical Report, an informational document available for use by all countries.

The work of the NNI has been broad. Still, there are challenges ahead. Among them is strong competition from other countries and regions, particularly the EU, Japan, and China, an issue with both economic and national security implications, and also for retaining our finest scientists.

I hope I have been able to communicate that the NNI has been a major driver for developments and applications of nanotechnology in the U.S. and the world. The NNI leadership sees tremendous opportunity ahead and fully realizes that much work remains to be done. We have a vigorous program underway to launch a new era in science and technology in the U.S., thanks to the support of the Administration and Congress. With continued support the NNI will advance discoveries in medicine, energy, security, and other areas that will bring us closer to achieving some of our greatest national and societal goals.

LIST OF FEDERAL AGENCIES PARTICIPATING IN THE NNI DURING 2006

Federal Agencies With Budgets Dedicated to Nanotechnology Research and Development

Department of Agriculture, Cooperative State Research, Education, and Extension Service (USDA/CSREES)
Department of Agriculture, Forest Service (USDA/FS)
Department of Defense (DOD)
Department of Energy (DOE)
Department of Homeland Security (DHS)
Department of Justice (DOJ)
Department of Transportation (DOT)
Environmental Protection Agency (EPA)
National Aeronautics and Space Administration (NASA)
National Institute of Standards and Technology (NIST, Department of Commerce)
National Institute for Occupational Safety and Health (NIOSH, Department of Health and Human Services/Centers for Disease Control and Prevention)
National Institutes of Health (NIH, Department of Health and Human Services)
National Science Foundation (NSF)

Other Participating Agencies

Bureau of Industry and Security (BIS, Department of Commerce)
Consumer Product Safety Commission (CPSC)
Department of Education (DOEd)
Department of Labor (DOL)
Department of State (DOS)
Department of the Treasury (DOTreas)
Food and Drug Administration (FDA, Department of Health and Human Services)
International Trade Commission (ITC)
Intelligence Technology Innovation Center, representing the Intelligence Community (IC)
Nuclear Regulatory Commission (NRC)
Technology Administration (TA, Department of Commerce)
U.S. Patent and Trademark Office (USPTO, Department of Commerce)

National Nanotechnology Initiative Infrastructure: Centers, Networks and User Facilities

(February 2006)

NNI Center, Network, or User Facility	Agency	Host Institution
Institute for Nanoscience	DOD	Naval Research Lab
Institute for Soldier Nanotechnologies	DOD	Massachusetts Institute of Technology
Nanoscience Innovation in Defense	DOD	U California-Santa Barbara
Functional Nanomaterials (pre-operations)	DOE	Brookhaven National Lab

National Nanotechnology Initiative Infrastructure: Centers, Networks and User Facilities—Continued

(February 2006)

NNI Center, Network, or User Facility	Agency	Host Institution
Integrated Nanotechnologies (pre-operations)	DOE	Sandia and Los Alamos National Labs
Molecular Foundry (pre-operations)	DOE	Lawrence Berkeley National Lab
Nanophase Materials Sciences	DOE	Oak Ridge National Lab
Nanoscale Materials (pre-operations)	DOE	Argonne National Lab
Biologically Inspired Materials Institute	NASA	Princeton U
Cell Mimetic Space Exploration	NASA	U California-Los Angeles
Intelligent BioNanomaterials & Structures for Aerospace Vehicles	NASA	Texas A&M
Nanoelectronics & Computing	NASA	Purdue
Engineering Cellular Control: Synthetic Signaling and Motility Systems	NIH	U California-San Francisco
NanoMedicine Center for Mechanical Biology	NIH	Columbia U
National Center for Design of Biomimetic Nanoconductors	NIH	U Illinois Urbana-Champaign
Protein Folding Machinery	NIH	Baylor College of Medicine
Cancer Nanotechnology Excellence	NIH/NCI	U. North Carolina
Cancer Nanotechnology Excellence	NIH/NCI	Massachusetts Institute of Technology/Harvard U
Nanomaterials for Cancer Diagnostics and Therapeutics	NIH/NCI	Northwestern U
Nanosystems Biology Cancer Center	NIH/NCI	California Institute of Technology
Nanotechnology Characterization Laboratory	NIH/NCI	NCI Frederick
Nanotechnology Excellence Focused on Therapy Response	NIH/NCI	Stanford U
Nanotechnology for Treatment, Understanding, and Monitoring of Cancer	NIH/NCI	U California-San Diego
Personalized and Predictive Oncology	NIH/NCI	Emory U/Georgia Institute of Technology
The Siteman Center of Cancer Nanotechnology Excellence	NIH/NCI	Washington U
Integrated Nanosystems for Diagnosis and Therapy	NIH/NHLBI	Washington U
Nanotechnology: Detection & Analysis of Plaque Formation	NIH/NHLBI	Emory U
Nanotherapy for Vulnerable Plaque	NIH/NHLBI	Burnham Institute
Translational Program of Excellence in Nanotechnology	NIH/NHLBI	Massachusetts General Hospital
Nanoscale Science and Technology	NIST	NIST/Gaithersburg
Affordable Nanoengineering of Polymer Biomedical Devices	NSF	Ohio State U
Directed Assembly of Nanostructures	NSF	Rensselaer Polytechnic Institute
Electron Transport in Molecular Nanostructures	NSF	Columbia U
Extreme Ultraviolet Science and Technology	NSF	Colorado State U
High-Rate Nanomanufacturing	NSF	Northeastern U
Integrated Nanomechanical Systems	NSF	U California-Berkeley
Integrated Nanopatterning & Detection	NSF	Northwestern U
Learning & Teaching in Nanoscale Science & Engineering	NSF	Northwestern U
Molecular Function at NanoBio Interface	NSF	U Pennsylvania
Nanobiotechnology	NSF	Cornell U
Nanoscale Chemical-Electrical-Mechanical Manufacturing Systems	NSF	U Illinois Urbana-Champaign
Nanoscale Systems & Their Device Applications	NSF	Harvard U
Nanoscale Systems in Information Technologies	NSF	Cornell U
Nanoscience in Biological & Environmental Engineering	NSF	Rice U
Nanotechnology Computational Network	NSF	Purdue and others

National Nanotechnology Initiative Infrastructure: Centers, Networks and User Facilities—Continued

(February 2006)

NNI Center, Network, or User Facility	Agency	Host Institution
National Nanotechnology Infrastructure Network	NSF	Cornell U and others
Network for Informal Science Education at the Nanoscale	NSF	Museum Of Science-Boston and others
Network for Nanotechnology in Society	NSF	Arizona State U, U California-Santa Barbara, and others
Network of Materials Research Science and Engineering Centers	NSF	Various
Oklahoma Nano Net	NSF	Oklahoma U, Oklahoma State U and others
Probing the Nanoscale	NSF	Stanford U
Scalable & Integrated Nanomanufacturing	NSF	U California-Los Angeles
Templated Synthesis & Assembly at the Nanoscale	NSF	U Wisconsin-Madison

The CHAIRMAN. Thank you very much.

Dr. Buckius?

STATEMENT OF DR. RICHARD O. BUCKIUS, ACTING ASSISTANT DIRECTOR FOR ENGINEERING, NATIONAL SCIENCE FOUNDATION

Dr. BUCKIUS. Thank you, Chairman Stevens and distinguished members of the Committee.

My name is Richard Buckius. I'm the Acting Assistant Director of the National Science Foundation, for Engineering. And I'm very pleased to be here today to discuss NSF's strong commitment to fundamental academic research in the area of nanoscale science and technology.

Before I begin, though, I want to thank you for the ongoing support of basic research. This support will help ensure our Nation's leadership in innovation in an increasingly competitive world.

Nanotechnology is our next great frontier in science and engineering. By tailoring molecules and manipulating individual atoms, we now have the ability to be able to design materials, medicines, and machines at the smallest, most fundamental level. This is an amazing capability, and it will have a profound and lasting impact on our quality-of-life.

In the early stages of—nanotechnology referred to simply as passive materials, such as nanoparticles found in composites materials and even paints. Today nanotechnologies are passive systems and active nanostructures, such as thin, nanoscale transisters and commercial electronics and the LEDs used in some traffic lights. As our ability to create new materials and technology increases, we can expect to see complete nanosystems with complex three-dimensional structures that will have the ability to perform multiple functions. NSF's unique contribution to the enterprise is its support of fundamental academic research and education through individual investigators and interdisciplinary groups.

Since the inception of NNI, NSF's investments have led to significant accomplishments, and I'd like to highlight a few.

NSF has created an interdisciplinary nanotechnology research community through support of the individuals, as well as the

groups, as well as a variety of programs in training and education. Within NSF's total FY07 investment in the nanotechnology initiative of $373 million, $65 million will be allocated to support these new interdisciplinary research teams.

NSF has established two user networks, the Network for Computational Nanotechnology and the National Nanotechnology Infrastructure Network.

Recently, NSF has established three other additional networks with national outreach addressing education and nanotechnology's societal dimensions; and let me just list these: The Nanoscale Center for Learning and Technology will reach out to a million students in all 50 States over the next 5 years. The Nanoscale Informal Science Education Network, along with others in the next 5 years, will develop approximately a hundred nanoscale science and technology museum exhibits. And, also, the Network for Nanotechnology in Society will address both the short- and long-term societal implications of nanotechnology.

In the first 5 years of the initiative, the National Science Foundation investment for fundamental research supporting environmental health and safety aspects of nanotechnology is approximately $82 million, or about 7 percent of NSF's nanoscale science and engineering investment. The support for research in nanomanufacturing and small-business innovative research has increased in funding and is helping industrial growth. The growth is clearly demonstrated by three nanomanufacturing centers which will advance our ability to integrate reliable, cost-effective manufacturing of nanoscale materials, devices, and systems.

I'd like to conclude with just a few examples of how this fundamental academic research is paying off.

The first is a group of researchers at the University of Kentucky who have demonstrated the potential to build membranes from billions of aligned nanotubes. The idea here is that nanotubes have an interior that is approximately friction-free, allowing the fluids to flow at more than 100,000 times than what would be expected in normal situations. Filters based upon these highly-efficient nanotubes may one day contribute to the purification of products ranging from industrial chemicals to pharmaceuticals to dairy products.

Another exciting example has been developed by the research at Northwestern in the University's Nanoscale Science and Engineering Center. They've developed a rapid and simple test to both diagnose HIV infection in patients and monitor the disease progression. This nanotechnology approach is capable of detecting proteins associated with HIV at concentrations several orders of magnitude smaller than was possible before with current technology.

I think you can see that even though we're just beginning to scratch the surface of this powerful new field, we have already witnessed remarkable achievements and the promise of great things to come. The United States currently is the world leader in nanotechnology, I'd claim, and it is a strategic area for NSF.

We seek your continued encouragement and support, and thank you for the opportunity to provide these remarks.

[The prepared statement of Dr. Buckius follows:]

PREPARED STATEMENT OF DR. RICHARD O. BUCKIUS, ACTING ASSISTANT DIRECTOR FOR ENGINEERING, NATIONAL SCIENCE FOUNDATION

Advancing the Frontiers of Nanotechnology Through Fundamental Academic Research

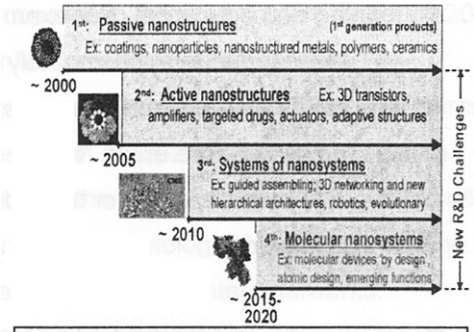
Chairman Stevens, Co-Chairman Inouye, and distinguished members of the Committee, my name is Richard Buckius, and I am the Acting Assistant Director of the National Science Foundation for Engineering. I am pleased to be here today to discuss the NSF's strong commitment to fundamental academic research in the area of nanoscale science and technology.

Before I begin, I wish to express my thanks for your ongoing support for basic research, which is absolutely necessary to ensure our Nation's leadership in innovation in an increasingly competitive world.

Nanotechnology is truly our next great frontier in science and engineering, and it represents an entirely new realm of technological capabilities. By tailoring molecules and even manipulating individual atoms, scientists and engineers now have the ability to design materials, medicines, electronics, and machines at the tiniest, most fundamental level.

This is an amazing capability, and it will have profound and lasting impact on our industry and economy, our national and homeland security, and our commitment to sustain the quality of life for all through advances in areas such as affordable healthcare and reliable energy.

In its earliest stages, nanotechnology referred simply to passive materials, such as nanoparticles found in composite materials and paint. We are now moving beyond passive systems and are beginning to see active nanostuctures, such as sub-100-nm transistors in commercial electronics and the LEDs used in traffic lights. As our ability to create new materials and technologies increases over the next decades, we can expect to see complete nanosystems with complex three-dimensional structures and the ability to respond and perform multiple functions.



Four generations of products: timeline for beginning of industrial prototyping and nanotechnology

Currently, U.S. industry and government agencies are working individually and collectively to enable these important developments. NSF, however, has a clearly defined yet vitally important role to play in this enterprise. Our focus is on fundamental science and engineering research and education. This research is supported primarily through grants to individuals and teams at our Nation's academic institutions.

One successful mechanism is through the NSF's support of interdisciplinary research teams and centers. These group awards related to nanoscale science and engineering are incredibly effective in helping advance our understanding of the nanoscale because they encourage collaborative and synergistic research.

These grants enable faculty-level scientists and engineers from diverse fields to come together as teams to conduct frontier, nanoscale research. Their efforts have been particularly fruitful because nanoscale research and education are inherently interdisciplinary pursuits, often combining elements of chemistry, biology, manufacturing, physics, optics and photonics, and nearly every other field of basic science. By fostering this type of research, NSF is able to accelerate innovation in this burgeoning field.

Within NSF's total FY 2007 investment for the National Nanotechnology Initiative of $373 million, $65 million will be allocated to support such interdisciplinary research teams.

Since the inception of the National Nanotechnology Initiative (NNI) in FY 2001, NSF investments have led to significant accomplishments.

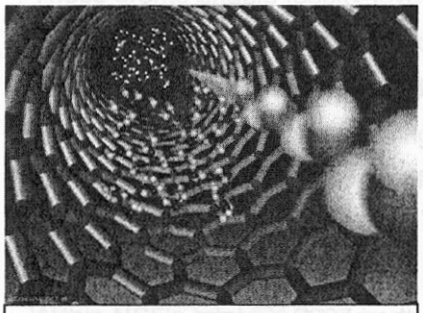
- NSF has created an interdisciplinary nanotechnology research community through support for large and small research groups and individual investigators, as well as a variety of programs for training and education. For example:
  - —NSF supports approximately 3,000 active R&D projects.
  - —NSF has founded 24 centers, networks, and user facilities (nearly half of the total created by the entire NNI).
  - —NSF has educated or trained about 10,000 students and teachers in nanotechnology in 2005 alone.
- Two user networks established by NSF, the Network on Computational Nanotechnology (established in 2002) and the National Nanotechnology Infrastructure Network (established in 2003) have attracted over 12,000 academic, industry, and government users in 2005:
  - —The Network for Computational Nanotechnology has a mission to connect theory, experiment, and computation to address the challenges in nanotechnology through new algorithms, approaches, and software tools with capabilities not yet available commercially.
  - —The National Nanotechnology Infrastructure Network (an outgrowth of the National Nanotechnology Users Network) broadly supports nanotechnology activities by providing users across the Nation access to leading-edge fabrication and characterization tools and instruments in support of nanoscale science and engineering research. In addition, this effort seeks to develop and maintain advanced research infrastructure, contribute to the education and training of a new workforce skilled in nanotechnology and the latest laboratory techniques, conduct outreach to the science and engineering communities, and explore the social and ethical implications of nanotechnology.
- The NSF has established recently three other NSF networks with national outreach addressing education and societal dimensions:
  - —The Nanoscale Center for Learning and Teaching aims to reach one million students in all 50 states in the next 5 years.
  - —The Nanoscale Informal Science Education network will develop, among others, about 100 nanoscale science and technology museum sites in the next 5 years.
  - —The Network on Nanotechnology in Society was established in September 2005, with four nodes at the Arizona State University, University of California at Santa Barbara, University of South Carolina, and Harvard University. The Network will address both short-term and long-term societal implications of nanotechnology, as well as public engagement.
- NSF has funded a research theme on nanoscale processes in the environment since FY 2001. In the first 5 years of NNI, the NSF investment for fundamental research supporting environmental, health, and safety aspects of nanotechnology is about $82 million, or 7 percent of the NSF nanoscale science and engineering investment. Research has addressed the sources of nanoparticles and nanostructured materials in the environment (in air, water, soil, biosystems, and work environment), as well as the nonclinical biological implications. The safety of manufacturing nanomaterials is investigated in four NSF centers/networks.
- The support for research in nanomanufacturing and Small Business Innovative Research has seen increases in funding and is helping industrial growth. More than 200 small businesses with a total budget of approximately $60 million have received support from NSF since 2001. This growth is clearly demonstrated in three NSF nanomanufacturing centers, which will advance our ability to integrate reliable, cost-effective manufacturing of nanoscale materials, structures, devices, and systems.

The NSF investment in nanotechnology is further leveraged and augmented through partnering among academic, industry, and state and local government organizations; today there are over 20 nanotechnology-related regional alliances and associations. An important example of this is the International Institute for Nanotechnology (IIN) at Northwestern University in Illinois. With support from NSF, NIH, DOE, and NASA, this institute has developed partnerships with the State of Illinois,

the City of Chicago, and private foundations to create a new kind of science-and-technology-driven regional coalition. With $300 million in funding for nanotechnology research, educational programs, and infrastructure, IIN has established a large pre-competitive nanoscale science and engineering platform for developing applications, demonstrating manufacturability, and training skilled researchers.

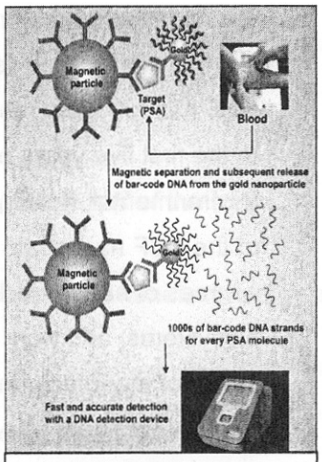
To conclude my remarks, let me quickly share with you two examples of how this fundamental academic research is paying off.

First, researchers at the University of Kentucky have predicted that membranes can be made from billions of aligned carbon nanotubes. The nanotubes have interiors that are nearly friction free, allowing some fluids to flow through them 100,000 times faster than we would normally expect. Filters based on these highly efficient nanotubes may one day contribute to the purification of products ranging from industrial chemicals and pharmaceuticals to dairy products.



Simulation of water moving through carbon nanotubes (Courtesy: Univ. Kentucky)

Next, researchers at Northwestern University's Nanoscale Science and Engineering Center in Chicago have developed a rapid and simple test to both diagnose HIV infection in patients, and monitor disease progression. This nanotechnology approach is capable of detecting a protein associated with HIV at concentrations several orders of magnitude smaller than is possible with current technology.



Nano Bio-Bar-Code Assay (Courtesy: Northwestern University and spin-off Nanosphere, Inc.)

As you can see, even though we are just beginning to scratch the surface of this powerful new field of science and engineering, we have already witnessed remarkable achievements that promise great things to come.

The United States currently is the world leader in nanotechnology, and that offers tremendous advantages as the field grows and matures over the next decade. The

current vision for the U.S. investment in nanotechnology has proven remarkably fruitful. We realize that nanoscale science and technology represent a major opportunity for the Nation. It is a strategic area for NSF, and we seek your continued encouragement and support.

National Science Foundation Nanotechnology Centers and Networks

Nanoscale Science and Engineering Centers (NSECs)	
Columbia University	Center for Electron Transport in Molecular Nanostructures
Cornell University	Center for Nanoscale Systems
Rensselaer Polytechnic Institute	Center for Directed Assembly of Nanostructures
Harvard University	Science for Nanoscale Systems and their Device Applications
Northwestern University	Institute for Nanotechnology
Rice University	Center for Biological and Environmental Nanotechnology
University of California, Los Angeles	Center for Scalable and Integrated Nanomanufacturing
University of Illinois at Urbana-Champaign	Center for Nanoscale Chemical, Electrical, Mechanical, and Manufacturing Systems
University of California at Berkeley	Center for Integrated Nanomechanical Systems
Northeastern University	Center for High-Rate Nanomanufacturing
Ohio State University	Center for Affordable Nanoengineering
University of Pennsylvania	Center for Molecular Function at the Nanoscale
Stanford University	Center for Probing the Nanoscale
University of Wisconsin	Center for Templated Synthesis and Assembly at the Nanoscale
Arizona State University	Nanotechnology in Society Network
University of California, Santa Barbara	
University of Southern California	
Harvard University	
Centers From the Nanoscale Science and Engineering Education Solicitation	
Northwestern University	Nanotechnology Center for Learning and Teaching
Boston Museum of Science	Nanoscale Informal Science Education
NSF Networks and Centers That Complement the NSECs	
Cornell University	National Nanotechnology Infrastructure Network
Purdue University	Network for Computational Nanotechnology
Cornell University	STC: The Nanobiotechnology Center

The CHAIRMAN. Thank you very much.

Our next witness is Dr. Jeffrey Schloss, Co-Chair of the Nanomedicine Roadmap Initiative at NIH.

STATEMENT OF JEFFERY SCHLOSS, PH.D., PROGRAM DIRECTOR, DIVISION OF EXTRAMURAL RESEARCH, NATIONAL HUMAN GENOME RESEARCH INSTITUTE; CO-CHAIR, NATIONAL INSTITUTES OF HEALTH NANOMEDICINE ROADMAP INITIATIVE, NATIONAL INSTITUTES OF HEALTH, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. SCHLOSS. Thank you, Senator Stevens and distinguished members, for the opportunity to come and describe to you——

The CHAIRMAN. Would you pull that microphone over and be sure to press the button?

Dr. SCHLOSS. Thank you. It's on, thank you—for the opportunity to speak with you about a few examples of some of the medical applications of nanotechnology, also to describe the Nanomedicine Roadmap Initiative, and then, finally, to close with a description of some of our recent activities and the ways in which NIH funds nanoscience and nanotechnology research.

This is an example of a very recently published study on the hearts of rats in which an attempt was made to mimic a heart defect—a loss of blood circulation to a region of the heart. That's shown here in this region. The study shows that by delivering a

protein factor that has been attached to a nanofiber that's made of protein—quite an innocuous substance, the same kinds of proteins that are found in our body—one can reduce the death of the cells in the heart, reduce the size of the injury, and increase the ability of the heart muscle cells to contract.

In the first figure, they're showing that, for quite a long time, even out to 2 weeks, in the presence of this factor that has been attached to these nanofibers, there is a biological effect of the material. The figure at the bottom shows the increased contractility. The difference between the first and second bars is the loss of ability of the heart muscle cells to contract as a result of the experimental myocardial infarction. And then, here at the end is shown the effect of treating with this factor in the presence of the nanofibers, retaining the majority of the normal contractility. The last figure shows—I won't go through the details—a decrease in the cell death that results from the injury.

This is very recently published, and shows hugely intriguing possibilities. Of course, it's research. We don't know yet all of the answers about this. I want to stress that the material that's being used to make the nanofiber is benign. It's protein. And it's a study that's being led by a physician who is board certified in cardiovascular disease and internal medicine. That means that issues of biocompatibility are very bright on the radar screen.

Another study, out of the University of Michigan, shows that nanoparticle targeting of anticancer drugs improves the therapeutic response, in an animal-model system of human epithelial cancer. This uses a very small particle, less than 5 nanometers, that has been designed with several functions, one of which is the anticancer drug, another is a molecule that directs this particle to bind very specifically to cancer cells, and the third is to help monitor the experiments—it has a fluorescent label, so a pathologist can see where the particle is going. This study showed improved therapeutic response over what would be obtained by using the drug by itself.

The point here is that you can target these particles to the location of the cancer. This means you dramatically reduce the body-burden of the drug, which would otherwise be used at higher concentration and therefore be very toxic.

The Nanomedicine Roadmap Initiative is part of a much larger effort, the NIH Roadmap for Medical Research, that is trying to bridge across the NIH organizationally, given that we have 27 Institutes and Centers, each with its own mission and budget. It is bridging organizationally, and from basic research to applications, and across scientific disciplines. The Nanomedicine Roadmap Initiative itself is trying to create both a conceptual and a literal interface between biology and medicine. It does this by starting out with study of the physical and chemical properties of molecules in the cell—which are nanomachines. We will build an understanding, from an engineering perspective, of what's going on in the cell, and then use the knowledge about how the cells works, and also the knowledge that we gained in building the tools to make the measurements, to actually build medical treatment devices.

I'm going to very quickly give you an example of one of the centers that was recently awarded, that takes the view of biology as

having parts out of which one builds devices that assemble into functional systems. This study uses an actin-based motility system, about which we already know quite a lot, to build programmable systems that incorporate guidance circuits and force-generation into systems that can be used for search and delivery, searching for problems in the body and delivering therapeutics.

The three examples I've given you all reflect different levels of control of the nanotechnology systems—passive, multifunctional, and active.

And finally, I'll close just by summarizing several of the ways in which NIH supports this kind of research through programs that are focused on engineering approaches to solving biological problems, some of which are specifically for nanotechnology. We take very seriously the ideas of investigators, who propose their best ideas to the NIH, to apply them to a variety of important medical problems. And finally, several of the institutes have now launched their own programs explicitly in nanotechnology. These include—I need to very quickly summarize a characterization laboratory within the NCI Alliance for Nanotechnology Cancer program, and several programs within the National Institute of Environmental Health Sciences, to address the safety- and health-related issues.

Thank you very much for the opportunity present this material, and I look forward to your questions.

[The prepared statement of Dr. Schloss follows:]

PREPARED STATEMENT OF JEFFERY SCHLOSS, PH.D., PROGRAM DIRECTOR, DIVISION OF EXTRAMURAL RESEARCH, NATIONAL HUMAN GENOME RESEARCH INSTITUTE; CO-CHAIR, NATIONAL INSTITUTES OF HEALTH NANOMEDICINE ROADMAP INITIATIVE, NATIONAL INSTITUTES OF HEALTH, DEPARTMENT OF HEALTH AND HUMAN SERVICES

I am Jeffery Schloss, a Program Director in the Division of Extramural Research at the National Human Genome Research Institute, a component of the National Institutes of Health (NIH) of the Department of Health and Human Services, with responsibility for DNA sequencing technology development. I have served as an NIH representative to the National Nanotechnology Initiative (NNI) even before it became a formal Federal initiative. And I am Co-Chair of the NIH Nanomedicine Roadmap Initiative, which I shall discuss below. I appreciate the opportunity to provide an overview of the Nanomedicine Initiative and nanoscience and nanotechnology research at the NIH.

Each of the twenty-seven Institutes and Centers (ICs) at NIH funds nanotechnology research to improve the quality of life for countless Americans.

Scientific Opportunities

Nanotechnology has the potential to radically change the study of basic biological mechanisms, as well as to significantly improve the prevention, detection, diagnosis, and treatment of diseases. One key to this potential is that nanotechnology operates at the same scale as biological processes, offering an entirely unique vantage point from which to view and manipulate fundamental biological pathways and processes. Most other technologies require the study of large numbers of molecules purified away from the cells and tissues in which they usually function; nanotechnology offers ways to study how individual molecules work inside of cells.

The most immediate near-term benefits envisioned for the use of nanotechnology in medicine arise because of novel properties of materials, and the ability to prepare and control materials properties with greater precision and complexity than can be achieved by other methods.

For example, early-stage proof-of-principle studies have been accomplished for most of the elements of a system, made of chemical subunits known as dendrimers, in which nanoparticles can be targeted to cancer cells wherever they may be in the body, bind exclusively to the cancer cells in that region, and deliver both an imaging agent to allow the physician to observe the cancer location, and a therapeutic agent to reduce or destroy the cancer. Further, the particle can be triggered to disintegrate upon release of the therapeutic agent, into harmless chemical subunits that no

longer have the characteristics of the nanoparticle and are readily cleared from the body. These device concepts can also be applied to other conditions, such as acute vascular injury and inflammation, and can also be achieved by building nanoparticles using materials other than dendrimers. Such particles can also be programmed to sense molecular and physiological signals, and activate the imaging agent, or release the therapeutic agent, only under specified molecular circumstances. These strategies should dramatically reduce side-effects of drugs by delivering them only when and where in the body they are needed. The name "smart" nanoparticle is therefore apt.

Metallic nanoparticles have been used in several ways for experiments on imaging and therapy. Quantum dots (*i.e.,* nanoscale crystalline fluorescent semiconductors) that absorb and emit colors of light that can penetrate body tissues have been used in animal experiments to demonstrate the potential to allow doctors to see, from outside the body, the exact location of certain tumors that occur near the body surface. Even though toxicity was not detected in these studies, the possibility that some of the particles used could be toxic has led to research on the permanence of the coatings and research on particles with the same optical properties but that are composed of non-toxic materials. A second type of metallic nanoparticle can be delivered specifically to tumor locations and heated by the application of colors of light that penetrate the skin, resulting in local heating to destroy tumor cells but not the surrounding healthy cells. Yet other metal particles are already in use to enhance magnetic resonance imaging, providing sharper images than previously possible with other MRI imaging agents.

