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Hearing on:

"Developments in Nanotechnology"

Testimony of:

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I would like to thank Chairman Ted Stevens, Ranking Member 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 Technologies 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 co-authored 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. E. Clayton Teague, director of the NNCO, has said that: "Until we have good, solid, scientifically validated information that would indicate significant 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

[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.

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 it's responsibilities then. Today, with a greatly expanded economy and workforce, OSHA has 2,208 employees, approximately 25% 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 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

[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, UK, 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.

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, 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

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

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

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

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 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."

[6] See Jane Macoubrie. *Informed Public Perceptions of Nanotechnology and Trust in Government.* Washington, DC: 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.