For tissue repair, several different materials are being tested for their ability to form nanofibers that mimic natural structures that surround cells (extracellular matrix) in the body. Such materials could be injected at sites of injury caused by trauma or syndrome-associated degeneration, to provide both a physical substrate and the molecular signals needed to stimulate and support tissue healing. For example, versions of these materials are being tested to support the growth of bone, muscle, and nervous tissue.

While the examples above describe use of nanomaterials inside the body, nanotechnology is also being used to produce sensors for use in the research or clinical laboratory, or possibly implanted in the body. These sensors have exquisite sensitivity and selectivity. Based on nanomaterials such as carbon nanotubes or silicon nanowires, whose electrical properties change depending on the materials bound to their surface, sensors have been developed that can detect very small amounts of material, such as biosignatures for infection or disease, in complex mixtures such as blood or saliva. These electrically-activated sensors could be deployed in simple, cost-effective devices that could record several different measurements at once from a very small patient sample.

The scientific research is thus proceeding at a good pace. But there is a difference between a successful experiment and a robust device or medical treatment that functions in real-life situations, can pass all regulatory requirements, and be cost-effectively manufactured, commercialized and adopted. The next few years will be very important in establishing the reality of the early vision.

NIH Support for Nanotechnology Research

The opportunities transcend the mission of any single NIH IC. Therefore, trans-NIH grant solicitations were developed by the NIH Bioengineering Consortium (BECON; *www.becon.nih.gov*), in which all of the ICs participate, and have resulted in funding of dozens of research grants to colleges, universities, research institutions, and small businesses. Since 1999, BECON initiatives have been reaching out to teams of physical scientists, biologists, and clinicians to apply state-of-the-art nanotechnologies that are emerging from research in non-biological disciplines, to solving important problems in biology and medicine, ranging from understanding the mechanisms of disease, to developing novel diagnostic and therapeutic methods. To stimulate those collaborations and explore opportunities, BECON hosted a nanotechnology symposium in 2000 that was attended by over 600 scientists and engineers, and NIH co-hosted with the National Science Foundation (NSF) and other agencies participating in the National Nanotechnology Initiative, a workshop on Nanobiotechnology in 2003.

In addition to support through BECON initiatives, much of the support for nanoscience and nanotechnology research is provided by the NIH ICs in response to various other initiatives that are focused on solving specific biomedical problems, and to investigator-initiated grant applications. In many such cases, the programmatic rationale is to develop understanding of biomedical phenomena or the causes of disease or to develop specific diagnostics or therapeutics, and the particular scientific

approach chosen by the investigators to achieve the goals incorporates nanotechnology.

Recently, several institutes have developed explicit nanotechnology programs that are central to achieving their missions.

NHLBI Programs of Excellence in Nanotechnology

The National Heart, Lung, and Blood Institute has initiated Programs of Excellence in Nanotechnology (PENs). Its goal is to create multidisciplinary teams capable of developing and applying nanotechnology and nanoscience solutions to the diagnosis and treatment of cardiovascular, pulmonary, hematopoietic, and sleep disorders. To accomplish this goal the centers will conduct research on causes and treatments for these diseases, train investigators to apply nanotechnology to this set of problems, and actively disseminate their results. Four center awards were made beginning in FY 2005, representing a five-year funding commitment of $53 million.

NCI Alliance for Nanotechnology in Cancer

The largest single nanotechnology program at NIH is the National Cancer Institute's (NCI) Alliance for Nanotechnology in Cancer. These activities are integrated with existing NCI programs and resources. The Alliance currently supports eight Centers of Cancer Nanotechnology Excellence (CCNEs) to serve as hubs to develop and apply nanotechnology devices and systems to the diagnosis, prevention, and treatment of cancer. Examples of the goals of the centers include: the development of smart, multifunctional, all-in-one platform capable of targeting tumors and delivering therapeutics; and development and validation of tools for early detection and stratification of cancer through rapid and quantitative measurement of panels of serum- and tissue-based biomarkers.

The Alliance also awarded twelve cancer nanotechnology platform development partnerships. Further, it is supporting the education, training, and career development of graduate, post-doctoral, and mid-career investigators for multi-disciplinary nano-oncology research through fellowship grants and, with NSF, institutionally-based awards. NCI also is engaged in outreach and communication via its publications and website (*nano.cancer.gov*) about nanotechnology research and development as it relates to cancer and other biomedical applications, including the full spectrum of societal issues attending the development of nanobiotechnology.

Finally, NCI is actively supporting environmental, health, and safety research relevant to the cancer mission, particularly through the Nanotechnology Characterization Laboratory (NCL). The NCL will provide critical infrastructure for studies supporting decisionmaking about the implications of nanotechnology-based products. It will develop a characterization cascade to characterize nanoparticles' physical attributes, their *in vitro* biological properties, and their *in vivo* compatibility using animal models, from the perspective of intentional exposure (*i.e.,* medical application or delivery). This will enable nanotechnology-based strategies to rapidly and safely transition to clinical applications. The work also will provide a framework for regulatory decisions by the Food and Drug Administration (FDA) concerning the testing and approval of nanoscale cancer diagnostics, imaging agents, and therapeutics. To achieve these goals, the NCL is conducted in collaboration with FDA and the National Institute of Standards and Technology at the Department of Commerce. Overall, the NCI Alliance for Nanotechnology in Cancer represents a five-year funding commitment of $144 million beginning in FY 2005.

NIEHS National Toxicology Program and Collaboration

The National Toxicology Program (NTP) is a partnership of the National Institute of Environmental Health Sciences (NIEHS) with the National Institute for Occupational Safety and Health (NIOSH) at the Centers for Disease Control and Prevention, and the National Center for Toxicological Research (NCTR) of FDA. NTP's research program to address potential human health hazards from unintentional exposure associated with the manufacture and use of nanoscale materials includes investigation of toxicology of nanoscale materials of current or projected commercial importance. The overall goal is to understand critical physical and chemical properties that affect biocompatibility, so in the future nanomaterials can be designed to minimize adverse health and safety issues. Most of the funding for this NTP activity is contributed by NIEHS. The NCTR contributes the use of state-of-the-art capabilities of its NTP Phototoxicology Center. Studies are currently underway examining the absorption, biological fate, and potential toxicity of quantum dots; metal oxides used in sunscreens; and selected carbon-based materials (fullerenes, carbon nanotubes) following application to the skin, or exposure by inhalation or oral ingestion. The NTP and the NCI NCL programs are coordinated to ensure the most efficient development of nanoscale cancer therapeutics that are both safe and effective.

Additionally, NIEHS is participating with the Environmental Protection Agency, NIOSH and NSF in funding a joint solicitation to investigate environmental and human health effects of manufactured nanomaterials. NIEHS will fund research on the routes of human exposure, toxicology, biotransformation, and bioavailability of nanomaterials. These partner agencies are currently designing the next phase of this solicitation and are in dialogue with the Science Directorate of the European Commission to explore the possibility of a joint U.S.–E.C. research solicitation.

NIH Nanomedicine Roadmap Initiative

The cross-cutting nature of this technology is exemplified by its inclusion in the NIH Roadmap for Biomedical Research, a program that began in 2002, to identify major opportunities and gaps in biomedical research that no single IC at NIH could tackle alone, but that the agency as a whole must address to have the greatest impact on the progress of medical research. The Nanomedicine Roadmap Initiative (*nihroadmap.nih.gov/nanomedicine/*) is a component of the "New Pathways to Discovery Theme" of the Roadmap (the other themes are "Research Teams of the Future" and "Re-Engineering the Clinical Research Enterprise"). All of the NIH ICs collectively support and are responsible for the implementation of all of the Roadmap initiatives.

The Nanomedicine Initiative is envisioned as a ten-year program whose eventual goal is to manipulate precisely cellular processes by repairing or building new structures in cells, to prevent and treat disease and repair damaged tissue. In the near-term, interdisciplinary research teams are assembling to devise new methods to study problems in cell biology and biophysics. Those efforts will enable measurement of a host of parameters we cannot measure inside of cells today. This new information will lead to better prediction of the behavior of subcellular assemblies of molecules, and of cells themselves. In combining the knowledge gained from new insights into how biomolecules work and from building the tools that made those measurements possible, research teams can then design new strategies to build molecular-scale tools for disease or injury intervention. Unlike conventional medicine, the approaches taken here should enable interventions to be made with greater precision, much earlier in the course of disease or tissue degeneration, and at a more fundamental level for repair of tissue damage caused by trauma.

In a sense, the goal of the Nanomedicine Roadmap Initiative is to use quantitative approaches to understand, from an engineering perspective, the design of biomolecular structural and functional pathways, and to use that information to design and build functional biocompatible molecular tools to "dial" the body's systems back into "normal" operating ranges after function has been perturbed by disease. One might think of this in context of the way in which we can design and build a functioning electromechanical system, such as the heating and cooling system in your house. We know how to draw it out on paper—which electrical parts and controls, and motors, and valves and structures are needed—and when we build according to those plans, it actually works. We want to be able to understand biology at the molecular and system level, in the way in which we understand the parts and logic of an engineered system. If we can do that, we should be able to precisely repair or replace parts and keep the system operating normally, at the fundamental level at which the system operates, namely, its molecular systems.

The teams that will carry out this initiative consist of people with deep knowledge of biology and physiology, physics, chemistry, math and computation, engineering, and clinical medicine. Even though the first few years require basic biology research, the choice and design of experimental approaches are directed by the need to solve clinical problems. These are extremely challenging problems, and great breakthroughs are needed if we are to be successful in achieving our goals within the projected timeframe. Therefore, NIH is willing to take risks and is working closely with the funded investigators to use the funds and the intellectual resources of the entire network of investigators to meet those challenges.

Nanotechnology is key to the Nanomedicine Roadmap Initiative in several aspects. First and most obvious, nanotechnologies critically enable us to measure things that we have been unable to measure in the past, to "fill in the blanks" in the equations we need to understand and to predict how biomolecules work. Those biomolecules are nanostructures, and if we are to be able to touch and measure them with precision, without destroying them and their ability to operate, we will need to employ biocompatible nanotechnologies. Second, successful creation of measurement tools informs the development of manipulation tools for biomolecular repair of cells or subcellular assemblies. And third, in the process of fulfilling goals that are central to the mission of the NIH, we gain knowledge of the design of biological systems that nature has produced over millions of years. That knowledge of system design can be used by scientists and technologists who are working outside of the

biomedical realm, to develop novel strategies to solve their own engineering problems, whether in computers, transportation, energy, or national security. In this way, the Nanomedicine Roadmap Initiative will give back in full measure to the physical scientists and engineers who developed the earliest ideas from which the National Nanotechnology Initiative was formulated.

To fulfill these goals, the Nanomedicine Initiative is establishing a network of highly-interactive centers around the Nation. The first four centers were established in FY 2005 with a $6 million investment. The initial centers are:

- *Center for Protein Folding Machinery,* Wah Chiu, Baylor College of Medicine.
- *National Center for the Design of Biomimetic Nanoconductors,* Eric Jakobsson, University of Illinois, Urbana-Champaign.
- *Engineering Cellular Control: Synthetic Signaling and Motility Systems,* Wendell Lim, University of California, San Francisco.
- *Nanomedicine Center for Mechanical Biology,* Michael Sheetz, Columbia University, New York.

While this list shows only the names of the team leaders and their home institutions, the teams include distinguished and experienced investigators, and bright new investigators, at institutions across the Nation and internationally. To exemplify the program, the themes of two centers are briefly described.

The first project is the *Center for Protein Folding Machinery.* Proteins are synthesized in cells as linear structures. These proteins must fold in very precise ways to achieve the correct shape required for their function. While a few proteins can fold by themselves, most require the action of other proteins in cells, called molecular chaperonins. The Center will study the mechanisms by which chaperonins select and fold specific proteins, and will use that information to develop chaperonins that can trap misfolded proteins or prevent folding (and therefore activity) of proteins that should not be present in a particular type of cell. This is important because protein misfolding is implicated in several neurodegenerative diseases, such as Huntington's disease and Alzheimer's disease. Some other diseases involve the accumulation of proteins that are normally not present or are present only at very low levels (*e.g.,* cancer), so the Center will develop specific adapters to control the interaction of the proteins with the folding machinery. Additional goals include designing novel chaperonins that can be used to deliver drugs in the body, or to be used during the processing of protein-based pharmaceuticals, to ensure correct folding and activity.

Another project, the *Engineering Cellular Control* center, will endeavor to develop "smart" cells or cell-like devices that have some of the properties of normal immune cells. They would be relatively simple systems (compared to real cells) that are programmed to detect a lesion (*e.g.,* injury) or threat (*e.g.,* infection or cancer cell), then move to that site in the body and respond precisely with a controlled action such as releasing a therapeutic agent or mediating recruitment of the body's own immune system.

The focus of each center is distinct and complementary to the others, and their discoveries will apply to many tissues and diseases.

NIH Participation in the National Nanotechnology Initiative

NIH activities in the development of nanotechnology for biology and medicine are coordinated with those of other Federal agencies through its active participation in the NNI. A highlight of that activity is the active participation of NIH staff in the planning and development activities conducted through working groups on issues such as environmental and health implications, public engagement, and global issues.

For example, NIH is participating actively in the Public Engagement working group. This group is developing the first stages of an ongoing commitment to engage the public in discourse about societal issues related to emerging nanotechnologies. A broad range of stakeholders, including people from universities, industry, and civic- and community-based organizations, will be involved in this process.

Conclusion

The NIH is fully engaged in a wide variety of nanoscience and nanotechnology research and development activities to achieve short- and long-term advances to reduce the burden of disease and disability. Peer-reviewed research support has been growing substantially since the initiation of the NNI, as has participation of NIH staff in the full range of NNI activities. The NIH is fully committed to continuing these activities in ways that capture maximum benefit for improving the health of the American people and individuals around the world.

The CHAIRMAN. Thank you very much, all of you, for coming.

Let me say, we are each going to have a round of 5 minutes, and then we'll call the next panel. But can you tell us, Dr. Teague, who started the National Nanotechnology Initiative and what challenges do you have that pose obstacles that you confront to your continued advancement in your area?

Dr. TEAGUE. Well, the National Nanotechnology Initiative has its roots in some terrific efforts started by a group out of several of the agencies, one of whom is here today, Dr. Michael—Mihail Roco—Mike Roco, as we refer to him. We just recently awarded him a plaque to recognize his leadership as the Chair of the Nanoscale Science, Engineering, and Technology Subcommittee. He is one of the—we say, one of the fathers of the NNI, and served as one of the major driving forces of the NNI. There were a number of others.

They had—they pulled together, first, an Interagency Working Group on Nanotechnology. My understanding is that they worked for several years before the NNI was proposed as an Initiative under the previous Administration. Following the movement then—it was formed in late 2000—the Initiative actually were kicked-off in late 2000. Moving on from there, in late 2003 we had the 21st Century Nanotechnology R&D Act, for which many of you, including Senator Allen here, was a big part of moving that forward. I—we could go quite a long time. The NNI has a long and very distinguished history as to how it came about. It really was a ground-up effort on the part of several representatives from the major agencies—Department of Defense, NIH, and others. Dr. Jeff Schloss was also a part of that initial Working Group on Nanotechnology. So there was a good groundswell to form this and to seize the opportunity that nanotechnology offered for our country, and, indeed, for the world.

In terms of the second part of your question, the challenges that we face ahead of us, I think that one of the real challenges—there are several that I would want to discuss—one is international competition. The United States is not the only country in the world that has realized the tremendous potential of nanotechnology for economic growth, for national security, for improvement of our overall health. So, I think we need to be very much aware, very keenly aware, of the competition as it's building in the world.

The EU, if you take all the countries in the EU, their investment already likely equals, or maybe even is beginning to exceed, the U.S. investment in nanotechnology, as far as public investment.

The CHAIRMAN. Were any of you involved in Norm Augustine's report we received on the problems of the growing disparity in education? The report is called "*Rising Above the Gathering Storm*." Were any of you involved in that? NSF was, weren't they?

Dr. BUCKIUS. I mean, I personally wasn't, but, yes, NSF was involved, from the point of view——

The CHAIRMAN. Well, I just wonder, has the role of technology been examined, as far as this education gap is concerned in our country? I notice every one of you has a doctorate.

Dr. TEAGUE. Yes. Well, certainly, the——

[Laughter.]

The CHAIRMAN. No, I'm serious now. We're asked to try and enlarge—we've got an Initiative here called PACE—we're asked to enlarge the monies that are available to teach another generation of scientists, engineers, and medical people. Is this something that bothers you, as far as this area is concerned, nanotechnology, the lack of enough funds to educate the coming generations to keep up with the world?

Dr. BUCKIUS. I have a two-pronged answer. From the point of view of engineering, which is where the "*Gathering Storm*" makes a very large point, engineering education is an important issue, and is—and we agree with the "*Gathering Storm's*" recommendations. We, in engineering at NSF, are investing, I consider, a lot of money into educational activities in the engineering field, particular—not in general from the point of view of all of education. So, our investment in engineering education is significant, because it is a problem. We have—we drop off too fast from the freshman class to the graduating class. So, from the—now you come to nanotechnology. If you read the testimony, there are a couple of points in there. We've started to fund nanoscience learning centers and teaching centers, for exactly the same point, to make sure that we have a population that understands nanotechnology. So, yes, we are investing.

Dr. TEAGUE. Yes. I'd like to just add one——

The CHAIRMAN. Well, I'm going to live within my limits, Doctors. I've got to tell you, we have meetings after this hearing, so I want to make sure everyone has time. But I do hope that you will keep in touch with us. And I think maybe we ought to have what I call a listening session sometime, sit around with you guys and kick the ball back and forth and understand further what is occurring in this important field.

Senator Ensign?

Senator ENSIGN. Thank you, Mr. Chairman.

There are several proposals out there. Chairman Stevens just mentioned the PACE proposal. Senator Lieberman and I introduced the National Innovation Act. The exciting development is that people are talking about innovation and competitiveness issues now. And people are looking at nanotechnology and other sciences as a competitiveness issue for the United States. The United States is in competition with other parts of the world. The National Institutes of Health received a doubling of funding over the last several years. Now we are considering doing the same thing for the National Science Foundation. We must ensure that support for the physical sciences keeps up with the funding that we have provided to support research in the life sciences. Supporting basic research is a fundamental role for the Federal Government, and nanotechnology is a great example of why basic research is important for the Federal Government to fund, because nobody else has the resources required to conduct this research.

Dr. Teague, because nanotechnology covers such a wide spectrum of scientific disciplines, could you address how the Coordinating Office effectively uses one single plan to administer this multi-agency Initiative?

Dr. TEAGUE. Well, in terms of how we work, my office serves as a support for the Nanoscale Science, Engineering, and Technology

Subcommittee. We also work very closely with the Office of Science and Technology Policy, liaison with them. Our support and, I think, the primary coordinating, management, and reporting aspects of the overall initiative, is done through this subcommittee, in the NSET Subcommittee. This subcommittee has been meeting monthly for the last 5 years.

And, as I mentioned in my testimony, through a lot of communication and coordination and full joint programs among the agencies, a lot of that coordination that you're talking about does actually—takes place very effectively. If you noticed, I bolded the words "working together" in the slide that I presented. And as I've said several times, that as I look at my job—I've been in it now for about 3 years—one of the things that I was most impressed with finding out while working with the—these 24 agencies was—I guess it shouldn't be too surprising—that the people that worked in those agencies are truly dedicated to the missions of their agencies. The people in Defense, they're really dedicated to defense, and so on.

But the other part of it is that they are beginning to work together in this particular area of nanotechnology. Because all of them realize that, while it is important that they accomplish their missions, I think, more and more, they're realizing that it is essential that they coordinate their efforts among the agencies to be as effective as they can in moving forward with their programs.

Probably the most concrete way in which this joint activity is manifest is in literal joint solicitations, where about four or five agencies would come together and agree upon one specific area that they would like to issue a solicitation in. The most recent one was led by the Environmental Protection Agency, but it also had cooperation from the National Science Foundation, from the National Institute for Occupational Safety and Health, and the National Institute of Environmental Health Sciences, to try to study the environmental, health, and safety aspects of engineered nanoparticles for the environment. One solicitation went out, proposals came in, and then each of the agencies chose the ones that were most appropriate for their individual agencies.

That's just a few examples of how they work together. It's workshops conducted jointly, as I say, many different meetings. We have working groups that are underneath that subcommittee that address various aspects of the work that we do. And——

Senator ENSIGN. Dr. Teague, thank you for your answer. I only have about a minute left, so——

Dr. TEAGUE. OK.

Senator ENSIGN.—let me just ask Dr. Buckius a quick question on how NSF is going to maximize. You know, you have limited funds. Obviously, every agency would love more funds. And, you know, additional funding makes things a little easier, but with limited funds how do you maximize the potential research that is being done? How do you pick those projects that are the most worthy and where you think you are going to get the most bang for the buck?

Dr. BUCKIUS. Well, let me start off by saying that NSF invests in the intelligence of the research community, period. That's just the way it works. We obtain proposals that have absolutely great

ideas and, as you've noted, just aren't able to fund them. We use the merit review process, so peers review proposals, they assess the quality, they assess and make recommendations on which ones are the great ideas, and then we try to fund as many of those as we can. And in the case of the nano area, because we have generated a very strong community now, I'd argue that the proposals are just absolutely superb, and we're doing our best to make sure that we get the money in the hands of the best ideas.

Senator ENSIGN. Just one last comment, Mr. Chairman. Many people, especially from NIH, are familiar with Michael Milken, the Prostate Cancer Foundation, some of the work that the Foundation has done, and the way that the Foundation has awarded its grants with both younger researchers and innovation in mind. And I have spoken to Mr. Milken about some of the ways that we can reform how we do things up here. Sometimes the groups that get funding, do so because they are very good at writing grant proposals. I think that, especially in a field like nanotechnology, that entails such exciting research, we have to make sure that we are encouraging innovative young researchers to go into these fields instead of other fields.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you.

Our next—Senator Allen?

STATEMENT OF HON. GEORGE ALLEN, U.S. SENATOR FROM VIRGINIA

Senator ALLEN. Thank you, Mr. Chairman, for holding this hearing. And we have some outstanding witnesses on both panels.

Senator Wyden and I, back in 2002, actually had the first hearing on this, and on the issue of nanotechnology, the competitiveness, where we were. It is the next transformative economic revolution. It is going to affect, and it is affecting, as Senator Ensign mentioned, in a variety of ways, so many different sectors, from microelectronics to materials engineering to the life sciences, health sciences. We had a hearing, by the way, this morning in the Energy Committee, and I was discussing with one gentleman, one of our witnesses, how solar photovoltaics now, or solar power, with nanotechnology you have can have shingles that actually look nice rather than they, you know, look like you have a sliding glass door on your roof——

[Laughter.]

Senator ALLEN.—for solar power. And there are a variety of ways that this is improving our lives. I love the medical and life sciences aspects of it. In fact, what we passed through this committee, Senator Wyden and I, in the bipartisan effort, was really in this nanotech initiative. We called it the 21st Century Nanotechnology Research and Development Act. But the practical matter is, it's the biggest investment in basic science since the space program back in the 1960s. Dr. Rocco here is really the founder of a lot of it, if you want to know who is a key leader; and Dr. Teague and Buckius and Dr. Schloss, are all important, as well.

In our briefing—let me point this out—the briefing from the Committee, it has different types of research. And I'm one who's very competitive. And one of the—the key impetus and why the

President was so strongly behind this and the funding of it, and actually focusing more in the Department of Energy, out of all the different Federal agencies, is to get collaboration with the private sector, with the—with college and universities, regional initiatives, which we'll hear about in the second panel. But I was over in China, and Senator Ensign and I, and Senator Lieberman and others, care about how we're falling behind in—with engineers and so forth. But I was at a facility in China, near Beijing, and they're—they were like—for carbon nanotubes, which are the basis of materials engineering—they wanted to get the best scientists in the world there. They're like George Steinbrenner, they were just going to get the best, and whatever it cost to get them.

Now, the Chinese investment in nanotechnology is clearly rapidly increasing. They are focused, it seems to me, on the materials engineering aspect of it. Do you find, Dr. Teague, that the funding that we have provided, and the President has initiated, now and in the future, to be adequate for us to continue—the education, the innovation, and development to continue?

Dr. TEAGUE. Probably if you ask anyone who's in the field, they would like to see the funding keep increasing, certainly at something like the rate that it has increased over the past years. Certainly, the funding that we currently have in the President's request for 2007 is, like, $1.2 billion. This request will meet many of the research needs and many of the research areas that we're expecting ahead of us.

One thing that I would point out, to go back to Chairman Stevens' question earlier on, is that—and yours, as well, just now—is that probably there's no field that has been established, in terms of science and technology, that offers as great an opportunity to attract young people into science and technology as nanotechnology does. It has many wonderful things that attract people, particularly young people, into it, the promise of being so beneficial to health, to the environment, and to the world, that it, I think, is a very attractive field for many people.

Senator ALLEN. Count on us—we even created a Nano Caucus to try to educate more Senators on nanotechnology. Let me ask Dr. Buckius—huh?

Senator SMITH. It's a pretty small caucus.

[Laughter.]

Senator ALLEN. Yes, it's—there are not many members, but it's not 1/100th of the width of the human hair; it's bigger than that.

[Laughter.]

Senator ALLEN. At any—Dr. Buckius—I only have a minute left—the United States, as I understand it, holds about 60 percent of the worldwide nanotechnology patents. Our patents, though—and this is the information I've received—have actually decreased in 2005. Do you have an explanation as to why there are fewer nanotechnology patents, or nanotech application patents?

Dr. BUCKIUS. I have a conjecture, only.

Senator ALLEN. Conjecture, please.

Dr. BUCKIUS. If you take a look at that curve, it was a rapidly increasing curve. OK? And when it got to 2004, there, it just flattened off, from the point of view of patents. And, as you know, the patenting process is an investment of many years. And so, I'm not

sure that that individual-year drop-off is an indication of a long-term trend; it might simply be the way the patents were coming into the system and how long it takes. We'll have to probably wait and see what happens in 2006 and 2007 to see how that curve changes. It's still very productive, though. I mean, if you take a look at the quantity of patents that are generated by NSF funding in this area, it really is—it—the documentation shows that we're way out there, from the point of view of comparisons with other agencies and other activities that do patents. So, I think we're in good shape. I think we have to wait and see what 2006 and 2007 is going to bring.

Senator ALLEN. Thank you very much. Thank you, all three.

The CHAIRMAN. Thank you.

Senator Pryor?

STATEMENT OF HON. MARK PRYOR,
U.S. SENATOR FROM ARKANSAS

Senator PRYOR. Thank you, Mr. Chairman.

And I'm a big supporter of nanotechnology. In fact, one of the things we've done in our State, which is a relatively small state, is, we have done a nanotechnology alliance with our universities and some businesses there. And they try to reach out regionally and nationally and try to pool resources and do things like that.

Let me ask this question. I am a very big supporter of nanotechnology. I think it has a very bright future. But I do think that we need to be careful when it comes to the possible environmental hazards with nanotechnology, health hazards, human safety hazards, et cetera. So, I would like to get all your thoughts, just whoever wants to take it, on whether we're spending enough money when we do research—whether we're spending enough money, or whether we have a close enough eye on the potential problems that might come from nanotechnology. Because I think once we build those safeguards in, we ought to really do our very, very best to make sure that we're the world leader in nanotechnology. But I think America and the world would like to see those safeguards.

So, who wants to take that?

Dr. SCHLOSS. Well, I can start off by saying that we completely agree with you that these are essential issues to address, and to address effectively. I don't know exactly how one decides what's the right amount of money to spend. I think what we want to do is approach the science as quickly as we can, but in a very effective way. We are able to base a lot of the studies of engineered nanomaterials on our knowledge of other kinds of particles, including natural nanomaterials. So, what we're doing now, through several different efforts, is building cascades of characterization of nanomaterials so that we can really understand: What are the physical attributes? How do these materials act in biological systems in glass, in test systems? And how do they act in animal studies? We're building on the knowledge we have, but these are difficult materials to work with and to characterize. A number of studies have been published that actually are somewhat misleading, because there was other stuff in there that wasn't the material that people thought was being tested.

Senator PRYOR. OK. I just hope that we, as a Nation, do think through all the ramifications of this. And then, like I said, I think once we feel like we have that under control, we need to really be aggressive in this area.

With regard to the universities doing research—Dr. Buckius, I'll ask you this—it would—I would think that the universities around the country are very, very important partners in nanotechnology research. Are they pretty much the backbone of the research that's being done in this area?

Dr. BUCKIUS. From NSF's perspective, yes.

Senator PRYOR. OK. I think that that's good. I just think that they're very innovative, and they can do great things.

Let me also ask this. The Consumer Product Safety Commission, are they involved in the National Nanotechnology Initiative at all? Do they have a seat at the table, so to speak? And do you have someone there who's a consumer advocate?

Dr. TEAGUE. Yes. We—on the NSET Subcommittee that I mentioned earlier, we do have a representative from the Consumer Product Safety Commission as an ongoing member of both the main subcommittee and also an active member of our Environmental Health and Implications Working Group. So, we do have someone who is an advocate and keeps us very much aware of the concerns for ensuring safety for our consumer products.

Senator PRYOR. From your perspective, at least—I know you can't speak for them—but does the Consumer Product Safety Commission, from your perspective, have enough staff and enough expertise to be competent, I guess, to opine on things like that?

Dr. TEAGUE. Certainly, in terms of the representative that we interact with, I would say that he is a—in terms of competency, without any question, he's a competent scientist in our area and, I think, certainly represents his organization very carefully, and the interests of the Consumer Product Safety Commission, very effectively.

Senator PRYOR. OK, thank you.

Mr. Chairman, the last thing I had, really, is more of an observation, and that is, I think nanotechnology potentially could be the next industrial revolution. Really, it has a ton of potential to do great things, long term. And just a very simple example would be these incandescent light bulbs right here. Supposedly, you guys tell me—you all are the experts on this—but, supposedly, about 90 percent of the energy that's used in these light bulbs don't go to make light, they go to make heat.

And so, in a way—even though Thomas Edison was a genius and all that, in a way these are very efficient—inefficient ways to light a room, because not only do you have to use too much energy to do it, but, also, you're, in effect, heating the room, and then you have to have a system to cool the room at the same time, so you're really using way too much energy in order to do that. But with nanotechnology, supposedly you can now make nanolights that—are either ready for the marketplace, or will be very shortly, because I know the University of Arkansas has been involved in some of that—but you can make nanolights that can save a—well, can heat this—I mean, can light this room at the same level, for a frac-

tion of the energy, and you don't have the heating problem that these bulbs cause.

So, this has applications really across the board that can help our economy so much, and my understanding is the FY07 budget that the President sent over a few days ago has a very small cut in nanoresearch, and I want to double-check that and track that down, but I may want to work with some of the Committee members here to see if we can't restore that to the funding level that it has been in years past.

Thank you.

The CHAIRMAN. Very astute observation, my friend.

Senator Smith?

STATEMENT OF HON. GORDON H. SMITH, U.S. SENATOR FROM OREGON

Senator SMITH. Thank you, Mr. Chairman. And thanks to our witnesses for being here for this very, very important hearing and topic. When you contemplate that in the coming years this is likely to be a one-trillion-dollar industry, it certainly behooves us, as a Nation and as academia, to get a headstart.

I'm also, like Senator Pryor, proud of my state. We've had the same kind of coming together of higher education and different industries, under an entity called ONAMI, which brings together commercial and academic nanotechnology.

I'm also very grateful, and want to state publicly, I appreciated the President's including nanotechnology in his budget for 2007, and specifically the establishment of an Institute for Nanotechnology within the State of Oregon.

I'm wondering if there is more we ought to be doing to provide the seed capital and, particularly, the link between the classroom, the science, and commerce. In that possibility, I have introduced a bill, called the Nanoscience to Commercialization Institutes Act, which would establish, I'm sure, in each of your states, these kinds of institutes to help make this transition. It establishes up to eight Nanoscience Commercialization Institutes. And the goal of each institute is to apply nanotechnology research to commercial goods or services—specifically, in industries including energy, electronics, agriculture, medicine, textiles, and transportation—and to achieve their full commercial realization.

Any comments on that? Is this—would this be helpful? Is this needed? Will this happen, just on its own?

Dr. TEAGUE. Well, I don't think anything like that happens on its own. I think it certainly needs to be driven. And I think some of those would be—sounds like it would be a very effective means of trying to aid in commercialization. I would point out that, within the agencies now participating in the NNI, through the Small Business Innovation Research program, certainly the degree to which the discoveries have been transitioned into commercialization has been quite successful and has received strong support through that program. We did a study of the amount of funding that had gone into nanotechnology from the SBIR grants, and it's something upwards of $500 million over the last 5 years has gone to SBIR programs, the SBIR grants, for nanotechnology development and to do

the commercialization of some of the ideas coming out of the laboratory.

Also, I would mention that we have been, just recently, interacting quite a bit with the Department of Labor and the Department of Education, as well as the ongoing activities from the National Science Foundation, to look into workforce issues, training issues relative to equipping people to move into this new field and to do the commercialization.

But this sounds like it might well bridge both the education, training, and, to some degree, the actual moving of nanotechnology from the laboratory to commercialization. We are very conscious of the need for this to happen, and have been trying to take some appropriate steps to work in this direction, as well.

Senator SMITH. Well on the basis of your recommendation, I'll recommend it to my colleagues, to become joint sponsors of this. Thank heavens for law school, huh?

Thank you, gentlemen, very much.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you very much.

We will print my statement and the statement of the Co-Chairman at the beginning of this hearing.

Thank you very much, gentlemen. We appreciate your keeping in touch with us, and we would welcome your comments at any time to assist in this initiative.

Dr. TEAGUE. We would welcome the chance to sit down with you, as you indicated in your remarks.

The CHAIRMAN. We do that once in a while, Doctor. It is off-the-record. We explore the subject to see if we really understand what is going on. It's helpful. We will try to do that.

The next panel is Dr. Alan Gotcher, President and Chief Executive Officer of Altair Nanotechnologies; Dr. Todd Hylton, Director of the Center for Advanced Materials and Nanotechnology at Science Applications International Corporation; Dr. Mark Davis, Professor of Chemical Engineering at the California Institute of Technology; Dr. Clarence Davies, Senior Advisor, Project on Emerging Nanotechnologies at the Woodrow Wilson Center; and Dr. Timothy Swager, Professor of Chemistry, the head of the Chemistry department at the Massachusetts Institute of Technology.

If you would, please. Thank you very much, gentlemen.

We have been joined by Senator Kerry, who would like to introduce Dr. Swager, I believe.

STATEMENT OF HON. JOHN F. KERRY, U.S. SENATOR FROM MASSACHUSETTS

Senator KERRY. Mr. Chairman, I—thank you, I wasn't really going to so much introduce them as both welcome Dr. Swager, from MIT—we're delighted with the work that's being done there; obviously, I'm very proud of what's happened—and, also, Bryant Linares, from Apollo Diamond. Very, very happy to have both to them here, and everybody.

This is a subject—Mr. Chairman, thank you for having this hearing—this is, as everybody on this committee knows, an area of extraordinary promise. And given the fact that, since World War II, I think something like 75 percent of the productivity increases in

the United States have been driven by technology advances, this is our future. So, I wish that the budget weren't being cut this year for it. There's about a $24 million cut, I think, in the budget, at this moment. Hopefully, we all can address that as we go forward.

But I welcome all of the witnesses on this panel. And thank you very much, Mr. Chairman, for having this important hearing. I'm told that it is possible that the worldwide market in this field could be as much as $700 billion, some people say, by about 2008. And the—therefore, the possibilities, beyond the sort of lightness of materials and strength of those materials and all the other advances that we could gain through it are just mind-boggling, to say the least. So, we look forward to your testimony today.

And thank you, Mr. Chairman, for putting the Committee's focus on this.

The CHAIRMAN. Thank you very much.

Let us proceed and just go through, from left to right. We will be pleased to have your statements. All of your statements that were prepared will be in the record. And if you have them on CD, we'll take them and print them directly. But we hope that you can hold your statements to a reasonable period. As I said before, I do not want to cut you all off. The whole panel has doctorate degrees, and I think we ought to sit and listen, rather than ask questions.

Dr. Gotcher?

STATEMENT OF ALAN GOTCHER, PH.D., PRESIDENT/CEO, ALTAIR NANOTECHNOLOGIES, INC.

Dr. GOTCHER. I'd like to thank you, Chairman Stevens, for your leadership on this issue and for holding this hearing. I'd also like to thank Senator Ensign for his support in ensuring Nevada is a leader and a strong supporter of nanotechnology.

I'm Alan Gotcher, President and Chief Executive Officer of Altair Nanotechnologies. Previously, I was the Senior Vice President of Manufacturing and Technology, and Chief Technical Officer at Avery Dennison, a $5 billion company, where I managed corporate research, product development, and manufacturing.

I led the development and commercialization of several hundred-million-dollar new product platforms. I was, and still am, a serial inventor and entrepreneur.

Altair Nanotechnologies, or Altairnano, is a small, rapidly growing company where innovative nanomaterials are created and commercialized into a wide diversity of globally competitive products. We are a Nevada-based company publicly traded on NASDAQ. We have about 60 employees located in Reno, Nevada, and Anderson, Indiana.

Our twin missions are to create innovative products, such as green batteries for fully electric vehicles, or drug therapies for renal failure in humans and animals, that can benefit our society as a whole, and then to ensure that those products are safe. Because we take product stewardship seriously, we are currently gathering data to measure the impact of our nanomaterials and manufacturing processes on the health and safety of our employees and the environment. We do this to protect the environment and to provide sustainable economic benefits to our shareholders.

Here's the view of nanotechnology from the trenches. The hyperbole surrounding this technology is significant, but the potential is real. It can truly change our lives in many fundamental and positive ways. We're already beginning to see some of those changes. Almost half of the U.S. consumption of imported oil comes from dependence on the internal combustion engine used in cars and trucks. Nanotechnology may provide significant new products that can break that dependence and win the quest for a practical alternative-energy vehicle. Those vehicles of the future are just several years down the road. At Altairnano, our innovative nanostructured electrode materials enable realistic production of vehicles unlike any that are available today. Imagine a fully electric six-passenger car, or full-size pickup trucks, operating on batteries that can offer conventional acceleration and cruising speeds. These batteries will provide a driving range of at least 200 miles and a recharge time of just a few minutes, under 6. These batteries are more than twice the life cycle of comparable batteries today, able to power a vehicle for more than 100,000 miles without replacement, batteries that will be affordable, inherently safe, and environmentally friendly. Even sooner, imagine plug-in hybrid electric vehicles that can be charged rapidly at home, at work, providing gas mileage dramatically better than similar vehicles today.

At companies such as ours, environmental stewardship is obligatory. We are strongly committed to that principle, both in our manufacturing processes and in the applications of our products. Our product portfolio includes ion exchange and photocatalytic materials for cleaner water, biochemical sensors for environmental monitoring and homeland security, photocatalytic materials for indoor air purification, and, as I mentioned previously, a new generation of "green" battery technology. We're seeking partnerships with the Government in this pursuit, as illustrated by a collaboration that we initiated with the National Institute on Occupational Safety and Health.

We ask, from Congress—our two separate thrusts—the first focus on continued funding to U.S. companies for basic and applied R&D. Priority spending would be on alternative energy and life sciences. The former would be for commercially-interesting nanomaterials and systems solutions to replace or decrease the use of internal combustion engines. The latter, life sciences, would be for nanotechnology that could help investigate, monitor, and treat cancer and cardiovascular disease; thus, improving the quality of life and decreasing the cost of healthcare.

The second thrust would provide increased Federal funding for environmental health and safety research and development. What is needed is a broad initiative aimed at establishing empirical data and models for the predictability of environmental health and safety risks of commercially-interesting nanomaterials. Included must be inducements for private-sector companies to engage in this research initiative.

Yesterday, Altairnano cosigned a letter to the Senate Appropriations Committee urging just this sort of research initiative. As the letter notes, "Myriad applications of nanomaterials, which can exhibit a range of novel or enhanced properties, can hold great promise, but much more needs to be known about their potential risks."

Other signatories include large and small business, environmental groups, and nongovernment organizations. It's not often that these diverse groups find themselves on the same page. While I recognize that this committee does not handle appropriations, this letter may be of interest to your members. With the Chairman's permission, I ask that it be included in the record of today's hearing.

Thank you for the opportunity to speak here today. I'd be pleased to answer any questions later.

[The prepared statement of Dr. Gotcher follows:]

PREPARED STATEMENT OF ALAN GOTCHER, PH.D., PRESIDENT/CEO, ALTAIR NANOTECHNOLOGIES, INC.

I thank Chairman Stevens and Co-Chairman Inouye for their leadership in holding this hearing on the Developments in Nanotechnology in the U.S. Further, I would like to thank Senator Ensign for his support to ensure that Nevada is a nanotechnology leader.

I am Alan Gotcher, President and CEO of Altair Nanotechnologies, Inc. Altair (Altairnano), based in Reno, Nevada, is a leading supplier and innovator of advanced ceramic nanomaterial technology. Previously, I was Senior Vice President of Manufacturing and Technology and CTO at Avery Dennison, where I managed R&D, product development, manufacturing and lead the development and commercialization of several hundred-million-dollar new product platforms. I am also an inventor and entrepreneur.

The hyperbole surrounding nanotechnology is significant. And yet the potential of the technology is real. I wish to take this opportunity to address three core issues:

1. The State of the Technology: How it Looks From the Trenches

Nanotechnology can truly change our lives in many fundamental and positive ways. We have barely scratched the surface of what the science of nanotechnology might be capable. Today I will tell you how two of Altairnano's platforms—its Lithium-ion nano battery initiative and its chem/bio sensors—are on the verge of changing our reality.

2. The Responsible Commercialization of Nanotech Products: Altairnano as Steward

As this infant industry grows, we—like the chemical industry before us—must learn how to be good stewards of our environment. I will briefly outline our corporate commitment to product and environmental stewardship, and what we are doing to ensure that our products and manufacturing processes are safe.

3. The Role of the Federal Government: Ensuring the Global Competitiveness of the U.S. Nanotechnology Industry

All members of our national science and engineering establishment need to come together and partner with people in the nano industry in order to ensure that nanotechnology is researched and developed properly from the beginning. This will require a major commitment of Federal resources, which will be an investment in our country's future competitiveness.

1. The State of the Technology: How it Looks From the Trenches

As I said earlier, the hyperbole about nanotechnology is tremendous, but the potential for this technology to change our lives in many fundamental and positive ways is real. To illustrate that point, I offer two examples of exciting technology that Altairnano has developed and is currently in the process of commercializing. In each instance, the Altairnano materials—specifically due to their "nano-ness"—provide revolutionary characteristics that are desired by the marketplace. In addition to stimulating significant national economic activity, these development programs at Altairnano will serve to protect and improve the environment.

My first example is Altairnano's advanced, rechargeable Lithium-ion (Li-ion) nano battery. This product is a response to the increasing need and demand for more affordable, less-environmentally damaging energy sources. Consider the factors that are driving this demand:

- Pollutants emitted by conventional cars and trucks are making the air we breath increasingly unhealthy. (Recognizing this danger, many states are looking to follow California's lead by requiring low- and zero-emission vehicles.)

- Nearly half our consumption of imported oil comes from a dependence on conventional cars and trucks with internal combustion engines.
- We need to win the quest for the production of a practical alternative-energy vehicle.

The solution? Altairnano has created an innovative, rechargeable Li-ion battery that will enable realistic production of a vehicle unlike any available today. Imagine a fully electric six-passenger car or full-size pickup truck operating on batteries that offer conventional acceleration and cruising speed. Imagine batteries with a range of 200 miles—and with a recharge time of just several minutes. And imagine batteries with twice the lifecycle of anything comparable today—powering a vehicle for more than 100,000 miles.

Just last week, we produced and tested our first batch of Li-ion battery cells, utilizing the company's nano-structured electrode materials, at our Anderson facility just north of Indianapolis, Indiana.

Unprecedented Battery Performance

Testing has revealed that they perform at 90 percent of capacity at −22 degrees, Fahrenheit. Conventional Li-ion batteries and the nickel-metal hydride batteries used in hybrid electric vehicles become either sluggish or unable to charge at temperatures below freezing. In addition, unlike conventional Li-on batteries that risk spontaneous and catastrophic failure at temperatures above 266 degrees, the safety threshold for Altairnano's nano-structured lithium titanate spinel electrodes is 480 degrees, an important consideration for such extreme environments as aerospace and military applications. And, unlike current Li-ion batteries that contain hazardous chemicals and materials, the Altairnano battery designs and materials are intrinsically safe because they do not contain any toxic materials. This also makes them recyclable without any special needs.

As this performance shows, the infrastructure now exists for the creation of a high-performance, all-electric vehicle. This technology could be rapidly adopted by American automobile manufacturers, and is just around the corner. We are already in negotiations with top automobile, truck and bus manufacturers. Similarly, our technology is being evaluated by major manufacturers of hand-held power tools. Just imagine a power tool with twice the power of today's 18- to 20-volt tools at the same price point, and one that can be fully recharged while the worker grabs a cup of coffee. That, also, is coming soon.

Chemical/Biological Sensors for National Security

My second example of how Altairnano's unique materials can change our world relates to national security. We have been collaborating with the Universities of Western Michigan and Nevada-Las Vegas to develop chem/bio sensor arrays capable of detecting the presence of a wide spectrum of potential explosives, chem/bio weapons and illegal drugs. These arrays, made possible by Titanium Dioxide (TiO_2) base technology unique to Altairnano, have been successful beyond our wildest expectations. Not only are they capable of sensing the presence of low levels of potential explosive and chem/bio hazards, they're also able to report this information to a local display or a remote monitoring station.

With the help of scientists and engineers at Genesis Air Technologies, we have also learned how to use these and similar materials to destroy target chem/bio agents introduced into, for example, a building's HVAC system. The application of this technology can provide protection against most airborne health or environmental hazards. These materials are now being incorporated and tested by Genesis Air in systems designed for "smart" buildings. Clean, safe air with a built-in early-alert system in the case of adverse action: It's within sight, thanks to nanotechnology.

2. Responsible Commercialization of Nanotech Products: Altairnano as Steward

Altairnano is strongly committed to a position of good stewardship. This includes concern for the safety and welfare of our employees, our customers and strategic partners. *Employees and consumers should be shielded from exposure to nanoparticles at every point along a product lifecycle.* That is why we are dedicated to creating "safe" products—safe for individuals and safe for the environment.

Altairnano-NIOSH-University of Nevada Collaboration

Since the Fall of 2005, Altairnano has been working closely with scientists at NIOSH and the University of Nevada-Reno to monitor air quality in our Reno facilities. Ultimately, the two goals of this program are to ensure minimal—or zero—worker exposure to fine and ultrafine materials in the workplace, and to establish

the basis (a series of standard operation procedures or best practices) for a responsible employee health monitoring system. Regarding the former, preliminary findings show that Altairnano's particulate aggregates are of a size that would not likely harm either the environment, employees or consumers.

As for the latter, if this collaboration results in the creation of new best practices for the safe handling and monitoring of nanoparticles, these practices will be broadly disseminated through scientific talks and publications. Hopefully, this collaboration will also serve as a template for similar future efforts within the industry.

Altairnano & University of California-Santa Barbara (UCSB)

We are committed to this explicit goal: There must be little or no direct worker exposure to nanoparticles at the manufacturing site, and there must be virtually no downstream-worker or consumer exposure to free nanoparticles throughout the manufacture, use, and normal disposal of products incorporating these nanomaterials.

We will be collaborating with UCSB chemists, and materials, biological and environmental scientists to evaluate the intrinsic health hazard of our materials. Based on the data available in the literature and from our own testing programs, we believe the materials we are using in our products and platforms are generally recognized as safe at normal levels of exposure. Our goal in this collaboration is to learn under what conditions—if any—these materials might pose health or environmental hazards. We will simultaneously be investigating how to modify the composition, surface functionality or morphology of our materials so that they concurrently provide superior performance and inherently low-to-zero health risk.

The Altairnano Lithium-ion battery mentioned earlier is just one of several Altairnano products and initiatives that are "green." The EPA recently suggested six foci for improving environmental sustainability. Our R&D pipeline is already devoted to addressing these four:

- *Sustaining water resources*—Some of our products remove contaminants like arsenic, promote photo-oxidation of microbes and dangerous organics, and inhibit algal growth.
- *Generating clean energy*—We improve the manufacture of high-efficiency photovoltaics and rechargeable, high-performance "green" batteries.
- *Sustaining clean and healthy air*—Our photocatalytic systems can be added to building HVAC systems.
- *Using materials carefully and shift to environmentally preferable materials*—We're achieving that through development of green products (*e.g.,* Altairnano's innovative Li-ion battery) and manufacturing processes that do not use hazardous solvents.

3. Role of the Federal Government: Ensuring Global Competitiveness of the U.S. Industry

The needs of our society require continued funding to U.S. nanotechnology companies for basic and applied R&D, including priority spending in:

- Alternative energy, for commercially-interesting nano-materials and system solutions to replace or decrease the use of internal combustion engines.
- Life Sciences—For nano-materials and methods to investigate, monitor and treat cancers and cardio-vascular diseases to improve quality of life and decrease the cost of care.

Additionally, the Altairnano safety partnerships outlined earlier are examples of the first step in the type of research still needed to fill in the gaps about nanotechnology. The list of gaps in our knowledge base—connecting characteristics of one type of nanoparticle or another to potential environment, health or safety risks—is very long.

The U.S. is at a critical point in the development of this infant industry. If we go the route of seeking better answers and understanding of the various families/classes of nanomaterials *before* imposing government regulation, it could lead to greater benefits to the consumers and the environment through dramatic changes within widely diverse industries.

Taking the other road—regulation first, without research—could lead to a disquieting moratorium on all future nano-research and development in the U.S., with great cost to our economy. There are some who feel that nanotechnology will require new regulatory legislation—for example, a recent report by Terence Davies with the Woodrow Wilson International Center for Scholars/The Pew Charitable Trusts Project on Emerging Nanotechnologies.

But much of this concern is founded on sparse and sometimes conflicting data. If anything is clear, it is that there is no single prototypical "nanoparticle." Asbestos-like fibrous nanotubes and toxic-metal containing quantum dots are not good surrogates for all nanomaterials. To fall into a "one-size-fits-all" approach to nanotechnology is irresponsible and counter-productive. There are no clear and comprehensive data available to let us really assess the general risk of the wide range of nanomaterials under consideration and/or development.

Many of the cognizant Federal funding and regulatory agencies—such as the National Institutes of Health (NIH), the National Cancer Institute (NCI), the Food and Drug Administration, EPA and NIOSH—recognize this reality and are working hard to understand the underlying science and to develop quantitative data and models to quantitatively assess risks.

What Altairnano asks from Congress is the following:

> *A broad, government-funded initiative (similar to the Human Genome project) with the goal of establishing broad empirical data and models for the predictability of the environment, health and safety risks of commercially-interesting nanomaterials.*

Today, we lack data to say what characteristics or properties of a nanomaterial make it potentially harmful. Nor are there sufficient models to predict how the characteristics of materials change upon exposure to the environment, to transport, or bioaccumulation for most of the types of nanomaterials being developed.

While industry, academic, and government scientists continue to vigorously explore nanotechnology's potential *applications* in a wide variety of fields, including groundwater cleanup and cancer therapy, research on nanotechnology's potential health and environmental *implications* has failed to keep up. Federal funding for programs to develop appropriate EHS data for use in responsible regulation of nanotechnology is critical. EHS types of R&D comprise less than 4 percent of the core National Nanotechnology Initiative funding for materials and applications R&D. So much more needs to be done.

Federal research dollars are *essential* to supporting the creation of methods and tools critical to developing a fundamental understanding of the risk potential of nanomaterials and nanotechnologies. A metrology and modeling infrastructure would help producers and users of nanomaterials to fulfill their responsibility to identify potential risks of their own materials and applications. With increased Federal funding, our society will be in a stronger position to address such risk while these materials are still in an early stage of development and commercialization. An early and open examination of the potential risks of a new product or technology is critical to responsible product development and technology application.

Others have presented the data gaps and modeling needs, and have priced such a program at the $0.5 billion to $1 billion range over the next five to 8 years. And, to be very clear, this would not be a program aimed at elucidating the connection of structure-function relationships of certain nanomaterials to performance enhancements in specific applications. Nor should it have a materials discovery thrust.

For a national prioritization of EHS research needs, we need to convene a dialogue of all informed stakeholders to assess what is known, what technologies are available, and what capabilities need to be developed.

Once the needs are prioritized—once we have a roadmap—we can then form teams and consortia, and attack the highest-priority problems. Hopefully a strong Federal participation (including staff at NIST, NIH, NCI, EPA, NIOSH, *etc.*) and substantial Federal funding will ensure that what we learn is broadly shared across our entire nanotech enterprise.

Private-sector participation is also critical. But participation by and Federal funding to for-profit companies has to be acceptable as a trade-off for their participation, and the sharing of results. Federal investment and participation in developing the underlying EHS metrologies, models and methodologies will dramatically accelerate the realization of the economic potential promised by nanotechnology. This would be an investment that will raise all boats.

I would like to ask you think back just 10 years. Take a minute to revisit the history of the gene chip. In 1994, it was just a dream—a concept that might have utility in clinical diagnostics. The government made a coherent suite of tailored investments in the mid-1990s—less than $200 million of government funding invested in industry-led R&D activities engaging over 100 companies, universities and national laboratories. With the help of that funding, by 2001 we had an infant gene-chip industry, with widespread use in academic and medical research labs and a changing view of what the technology could do. By 2005, gene-chip sales had reached nearly $1 billion and micro- and nano-arrays are now a core tool of modern

drug development, as well as powerful diagnostics. Now, healthcare professionals can't imagine modern medicine without the presence of the gene chip.

This is an excellent example of how the right types of investments at the right time in history can make all the difference. Federal investment into nanotechnology EHS research today could lead nano along similar time and economic development trajectories.

Inducements for Private-Sector Companies to Engage in That Research Project, Within a Framework That Is as Open and Accessible as Possible

Neither academia nor the Federal Government is going to be able to develop the requisite knowledge-base without the help of private industry—especially not without technology start-ups and small materials development companies. Smaller, independent companies like ours are the ones that will ultimately bring the majority of new nanomaterials into the marketplace. These types of companies not only provide insight into the types of materials to which workers, consumers and the environment will soon be exposed, they also provide a window on manufacturing processes and waste streams.

It is in *our Nation's* best interest to have them involved, in order to get this right, and to get it right from the start.

To ensure the participation of smaller nanomaterials companies, reimbursement for their participation in such programs is crucial. Unfortunately, most of the NNI funding mentioned earlier goes to Federal agencies, like NIH and EPA, which do not generally fund companies. If funding is provided, it's limited to materials-discovery R&D. Even the NIOSH and NIEHS components of the joint STAR grants are limited to the modest funding of $133,000 per year.

Open Source Infrastructure

Beyond the absence of company participation in most of the current nanomaterials EHS research, there is a fundamental problem with our collective approach to ensuring the responsible development of nanotechnology.

Most large chemical companies involved in nanotechnology have established safety programs and diverse product pipelines. They know what to do, but will wait until specific materials and product concepts have passed through multiple developmental-stage gates prior to undertaking any substantive EHS studies. Even then, the methods used and results will remain proprietary. Because new metrologies and predictive models need to be developed for nanoparticles and materials, this business-as-usual approach is highly inefficient, and will create a few winners and many losers.

What we need are Federal R&D programs geared toward bringing companies and academics together to develop a suite of metrology tools and predictive models that will be accessible to and usable by all. This is a critical point in history. Five years ago it was *too early* in the lifecycle of nanotechnology for such a bold plan. Five years from now, it could be *too late* for us to catch up with advances made by competing nations.

Regulatory Mentoring

Many smaller nanotechnology companies have no prior experience with worker safety or regulatory compliance programs, and are fearful of "big government's stick." Regulatory agency staffers need to establish informational outreach programs that make it easy to "do it right" from day one. Programs that encourage mentorship from larger, established chemical companies in the same materials or applications space would be especially useful.

Altairnano, and companies like us, need to be able to know that we can approach these Federal agencies and get helpful guidance for moving forward. Because we are investing shareholder monies in our R&D and product development programs, we also need to know that evolving regulations will be predictable and based on *sound science*—not political expedience.

One suggestion would be to fund regularly held workshops that gather scientists, technologists and engineers from large and small companies, academic and government research labs, and legal advisors and regulators to discuss application- or materials-specific regulations and appropriate regulatory pathways from product concept to market entry and beyond.

A Transparent and Consistent Regulatory Environment That Is Truly Data Driven

I believe we can all agree that there is insufficient quantitative data to inform the development or application of any new regulatory activities. And, anything we attempt to put in place today would likely prove to be an imperfect solution that might be a greater drag on economic development than no regulation at all. There seem to be two common concerns: There is no clear central point of contact and con-

trol for nanotechnology, and the number of new materials being developed would swamp the system

I would like to propose a solution that I believe would be embraced by both large and small nanomaterials companies. Let's create a portal to a unified governance committee that operates in a manner analogous to the FDA.

While holding regulatory authority, the FDA is probably one of the single most powerful drivers of economic development throughout the medical industry. The agency staff helps innovators and inventors at early stages of product and process development by teaching them what they need to know and do to comply with the appropriate regulatory framework. The staff provides a way for the innovator's product ideas and work to come up to speed on new technologies as they arise, a single point-of-contact and control, constant and transparent processes, strong outreach and advocacy.

The approval process is also a staged process. For example, in developing a new drug, one might evaluate (at the sub-gram level of manufacture) tens of thousands of molecules before striking the handful of potential leads that the company considers commercially relevant. It is only at this point that manufacture is scaled up to tens or hundreds of grams and animal trials are undertaken. Only those lead candidates that pass initial animal trials are submitted for limited evaluation for safety (Phase I Clinical Trials).

Essentially, what this means is that only one in many compounds are presented to the FDA for regulatory approval. Clearly, it is at this point that the analogy between development of nanomaterials and therapeutic drugs breaks down. But my point is that there are examples that demonstrate responsible and effective regulatory oversight without imposition of unreasonable burden to the innovators. From a corporate-governance perspective, having an established and rigorous regulatory pathway to market enables innovators to know that they are acting in good faith as product stewards.

Support Math and Science Education at All Levels

We all have seen the numbers from the National Science Foundation—while 70,000 Ph.D. engineers are graduating from universities in China and 35,000 from universities in India, there are fewer than 10,000 engineering graduates from universities in the U.S. Plus, many of the U.S. graduates are foreign nationals, many of whom return home with the benefits of their education. This is a national crisis.

For Altairnano, it is also a company crisis. It is extremely difficult for us to recruit science and engineering students from the University of Nevada-Reno. There just are not enough students in the pipeline to go around. Nanotech—the "sexy" science of the 21st century—might be the catalyst needed to stimulate renewed interest in math and science in American students, from K through graduate school. One approach would be to fund the development of curricula, in coordination with scientists and engineers from local/regional nanotechnology companies, and focused on, perhaps, grades five and six, junior high, and high school.

Another approach could be to fund scholarships to nanoscience camps for students at the junior high and high school levels. A third approach could be to provide scholarships for students enrolling in nanotechnology programs at undergraduate and graduate levels—including curricula focused on nanomaterials and nanochemistry, nanobiology, and nano-environmental engineering. All of these programs should include a component devoted to considerations of public policy issues affecting nanotechnology.

Thank you for the opportunity to speak here today. I will be pleased to try to answer any questions that you might have.

[Individually addressed copies of this letter were sent to all members of the Senate and House Appropriations Committees]

February 14, 2006

Dear Senator:

The undersigned organizations strongly urge you to significantly increase appropriations directed to research on the health and environmental implications of nanotechnology. Although the National Nanotechnology Initiative (NNI) has an annual budget of more than $1 billion, health and environmental implications research currently accounts for less than 4 percent of that amount ($38.5 million for FY06).

Nanotechnology, the design and manipulation of materials at the molecular and atomic scale, is one of the most exciting fields in high technology—one that could revolutionize the way our society manufactures products, produces energy, and

treats diseases. Myriad applications of nanomaterials, which can exhibit a range of novel or enhanced properties, hold great promise, but much more needs to be known about their potential risks.

While industry, academic, and government scientists continue to vigorously explore nanotechnology's potential *applications* in a wide variety of fields, such as groundwater cleanup and cancer therapy, research on nanotechnology's potential health and environmental implications has failed to keep up. Federal research is essential to providing the underlying methods and tools critical to developing a fundamental understanding of the risk potential of nanomaterials and nanotechnologies—methods and tools that all producers and users can then use to fulfill their appropriate responsibility to identify potential risks of their own materials and applications. With increased Federal funding, our society will be in a stronger position to address such risks while these materials are still in an early stage of development and commercialization. An early and open examination of the potential risks of a new product or technology is critical to responsible product development and technology application.

We appreciate your consideration of this request. For further information, please contact Mr. Terry Medley, Global Director, Corporate Regulatory Affairs, DuPont, at (302) 773–3191, or Ms. Karen Florini, Senior Attorney, Environmental Defense, at (202) 387–3500.

Sincerely,

Air Products & Chemicals, Inc.
Altair Nanotechnologies Inc.
BASF Corporation
Carbon Nanotechnologies, Inc.
Degussa
DuPont
Environmental Defense
Foresight Nanotech Institute
Houston Advanced Research Center
Lux Research, Inc.
NanoBusiness Alliance
Natural Resources Defense Council
PPG Industries, Inc.
Rohm and Haas Company
Union of Concerned Scientists

The CHAIRMAN. Thank you.

All of the statements you have, and attachments, will be printed in the record.

Dr. Hylton?

STATEMENT OF DR. TODD L. HYLTON, DIRECTOR, CENTER FOR ADVANCED MATERIALS AND NANOTECHNOLOGY, SCIENCE APPLICATIONS INTERNATIONAL CORPORATION

Dr. HYLTON. Chairman Stevens and distinguished members of the Committee, I want to thank you for inviting me to testify on developments in nanotechnology. It is a subject that's near and dear to my heart.

I have spent my entire career working to transition nanotechnologies from the research laboratory to products. Trained as an applied physicist, my career includes work for large and small technology companies working variously in the fields of semiconductors, magnetic storage, sensing, equipment, and defense.

I am currently employed by Science Applications International Corporation, in McLean, Virginia, where I manage a group of scientists and engineers providing nanotechnology development and transition services to government and commercial clients.

Nanotechnology is not an isolated technical innovation. Rather, nanotechnology is a convergence of emerging capabilities from the physical, chemical, and biological sciences dealing with the manipulation and design of matter at the nanometer scale. I believe that the term "nanotechnology" ultimately will be recognized as an era of innovation, lasting throughout most of this century, that transforms human existence with profundity and scope never before seen.

In the past 2 decades, I have observed a seemingly inexorable displacement of the technology industries in this country. For example, most of the newest semiconductor and display manufacturing facilities are being located offshore. In large part, this transformation is a consequence of global competition, technology access, and a general leveling of the quality of life across the world. From a global humanitarian perspective, this transformation is long overdue, and I believe it will continue unabated.

From a national perspective, however, we must maintain leadership in the commercialization of new technologies, as this leadership will be the material basis of our economic prosperity and our global leadership.

My testimony today focuses on the challenges of transitioning nanotechnologies from the research laboratories to commercialization. Because of the inherent complexities associated with nanotechnologies, many of the most valuable of these transitions will be extremely difficult. In addition to its basic research investment, I propose that the country consider investment in a new means to effectively commercialize nanotechnologies.

I'm going to refer now to a chart which is contained within the materials that you have in front of you, committee members, but which is not projected.

The first chart. I illustrate—in the first chart, I illustrate a typical technology transition process in the United States today. Basic research at universities and research laboratories results in the creation of novel technical capabilities whose applicability is generally poorly understood. A small fraction of these capabilities are absorbed by a small company, which invests in the transition of that capability into a commercially-viable concept. A larger company then generally enters to provide late-stage product development and market access. The critical portion of the transition process is borne by the small company and its investors.

Prior to the emergence of this model, the prevalent model involved very large, very profitable companies transitioning internally funded basic research into new products. This older model became obsolete with the advent of increased domestic competition and the emergence of similarly powerful foreign competitors. By virtue of evolving global competition and investor sentiments, the current model, featuring small companies and venture capital investors, is now under stress.

The current technology transition model poses three major challenges for nanotechnology commercialization.

The first challenge is that the technology transition process is very long, often exceeding 10 years, because the technical breadth and complexity inherent in most nanotechnologies. Research institutions and large companies typically cannot support a technology transition effort exceeding 2 years. Venture capitalists are typically uninterested in investments exceeding 5 years. And very, very few small companies can sustain a decade-long transition process.

The second challenge is access to intellectual property, which initially may be distributed among various research institutions and which freedom to employ is required for successful commercialization.

The third challenge is access to, or existence of, supporting hardware infrastructure—for example, prototype manufacturing—to demonstrate product scalability and cost.

Referring now to the second chart, I illustrate an alternative technology transition model intended to address these challenges. The critical piece is the creation of public/private organizations dedicated to the technology—dedicated to technology transition in a specific industry segment that coordinate and serve a large array of research institutions, a consortium of small and large technology companies, and public economic development organizations nationwide. At the interface with the research institutions, the new organization provides a conduit for intellectual property to the business consortium.

At the interface with the established industry, which is mostly large companies, the new organization provides well-developed technologies and a new—and new product opportunities and receives financial support and product-development resources and market guidance.

At the interface with small technology companies, the new organization provides business, technical, and infrastructure-related services and receives product-development resources.

And at the interface with the private sector—with the public sector, excuse me, the organization provides economic-development opportunities and receives assistance for participating businesses.

Public funding for the new organization would be used to establish and maintain core staff and facilities, while participating businesses and research institutions would contribute technical staff, as needed.

The many challenges of establishing such an organization notwithstanding, the advantages of such an approach include sufficient longevity to address the length of the technology transition process, a comprehensive approach to access and employ the intellectual property assets of the Nation, and, thereby, to maximize the value of the national investment in basic research in nanotechnology, a means to effectively share expensive infrastructure, such as prototype manufacturing capabilities, a means to target markets through the market leaders, a large reduction in risk for private investors and entrepreneurs, thereby generating greater private investment and more new-company starts, a coordination of regional economic development resources nationwide, and, finally, a competitive posture that does not attempt to select winners in the marketplace.

I propose that the country consider the creation of a network of these technology transition organizations, each with a specific industry focus, many of which have already been discussed, things such as energy, medical devices, medical therapeutics, and computing. This network would closely parallel the research activity sponsored by the National Nanotechnology Initiative and would seek to capitalize on the research that it supports.

Last, I would like to comment on the often-heard statement that we need to educate more scientists and engineers in the United States. The unstated assumption behind this assumption—behind this statement is that, by educating more scientists and engineers,

we will be able to maintain our leadership in technical innovation and technology-based economic development.

I would like to point out that the career of the technical professional generally parallels the transition of new technologies. In response to our recent difficulties in transitioning new technology and the corresponding dearth of career opportunities, the best and brightest students in the U.S. increasingly, and, I think, correctly, select other professions. When the opportunities return, the U.S. students will return, as well.

Thank you very much for the opportunity to testify today.

[The prepared statement of Dr. Hylton follows:]

PREPARED STATEMENT OF DR. TODD L. HYLTON, DIRECTOR, CENTER FOR ADVANCED MATERIALS AND NANOTECHNOLOGY, SCIENCE APPLICATIONS INTERNATIONAL CORPORATION

Chairman Stevens, Senator Inouye, members of the Committee, I want to thank you for inviting me to testify on developments in nanotechnology, a subject near and dear to my heart. I have spent my entire career working to transition nanotechnologies from the research laboratory to products. Trained as an applied physicist, my career includes work for large and small technology companies working variously in the fields of semiconductors, magnetic storage, sensing equipment, and defense. I am currently employed by Science Applications International Corporation in McLean, Virginia, where I manage a group of scientists and engineers providing nanotechnology development and transition services to government and commercial clients.

Nanotechnology is not an isolated technical innovation; rather, nanotechnology is a convergence of emerging capabilities from the physical, chemical and biological sciences dealing with the manipulation and design of matter at the nanometer scale. I believe that the term *nanotechnology* ultimately will be recognized as an era of innovation lasting throughout most of this century that transformed human existence with profundity and scope never before seen.

In the past two decades I have observed a seemingly inexorable displacement of the technology industries in this country. For example, most of the newest semiconductor and display manufacturing facilities are being located offshore. In large part this transformation is a consequence of global competition, technology access, and a general leveling of the quality of life across the world. From a global humanitarian perspective this transformation is long overdue, and I believe it will continue unabated. From a national perspective, however, we must maintain leadership in the commercialization of new technologies, as this leadership will be the material basis of our economic prosperity and our global leadership. My testimony today focuses on the challenges of transitioning nanotechnologies from the research laboratories to commercialization. Because of the inherent complexities associated with nanotechnologies, many of the most valuable of these transitions will be extremely difficult. In addition to its basic research investment, I propose that the country consider investment in a new means to effectively commercialize nanotechnologies.

Referring now to Chart 1, I illustrate a typical technology transition process in the United States today. Basic research at universities and research laboratories results in the creation of novel technical capabilities whose applicability is generally poorly understood. A very small fraction of these capabilities are absorbed by a small company, which invests in the transition of that capability into a commercially-viable concept. A larger company then enters to provide late-stage product development and market access. The critical portion of the transition process is borne by the small company and its investors. Prior to the emergence of the current model, the prevalent model involved very large, very profitable companies transitioning internally-funded basic research into new products. This older model became obsolete with the advent of increased domestic competition and the emergence of similarly powerful foreign competitors. By virtue of evolving global competition and investor sentiments, the current model featuring small companies and venture capital investors is now under stress.

The current technology transition model poses three major challenges for nanotechnology commercialization. The first challenge is that the technology transition process is very long, often exceeding 10 years, because of the technical breadth and complexity inherent in most nanotechnologies. Research institutions and large companies typically cannot support a technology transition effort exceeding 2 years; ven-

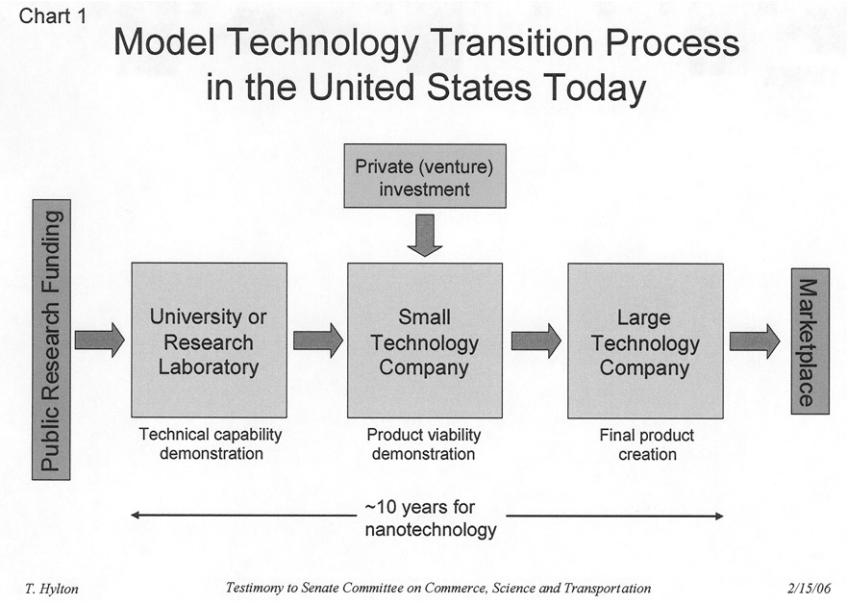
ture capitalists are typically uninterested in investments exceeding 5 years; and very, very few small companies can sustain a decade-long transition. The second challenge is access to intellectual property, which initially may be distributed among various research institutions and which freedom to employ is required for successful commercialization. The third challenge is access to (or existence of) supporting hardware infrastructure, for example prototype manufacturing to demonstrate product scalability and cost.

Referring now to Chart 2, I illustrate an alternative technology transition model intended to address these challenges. The critical piece is the creation of public-private organizations dedicated to technology transition in a specific industry segment that coordinate and serve a large array of research institutions, a consortium of large and small technology companies, and public economic development organizations nationwide. At the interface with the research institutions, the new organization provides a conduit for intellectual property to the business consortium. At the interface with the established industry (mostly large companies), the new organization provides well-developed technologies and new product opportunities and receives financial support, product development resources, and market guidance. At the interface with small technology companies, the new organization provides business, technical and infrastructure-related services and receives product development resources. At the interface with the public sector, the organization provides economic development opportunities and receives assistance for participating businesses. Public funding for the new organization is used to establish and maintain core staff and facilities, while participating businesses and research institutions contribute technical staff. The many challenges of establishing such an organization notwithstanding, the advantages of such an approach include:

- sufficient longevity to address the length of the technology transition process;
- a comprehensive approach to access and employ the intellectual property assets of the Nation and, thereby, to maximize the value of the national investment in basic research in nanotechnology;
- a means to effectively share expensive infrastructure such as prototype manufacturing capabilities;
- a means to target markets through the market leaders;
- a large reduction in risk for private investors and entrepreneurs, thereby generating greater private investment and more new-company starts;
- a coordination of regional economic development resources nationwide; and
- a competitive posture that does not attempt to select winners in the marketplace.

I propose that the country consider the creation of a network of these technology transition organizations, each with an industry focus such as, for example, energy conversion (*e.g.,* solar, thermal), energy storage (*e.g.,* batteries, hydrogen), agriculture, medical diagnostics and devices, medical therapeutics, high-speed electronics, flexible electronics, and high-strength materials. This network would closely parallel the research activities sponsored by the National Nanotechnology Initiative and would seek to capitalize on the research that it supports.

Lastly, I would like to comment on the often heard statement that we need to educate more scientists and engineers in the United States. The unstated assumption behind this statement is that by educating more scientists and engineers we will be able maintain our leadership in technical innovation and technology-based economic development. I would like to point out that the career of the technical professional generally parallels the transition of new technologies. In response to our recent difficulties in transitioning new technology and the corresponding dearth of career opportunities, the best and brightest students in the U.S. increasingly (and correctly) select other professions. When the opportunities return, the U.S. students will return, as well.



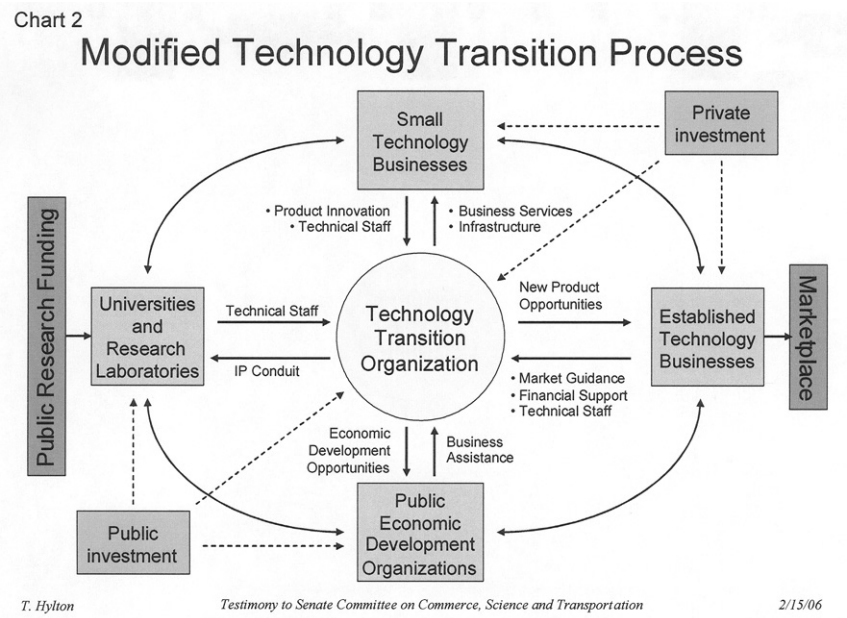


Chart 3

FUNCTIONS OF THE TECHNOLOGY TRANSITION ORGANIZATION

- Intellectual Property Coordination
- Product Development Infrastructure
- Small Business Services
- Participant Relationship Management
- Technical Development Coordination

- Economic Development Coordination
- Market Strategy Coordination and Roadmapping

Chart 4

POTENTIAL INDUSTRY FOCUSED TECHNOLOGY TRANSITION ORGANIZATIONS

- Energy conversion (*e.g.,* solar, thermal)
- Energy storage (*e.g.,* batteries, hydrogen)
- Agriculture
- Medical diagnostics and devices
- Medical therapeutics
- High speed electronics
- Flexible electronics
- High strength materials
- *The Focuses of the Technology Transition Organizations should parallel the investments of the National Nanotechnology Initiative*

The CHAIRMAN. Thank you very much, Doctor.

Our next witness is Dr. Timothy Swager, Professor of Chemistry at MIT.

STATEMENT OF TIMOTHY M. SWAGER, PH.D., PROFESSOR OF CHEMISTRY, MASSACHUSETTS INSTITUTE OF TECHNOLOGY (MIT); ON BEHALF OF THE INSTITUTE FOR SOLDIER NANOTECHNOLOGIES (ISN)

Dr. SWAGER. Thank you, Chairman Stevens, for the invitation to be here. And thank you, Senator Kerry, for——

The CHAIRMAN. I might say, it is a courtesy of the Chair to call on witnesses who have home state Senators up here. So, I apologize to the rest of you, but——

Dr. SWAGER. OK. Thank you for the introduction. I appreciate it.

I'm a Professor of Chemistry at MIT, and representing today the Institute for Soldier Nanotechnologies, which is an Army-funded research center.

The Institute for Soldier Nanotechnologies is dedicated to the development of nano-enabled technologies to protect dismounted soldiers. The ISN mission is to increase capabilities by simultaneously decreasing the weight soldiers must carry. Present-day soldiers, like the one shown in this picture from Iraq, often carry in excess of 100 pounds of equipment, which reduces their effectiveness and survivability in the field.

The CHAIRMAN. I'll tell you, Doctor, when they appeared here, we added it up, and they weighed more than I do.

[Laughter.]

The CHAIRMAN. The stuff that they were carrying weighed more than I do.

Dr. SWAGER. It's impressive how resilient these soldiers are.

Our vision is to design, from the ground up, a new battlesuit with a number of integrated systems that automatically activate on on-demand, much in the same way as airbags deploy in automobiles. It will include sensing subsystems to detect chemical and biological threats, as well as perform physiological monitoring. It will provide mechanical performance enhancements, integrated power, and informational systems.

Nanotechnology will help us integrate these many functions into the uniform. One materials platform we envision is the fabric of the uniform itself, wherein a diversity of functional nanocoatings will be developed which provide massive new capability to the soldier, with an insignificant increase in weight.

The ISN has over 30 research projects, but today I will focus on only two examples of new sensory systems for enhanced situational awareness.

New nanostructured optical fibers have been developed to detect specific kinds of light, such as that coming from a targeting laser. These fibers are produced by a drawing process and contain metal electrodes interfaced with semiconductors. When illuminated with light, electrical currents are generated between the metal electrodes. The optical fibers display selected responses to different colors of light due to a photonic coating. Grids of fibers can be used to determine the point of illumination, and extensions of this technology will eventually be able to tell a soldier the direction from which the light originated.

We are also developing networks of photonic molecular wires for the detection of explosives. These materials are electronic plastics that absorb and emit light, and have high sensitivity to explosives like TNT. These materials have the unusual ability to self-amplify their own sensory responses due to transport of energy packets through the network. This process behaves similar to a string of holiday lights, wherein only one light need be broken to cause the entire system to become dark. In a similar way, one molecule of TNT can produce a massively amplified response.

To transition our technologies to the military, the ISN works with partner companies, both large and small, distributed throughout the United States. MIT has licensed our explosive-detection technology, to Nomadics, a small company based in Oklahoma, also with a site in Massachusetts, which has developed ultrasensitive explosive detectors. I am a paid consultant for Nomadics and actively assist them in extending this technology.

The Nomadics sensor, known as Fido™, one of which I have brought with me here today, detects vapors of explosives as they pass through a capillary tube. I also have a capillary that is coated with our molecular wires.

The CHAIRMAN. I don't think they saw that. Hold that up——

Dr. SWAGER. It's just a small capillary that has a nanocoating of our electronic polymer inside. You can't even see it. It's what I call a definition of very-high-value material. These systems can detect explosive vapors at distances more than 2 meters away from the source. Only trained dogs are capable of similar detection limits; and, hence, Fido™ represents a new capability for our soldiers.

Fido™ sensors are undergoing evaluation in Iraq, both as handheld systems and on robotic platforms. I show here Fido™ mounted on a PackBot, which is a robotic platform developed by iRobot. As shown in the photograph, this integrated system can be used at checkpoints for vehicle interrogation at safe distances. It can also be used for investigating potential roadside bombs and in identifying individuals who have recently handled explosives. The feedback from the soldiers has been very promising.

Thank you.

[The prepared statement of Dr. Swager follows:]

PREPARED STATEMENT OF TIMOTHY M. SWAGER, PH.D., PROFESSOR OF CHEMISTRY, MASSACHUSETTS INSTITUTE OF TECHNOLOGY (MIT); ON BEHALF OF THE INSTITUTE FOR SOLDIER NANOTECHNOLOGIES (ISN)

(Slide 1)

The Institute for Soldier Nanotechnologies (ISN) is dedicated to the development of nano-enabled technologies to protect dismounted soldiers. The ISN mission is to increase capabilities while simultaneously decreasing the weight soldiers must carry. Present day soldiers, like the one shown in this picture from Iraq, often carry in excess of 100 pounds of equipment, which reduces their effectiveness and survivability in the field.

(Slide 2–3)

Our vision is to design from the ground up a new battlesuit with a number of integrated systems that activate automatically on-demand, much in the same way as airbags deploy in automobiles. It will include sensing subsystems to detect chemical and biological threats as well as perform physiological monitoring. It will further provide mechanical performance enhancements, integrated power, and informational systems.

(Slide 4)

Nanotechnology will help us to integrate these many functions into the uniform. One materials platform we envision is the fabric of the uniform itself wherein a diversity of functional nanocoatings will be developed which provide massive new capability to the soldier with an insignificant increase in weight. The ISN has over 30 active research projects, but today I will focus on two examples of new sensory systems for enhanced situational awareness.

(Slide 5)

New nanostructured optical fibers have been developed to detect specific kinds of light such as that coming from targeting lasers. These fibers are produced by a drawing process and contain metal electrodes interfaced with semiconductors. When illuminated with light, electrical currents are generated between the electrodes.

(Slide 6)

The optical fibers display selective responses to different colors of light due to a photonic coating. Grids of fibers can be used to determine the point of illumination, and extensions of this technology will eventually be able to tell a soldier the direction from which the light originated.

(Slide 7)

We have also developed networks of photonic molecular wires for the detection of explosives. These materials are electronic plastics that absorb and emit light and have a high sensitivity to explosives like TNT. These materials have the unusual ability to self-amplify their own sensory responses due to the transport of energy packets throughout the network. This process behaves similarly to a string of holiday lights wherein only one light need be broken to cause the entire system to become dark. In a similar way one molecule of TNT can provide a massively amplified response.

(Slide 8)

To transition our technologies to the military, the ISN works with partner companies, both large and small, distributed throughout the United States. MIT has licensed our explosives detection technology to Nomadics, a small company based in Oklahoma, which has developed ultra-sensitive explosive detectors. I am a paid consultant of Nomadics and actively assist them in extending this technology.

(Slide 9)

The Nomadics sensor, known as Fido™, detects vapors of explosives as they pass through a capillary containing a nanocoating of our electronic plastic. These systems can detect explosive vapors at distances more than 2 meters away from the source. Only trained dogs are capable of similar detection limits, and hence Fido™ represents an important new capability for our soldiers.

(Slide 10)

Fido™ sensors have been fielded in Iraq both as hand held systems and on robotic platforms. I show here Fido™ mounted on a PackBot, which is a robotic platform developed by iRobot. As shown in the photograph, this integrated system can be used at checkpoints for vehicle interrogation at safe distances. It can also be used for investigating potential roadside bombs and identifying individuals who have recently handled explosives. The feedback from soldiers has been very promising.

ISN Mission:

"Use nanotechnology to dramatically improve the survivability of Soldiers."

QuickTime™ and a TIFF (Uncompressed) decompressor are needed to see this picture.

Soldiers are the first customers – and improved protection offers benefits to others.

Goal: **reduce weight carried** while **improving protection** from multiple threats, such as blast, ballistic, chemical/biological toxins, physical injury, climate, environment, terrain.

The ISN Vision: *Dynamic Battlesuit Enabled by Integrated Systems of Nanotechnologies*

Battlesuit Guiding Concept:
On board, on-demand protection systems, automatically deployed when threat sensed.

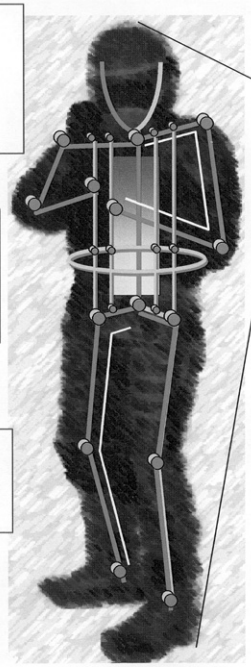
QuickTime™ and a TIFF (Uncompressed) decompressor are needed to see this picture.

The ISN Vision: *Dynamic Battlesuit Enabled by Integrated Systems of Nanotechnologies*

On-Demand
Chem, Bio & Blast/Ballistic
Sensing & Protection

Physiological Monitoring
Medicines & Healing Agents
Thermal Management

Mechanical Performance Improvement



Networked Sensors, Mechanical Actuators, Chemical Reactors, & Storage Reservoirs…

Future Directions:
Information & Power Networks
Control of Suit Subsystems

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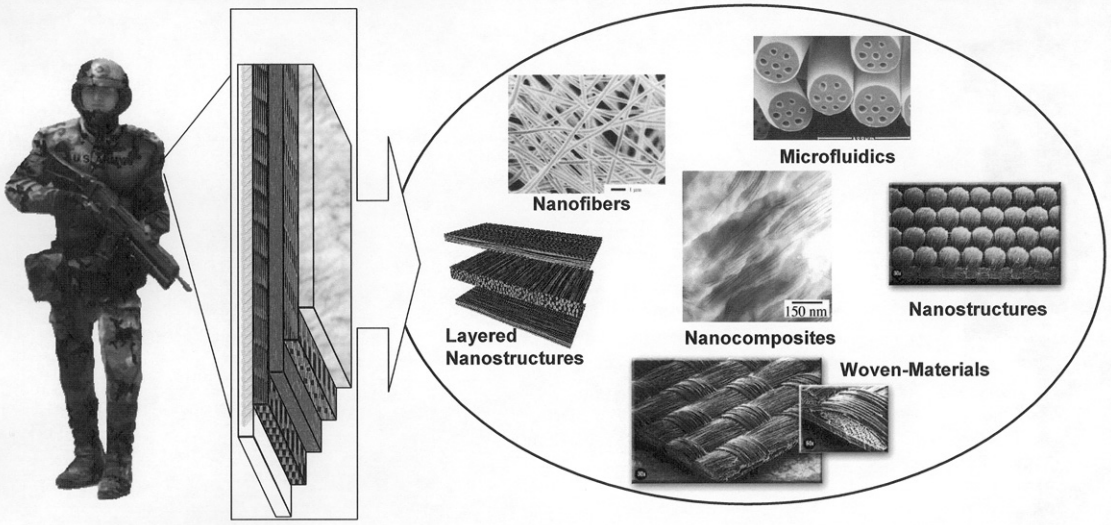
Multifunctional Adaptive-Active Nanostructured Fibers and Materials



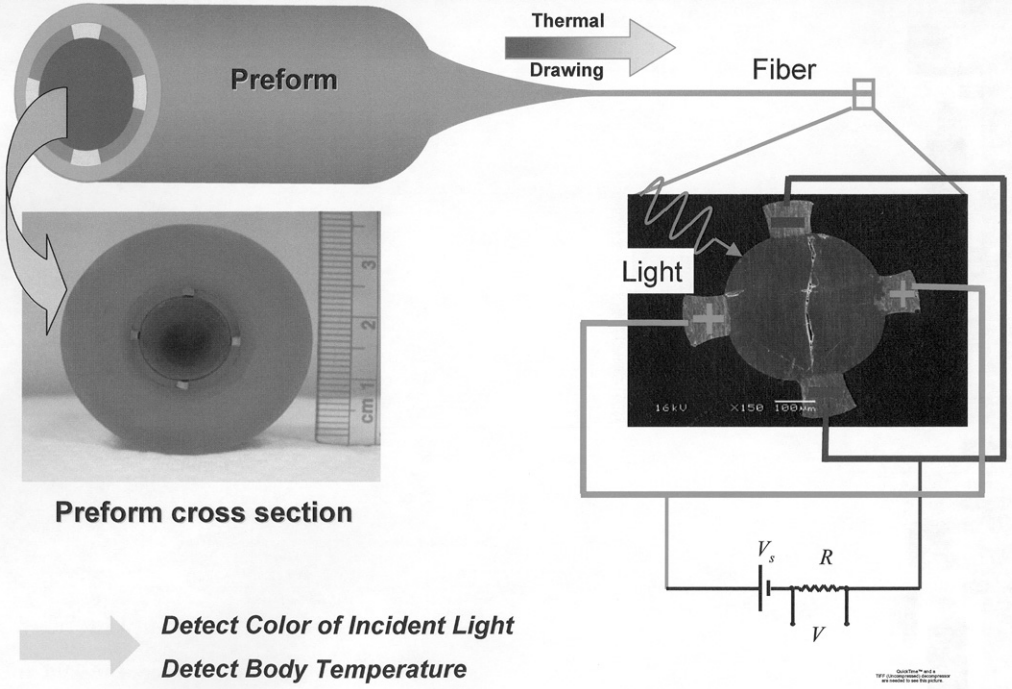
The Battlesuit:

Layers of Multifunctional Nanomaterials
Systems of Nanosystems

Massive Functionality with Decreased Weight / Volume

Fibers that See and Feel:

Integration of semi-conducting and optical functions into fibers and fabrics

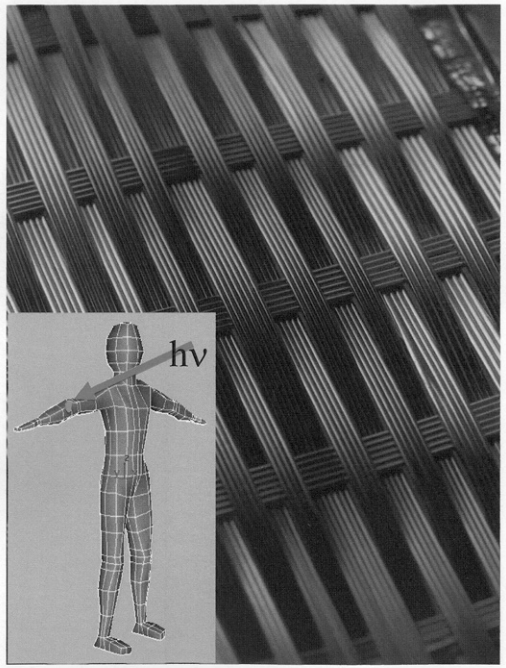


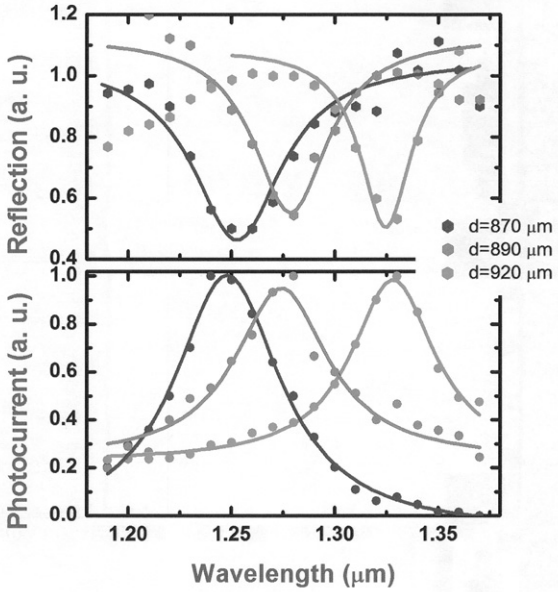
Preform cross section

Detect Color of Incident Light

Detect Body Temperature

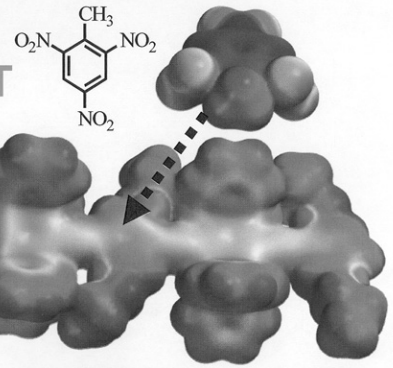
From Narrow Band Photodetector Fiber To Color Sensing Fabric



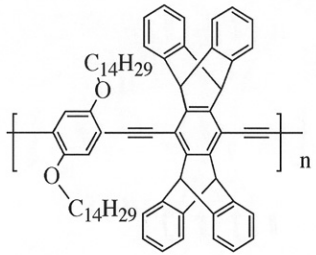


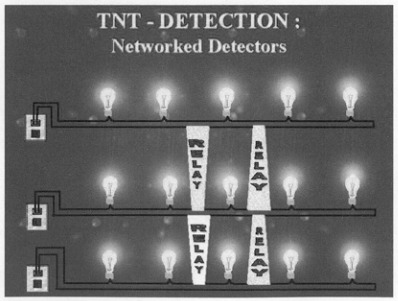
Networks of Fluorescent Molecular Wires For Detection of Explosives

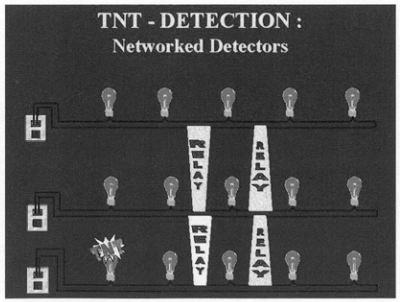
TNT



MIT Polymers are extremely sensitive TNT Detectors







Team ISN - Industry

Founding Partners

DuPont
Partners HealthCare
Raytheon

Major Industrial Members

Dow Corning
JEOL USA

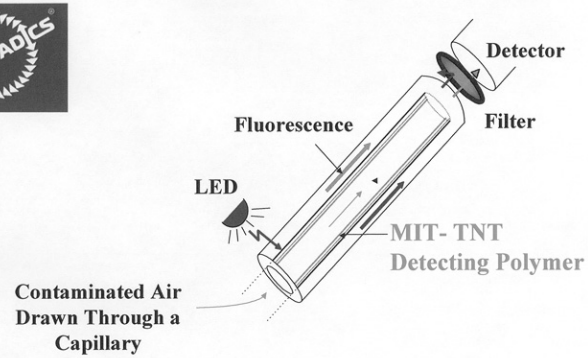
Small Business Industrial Members

CNI
dnt
zyvex
tsi
Nomadics

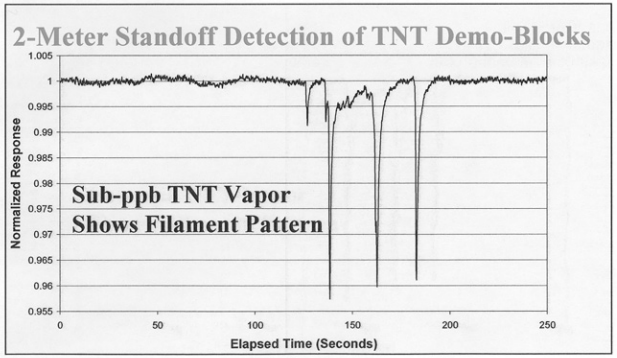
Interested Industrial Participants

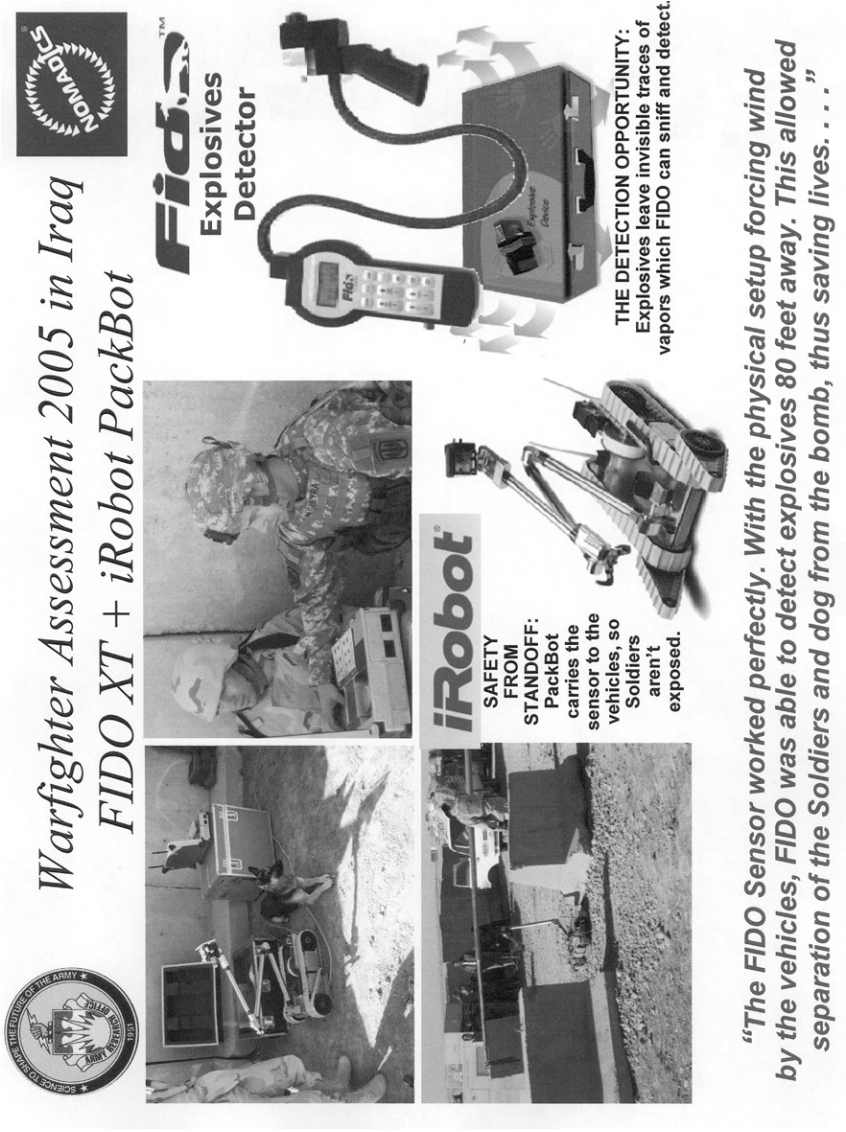
Honeywell
Gore — Creative Technologies Worldwide
MSA

TNT Vapor Sensing with Fido Sensors



Sensitivity Only Rivaled by Trained Dogs





The CHAIRMAN. Tremendous.

Mr. Bryant Linares, President and Chief Executive Officer of Apollo Diamond, Incorporated.

STATEMENT OF BRYANT R. LINARES, PRESIDENT/CEO, APOLLO DIAMOND, INC.

Mr. LINARES. Thank you. I would like to thank Chairman Ted Stevens, Co-Chairman Daniel Inouye, and our Senator from my home State of Massachusetts, John Kerry, for the opportunity to testify before this committee.

My name is Bryant Linares. I'm the CEO and President of Apollo Diamond, and a representative of the NanoBusiness Alliance.

I'm here today to tell you that the philosophers and alchemists of Ancient Greece actually had it wrong trying to turn lead into gold. They should have been trying to turn carbon into diamonds.

At Apollo Diamond, we're using nanotechnology production principles to grow one of the most coveted and desired materials known to mankind: diamond. I have a couple of diamonds. This is a 1-carat diamond that we've grown at Apollo Diamond, here. And Jason Mulvihill, from the subcommittee, is—staff—has some diamonds to show you, Senators. And we all do this—we do this atom by atom from ordinary carbon.

Diamond is an extremely useful material. It is the hardest material known to man. It is one of our planet's best electrical insulators; and it transmits the entire spectrum of light through it. Equally amazing and important is that diamond is totally biocompatible with the body's chemistry. Diamonds will lead to advanced applications in a wide range of fields, from computing to communications to medicine. And yet, diamonds' usage today has really been limited to jewelry, on the high end, and cutting and grinding applications, on the industrial end. The reason for this is simple. Current supplies of diamond, either from mines or from traditional industrial sources, do not provide diamond in a form, purity, or cost that allows its superior characteristics to translate into highly useful technical and commercial applications. Nanotechnology promises to change the availability of high-quality diamond and allow us to unleash the potential of this highly useful material.

At Apollo Diamond, we're using nanotechnology to control atoms and molecules so that we can produce diamond in a prepared medium of carbon gas. We are able to produce real-world sized diamonds, 5 carats and larger, that are purer than the finest mine diamonds. This process, we call culturing. It produces diamonds that are 100 percent real diamond. They are optically, chemically, and physically identical to diamonds mined from the Earth. They differ from mined diamonds only in the following three respects. Apollo diamonds are ultrapure, they are large—we're in the process of developing capabilities to grow these into 4-inch wafer sizes suitable for semiconductors and optics—they are cost-effective for the use in electronics, similar to the cost of other high-grade semiconductor materials.

These features are what will make diamond useful for high-tech applications. They were also the prerequisite material characteristics for silicon, which has powered our country's high-tech boom over the last 30 years. Diamond is now the beginning of a similar 50-year growth curve, in which we will see it used in every corner of our society, courtesy of nanotechnology manufacturing techniques.

Apollo plans to use gem diamond sales to fund its commercialization of its technology initiatives, which makes us very unique, that we have a commercial application early in our product's lifecycle. However, most nanotechnology start-ups face tremendous challenges taking their technology from the lab to the store shelves.

While there is money for research and for companies that are almost ready to sell products, the rest of the commercialization proc-

ess lies in the—what's called the "Valley of Death." And this is the period, between initial research and the final commercialization, where investment money is limited. Start-up companies need financing. If America is going to maintain its leadership position in the global nanotechnology race, government must help create incentives to invest in nanotechnology commercialization. This will lead to a whole range of high-quality new jobs and new products spread across almost every industry, reduce our Nation's independence—dependence on foreign oil, generate positive effects for our environment and human health.

We have four recommendations for the Federal Government. First, level the playing field by creating incentives for nanotech commercialization. This will ensure that the private sector takes full advantage of Federal investments in infrastructure development to date. Second, develop policy that creates export and trade controls that maintain access to global markets. Avoid export controls in nanotechnology, except where they have national security impact. Combat foreign interference with domestic trade institutions to ensure that we are able to develop sound business platforms for foreign trade here domestically. Third, address environmental health and safety implications of nanotechnology using existing regulatory structures. We believe that existing laws can, and should, be updated to address nanotechnology, rather than creating new laws. We must ensure that there are appropriate safeguards without diminishing our competitive advantage through—under regulations that can strangle small businesses like Apollo. Finally, encourage U.S. students to enter science and engineering programs, and develop policies that encourage foreign graduates to stay in the United States.

In summary, we feel fortunate to live in the United States and to have the ability to develop a world-leading diamond technology platform here, domestically. With the right nurturing, we can develop a large diamond-based electronics and optics industry right here at home. American nanotechnology companies are making breakthroughs that could develop into full-fledged U.S.-based industries, but in order to realize this potential, we need to ensure that we are effectively competing with the rest of the world.

Nanotechnology has the opportunity to profoundly improve our quality of life, increase our national security, provide good-paying, high-tech domestic jobs for our citizens. We are on the verge of a large wave of positive change. Let's make sure it stays here in the United States.

Thank you for the opportunity to address this Committee.

[The prepared statement of Mr. Linares follows:]

PREPARED STATEMENT OF BRYANT R. LINARES, PRESIDENT/CEO, APOLLO DIAMOND, INC.

As the President and Chief Executive Officer of Apollo Diamond, Inc., I would like to thank Chairman Ted Stevens, Co-Chairman Daniel Inouye, and our Senator from my home State of Massachusetts, John Kerry, for the opportunity to testify before this committee.

The Potential of Nanotechnology

The National Nanotechnology Initiative defines nanotechnology as the understanding and control of matter at dimensions of roughly 1 to 100 nanometers (for comparison, a sheet of notebook paper is about 100,000 nanometers thick) and ex-

ploiting the unique phenomena that occur at that scale to enable novel applications. Market impact estimates for nanotechnology have reached as high as $1 trillion by 2015.

At Apollo Diamond we are now using nanotechnology production principles to grow one of the most coveted and desired materials known to mankind, diamond.

The Need for Diamond

Diamonds have long been desired not just because of their beauty in a necklace or an engagement ring, but also for their utility as an extreme material that surpasses all other known materials in its physical ability.

Diamond's physical properties are truly amazing: diamonds are the hardest material known to man, they are known to be our planet's best electrical insulator, they can pass heat through their structure faster than any other known substance, they offer minimal expansion through large temperature variations, they are inert to most chemical and radioactive environments, and they are optically transmissive through the infrared, visible and ultraviolet spectrums of light. Yet, equally amazing and important, they are also totally biocompatible with the body's chemistry.

Diamond is a material of the highest utility, yet its use has been limited to gem jewelry applications on the high end and cutting/grinding applications on the industrial end. The reason for this is simple: current supplies of diamond, either from the mine or from other conventional diamond sources, do not provide diamond in a form, purity or cost that allows its superlative physical characteristics to translate into useful high-technology and commercial applications.

The Defense Advanced Research Projects Agency (DARPA) has kept an early eye on diamond's development over the years because of the tremendous promise of the material's performance. In a Naval Research Lab/DARPA analysis on various semiconductor materials, diamond was shown to have a performance potential 100,000 times greater than that of silicon and hundreds of times that of the then state-of-the-art semiconductor materials gallium nitride and silicon carbide. The prospect of discovering a path to make such diamond material, however, appeared so daunting that the United States basically gave up all government-funded research on diamond's fundamental materials development in the mid-1990s.

The Nanotechnology Solution

At Apollo Diamond, we are using nanotechnology manufacturing processes (*i.e.,* controlling atoms and molecules) to reproduce diamond on an atomic level, while producing real-world sized diamonds (*i.e.,* 5+ carat crystals) that have the purity of the finest diamond crystals found in mines. This process is called "culturing," the growth of diamond through a prepared medium.

The Apollo process produces diamonds that are 100 percent real diamond. They are optically, chemically and physically identical to diamonds mined from the Earth. They differ from earth-mined diamonds only in the following respects. Apollo Diamonds have:

1. Costs similar to other semiconductor materials (when in wafer form);
2. Large sizes heading toward super sizes (4 inch wafers); and
3. Ultra purity.

These three features of cost, size and consistent purity are the hallmarks of an industrialized materials platform and were prerequisites for another fundamental high-utility material that has powered our country's high-tech boom over the last thirty years: silicon. Diamond is now at the beginning of a similar fifty-year growth curve, in which we will see it used in every corner of our society, courtesy of nanotechnology manufacturing techniques.

Nanotechnology manufacturing techniques in essence let us to do two things: (a) control the diamond material at the nano scale to create an exact copy of a high-quality natural diamond; and (b) impart (if we so choose) nano scale features in the body of the diamond or on the surface of the diamond that can be electrically, optically or biologically activated.

In our diamond growth chamber, thin slivers of diamond (diamond seeds) are placed on a pedestal. Purified gas is introduced into the growth chamber and superheated, stripping the carbon atoms away from other impurities. The plasma gas of superheated carbon atoms envelops the diamond seeds and begins the deposition of individual carbon atoms on top of the seed diamond in the growth chamber. By maintaining this process the diamond grows literally atom by atom. A pure, perfect diamond crystal forms from what was previously gas.

Through the selective introduction of other atoms (such as boron or nitrogen) into the pure carbon-based diamond, nano/atomic scale features can be imparted into the interior of the diamond or on its surface. These features and their consistent, engi-

neered placement connect the potential of the diamond to the full utility of the material's promise. Consistent manufacturing, over large areas, with controlled impurity content create the platform for semiconductor, optical, and life science applications.

There is enormous opportunity for diamond to shape our world in the same way that other blockbuster materials technologies like silicon have done. Diamond is poised to be the materials platform of choice for many advanced semiconductor, optical and life science applications that will radically change the world.

The Commercialization Path

The culture of entrepreneurship is critical to innovation in the nanotechnology sector. Apollo Diamond is an excellent example of this. Like many high-potential, fast-growing American technology companies, Apollo Diamond is a start-up company with twenty full-time employees. The company was started in a garage but has its roots in the success of the previous technology companies started and sold by its founders. Our company places the good fortune of its success squarely on the fertile ground of the United States capital system, the work ethic and ingenuity of our American employees, and a band of 300 dedicated angel investors who want to see this diamond technology stay domestic and morph into a globally dominant business. This intersection of business propellant only happens in the United States and we are truly fortunate!

Apollo Diamond's Unique Approach to Commercialization

Materials technologies are time-consuming and capital-intensive to commercialize. Fortunately, Apollo was able to leverage some unique capabilities and opportunities that most semiconductor materials science companies cannot access. First, the founders were commercially successful in other technology ventures and could fund the preliminary growth of the company despite lack of government funding. Second, and more importantly for Apollo, it was the early business opportunity to commercialize Apollo diamonds as gemstones that gave the company the business strategy it needed to develop this difficult technology. The gemstone opportunity is truly unique for a new materials technology because it represents an extremely large market opportunity early in the lifecycle of the product. Gem quality diamonds make up a $60 billion global market at the retail level and an $11 billion market at wholesale.

Furthermore, a precedent had already been set in the gemstone business with the introduction of cultured pearls early in the 1900s, which essentially allowed the introduction of cultured pearls into what was then a totally natural pearl market. Cultured pearls now represent over 90 percent of the cultured pearl business as natural pearls have become scarcer on a per capita basis because of environmental sustainability issues surrounding pearl diving.

Enter the cultured diamond! Despite the fear in the diamond industry surrounding the introduction of a competing product, the cultured diamond actually makes the industry healthier. Diamonds remain robust as a product category by allowing consumers to purchase larger, more perfect diamonds than they were previously able to afford, opening new markets while allowing mined diamonds to grow in value. A gem market commensurately allows a technology company like Apollo to attract investments which require early commercialization, while building for the larger, long-term technology play.

The opportunity is large. As in other areas, the United States has the opportunity to thrive in this emerging multi-billion dollar market. But, the stakes are high and we cannot take victory for granted. As a fundamental technology, we can not afford to hold anything less than a commanding lead. A national effort in diamond will lead to a whole range of technology sector jobs and allow our country to maintain our lead in the applications spin-offs from diamond technology that will directly affect our Nation's strategic capabilities.

Industry Challenges

Innovation is the key to America retaining its competitiveness in nanotechnology. The source of innovation in America is our distinctive culture of entrepreneurship. This culture and its advantages, however, have come under increasing pressure in recent time. Investors want quick returns and the private and public-market sector do not want to invest in research or development. This comes at a time when foreign governments are directly supporting product focused R&D in their companies.

Although there are seemingly many new technology start-ups every year in the United States, these startups need risk capital to bring innovations to market. The period between a company's formation and its achieving positive cashflow, known as the "Valley of Death," is particularly acute for new technologies including nanotechnology start-ups. Start-ups are most vulnerable during this time. Apollo is end-

ing this phase with early stage revenues starting from gemstone sales which will ideally in turn support further technology development. To get here, however Apollo required investments in "platform" development and capital support to make the fundamental breakthroughs in basic research that power our product.

From our perspective, we see that the U.S. has the opportunity to seed a large diamond-based electronics and optics industry here. The industry can give us leadership in a number of areas including electric power controls, high-speed wireless, water purification and bio-medical sensors for life science applications. These products could profoundly improve our quality of life, increase our national security and provide well-paying high-tech, domestic jobs. We are however under competitive threat from a declining local capital environment and growing foreign subsidies for our competitors. Leveling this playing field by encouraging investments in research and development will ensure that we are not in the nanotech race just to play, but that we are going to win.

Policy Recommendations

We recommend that the U.S. Government:

- *Level the playing field by creating incentives for commercially-focused nanotech R&D.* This will ensure that the private-sector takes full advantage of the Federal investments in infrastructure development to date. We believe that a focus on commercialization will show an increased rate in new start-up development, successful companies and a good return on investment.
- *Engage the environmental, health and safety implications of nanotechnology using the existing infrastructure and Acts for materials regulation.* We believe that the existing laws can and should be updated to reflect nanotech rather than creating a new law. The question is how we ensure that there are appropriate safeguards without diminishing our competitive advantage through undue regulations. We believe that when answering this question we must make sure we consider engineered nanomaterials in the context of other, known materials rather than as a separate class.
- *Encourage U.S. students to enter science and engineering graduate programs and developing policies that encourage foreign graduates to stay in the United States.* In the near-term, we must continue to attract and retain the best technological minds from around the world. In the medium- to long-term, we must redevelop a pool of skilled domestic talent that has always been a cornerstone of U.S. industry.
- *Develop policy that creates export and trade controls that do not restrict access to global markets.* Support free and open trade and avoid export controls on nanotechnology except where they have a clear, direct, and material national security impact relative to existing non nanotechnology based alternatives. Commensurately, ensuring that foreign competitors do not unduly access and influence institutions such as the Federal Trade Commission or other governing bodies would ensure that we are able to develop sound domestic business as a platform for foreign trade.

In summary, we feel fortunate to be in the United States and have had the benefits of our system to fund a world-leading diamond technology like the one we have at Apollo Diamond. With the right nurturing, we collectively have the opportunity to seed a large diamond-based electronics and optics industry here in the United States similar to the silicon-based renaissance that happened in the 1960s and 1970s with silicon-based integrated circuit technologies. As *Wired Magazine* stated, a "New Diamond Age" is upon us where we will see diamond in every aspect of our society including electric power controls, high-speed wireless, water purification and bio-medical sensors for life science applications. These products have the opportunity to profoundly improve our quality of life, increase our national security and provide good-paying, high-tech, domestic jobs for our citizens. We are on the verge of a large wave of positive change, let's make sure it stays here in the United States.

Thank you.

Senator ALLEN. Mr. Chairman?

The CHAIRMAN. Yes, sir?

Senator ALLEN. Just for a point of clarification, may I ask, do you own the intellectual property to the manufacturing of these nano——

Mr. LINARES. Yes, we do.

Senator ALLEN.—diamonds? You do.

Mr. LINARES. Yes, we do.

Senator ALLEN. Thank you.

The CHAIRMAN. Our next witness, Dr. Mark Davis, Professor of Chemical Engineering, at Caltech.

STATEMENT OF MARK E. DAVIS, PH.D., PROFESSOR OF CHEMICAL ENGINEERING, CALTECH; MEMBER OF THE COMPREHENSIVE CANCER CENTER, CITY OF HOPE

Dr. DAVIS. Mr. Chairman and Committee Members, thank you for the opportunity to speak to you today.

My objective is to tell you all about the excitement around nanoparticles used in medicines, and how they might be able to revolutionize the treatment of cancer.

The summary points from my written testimony are that not all nanoparticles are alike, that nanoparticles that are made for injection into humans for therapeutics are well-designed and rigorously tested before they are injected into humans; these nanoparticle therapeutics, as I will try to show you, have the potential to change the way cancer is treated; and that the regulatory processes for these high benefit-to-risk ratio nanomedicines are working and constantly evolving, both from a scientific and regulatory point of view.

Now, there has been great progress in understanding cancer, but there is still a great need to try to reduce the number of deaths due to cancer. And the ultimate cause of death in most cancer patients is drug-resistant metastatic cancer. What does that mean? That means that you have tumors disseminated through your body that no longer respond to chemotherapeutic treatments. And it's actually this state that nanoparticles have an opportunity to attack, precisely because of their unique properties.

Here, I show a picture of nanoparticles. These particles contain polymers that are carrying therapeutic agents; and they're in the size of about 100 nanometers. And what that means is, they're very small. And, being small, they can circulate through your blood for a long period of time, access tumors throughout your body, and penetrate into the tumors. And we, and others, have shown that when you're in this size range between 50 and 100 nanometers, you can actually enter cells to bring in the drug that would normally be resistant to the molecule itself. So, it's an access plus also a treatment to drug resistant cells, that's important with that size.

Now, although these are small, relative to particles you can see with your eye, and feel, they're large, relative to molecules. A molecule is about one nanometer in size. And so, when you have a 100-nanometer particle, you can really carry a lot of drug molecules with it. So, in addition to the access, you can carry a big payload.

Now, let me illustrate how that can work. I hope we've all seen fireflies; and the back of a firefly lights up. And that's a protein that gives off that light. We can take the gene for that protein, put it in cancer cells; and so, we can follow those cancer cells through animals, because they light up. What I've shown you here is a series of images of a mouse where we've put human cancer cells in; and where you see the color in the white fur is actually where the tumors are. In the top sequence of days that you see there, there are three treatments at—where the stars are, of the normal

chemotherapeutic drugs used in its optimum conditions. And this is one that's commercially used in patients. What you see is that the tumors start to shrink, but they ultimately come back in multiple locations and ultimately cause the death of the animal.

On the bottom panel, we've given a nanoparticle with—holding essentially the same drug, at one-tenth the amount of drug going into the animal, which can then access, very efficiently, these tumors. As you can see, those tumors are eradicated, and they stay away. And the animal lives a long life and dies of old age. These principles are—I show you today in animals—actually being tested in humans right now in early clinical trials.

So, there's an amazing excitement, but also caution, because of safety. But what I want to make clear to you today is, nanoparticles in medicine are not new. There have been nanoparticles in humans used for therapeutics for at least 25 years now. And there's a history of safety with these. In fact, the safety profile of these nanomedicines are actually better than the drugs that they're carrying when they're used alone.

The features of these medicines that are really exploited are not only the size, but the surface properties. And it's the control of those properties that's important to these nanomedicines and doesn't happen when you get environmental exposures to nanoparticles. It's this control and then all of the regulatory safety issues that we have to go through, first in animals and in humans, before these are released to the public that make this different than other areas of nanoparticles.

So, to conclude, where's the future and what are the challenges?

Well, in the future, these newer nanoparticles are only going to get better. They're going to get more uniform in size and surface properties, which will make them more effective, and also we'll be able to make them more definable from their safety profiles. And, in fact, this year alone, for the first time, new nanomedicines that were designed from first principles are reaching the clinic.

These new particles are going to have greater functionality, in the sense that they're going to be "smart." They can recognize what's going on and do their functions only when they're in the right place to do them.

We'll also have, simultaneously, imaging in therapeutic particles so that we can go into a patient and make sure that the target of the disease is in the patient before you treat the patient. And so, in a way, this is one aspect of personalized medicine.

Now, what are the challenges? These are complex particles. They have many components. And so, their costs are going to be high. Also, we—any new medicine has long regulatory pathways. And in this space here, there are many, many intellectual property issues that have to be resolved to be able to make a functioning particle. Also, because of these regulatory issues, there are long times for approval, which turn into being very capital-intensive. These are really the rate-limiting steps to getting these medicines through to the public. So, because of those time-scales and so forth, if we're to get these medicines to the public in the next 10 years, they either have to exist today or in the very near future to be able to get it to them in the next few years.

Thank you very much.

[The prepared statement of Dr. Davis follows:]

PREPARED STATEMENT OF MARK E. DAVIS, PH.D., PROFESSOR OF CHEMICAL ENGINEERING, CALTECH; MEMBER OF THE COMPREHENSIVE CANCER CENTER, CITY OF HOPE

Mr. Chairman and members of the Committee, thank you for the opportunity to testify at this hearing. Since the early 1980s, I have been working in areas of science and technology that are now classified as nanoscience/nanotechnology. My objective today is to present the potential of nanoparticles for use as therapeutics to treat human disease. In particular, I wish to convey the excitement over what these new medicines could mean to the diagnosis and treatment of metastatic cancer. Additionally, I want to emphasize that not all nanoparticles are the same: those created for the purpose of injection into humans for therapeutic purposes are well designed and rigorously tested for safety offer a tremendous benefit-to-risk ratio for the treatment of cancer, unlike nanoparticles that enter the body from environmental exposure.

Numerous diseases occur throughout the human body, and systemic imaging and therapy are necessary to treat and eradicate them. Metastatic cancer, for one, is a particularly important disseminated disease requiring such an approach, because treatment-resistant metastases (tumors located throughout the body that are not the primary tumor or site of the cancer) ultimately are the cause of death in most cancer patients. Detection and treatment of systemic diseases present numerous challenges, since humans possess a variety of defense mechanisms against the foreign agents that must be inserted into the body for imaging and therapy. Additionally, systemically-delivered agents need to reach all their intended tissue and cellular targets to be effective. These features and many others make the creation of systemic imaging and therapeutic agents a daunting task.

Nanoscaled materials typically have properties not manifested either in larger particles with the same composition or in individual molecules, a distinguishing feature of great significance. While this motivation has driven nanoscience and technology in physics and engineering, it is not the main reason that nanoparticles are useful for systemic applications in the human body. Nanoparticles in the body behave differently compared with larger particles, not because of any fundamental difference in physical or chemical properties, but instead because the small size of a nanoparticle allows it access to sites that larger particles cannot reach.

To achieve systemic localization, medicines must at some point enter the circulatory system for dissemination throughout the body. Molecular medicines that are typically 1 nm in size are quickly removed from the body by the kidneys. In order to stop this fast elimination, nanoparticles must be larger than 10 nm in diameter. Thus, an advantage of nanoparticle medicines over molecular medicines is that they can remain in circulation for longer times and provide for extended length of therapy (in addition to the enhanced localizations). Through careful experimentation, we and others have shown that nanoparticles can access tumors from the circulatory system and move throughout them if they are "well designed," and have sizes in the 50–100 nm range (Hu-Lieskovan *et al.,* 2005 and Kim *et al.,* 2006). By "well designed", I mean the surface of the particles are carefully controlled as the surface properties of the nanoparticles can greatly influence their behavior in humans (Chen *et al.,* 2005). It is the purposeful control of size and surface properties of nanoparticle medicines that distinguishes them from other types of nanoparticles.

Nanoparticles for imaging and therapy will be of size 10–100 nm and are composites of polymers and other organic materials and the therapeutic/image agents. These particles are typically spherical and they are seven orders of magnitude smaller than a soccer ball. That is, the increase in size from the nanoparticles to the size of a soccer ball is the same increase in size as going from the size of a soccer ball to the size of the Earth. While these nanoparticles are small compared to other particles, they are large compared to molecules. For example, the size of a molecule (ca. 1 nm) to the size of a 100 nm nanoparticle is analogous to the size relationship between a soccer ball and the Goodyear blimp (think about how many soccer balls could be held in the blimp). This size allows nanoparticles to have a variety of features and functions that are not possible with molecules. It is precisely these features and functions that can be exploited to create nanoparticle medicines.

What particular features will be exploited when nanoparticles are used for systemic imaging and therapy? First, control over size and surface properties allows access to locations that are either denied to larger entities or difficult to reach in significant quantities with smaller entities such as molecule therapeutics because of rapid loss from the body (renal clearance). Additionally, if the drug or imaging agent

needs entrance into the cell, nanoparticles can be engineered so that they can be internalized. There are at least two important consequences of this feature. Nanoparticles can be used to attack intracellular disease targets. Many of these intracellular targets have been known for some time but have been considered undrugable. Also, nanoparticles can be designed to release a significant portion of their "payload" when they enter cells, and this feature can be very advantageous. For example, many anticancer drugs lose their effectiveness when tumors become resistant owing to surface proteins that deny entrance to the drug molecules. Nanoparticles internalize into cells in ways that bypass the surface proteins, and can thus facilitate new therapies using existing drugs that, administered alone, would be ineffective. This capability of nanoparticles may provide whole new treatment methodologies for cancer patients.

These attributes lead to a second feature of nanoparticles that makes them useful for systemic imaging and therapy: their ability to perform multiple functions, since the particles are large enough to accommodate numerous components within the same particle. Multiple agents can be assembled into individual nanoparticles (multiple therapeutic agents, multiple imaging agents, and their combinations), making it possible, for example, to combine small molecular chemotherapeutic agents with other types of agents to simultaneously attack cancer at multiple pathways.

A third feature important for systemic imaging and therapy is the large number of atoms contained in a nanoparticle relative to that contained in a molecule (think of the soccer balls in the blimp). The nanoparticle thus delivers a greater "package" of material, and this increased payload size can help enhance the signal for imaging or provide a localized "bolus" of drug. One can imagine nanoparticle imaging agents that provide information on intracellular targets. The molecular target of the disease could be verified to exist in a patient prior to treatment, and since the observation was made via a nanoparticle with the same size and surface properties as the therapeutic particle, the therapy would be expected to reach the target. This combination will allow personalized medicine in the sense that treatment does not have to be administered until the target is known actually to be present in the patient. Also, follow-up imaging can be performed to verify that the target has been reached and that the therapy is working.

While there is tremendous excitement over the potential of nanopaticles for cancer imaging and therapy, there are also words of caution about their safety appearing in the literature. Concerns about nanoparticle toxicity are legitimate since not much is known about how these entities behave in humans. The size and surface properties of nanoparticles give them access to locations that were not previously available with larger particles, and the size of properly designed nanoparticles can affect their localization. Studies in this area suggest that more investigation is needed in order to define the biocompatibility of nanoparticles in humans. On the one hand, there are examples where nanoparticles have no detrimental effects (silica coated magnetic 50 nm particles: *Kim et al.,* 2006), and, on the other hand, examples where they do (carbon nanotubes: Salvador-Morales *et al.,* 2006). As expected, the size and surface properties of nanoparticles dictate their behavior, and much more data are necessary to develop a fundamental understanding of the structure-property relationships. However, one must consider the benefit-to-risk ratio for the intended application when assessing the biocompatibility of nanoparticles. In cancer, this ratio is very high and therapeutic agents in current use are not without their own safety risk profile. In fact, current nanoparticle medicines have superior safety profiles to the drugs that they are carrying. Also, in order to use a nanoparticle in humans, they must pass rigorous and lengthy regulatory processes prior to approval.

Nanoparticle medicines and imaging agents already have a history of use in humans. Commercial therapeutics and imaging agents such as AmBisome (liposomal amphotericin B), SMANCS (synthetic polymer-drug conjugate), Abraxane (albumin-paclitaxel nanoparticle), and Feridex (dextran-iron oxide nanoparticle for MRI) are just a few of the nanoparticulate drugs and imaging agents currently available for human use. Some of these nanoparticles are in the 10–100 nm range (AmBisome has an average size of 60–90 nm, Feridex an average size of approximately 30 nm), while others are not (Abraxane has an average size of 130 nm). Other nanoparticulate materials such as the polymer-drug conjugate XYOTAX (polygutamate-paclitaxel) are in late-stage clinical trials. Thus there is at least a 25-year history of using nanoparticles in medicine (AmBisome being the first and used in clinical trials in the 1980s). These commercial nanoparticles have gone through rigorous toxicity testing for regulatory approvals and have years of experience in humans. This increasing store of information provides an initial understanding of how nanoparticles can exist and function in the body. Although each new nanostructure will need to be tested individually, there is reason to believe that nanoparticles can be used as effective systemic medicines and imaging agents. As more biocompatibility

data become available, a further understanding of how to tune size and surface properties to provide safety will permit the creation of new, more effective nanomedicines for systemic use.

Since nanoparticles already exist as commercial medicines and imaging agents, what might be expected in the future? To begin, control over the size distribution and surface properties will see great improvements. Although *average* sizes of commercial nanoparticulate medicines and imaging agents fall within the range 10–150 nm, the distribution in size (that is, the spread of values about the average) and the consequent variation of surface properties are quite large for each product. Newer nanoparticles will be much more uniform in their size and surface properties than current ones, and this uniformity should translate into more effective medicines and imaging agents with better definable biocompatibilities. Additionally, nanoparticles will become "smart" in the sense that they will be able to take cues from their local environment to activate functions at specified times and locations. Early examples of this phenomenon already exist for nanoparticles designed to sense their entrance into cells and trigger the release of therapeutic agents (Davis *et al.,* 2004).

There is no doubt that these types of nanoparticles will exist in the future. Current nanoparticle medicines and imaging agents provide initial support for low toxicity with properly designed nanoparticles, and significant advancements in nanoparticle uniformity will further improve this situation. As newer and more complex nanoparticle systems appear, better methodologies to define biocompatibility will need to be developed, especially those that can assess intracellular biocompatibility. A significant remaining question is whether complex nanoparticle agents for imaging and therapy will be commercially-viable in the face of numerous impediments to their development and implementation. These complex, multifunctional nanoparticles will be expensive to produce, and issues regarding scale-up and cGMP production are not often discussed. The multi-component nature of the nanoparticles also renders their manufacture and regulatory approval very difficult. Beyond the cost of development itself, intellectual property costs can be very high as well, because each of the many components needed to create the nanoparticle might require multiple licenses. Given these high barriers to commercialization, some excellent medical nanoscience will doubtless never attain clinical or commercial status, and those products that do win approval will likely be expensive. Finally, we must recognize that the time-frame for regulatory approval is sufficiently long that new nanomedicines of the next 10 to 15 years—if they are to be realized—must already exist and be in some stage of research or development, or else be invented within the next few years. If advanced nanomedicines are to reach the public within 10 or 15 years, there must be a significant effort underway in their discovery and development *today* because of lengthy approval processes.

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The CHAIRMAN. Thank you, Doctor.

Our last witness is Dr. Clarence Davies, Senior Advisor to the Project on Emerging Nanotechnologies at Woodrow Wilson International Center.

Dr. Davies?

STATEMENT OF DR. J. CLARENCE (TERRY) DAVIES, SENIOR ADVISOR, PROJECT ON EMERGING NANOTECHNOLOGIES, WOODROW WILSON INTERNATIONAL CENTER FOR SCHOLARS; SENIOR FELLOW, RESOURCES FOR THE FUTURE

Dr. DAVIES. Thank you, Mr. Chairman.

My name is J. Clarence Davies. I am Senior Advisor to the Project on Emerging Nanotechnologies at the Woodrow Wilson International Center for Scholars, and a Senior Fellow at Resources for the Future. However, my testimony represents my personal views, and not the views of any of these organizations.

The Project on Emerging Nanotechnologies asked me to examine the strengths and weaknesses of the current U.S. regulatory system in relation to nanotechnology. My report, "*Managing the Effects of Nanotechnology,*" is the subject of my testimony. And I gather that will be included in the hearing record, Mr. Chairman.

It is a critical time for nanotechnology. It can offer solutions to many of the most serious problems our society faces, as you have heard from many of the other witnesses today. However, we currently know little about its short- and long-term effects on human health or the environment. The public's views of nanotechnology remain——

The CHAIRMAN. Can you all hear him back there? I don't think they can hear you. Pull that mike up a little bit closer. Thank you.

Dr. DAVIES. That better?

The CHAIRMAN. Yes.

Dr. DAVIES. OK.

The CHAIRMAN. Thank you.

Dr. DAVIES. The public's views of nanotechnology remain unformed. Most people have never heard of nanotechnology. We now have a unique opportunity to get it right, to introduce a major new technology without incurring significant public opposition, and without gambling with the health of citizens, workers, consumers, or the environment.

A lot depends on our ability to get it right. If we fail, we run a double risk. First, a risk of unanticipated harm to health and the environment. Second, a risk of public rejection of the technology. Our past experiences with agricultural biotechnology, nuclear power, and asbestos, for example, illustrate how tragic either of these risks could be. Industry, as well as the general public, has a big stake in ensuring that nanotechnology is developed responsibly from the start.

Adequate government oversight of nanotechnology is an essential part of getting it right. The Federal agencies have maintained that they have adequate statutory authority to deal with nanotechnology. The analysis in my report clearly shows that the existing regulatory structure for nanotechnology is not adequate. Some programs, like FDA's oversight of drugs, are OK, as Dr. Davis has commented, but the regulatory structure as a whole suffers from

three types of problems: gaps in statutory authority, inadequate resources, and a poor fit between some of the regulatory programs and the characteristics of nanotechnology.

The CHAIRMAN. What was that, the third one?

Dr. DAVIES. A poor fit between some of the regulatory programs and the characteristics of the technology. In other words, the definitions in the laws and, you know, the way the program is oriented don't fit very well.

The gaps in statutory authority are most obvious with respect to two of the most common uses of nanomaterials, cosmetics and consumer products. In both cases, there is essentially no statutory authority to review the health and safety of these products. In both areas, there is a large potential for human exposure.

Originally, I did not believe that new legislation would be necessary; however, given the shortcomings of the existing system, I now believe that it is in everyone's interest to start thinking about a new law. The existing laws cannot provide protection for the public or offer a predictable marketplace for nanotechnology businesses and investors. No amount of coordination or patching will fix this problem.

One of the frequent reactions that I got to the report after its release was, shouldn't we wait for more information before we regulate? Waiting for more information is a reasonable and valid option in the scientific world; however, in the policy world, waiting for more information is not delaying a decision, it is making a decision. It is making a decision to not do something. Put another way, our policy choice is not between acting or waiting for more information, it is between reviewing products for their health and safety or allowing people to be exposed to products without any government oversight of their effects.

Do we need more scientific information to help us evaluate the health and safety of nanoproducts? Absolutely. And I support the kinds of initiatives that Dr. Gotcher talked about in his testimony.

Is there reason now to believe that some nanoproducts could have adverse effects? Yes, for reasons that I outlined in my written testimony and also in a scientific review article which I have submitted for the record.

We might not need regulation if all companies were good product stewards, just as we would not need criminal laws if all people were angels. Unfortunately, there are bad actors in the corporate world, and all companies face pressures not to invest money in so-called nonproductive efforts, like testing for health and environmental effects. It is in a firm's interest to test products for acute, immediate adverse effects, but when it comes to testing for chronic effects, like cancer immunogenesis, or to testing for environmental effects, it can be tempting for companies to not test their products.

The greatest threat to the future of nanotechnology and to nano-based businesses is not regulation, but a collapse in public confidence. A dialogue among interested parties, including industry, environmental and consumer groups, and government agencies can, I think, arrive at a reasonable regulatory approach that does not unduly inhibit technological innovation. This dialogue needs to start now. We cannot afford to lose the opportunity to get it right.

Thank you, Mr. Chairman.

[The prepared statement of Dr. Davies follows:]

PREPARED STATEMENT OF DR. J. CLARENCE (TERRY) DAVIES, SENIOR ADVISOR, PROJECT ON EMERGING NANOTECHNOLOGIES, WOODROW WILSON INTERNATIONAL CENTER FOR SCHOLARS; SENIOR FELLOW, RESOURCES FOR THE FUTURE

I would like to thank Chairman Ted Stevens, Co-Chairman Daniel Inouye, and the members of the Senate Commerce, Science, and Transportation Committee for holding this hearing on developments in nanotechnology. I appreciate the opportunity to appear here before you today.

My name is J. Clarence (Terry) Davies. I am a Senior Advisor to the Project on Emerging Nanotechnologies at the Woodrow Wilson International Center for Scholars and a Senior Fellow at Resources for the Future. However, my testimony represents my personal views and not those of the Project on Emerging Technologies, the Wilson Center, or Resources for the Future.

Last summer, the Project on Emerging Nanotechnologies asked me to examine the strengths and weaknesses of the current U.S. regulatory system in relation to nanotechnology. My report, "*Managing the Effects of Nanotechnology,*" is the subject of my testimony today. I request the Committee's permission to include the report as part of the hearing record.

I was asked to do the study because I have spent more than 40 years as an analyst and participant in environmental policy. I have a Ph.D. in American Government from Columbia University, and have been on the faculties of Bowdoin College and Princeton University. I have worked in the Federal Government at three different times, most recently as Assistant Administrator for Policy at the Environmental Protection Agency (EPA) in the George H.W. Bush Administration. In 1970, as a consultant to the President's Advisory Council on Executive Organization, I coauthored the plan that created EPA.

I have served on a number of committees of the National Academy of Sciences, chaired the Academy's Committee on Decision Making for Chemicals in the Environment, and in 2000 I was elected a Fellow of the American Association for the Advancement of Science for my contributions to the use of science and environmental policy analysis.

When I began the study for the Project on Emerging Nanotechnologies, I spent several months focusing on the applications and implications of nanotechnology. As I learned more, I was impressed by what a critical time this is for the development of this marvelous technology. Nanotechnology is still very new and it is full of promise. It may offer solutions to many of the most serious problems our society faces. It offers the hope of significant breakthroughs in areas such as medicine, clean energy and water, environmental remediation, and green manufacturing. However, we currently know little about the short- and long-term effects of nanotechnology on human health or the environment.

Additionally, the public's views of nanotechnology remain largely unformed. The vast majority of people have never heard of nanotechnology, though it is anticipated that they will learn about the technology as applications emerge and as products enter the market. For this reason, we now have a unique opportunity "to get it right"—to introduce a major new technology without incurring significant public opposition and without gambling with the health of citizens, workers, consumers, or the environment.

A lot depends on our ability to "get it right." If we fail, we run a double risk. First, we run the risk of unanticipated harm to health and the environment. Second, we run the risk of public rejection of the technology. Our past experiences—with agricultural biotechnology, nuclear power, and asbestos, just to name a few—illustrate how tragic either of these scenarios could be. Industry, as well as the general public, has a big stake in ensuring that nanotechnology is developed responsibly from the start.

Adequate government oversight of nanotechnology is an essential part of "getting it right." The public does not trust industry to regulate itself. Past experience, as well as surveys and focus groups, show that if the public does not think that the government is exercising adequate regulatory oversight of a potentially hazardous new technology then it will mistrust and likely reject that technology. If this happens, literally billions of dollars of investment by government and industry in nanotechnology research and development may be jeopardized.

To date, the National Nanotechnology Coordinating Office (NNCO) has maintained that the Federal agencies have adequate statutory authority to deal with nanotechnology. Dr. E. Clayton Teague, Director of the NNCO, has said that: "Until we have good, solid, scientifically validated information that would indicate signifi-

cant inadequacies in existing regulatory authorities, additional regulations would just be unnecessarily burdensome."[1] This is an insufficient response to the challenge, and, I believe, misleading to both the public and industry. By overstating the case for regulatory adequacy, one shifts risks onto corporate investors, shareholders, and the exposed public.

The analysis in my report clearly shows that the existing regulatory structure for nanotechnology is not adequate. It suffers from three types of problems: (1) gaps in statutory authority, (2) inadequate resources, and (3) a poor fit between some of the regulatory programs and the characteristics of nanotechnology.

(1) The gaps in statutory authority are most obvious with respect to two of the most common uses of nanomaterials—cosmetics and consumer products. In both cases, there is essentially no statutory authority to review the health and safety of these products. In both cases, the principle is *caveat emptor*—let the buyer beware. In both areas, there is large potential for human exposure to nanomaterials. A wide variety of nano-based consumer products have already begun to enter the market as sporting goods, clothing, cleaning materials, and kitchen appliances. Similarly, nano-based cosmetic products already range from skin creams to spray-on foot deodorizers, all with significant exposure potential (dermal, inhalation, and ingestion) and little publicly-available risk data.

A more subtle set of statutory problems relates to the Toxic Substances Control Act (TSCA), which many have suggested as the primary law that should be used to regulate nanotechnology. TSCA is a very weak law for reasons that I describe in the report. One weakness is particularly important in relation to nanotechnology. TSCA implicitly assumes that if there is no information on the risk of a chemical then there is no risk. In other words, the law acts as a significant disincentive to generating information on possible risks of a chemical. This is exactly the opposite of what is needed. A major reason to adequately regulate nanotechnology is to provide an incentive for generating information. There is an interaction between regulation and information. A certain amount of information is needed to make regulation work, but regulation, properly crafted, can provide an important incentive to produce health and safety information.

(2) All of the Federal regulatory programs suffer from a shortage of resources. This shortage of resources is not only related to funding levels. There is also a shortage of personnel—particularly individuals with the appropriate expertise to deal with nanotechnology. For some of the programs most relevant to nanotechnology the deficiency is so great that it raises doubts about whether the program can function at all. In 1980, The Occupational Safety and Health Administration (OSHA) had 2,950 employees, a number that was inadequate for its responsibilities then. Today, with a greatly expanded economy and workforce, OSHA has 2,208 employees, approximately 25 percent fewer. The Consumer Product Safety Commission (CPSC) has, since its creation, suffered from both statutory and resource problems. Today CPSC has half the staff that it had in 1980. Statutory authority without the resources for implementation will not lead to adequate oversight. This committee should ask for a more detailed accounting of available resources [including personnel (FTEs) and research dollars] dedicated specifically to nanotechnology oversight in key agencies (EPA, FDA, OSHA, CPSC, and the U.S. Department of Agriculture).

(3) None of the health and environment laws were drafted with nanotechnology in mind, and fitting nanotechnology into the existing statutory framework can be problematic. For example, many of the environmental statutes are based on an assumption that there is a direct relationship between quantity or volume on one hand and degree of risk on the other. This relationship does not hold for most nanomaterials.

In the near-term, we will have to make do with current laws and programs. My report discusses adjustments to existing laws. It also discusses voluntary programs that can be used in the near-term. Though voluntary programs have been put forth as an interim solution, they are not a solution over the long-term.

Voluntary programs tend to leave out the firms that most need to be regulated. Such programs also lack both transparency and accountability and thus do not contribute to public confidence in the regulatory system.

When I began working on the report, I did not believe that new legislation would be necessary. However, given all of the shortcomings of the existing system, I now believe that it is in everyone's interest to start thinking about what a new law might look like. The existing laws are not adequate. They cannot provide protection

[1] Susan R. Morrissey, "Managing Nanotechnology: Report Evaluates Ability of US Regulatory Framework to Govern Engineered Nanomaterials," *Chemical & Engineering News,* Volume 84, Number 5, January 30, 2006, p. 34.

for the public, or offer a predictable marketplace for nanotechnology businesses and investors. No amount of coordination or patching is likely to fix the problem.

The report devotes a whole chapter to what a new law might contain. However, the details are less important than getting the major interested parties talking about what needs to be done. Such a dialogue depends on recognizing the shortcomings of the existing regulatory framework. All-out defense of the *status quo* does not serve the interests of public safety or technological innovation. If nanotechnology is to reach its full potential, then the problems that I raise in my report need to be faced.

Since its release in January 2006, the report has attracted a good deal of attention. I have frequently been asked three questions which are worth briefly addressing here:

1. Is there any reason to believe that there are any adverse effects from nanotechnology?
2. Can't industry be trusted to test new products since it is in its best interest to do so?
3. Don't we need to wait for more information before we can regulate nanotechnology?

(1) *Adverse effects*: I am not a toxicologist, and I do not have the qualifications to address in depth the potential adverse effects of nanotechnology. However, there are three reasons to believe that such effects are likely. First, every technology of the scope of nanotechnology has had adverse effects. The idea that nanotechnology could be completely innocuous flies in the face of what we have learned over many years of dealing with technological innovation.

Second, many decades of studying exposure to fine particles—in the workplace and the environment in general—have shown that inhaling fine (and possible nanometer-sized) particles can be harmful. Third, on-going research into the health implications of engineered nanomaterials raises many questions and concerns. For instance, we know that:

- Nanometer-scale particles behave differently from larger sized particles in the lungs—possibly moving to other organs in the body;
- The surface of some nano-structured particles is associated with toxicity—rather than the more usually measured mass concentration; and
- Conventional toxicity tests do not seem to work well with nanomaterials such as carbon nanotubes.

My report references several summaries of the results of these tests.[2]

The debate over how safe nanotechnology is, and how risk should be governed, must be conducted in the knowledge that nanotechnologies—or the specific applications of nanotechnology—are diverse. Some will present a far greater risk to health and the environment than others.

For example, a review article, which I also ask permission to submit for the record, notes that nanomaterials and products which present the greatest risk to human health are those that can both get into the body and possess a nanostructure that is associated with toxic effects. These include unbound nanometer-diameter particles (in powders, aerosols and liquid suspensions); agglomerates and aggregates of nanometer-diameter particles, and particles produced as nanotechnology products degrade or are machined in some way.[3]

Overall, the current state-of-knowledge on nanotechnology and risk does not provide definite answers to how harmful nanotechnologies are. Rather, it raises red flags concerning some materials and products, and enables us to start asking important questions. Now that we can begin to ask the right questions, it should be possible to develop scientifically sound, rational and responsible approaches to understanding and managing the possible impacts of nanotechnology on health.

(2) Voluntary testing. It is in the interest of most manufacturers to do some tests of their products. A number of companies have a reputation of exceeding current regulatory requirements in regards to product testing, and no manufacturer wants its customers or workers to be adversely affected by its products. However, testing,

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[2] Additionally, see: Günter Oberdörster, Eva Oberdörster, Jan Oberdörster. "Nanotoxicology: An Emerging Discipline Evolving for Studies of Ultrafine Particles," *Environmental Health Perspectives,* July 2005, 113(7): 823–839; The Royal Society and The Royal Academy of Engineering. *Nanoscience and Nanotechnologies,* London, U.K., The Royal Society and The Royal Academy of Engineering, 2004; and Tracy Hampton. "Nanotechnology Safety," *JAMA* 294(20): 2564–2564.

[3] Andrew D. Maynard and Eileen D. Kuempel. "Airborne Nanostructured Particles And Occupational Health," *Journal of Nanoparticle Research,* 2005 7: 587–614.

when done, is largely for short-term acute effects and not for long-term effects, such as cancer, mutagenesis, and environmental effects. Testing for long-term health and environmental effects can be expensive and, if there is some adverse effect, it is unlikely that the effect will ever be associated with the particular product. Thus it can be tempting not to do such testing, if not required.

(3) Information and regulation. We do need more information before an adequate oversight system can succeed. But it is not too early to start thinking and talking about the outlines of such a system. It is not too early because nanotechnology products are being commercialized now, and the regulatory system must deal with them. A survey by EmTech Research of companies working in the field of nanotechnology has identified approximately 80 nanotechnology consumer products, and over 600 nanotechnology-based raw materials, intermediate components and industrial equipment items that are used by manufacturers.[4] Experts at the Project on Emerging Nanotechnologies believe that the number of nanotechnology consumer products on the market worldwide is actually larger than the EmTech data suggest.

Furthermore, it also is not too early to start thinking and talking about an oversight system because knowing what a regulatory structure will look like can provide important guidance about what information is needed. Given the realities of the legislative process, it could be years before new legislation is enacted. The process of discussing a better system can itself help generate agreement about what needs to be done, and help foster international harmonization, research, and public participation.

We will never have all the information we want, but now is the time to begin putting in place an oversight system to utilize the available information and encourage the generation of more.

My report is intended to help advance a powerful and beneficial new technology while at the same time ensuring that it does not produce avoidable adverse effects. These twin goals are mutually compatible. In reality, they are inseparable. If we do not create a system that can adequately review nanotechnology products for potential adverse effects, we not only may endanger human health and the environment, we will also endanger the future of the technology itself.

The *Financial Times* last year in an editorial, "Nurturing Nanotech" said: "No one wants to strangle a fast-expanding young industry with regulations. The Internet illustrates the benefits of allowing an exciting new technology to explode in a virtually unregulated environment. But some promising new fields are likely to grow better inside a well-constructed regulatory framework, either because they are exceptionally sensitive in moral and ethical terms or because they pose a potential hazard to health and the environment. Nanotechnology comes clearly into the latter category."[5] I agree.

Existing laws and regulatory programs are inadequate for dealing with the possible adverse effects of nanotechnology. Failure to develop a better system could leave the public unprotected, the government struggling to apply existing laws to a technology for which they were not designed, and industry exposed to the possibility of public backlash, loss of markets, and potential financial liabilities. Nanotechnology holds great promise for a better life. If it is to fulfill this promise, we must openly face the issues of whether the technology has adverse effects, what these effects are, and what kind of a regulatory system can prevent adverse effects from occurring.

The greatest threat to the future of nanotechnology and to nanotechnology-based businesses is not regulation but a collapse in public confidence. Based on polling and focus groups, I believe that the public will hold both government and industry to a higher standard of safety for nanotechnology than it has for any previous technology.[6] Citizens are both more sophisticated and more suspicious of new technologies and will be largely intolerant if adverse effects occur. If a problem develops and public confidence collapses, it will be impossible to go back and argue that the existing system of statutes was adequate. There will be great public pressure to do

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[4] U.S. Environmental Protection Agency, *External Review Draft Nanotechnology White Paper,* December 2, 2005, p. 14.

[5] "Nurturing Nanotech," *The Financial Times.* February 26, 2005.

[6] See Jane Macoubrie. *Informed Public Perceptions of Nanotechnology and Trust in Government.* Washington, D.C.: Woodrow Wilson International Center for Scholars, 2005. Available at *http://www.wilsoncenter.org/news/docs/macoubriereport1.pdf;*

Nanotechnology: Views of the General Public. London, U.K.: BMRB Social Research, January 2004, BMRB/45/1001–666. Available at *www.nanotec.org.U.K./Market%20Research.pdf;* and Andrew Laing. "A Report on Canadian and American News Media Coverage of Nanotechnology Issues" in *First Impressions: Understanding Public Views on Emerging Technologies.* Ottawa, Canada: Canadian Biotechnology Secretariat, 2005. Available at *http://www.biostrategy.gc.ca/english/View.asp?x=802.*

something. We will not have the time to undertake the careful deliberation and consultation with stakeholders that can take place now. We will have lost the opportunity to "get it right."

The CHAIRMAN. Well, thank you very much.

You really hit the area that I was going to ask about, harder than I intended to hit it. We have on the floor, as you know—well, it is not in the floor now. It missed staying on the floor by one vote last night on asbestos. The problems of whether any of these new substances or new combination of substances—am I using the right words?—could cause us problems of exposure, contamination, diseases, or not. Who is going to look into that? Dr. Davies, you sort of indicate we don't have enough basic law to deal with that. Have you written anything on that, in particular?

Dr. DAVIES. On the need for further research or on the gaps in the laws?

The CHAIRMAN. On gaps in the law.

Dr. DAVIES. Yes. I mean, the best example is cosmetics, which are being—nanomaterials are being widely used now in face creams, hair lotions, foot deodorants, a whole range of cosmetic products. They are not tested—or, I mean, so far as we know, they are not tested for their effects, or at least there is certainly no public requirement that they be tested. There is no governmental review of those products for their safety or their environmental effects. So, that's—you know, that's the kind of gap that I'm talking about.

There are whole other areas of—Dr. Davis talked about FDA review of drugs and so on—which I think are fine, which are functioning, you know, reasonably well now, and, you know, I wouldn't tamper with at all. But there are large gaps, in terms of the statutory authority, and there are also major resource problems. There was an earlier question, I think by Senator Pryor, about the resources for the Consumer Product Safety Commission. The Consumer Product Safety Commission has slightly over 400 people, total staff. That's 50 percent down from what it was in 1980. And in 1980 it didn't have anywhere the staff it needed to keep track of consumer products. So, that's the kind of resource problem that I'm talking about.

The CHAIRMAN. Well, I was told last night that the last time asbestos was really utilized in our industry was around 1970, but the exposure continues for years, as we found in schools and other places around the world. It's a very serious subject, I think. We are getting into newly developed substances, in effect, either manmade or at least isolated by man, that might have the potential for contamination or exposure leading to difficulty. I think it is something that we ought to explore with you further, Dr. Davies. It may send shudders up and down the back of people, like Dr. Gotcher here, but who is going to think about the delay that might come from such a review to determine whether exposure—whether there is an environmental potential for such contamination for the future, or cause of illness in the future? I think it is something we ought to explore.

I do want to thank all of you for your testimony, and I think you probably testified more about the real application of some of these

nanotechnologies. What challenges did you really face as you developed these new concepts, particularly in the battery area?

Dr. GOTCHER. Well, I think I'd like to address your question about health and safety, just for a moment, if I may.

The CHAIRMAN. Sure.

Dr. GOTCHER. The asbestos issue is a severe issue. But what happened there was, a lot of material was mined and incorporated into products before any health or safety work was done at all. And I think in the nanomaterial world——

The CHAIRMAN. There was a war going on, Doctor.

Dr. GOTCHER. Well, absolutely. But, I think, in the nanomaterials, I think a number of us are trying to react much more responsibly and look at the health and safety impact of these materials before they're widely used, before millions of pounds are used in products. And so, I think we're trying to address some of the concerns that Dr. Davies is raising.

Now, with respect to batteries, our materials are used inside of a product, they're encapsulated in materials. And so, the nanomaterials are not readily available to the environment.

The CHAIRMAN. Let me back up and tell you about a pit in Alaska, where they went back and excavated all of the residue of rehabilitated and reprocessed materials. A man took old batteries, and he combined pieces of them and made new types of batteries. And he lined a pit with some substance, thinking it was enough protection, and he put batteries that he had gotten for several years in that pit. It was found that there was leaching out of that pit, chemicals that had been blended together by virtue of his disposal, and it became a Superfund site.

Now, what about your batteries? What happens when they dispose of them?

Dr. GOTCHER. Well, our materials are much more environmentally friendly. There are no caustics, no acids, no lead, no chromates, no cadmium, and no hazardous metals at all. And our anticipation is that these batteries will be recyclable. So, what we're trying to do is look ahead, and learn from the past, and develop an attitude to bring new products to market with this product stewardship concept in mind that has been used in the chemical industry for decades.

The CHAIRMAN. You use a lithium ion, don't you?

Dr. GOTCHER. That's correct.

The CHAIRMAN. Can that be reprocessed?

Dr. GOTCHER. Yes, it can.

The CHAIRMAN. Is there any danger, if it is not?

Dr. GOTCHER. Not that we're aware of. In fact, lithium, in small quantities, is considered to be a favorable metal to have in your body. It's actually used as a positive drug to treat depression, in low quantities.

The CHAIRMAN. Well, my time is almost running out. I would like to have any comment from any of you who would like to make one on the following question: Is there anything here that we should do in the near future that we have not done with regard to this new whole concept in nanotechnology? I am talking about Congress. I have Dr. Davies' concept about reviewing the laws, but do

you have any gaps in the legal processes or the availability of assistance that you think we should know about?

Dr. DAVIES. Yes, absolutely. I mean, I—as I say, things like cosmetics, many kinds of consumers products have gaps, which the Congress should address. Also, with respect to the resource shortages, which I think are very acute in the regulatory process, or among regulatory programs, I think this committee, or a committee of the Senate, could request from the regulatory agencies what resources they do have available to deal with the health and safety consequences. And just as a starting point——

The CHAIRMAN. Let me go to Dr. Hylton, and then I have got to move on. Doctor, you looked like you wanted to say something.

Dr. HYLTON. So, my comment about nanotechnologies and environmental health and safety is much along the lines that they're—they may be hazardous materials, and we should think of them as hazardous materials, not necessarily because they're nanotechnology, but because they're new and we don't know what they do yet. So, we've dealt with hazardous materials for a long, long time, and sometimes in not very smart ways, the examples of which, or some of which, were just mentioned. So, I think—but it's an immensely complicated problem. I think it would be—it would be very difficult to come up with a piece of legislation that could address all of the risks associated with nanotechnology. So, I think one approach might be to employ a team of experts to identify where the hotspots are—cosmetics being one example, perhaps—where there might be risks that are large in comparison to the current usage of the materials, or the anticipated usage of the materials in the near future, and then attack those one by one. Because I think attacking them will require a different approach in each case.

The CHAIRMAN. Very well. I thank you.

Senator Ensign?

Senator ENSIGN. Thank you, Mr. Chairman.

With such a diverse panel with different ideas, it is hard to know where to begin questioning. But, let me try to address it this way. First of all, Dr. Hylton—is it Hylton or——

Dr. HYLTON. It's Hylton.

Senator ENSIGN. Hylton, OK. Dr. Hylton, regarding the model that you have drawn up to try to get products to market via more public/private partnerships, I was just mentioning to Senator Allen, that I could foresee potential future problems. We even hear criticisms now, and we do not have these centers set up. For instance, when the government conducts basic research on drugs, and then the drug companies take a product to market, we get criticized, because people wonder why the government does not get funds in return for its investment. How do you foresee answering criticisms that this would happen? You know those kind of criticisms would occur in a situation like that. The product is developed out of government-funded basic research, then somebody takes the product and makes a gazillion dollars out of it. Does the government get any benefit, other than a stronger economy from that? How do you address this issue?

Dr. HYLTON. I guess I would say two things, the most obvious benefit being the economic one, which you brought up.

Senator ENSIGN. Sure.

Dr. HYLTON. We get more—public invests money, we get taxes for it in return.

I think, however, if we could—we could level the playing field to a great deal—a great deal if we had organizations such as the ones that I suggested, because they would make it—they would make intellectual-property access, for example, much easier to a much larger group of people. I think it's partly a problem of transparency. There's a—if many more people could see the opportunities, many more people would take the leap and start a new company or invest in a new product or so forth. So, it's partly one of providing transparency, and also by providing, I think, critical pieces of infrastructure—that maybe only very rich organizations could afford—to smaller organizations will also help to level the playing field there.

So, I guess that would be my comment there, about why an organization—that's how you might respond to a criticism such as that.

Senator ENSIGN. Interesting idea. I think that the health issue related to nanotechnology is something that should be a concern. Dr. Gotcher, I am very proud of the efforts that you and your company are making to address health concerns. I think that is very responsible. A company should be applauded when they are doing that right up front. And, based on what the trial lawyers do to companies, I think it is actually a smart business move, because, as you have seen, the reason we are trying to fix the asbestos problem is because of the huge potential liabilities. If there turns out to be problems with nanotechnology, trial lawyers will exploit it. So, it is a smart move on your part to behave so responsibly up front.

In addition, I just want to point out the difficulty in this. Dr. Davies, I appreciate the concerns you raised in your testimony. How do we balance the importance of safety with the danger of over-regulating, and trying to be too safe. Over-regulation can stop products coming to market that may save hundreds of thousands of lives a year. You know, this balancing act is so difficult. I once heard an illustrative and analogous hypothetical—if we had OSHA around when the Wright Brothers were developing the first airplane an OSHA regulator might have looked at what the Wright Brothers were doing and said "Wait a second. You're going to take this thing up into the air, where man has never been before, and you're going to have employees, potentially, on this thing, test pilots. But how are we going to ensure safety on this thing? I don't think we can go for this." I'm just saying that we may never have been able to break into the heavens if we regulated the wrong way. And you could seriously impede progress if you regulated product after product after product in this overly burdensome manner.

I think, that it is sometimes very beneficial when the Congress is so slow to act that we actually allow products to evolve into their final versions before we can actually act and over-regulate. And so, I want to make sure that, as we move forward in the nanotechnology field, that we all consider the related issue of global competitiveness. We are worried about being competitive in the world, and we want to ensure that safe nanotechnology products are made here in America, not China. I don't think, the Chinese are going to be nearly as worried about safety. If we over-regulate, and, be-

cause of that burdensome activity, the costs are too high to do the research in this country and to take the risk here in this country, we will drive innovative nanotech productions to China and to India and to other places in the world that have less burdensome regulations. Nanotechnology research is going to occur. Whether it happens in the United States or not, it is going to happen. And that is why we have to be very, very careful as we're going forward to make sure that nanotech research continues to occur in the United States.

I want to applaud everybody here. You know, you all provided excellent, excellent oral testimony. And your written testimonies are very good. And regarding the diamonds, I just want to know, are those diamonds going to be available commercially? And if so, what will the cost of such diamonds be?

[Laughter.]

Mr. LINARES. We're actually starting to sell some diamonds now——

Senator ENSIGN. What are the comparable prices for your diamonds versus diamonds extracted from the Earth? I'm actually thinking about this from a competitive perspective, as well, because right now the diamond market is totally dominated by such a small number of people in the world. And, obviously, if your diamonds are true diamonds, it could really become a competitive market for the United States.

Mr. LINARES. Sure, absolutely. The opportunity is huge. The global retail market for diamonds is $60 billion. It's large. And we're looking for the right value proposition right now. The analogy that we use is cultured diamond, and these are 100 percent real diamond in every respect to a mined diamond, except that we culture them. It's like the cultured pearl.

Senator ENSIGN. Right.

Mr. LINARES. So, we see the markets starting to mimic each other over time. So, we're starting to sell, right now, privately, and expect to move into a commercial venue toward the end of this year.

Senator ENSIGN. I think we could spend a lot of time discussing the issues raised by members on both panels. I think that having more listening sessions that this committee has had earlier is a great idea, because the complexity of these issues is so great. And to have such listening sessions on a little more informal setting, I think, would be very, very helpful, Mr. Chairman.

So, thank you.

The CHAIRMAN. It's one thing to have a hearing, but it's another thing to ask people to just come by and talk. So, I don't know, do you all have a national association of any kind? Is there a national association of people involved with nanotechnologies?

Mr. LINARES. Yes, absolutely. There's the NanoBusiness Alliance.

VOICE. The NanoBusiness Alliance. In fact, we have about——

The CHAIRMAN. I'm wondering—things that these guys are members of. That's what I'm talking about. Is—we've got to find—to answer your question, we've got to find sometime when these people will be in town, anyway, and ask them to give us a little bit of their time.

Dr. Allen?

[Laughter.]

Senator ALLEN. Thank you, Dr. Chairman Stevens.

[Laughter.]

Senator ALLEN. I have very much enjoyed listening to all these applications and—of what I said in the beginning, being such a multifaceted discipline, from the microelectronics to the life science and health sciences, which I think will be really the great applications of the future, where you kill the cancerous cells without this shotgun-blast approach of killing healthy and bad cells together. I think that we'll look, someday in the future, back at chemotherapy and these sort of approaches differently, maybe the way we look at leeches in medicine. But much—it's just targeted to kill the cancerous cells. And then, the materials engineering, where—which really, as a practical matter, has the most application commercially right now.

What we are doing, as a country, with this nanotechnology initiative, is to fund this collaboration that people have been talking about, whether it's the Department of Energy, the Department of Defense with some of these applications, NASA and a lot of the things that we learned from space in the past are being made applicable today, the engines, the energy aspects of it, the lighter, stronger materials that'll be made out of nanomaterials, the area—in EPA, there are some ways for environmental cleanups. And so, while we need to be concerned, as we always are, about health and safety, what Mr. Linares said is, we do have the protocols, the principles of safe workplaces, clean rooms. If your diamonds are going to be used as a substitute for silica for microelectronics, or microchips, semiconductor chips, those rooms are as clean as possible. It's probably more dangerous to be drinking this water here, with the dust from the carpet and all the rest, than what are in those working places. Dr. Gotcher, in his company there in Nevada—it's just fantastic. And there are others like that. There's a Luna Innovations, in Virginia, which are making—manufacturing these Trimetaspheres, which will have all sorts of applications; and they're in the old tobacco warehouse district in Danville, Virginia. That's at—almost a symbol of the transformation of old industry, loss of textile jobs, tobacco's gone down, and now there's something there for the future.

What we need to do, Mr. Chairman, is make sure that our tax policies, our regulatory policies—which need to be reasonable—there's nothing wrong with reasonable regulations, but they need to be science-based. In this area, just like what happened with genetically modified crops or seeds, if people do not know—are not sufficiently conversant, they can be frightened, unnecessarily frightened. Genetically modified organisms are no more than, really, hybrid crops. No one cared about hybrid crops. But, because they didn't know about it, we've seen the problems we've had with the Europeans. And it is important that Senators are conversant and the American people are conversant. So, then we make the right decisions so that we don't cutoff what is really a transformative part of our economy and making sure that that intellectual property is owned here in this country from creative inventors, innovators, scientists, technologists, and materials engineers, for example.

So, I have about a minute or two minutes left, but what—if each and every one of you all just said, number one, would be the number-one thing that the government, your government, can do to make sure that we're preeminent in this multifaceted field, just—I just want number-one thing from each and every one of you, starting with you, Dr. Gotcher.

Dr. GOTCHER. I'd say the one thing that weighs on my mind is the cost to do the last two steps of commercializing a product. It takes the most people, and it's the most costly. And it isn't risk-free. Many people think the invention is the most difficult part. And, frankly, that's the easiest step. It's the last two or three steps in the commercialization as you scale-up that, I think, concerns me most about——

Senator ALLEN. What——

Dr. GOTCHER.—the competitive——

Senator ALLEN. OK, what should government do, if we can, anything, on that?

Dr. GOTCHER. What I would ask is that the government help mentor and help fund the last step or two of the commercialization process. Share the risk, share the funds, and share the reward.

Senator ALLEN. Hopefully, the National Nanotechnology Initiative, with the peer review, can determine which ones to fund, because there are not enough funds for every single one of them.

Dr. GOTCHER. I think that's an excellent idea.

Senator ALLEN. Dr. Hylton?

Dr. HYLTON. Along the same lines. I would say, more generally, to focus on this problem of transitioning the technologies. I think we are institutionally handicapped, in that we don't have an appropriate institution in place that can do the thing that needs to be done. The small companies struggle with various parts. He mentioned the late-stage part. Getting the company off the ground is another hard thing to do, as well. It's just that—I've done it, and I know he's past it, so—but all of the stages are difficult. And I think they're going to be really, especially difficult in nanotechnologies. And if we don't go and solve that problem, we risk, I guess, several things. We risk that other countries that figure it out before we do can take advantage not only of their research, but also of ours, because the information is public, generally speaking. And I think we will also miss, I think, sort of the next wave, the next industrial revolution if we don't solve that problem.

Senator ALLEN. Well, you've worked in a collaborative way in Virginia, Maryland, and D.C., together in this Chesapeake Initiative. And those are universities, the——

Dr. HYLTON. Correct.

Senator ALLEN.—private-sector, and the government. Are those not helpful ways that others may wish to emulate, as far as that development——

Dr. HYLTON. I——

Senator ALLEN.—structure of a company and what they need to—what these scientists need?

Dr. HYLTON. I would be happy to share the—those findings—that report is relatively recently completed. I'd be happy to share it with others who would be interested. But, yes, it does attempt to address many of those issues.

Senator ALLEN. Thank you, Dr. Hylton.

Dr. Davis?

Dr. DAVIS. In medicine, everything funnels through the FDA.

Senator ALLEN. Right.

Dr. DAVIS. So, I would request that the FDA continue to get resources so that they can evolve to evaluate these new medicines properly and help speed the processes through.

Senator ALLEN. Good advice. We hear that a lot. Thank you.

Dr. Davies?

Dr. DAVIES. I'd just make the point that, in terms of competitiveness, the health and safety is an important element of competitiveness, and that a product that causes adverse health effects or causes adverse environmental effects is not going to be competitive for long in the modern world.

Senator ALLEN. Dr. Swager?

Dr. SWAGER. Yes, I'd make a comment that's specific to national security and military issues. I think there's a tendency right now to over-regulate universities in terms of asking for censorship of publications and restricting what students can work on a project. MIT's taken a very firm stand on this. And for me to get money to do explosives detection these days—I won't go into it here, but it is very difficult, because the Department of Homeland Security can't fund me.

The CHAIRMAN. Senator Inouye and I also Co-Chair the Defense Appropriations Committee. We will talk to them.

Dr. SWAGER. Some of the agencies actually have policies which are not consistent with universities and what we do. I think that we really need a free and open network, in terms of our research. Our goal is to educate the world. And I think one of the things we do best, as Americans, is, we run faster, we innovate—we work harder, and we innovate more than the rest of the world. If we get attenuated on that because of security issues, I think it'll be a problem.

Senator ALLEN. Thank you.

Mr. Linares?

Mr. LINARES. Thank you. I would recommend that the Federal Government fund fundamental research into diamond-based semiconductor and optics for the——

[Laughter.]

Mr. LINARES.—obviously, directly, but I was too specific. Specifically, materials development and devices. And there are two specific areas there. The Air Force and Navy have a direct need for immune—systems that are immune from electrical interference, essentially, from directed energy weapons, and for—the Army has specific needs for high-energy laser systems for things like remote mine detonation and potentially knocking down certain missiles. And those require fundamental developments in—largely in material and specific device development.

Senator ALLEN. Thank you. Thank you, and good luck next Valentine's Day with your diamonds——

[Laughter.]

Mr. LINARES. Thank you.

Senator ALLEN.—and anniversaries.

Thank you, Mr. Chairman.

The CHAIRMAN. Well, thank you very much.

Mr. Linares, I think you ought to talk to DARPA, at the Defense Department.

I'm pleased to say that the staff tells me that the NanoBusiness Alliance will be up here on Capitol Hill tomorrow, and they're holding a staff briefing on nano in this building for staff. So, we thank you very much for that.

We thank you all for taking the time. I think you're in one of the most fascinating areas of the developing technology base that we have, and we want to keep up with you and try to understand what you're doing, as much as possible, and to be of as much help as we can. So, we will try, sometime, to see if we can find a way to—not inconvenience you—to find a way when you could come back and just have some conversations with our people about—here in this committee—what's going on and what we could do, and what we shouldn't do.

But, Dr. Swager, in our—with other hats that Senator Inouye and I wear, your briefing, in terms of what you're doing, in terms of protection of our people wearing uniforms, just is overwhelming. I'd like to see you come back to the Defense Subcommittee soon and tell us more about that.

Dr. SWAGER. I'd like to do that, thank you.

The CHAIRMAN. Thank you very much.

We thank you very much for your patience and your contribution. We hope to see you again soon. Thank you all very much.

[Whereupon, at 4:40 p.m., the hearing was adjourned.]

A P P E N D I X

RESPONSE TO WRITTEN QUESTIONS SUBMITTED BY HON. GORDON H. SMITH TO DR. E. CLAYTON TEAGUE

Question 1. Nanotechnology is an emerging technology in which many countries around the globe are making significant investments and advancements. What steps are necessary for the United States to be the world leader in nanotechnology in the long run?

Answer. U.S. leadership in nanotechnology is at the heart of the National Nanotechnology Initiative (NNI). The strategy for realizing the benefits of nanotechnology and sustaining U.S. leadership is detailed in the NNI Strategic Plan released in 2004,[1] and was developed with input from academic, industry, and government experts. The plan identifies four overarching goals for the initiative. Progress toward these goals will go a long way toward sustaining U.S. leadership in this important emerging area. The goals are:

1. Maintain a world-class research and development (R&D) program aimed at realizing the full potential of nanotechnology.
2. Facilitate transfer of new technologies into products for economic growth, jobs, and other public benefit.
3. Develop educational resources, a skilled workforce, and the supporting infrastructure and tools to advance nanotechnology.
4. Support responsible development of nanotechnology.

The ability to be a world leader in nanotechnology is underpinned by a healthy innovation ecosystem in which discoveries can be made and ideas can flourish. The President's American Competitiveness Initiative (ACI), announced in the 2006 State of the Union address, proposes a comprehensive approach to strengthening this ecosystem, targeting policies and programs in the areas of research and development (R&D), math and science education, high-skilled immigration, and workforce training. A primary role of the Federal Government in fostering innovation is sustaining strong support for basic research. As such, the centerpiece of the ACI is a commitment to double, over 10 years, funding for the most critical basic research in the physical sciences; funding for this nanotechnology research is an important component of this commitment.

Within this overall framework, here are five Federal specific areas that will be important to maintaining U.S. leadership in nanotechnology in the long run:

Basic research. Continued strong Federal support for nanotechnology research, especially in the physical sciences, across the Federal R&D enterprise. At the same time, agencies that fund R&D should make nanotechnology research a priority. At the Federal level, the United States invests approximately one quarter of the amount spent by governments worldwide; Japan and the European nations combined each spend a similar amount. Although the United States leads all nations in the level of funding for nanotechnology research, other nations are growing their own programs in this emerging area. Investment in basic research today will fuel innovation and American competitiveness in the future.

Infrastructure. Continued strong support for the advanced infrastructure of facilities and instrumentation that is necessary in order to perform nanotechnology research. Researchers need access to costly equipment necessary to fabricate and characterize nanoscale materials and devices. User facilities and research centers specifically aimed at supporting nanoscale science and engineering research are supported by many of the NNI agencies, including the National Science Foundation, the Department of Energy, the National Cancer Institute, and the National Institutes for Standards and Technology. The United States investment in this area has been crucial to enabling cutting-edge research and support for maintenance and operations

[1] Available at *http://www.nano.gov/NNI_Strategic_Plan_2004.pdf.*

will sustain this valuable resource. In addition, research is needed to develop the next-generation tools and instruments that will continue to allow advances to take place going forward.

Technology transfer. Support for transitioning the results of research from the laboratory to the marketplace, including by creating an environment in which entrepreneurial activity can thrive. Generally, the challenges associated with transitioning the results of nanotechnology research are not unique or specific to nanotechnology. Therefore, existing mechanisms and authorities (*e.g.,* those provided for by the Bayh-Dole and Stevenson-Wydler Acts, Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) and other technology transfer statutes) can and should be utilized. In addition, making permanent and modernizing the Research and Experimentation (R&E) tax credit will strengthen incentives for private-sector investment in nanotechnology commercialization.

Specific actions by the NNI to promote technology transfer and commercialization include the following:

- Utilizing the SBIR and STTR programs to fund development of new applications of nanotechnology in small companies.
- Increasing support for research on environmental, health, and safety (EHS) aspects of nanotechnology to allow industry, regulatory agencies, and others to assess and manage risks associated with nanotechnology.
- Strengthening of expertise and structures within the U.S. Patent and Trademark Office to improve the ability of U.S. inventors and businesses to protect intellectual property related to nanotechnology.
- Working with the U.S. Patent and Trademark Office as they strengthen the protection of intellectual property through continued work on the cross-referencing of nanotechnology-related patents and in-depth technical training of patent examiners on the state-of-the-art in nanotechnology.
- Facilitation of communication with and among local, state, and regional nanotechnology economic development initiatives, *e.g.,* through workshops such as those organized in 2003 and 2005.

Standards for materials and processes. In industries where materials and components are manufactured by one business and integrated into products by another, standards are vital to business-to-business commerce. Standards also allow consumers to know what they are buying and allow regulators to establish guidelines for safe practices. Already, a number of U.S. standards developers are engaged in the development of nanotechnology standards and, following an inquiry by OSTP Director John Marburger, the American Nationals Standards Institute (ANSI) has established a Nanotechnology Standards Panel to coordinate U.S. activities in international standards forums, including the International Organization for Standards (ISO). The NNI supports the ANSI-led efforts and the Director of the National Nanotechnology Coordination Office (NNCO) currently chairs the ANSI-accredited Technical Advisory Group, which represents the United States at the ISO Technical Committee on Nanotechnologies (TC 229). In addition, the U.S. leads the subgroup under TC 229 on standards for health, environment, and safety of nanotechnology.

Communication with stakeholders. It is important to educate the public about nanotechnology and the steps being taken both to realize its potential benefits and to assess and manage, or even avoid, risks. Stakeholders include the business, research, policymaking, and investor communities, as well as the general public. In general, research results are communicated to the scientific and technical community through scientific publications, conferences, and workshops (a number of which are supported by NNI agencies). To promote communication with the broader public, the NNI, through the NNCO, maintains a website with regularly updated information about nanotechnology and NNI programs, as well as link to agency-specific information (*e.g.,* workplace safety information at the National Institute for Occupational Safety and Health). The NNCO acts as a portal for questions about the NNI and nanotechnology, and works proactively to communicate with the science reporters at major media outlets. Finally, the NNCO has conducted meetings to plan for public engagement as called for in the 21st Century Nanotechnology Research and Development Act.

As the agencies make progress in the areas outlined above so as to advance nanotechnology for government needs and for U.S. economic and societal benefit, it is important to bear in mind that the United States is not the only nation investing in nanotechnology for the future. New knowledge and innovative ideas are being created around the world and Federal agencies that support nanotechnology R&D and that have needs that can be addressed by nanotechnology solutions should be informed about activities taking place elsewhere. Advances in nanotechnology in the

United States will be expedited by working cooperatively in areas of nanotechnology research that are pre-competitive or noncompetitive, such as research on environmental and health implications and research to promote the incorporation of U.S. standards and concepts into international standards.

To assess U.S. global performance in nanotechnology, the NNI, through the interagency Nanoscale Science, Engineering, and Technology (NSET) Subcommittee of the National Science and Technology Council, tracks activities internationally, including investments, scientific publications, and patent activities. The NSET Subcommittee also provides input and feedback to U.S. representatives to international bodies that are considering nanotechnology, such as the ISO and other standards developers, the Organization of Economic Cooperation and Development (OECD), and the Wassenaar organization.

The NNI, through the activities of the participating agencies, the interagency NSET Subcommittee and its subgroups, and the National Nanotechnology Coordination Office is working to address the areas outlined above. In its review of the NNI released in 2005,[2] the President's Council of Advisors on Science and Technology (PCAST) concluded that "the United States is the acknowledged leader in nanotechnology R&D," and that the NNI is well managed. PCAST goes on to caution that the U.S. lead in nanotechnology is under increasing competitive pressure from other nations. While encouraging efforts by the NNI to facilitate technology transfer, the PCAST report emphasizes that the primary focus is on supporting and coordinating a broad, multidisciplinary program of world-class basic research.

Question 1a. What are other countries doing that we could learn from?

Answer. As the first of its kind, the NNI is the model for nanotechnology programs in many other countries. Yet each country or region has adapted the U.S. approach to its needs and strengths. Notably, a number of countries have elected to focus research around one or more particular areas of application, such as materials science, biomedicine, or electronics. The members of the NSET Subcommittee representing the diverse Federal agencies participating in the NNI have considered such an "application-driven" strategy and continue to support the current broad program of basic research at the level of the initiative as a whole. Individual mission-oriented agencies, such as the Department of Defense, Department of Energy, and the National Institutes of Health, is the level at which application-driven nanotechnology research is and should be organized.

The NNI has established a Global Issues in Nanotechnology Working Group under the NSET Subcommittee. One objective of the Working Group is to track international activities related to nanotechnology. The Working Group reports to the Subcommittee, thereby providing information about "lessons learned" from around the world to the Subcommittee as it manages the initiative and periodically reviews the U.S. strategy for the Federal nanotechnology R&D program.

RESPONSE TO WRITTEN QUESTION SUBMITTED BY HON. GORDON H. SMITH TO DR. RICHARD O. BUCKIUS

Question. Do you support the concept of my legislation, S. 1908 the Nanoscience to Commercialization Institutes Act, that emphasizes commercialization of nanotechnology? What more should be done to promote the commercialization of nanotechnology?

Answer. NSF cannot comment on provisions in legislation that do not affect the agency. The long-term objectives of this Nation's broad initiatives in nanotechnology—as contained in the National Nanotechnology Initiative (NNI)—focus on building a foundation of fundamental research to understand nanoscale concepts, and to apply novel principles to the most promising opportunities in measuring and manipulating matter on the nanoscale. Another objective is ensuring that U.S. institutions have access to a full range of nano-facilities, enabling access to nanotechnology education, and catalyzing the creation of new commercial markets that depend on three-dimensional nanostructures. These are intended to facilitate the transfer of new technologies into products for economic growth, jobs, and other public benefit. The promise of nanotechnology resides in controlling the atomic and molecular realm, where new principles and possibilities emerge. This is a fundamental distinction between nanotechnology and micro-technology. Additionally, a comprehensive peer-review process should be carried out by expert groups to select any potential awardees.

To facilitate the commercialization of nanotechnology and bring discovery to innovation, NSF supports and maintains strong partnerships with industry, national

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[2] See full PCAST at *http://www.ostp.gov/pcast/PCASTreportFINAL.pdf.*

laboratories, and international centers of excellence. This support includes investments in 16 Nanoscale Science and Engineering Centers, and grants for nanoscale research through the Small Business Innovation Research (SBIR) program and the Small Business Technology Transfer (STTR) program.

RESPONSE TO WRITTEN QUESTIONS SUBMITTED BY HON. GORDON H. SMITH TO JEFFERY SCHLOSS, PH.D.

Question 1. The potential applications of nanotechnology to diagnose and treat cancer are remarkable. Do you have any recommendations on how we can further support advancements in this area?

Answer. Nanotechnology does indeed encompass a wide range of materials and techniques that are being applied to a remarkable range of cancer problems, including:

- Early imaging agents and diagnostics that will allow clinicians to detect cancer in its earliest, most easily treatable, presymptomatic stage;
- Systems that will provide real-time assessments of therapeutic and surgical efficacy for accelerating clinical translation;
- Multifunctional, targeted devices capable of bypassing biological barriers to deliver multiple therapeutic agents at high local concentrations, with physiologically appropriate timing, directly to cancer cells and those tissues in the microenvironment that play a critical role in the growth and metastasis of cancer;
- Agents capable of monitoring predictive molecular changes and preventing precancerous cells from becoming malignant;
- Surveillance systems that will detect mutations that may trigger the cancer process and genetic markers that indicate a predisposition for cancer;
- Novel methods for managing the symptoms of cancer that adversely impact quality of life; and
- Research tools that will enable investigators to quickly identify new targets for clinical development and predict drug resistance.

The National Cancer Institute's Alliance for Nanotechnology in Cancer (*http://nano.cancer.gov*) is developing more effective interventions to accelerate progress against cancer in the next decade. New nanotechnology-based therapeutic delivery systems could significantly enhance the efficacy and tolerability of cancer treatments, immediately benefiting cancer patients. The Alliance is also leveraging nanotechnology as a catalyst to build the multidisciplinary teams that are the future of biomedical research and molecular, personalized medicine. In addition, NCI's close collaboration with the FDA through the Interagency Oncology Task Force (IOTF) and the Alliance's Nanotechnology Characterization Laboratory will help to ensure that the science needed to inform the review of these new products keeps pace with the research. This is a crucial step in ensuring that the critical pathway to clinical application is well-defined for these novel technologies.

In short, advancements in applying nanotechnology to the diagnosis and treatment of cancer can be further supported along the following lines:

- Facilitate team science with integration into clinical oncology to accelerate matching of key cancer problems with cutting-edge nanotechnology-based solutions.
- Foster development of standards and informatics to more effectively integrate researchers and clinicians across disciplines and sectors.
- Establish the general clinical development pathway that includes characterization of materials and biological responses to encourage researchers to pursue nanotechnology therapeutic development through to commercialization and broad application.
- Remove barriers to cross-licensing of nanotechnology platforms that will be needed to develop integrated components for diagnostics in particular.
- Support research through user facilities to enhance uniformity of materials and improve nanotechnology platform manufacturing capabilities and quality assurance/quality control measures.
- Support additional research toward understanding fundamental interactions of biological components (nucleic acids, proteins) and a wide range of nanomaterials to address practical problems such as biocompatibility/biofouling, aggregation, and overcoming biological barriers.

- Distinguish environmental (incidental) and medical (intentional) toxicological issues, and quantify and clarify the risk-benefit ratio for novel nanotechnology applications in comparison to current standards of care.

For more information: The NCI Alliance for Nanotechnology in Cancer website *http://nano.cancer.gov* provides comprehensive information on the program and on current nanotech advances relevant to cancer.

Question 2. To what extent have other countries made advances in nanomedicine?

Answer. Based on information available through the National Nanotechnology Coordination Office (NNCO), below is some information on what other counties are doing in the area of nanomedicine.

Europe

The European Science Foundation has identified (ESF Scientific Forward Look on Nanomedicine, 2004) needs and opportunities, and the trans-European ability to achieve significant advances, in the following areas:

- nanomaterials and nanodevices for drug delivery (including an emphasis on scale-up manufacturing and materials characterization); the goal is to realize clinical benefit by 2010. Substantial potential exists for direct targeting of specific diseases and transport across biological barriers.
- multiplex sensing of complex analytes *in vitro* for tissue engineering, regenerative medicine and complex diagnostics (application by 2015). Scaffolds for tissue regeneration.
- externally controlled. multifunctional, mobile devices for combined diagnostics and drug delivery (application by 2015). The subsequent generation of devices would be bioresponsive or autonomously controlled. To realize these opportunities, a better understanding of potential toxicological and environmental implications of these materials is needed, as are risk management strategies. Effective communication among workers from multiple fields in academia, industry and regulatory bodies will facilitate development, and clinical and regulatory evaluation, of products. Multidisciplinary education from undergraduate through graduate and professional levels is needed to support rapid development and clinical application of the field. The level of preparedness to exploit emerging nanomedical technologies was seen as a weakness to be addressed. Better information needs to be conveyed to the public, politicians and policymakers.

In late 2004, about 40 nanotechnology-related products were reported as being in clinical testing or use for medical applications with emphasis on treating cancer and infections (including HIV/AIDS and STDs), and included examples for mitigation of hereditary or degenerative diseases and side-effects of chemotherapy. More than 30 European companies were involved in nanomedicine product development.

Asia

Japan, one of the non-U.S. countries with the largest nanotechnology investment (~$780M overall nanotechnology investment in FY 2005), includes both nanotechnology/materials and life sciences among four S&T high priorities (the others being information technology and environmental sciences). (Second-ranked areas include energy, manufacturing technology, social infrastructure, and "frontier-sciences.) It is difficult to know with precision how the nanotechnology and life sciences interests overlap. One sees credible reports in the scientific literature and in news releases in areas similar to those of interest in the U.S., including use of nanotechnologies for medical imaging, diagnosis of disease signatures, and drug delivery.

Bionanotechnology is China's second largest nano-related funding target after nanomaterials. China anticipates a very strong market in pharmaceuticals, medical devices, *etc.,* and has invested in industry with specific focus on biomedical materials. For example, a Chinese company announced last year a patent on a biodegradable nanosilicon material for drug delivery, with early intended applications for treatment of liver cancer.

Taiwan supports activities in nanobiotechnology basic science contributing to imaging and detection, manipulation of DNA and genes, and drug delivery and treatment of disease. The relatively small investment is focused on developing products with strong commercial potential.

Singapore has a focus on nanobiotechnology and nanomedicine, and has built a dedicated research facility called Biopolis. Scientists in Singapore have reported progress in developing materials for drug delivery and tissue engineering, and efficient batteries for diagnostic and implantable devices. Alliances have been estab-

lished for nanomedicine research with U.S. institutions such as the University of Washington and MIT.

The size of Korea's activity in this area is difficult to separate from other S&T activities. One sees reports on nanobiomaterials for use in tissue repair, drug delivery and medical diagnostics.

RESPONSE TO WRITTEN QUESTION SUBMITTED BY HON. GORDON H. SMITH TO DR. J. CLARENCE (TERRY) DAVIES

Question. Nanotechnology is an emerging technology with a short history, specifically in the area of regulation and health and safety issues. How do you propose we move forward in advancing this technology without stifling this industry and preventing its benefits from reaching the marketplace?

Answer. The future of nanotechnology depends on striking a balance between over-regulation and under-regulation. The former can stifle innovation and technological progress. The latter can turn the public against the technology and similarly stifle innovation and technological progress. We need to start talking about how to strike the necessary balance.

In a discussion sponsored by the Senate Committee on Environment and Public Works, I proposed 15 initiatives that the Congress can take now to encourage the development of nanotechnology. They are as follows:

Research

1. Amend Nanotech R&D Act (117 Stat. 1923) to require separate strategic plan for health and environmental research.
2. Under NNI, establish separate pot of money (5–10 percent of agency nano budgets), distributed by OMB and OSTP for filling gaps identified in H&E plan.
3. Create a Nanotechnology Effects Institute, modeled after the Health Effects Institute (EPA and auto industry), jointly funded by government and industry.
4. Commission GAO or Library of Congress, working with State Department and U.S. embassies, to do a report on what other countries are doing with respect to nano R&D, effects research, and regulation.
5. Commission a study, funded through NSF, on the economic impacts of nano in the U.S. over the next decade.
6. Conduct a hearing on how to encourage "green" nanotechnology.
7. Provide funding (through NSF) to develop and distribute a layman's primer on nano.

Management

8. Amend Nanotech R&D Act to establish an interagency Nanotechnology Regulatory Coordinating Committee.
9. Commission a GAO study of what resources (Dollars, FTEs, expertise) Federal agencies are currently devoting to nano health and safety.
10. Fund NIOSH/OSHA to: (1) examine existing worker protection practices in nano-manufacturing; (2) evaluate the adequacy of such practices; and (3) promulgate best practices.
11. Amend the Food, Drug and Cosmetic Act to provide pre-market approval of cosmetics. (Limit to products containing nanomaterials if politically necessary.)
12. Amend the Toxic Substances Control Act to allow EPA to require additional data for nanoproducts with human exposure.
13. Start stakeholders' dialogue on nano management/oversight needs.
14. Start House/Senate dialogue on management/oversight needs.
15. Commission a study by Library of Congress or GAO (cooperating with Consumer Product Safety Commission, FDA, and Federal Trade Commission) on labeling of nano products.

I would be happy to discuss any or all of the above items with your committee.

RESPONSE TO WRITTEN QUESTIONS SUBMITTED BY HON. GORDON H. SMITH TO MARK E. DAVIS, PH.D.

Question 1. Are we on the verge of witnessing a revolution in the way we treat and cure disease?

Answer. Yes. Many factors are contributing to this revolution but a specific example is now the ability to attack diseases at their genetic level.

Question 1a. Are other countries making advances in this area?

Answer. Yes. As expected because of the huge societal and economic impacts, many countries throughout the world are making large investments in new therapeutics that are taking advantage of the new breakthroughs in science/engineering and understandings of the molecular basis of disease.

Question 1b. What are other countries doing, if anything, that we could learn from?

Answer. I believe that the most difficult step on the route to bringing new therapeutics to the public is getting them through clinical trials for approval. It is lengthy and costly. However, it is necessary to provide for public safety. While the FDA is doing a good job in my opinion, the European regulatory agencies have adopted a better strategy for life-threatening diseases. They allow biological markers to be used to test the effectiveness of a new drug rather than having to wait for a survival say in a cancer trial. This automatically allows companies to go after types of cancers that would take long times to determine survival. Because of economic reasons, companies tend to go to diseases where the trials can be done in a reasonable time-frame and therefore trials in Europe can be performed on disease states that would not be done in the U.S. While the FDA is moving toward the concept of molecular markers, there is still a large difference in what can be used as trial end-points in Europe vs. the U.S. This will certainly not favor trials of new revolutionary drugs in the U.S. because they tend to all attack molecular targets of disease for which molecular markers can be developed. Additionally, the U.S. Patent Office is very problematic. The inconsistencies in what is allowed and not allowed is causing significant issues for commercialization of new drugs. My own experiences with the U.S. Patent Office (I have 35 U.S. patents) has taught me that it is an organization that needs dramatic change. Other countries have variations on how Intellectual Property is handled and I not able to recommend a particular country that I would single out who is performing well. I just believe that the U.S. Office is a real problem at this time.

Question 2. Do you have specific examples of institutions that are not in compliance with Title IX?

Answer. No.

RESPONSE TO WRITTEN QUESTIONS SUBMITTED BY HON. GORDON H. SMITH TO BRYANT R. LINARES

Question 1. What specific barriers do entrepreneurs like yourself experience in advancing commercialization on nanoscience research?

Answer. There is a great time-lag between getting from the discover phase, through research and development to finishing with a commercialized product. In the case of Apollo Diamond, this time-frame has lasted for over ten (10) years. Funding is very difficult in the early phases and relies (from a small company perspective) on mainly government funds. Any research funding however is sketchy and may be out of phase to the specific technology that is being developed. In our case, we relied mainly on private funds from investors. This is a difficult process and adds extreme risk to the early stage company.

In summary adequate funding is the main barrier to thorough commercialization.

Question 1a. What can be done to benefit entrepreneurs in this field?

Answer. Better sources of funding and support infrastructures to connect small businesses with good technologies with large companies getting government funding and government institutions.

Apollo Diamond supports the Nanoscience to Commercialization Institutes Act.

RESPONSE TO WRITTEN QUESTION SUBMITTED BY HON. GORDON H. SMITH TO TIMOTHY M. SWAGER, PH.D.

Question. How has collaboration with industry made a difference in attaining your institute's objectives?

Answer. The Institute for Soldier Nanotechnologies (ISN) at the Massachusetts Institute of Technology (MIT) considers the collaboration with industry to be a critical underpinning that is essential for our continued success. One obvious advantage of engaging industry is the fact that MIT is a university and hence is not able to manufacture. The ISN has a portfolio of activities at different levels of scientific and technological maturity. Companies actively engaged in the ISN can best identify opportunities for transitioning technologies at an early stage to the Army. The most successful transition thus far have been in the area of sensors that can detect bombs based upon an explosives vapor signature. A small company, Nomadics Inc. of Stillwater, OK, was responsible for this transition. Multiple other transitions in materials for protection from ballistic impacts and optical sensors are anticipated in the future. Companies understand that the ISN has established creditability with the Army. Hence, companies are becoming more willing to help to underwrite part of the ISN and will help us to expand our program in the future.

RESPONSE TO WRITTEN QUESTIONS SUBMITTED BY HON. GORDON H. SMITH TO ALAN GOTCHER, PH.D.

Question 1. What impediments do you face in achieving your business goals relating to nanotechnology?

Question 1a. Do you believe more can be done to support the commercialization of nanoscience research?

Answer. In the development of any new technology the coordinated roles of industry and government are critical to world leadership in the sector. In general industry's role is to marry scientific development with exploiting market opportunities for the new technology, while government's role is to provide funding that accelerates time to market, ensure a regulatory environment that removes impediments to market, and fund educational establishments to provide a skilled pool of scientists.

With regard to nanotechnology we believe the U.S. Government should work with industry to ensure the global competitiveness of the U.S. nanotechnology industry by focusing on the following key areas:

1. *Funding that accelerates time to market.* Two specific areas are critical to the development of commercial nanotechnology. The first is judicious, continuing funding of programs in segments critical to our society—life sciences, nanomaterial manufacturing technology and alternative energy. By appropriately funding basic and applied R&D in U.S. nanotechnology companies we can ensure we stay in a world leadership position. A further area for funding is providing a national infrastructure for the testing and analysis of new materials. Frequently innovators are unable to afford the leading-edge analytical equipment required to ensure rapid time to market. Examples of these are very high resolution transmission electron microscopes.

2. *Ensure an appropriate regulatory environment.* The U.S. is at a critical point in the development of this infant industry. If we go the route of seeking better answers and understanding of the various families/classes of nanomaterials *before* imposing government regulation, it could lead to greater benefits to the consumers and the environment through dramatic changes within widely diverse industries. Taking the other road—regulation first, without research—could lead to a disquieting moratorium on all future nano-research and development in the U.S., with great cost to our economy. There are some who feel that nanotechnology will require new regulatory legislation—for example, a recent report by Dr. Clarence Davies with the Woodrow Wilson International Center for Scholars/The Pew Charitable Trusts Project on Emerging Nanotechnologies. But much of this concern is founded on sparse and sometimes conflicting data. If anything is clear, it is that there is no single prototypical "nanoparticle." Asbestos-like fibrous nanotubes and toxic-metal containing quantum dots are not good surrogates for all nanomaterials. To fall into a "one-size-fits-all" approach to nanotechnology is irresponsible and counter-productive. There are no clear and comprehensive data available to let us really assess the general risk of the wide range of nanomaterials under consideration and/or development. Many of the cognizant Federal funding and regulatory agencies—such as the National Institutes of Health (NIH), the National Cancer Institute (NCI), the Food and Drug Administration, EPA and NIOSH—recognize this reality and are working hard to understand the underlying science and to develop quantitative data and models to quantitatively assess risks. What is needed is a broad, government-funded initiative (similar to the Human Genome project) with the goal of establishing broad empirical data and models for the predictability of the environment, health and safety risks of commercially-interesting nanomaterials.

3. *Supply of educated personnel.* We all have seen the numbers from the National Science Foundation—while 70,000 Ph.D. engineers are graduating from universities in China and 35,000 from universities in India, there are fewer than 10,000 engineering graduates from universities in the U.S. Plus, many of the U.S. graduates are foreign nationals, many of whom return home with the benefits of their education. This is a national crisis. For Altairnano, it is also a company crisis. It is extremely difficult for us to recruit science and engineering students from the University of Nevada-Reno. There just are not enough students in the pipeline to go around. Nanotech—the "sexy" science of the 21st century—might be the catalyst needed to stimulate renewed interest in math and science in American students, from K through graduate school. One approach would be to fund the development of curricula, in coordination with scientists and engineers from local/regional nanotechnology companies, and focused on, perhaps, grades five and six, junior high, and high school. Another approach could be to fund scholarships to nanoscience camps for students at the junior high and high school levels. A third approach could be to provide scholarships for students enrolling in nanotechnology programs at undergraduate and graduate levels—including curricula focused on nanomaterials and nanochemistry, nanobiology, and nano-environmental engineering. All of these programs should include a component devoted to considerations of public policy issues affecting nanotechnology.

Question 1b. Do you support the concept of my legislation, S. 1908, the Nanoscience of Commercialization Institutes Act, that emphasizes commercialization of nanotechnology?

Answer. We believe that more needs to be done to harness the potential of nanotechnology for the U.S. economy. Currently specific programs are funded by individual government departments, often as collaborative projects between academia and industry. These are, in general, excellent programs and Altairnano is grateful for the support it has received under these fundings, often leading to new commercial opportunities such as our battery program. However the programs are silos and need to be self-contained from a funding perspective.

A key missing component to this funding allocation model is that there is fundamental infrastructure that is not getting built which would significantly help each project. Examples of this include state-of-the-art analytic equipment such as transmission electron microscopes. This type of equipment is too expensive to justify either for an individual project or for an entrepreneurial industrial partner. Although only occasional access would be required, when the equipment is used it would provide invaluable insight to the materials being investigated and could save unnecessary additional experimental work and time to market delays.

We support the concept of S. 1908, that is the establishment of centers of nanoscience excellence. We believe the greatest contribution that these centers could make to the progress of nanotechnology would be to provide regional centers of nanoscience infrastructure. These centers would provide shared access to a range of analytic and experimental equipment key to nanotechnology. They would also naturally act as centers for information exchange and potentially technical recruitment.

RESPONSE TO WRITTEN QUESTIONS SUBMITTED BY HON. GORDON H. SMITH TO DR. TODD L. HYLTON

Question 1. Do you believe that more can be done to support commercialization of nanoscience research?

Answer. I strongly believe that more can be done to support commercialization of nanoscience research. The country has to date invested well and wisely in support of basic research, but many of the commercial benefits of this research will not be realized without effective support of commercialization. Because of the complexities associated with nanotechnologies, conventional commercialization paths are not likely to be as effective as they have been with other recent technology transformations (*e.g.,* the Internet and telecommunications). In addition to the impact on the U.S. economy, effective commercialization of nanotechnologies promises to address many of the most pressing problems facing humanity today (in energy, healthcare and national security) and, thereby, to dramatically improve the quality of life worldwide. The principal problem to be addressed is to effectively coordinate the many academic, national laboratory, small and large technology businesses, capital investors, and public-sector support organizations along selected high-value market opportunities. I believe that this coordination should be led by public-private partnerships focused in these high-value market/application areas. The U.S. Government should sponsor the creation of these partnerships and sustain support for them for a sig-

nificant period of time. In proportion to the benefit that would be derived, the investment needed from the U.S. Government is very small.

Question 1a. Would you support public-private partnerships to promote the application of research to commercialization?

Answer. As stated in my response to *Question 1,* I strongly support this concept and believe that it is the best way to enhance nanotechnology commercialization.

Question 1b. Do you support the concept of my legislation, S. 1908, the Nanosciences to Commercialization Institutes Act that emphasizes commercialization of nanotechnology?

Answer. I was very pleased to read the S. 1908. It clearly recognizes the challenges and importance of nanotechnology commercialization. I would offer, however, the following comments on the measure that I believe will make it more effective in its intended purpose.

1. Because nanotechnologies are so complicated and because of the substantial amount of time that will be required to implement the type of organization required of the Institutes, I believe that 3 years is an inadequate period of support. I recommend 5 years as a minimum.

2. My concept of such an Institute would include the following minimal set of personnel. The role of this staff is to build and sustain a national partnership of universities, research laboratories, capital investors, regional economic development organizations and small and large technology businesses. I believe that the $1.5M/yr maximum allocation is approximately $1M too low to support such a staff.

a. Director (1)
b. Intellectual Property expert or attorney (1)
c. Technical specialists (2)
d. Business services specialists (2)
e. Economic development specialist (1)
f. Communications/liaison staff (2)
g. Administrative staff (1)

3. While it may be advantageous from a technical resource perspective to locate the Institutes in the vicinity of universities or national laboratories, I strongly recommend that the Institutes be managed by (impartial) technology businesses with expertise in technology commercialization. Universities and national laboratories do not have the appropriate experience or backgrounds in commercialization to manage these Institutes effectively. These managing businesses should be held accountable for the results and replaced as necessary to continue the mission. Also, I believe that a strong affiliation with a single university or government laboratory would unavoidably give the Institutes strong biases and discourage the participation of other similar institutions. The result would be much smaller, more regional efforts that do not draw upon the resources and investment in nanotechnology nationwide.

4. The Institutes should strive to continually increase private-sector support and correspondingly decrease public-sector support. At the end of the public-support period, the successful Institutes will be self-sustaining privately-funded organizations playing a role similar to that played by Sematech in the microelectronics industry.

5. I recommend that there be two energy institutes—one focused on conventional sources (*e.g.,* fossil, bio, nuclear) and one focused on renewable sources (*e.g.,* solar, fuel cells, hydrogen).

The comments and opinions described here are derived largely from my testimony of 15 February 2006. A key piece of that testimony describes what I call a "Technology Transitions Organization," which corresponds closely to the "Institutes" in S. 1908. Here I insert two charts from that testimony illustrating the function of that organization for your ease of reference. I believe that these ideas in these charts are highly relevant to the underlying purpose of S. 1908.

I appreciate the opportunity to be of service in this matter. Please contact me if I can be of further assistance.*

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* Charts attached to questions are printed on pg. 44.