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SUBJECT: Public Meeting on Research Needs and Priorities Related to the Environmental, Health, and Safety Aspects of Engineered Nanoscale Materials

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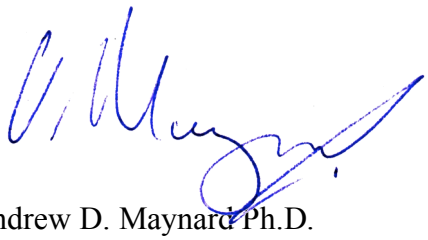
Attached please find the comments I am presenting for this public meeting on research needs and priorities related to the environmental, health, and safety aspects of engineered nanoscale materials.

Sincerely Yours,



Andrew D. Maynard Ph.D.
Chief Science Advisor, Project on Emerging Nanotechnologies

Public Meeting on:

"Research Needs and Priorities Related to the Environmental, Health, and Safety Aspects of Engineered Nanoscale Materials"

Sponsored by the National Nanotechnology Coordination Office on behalf of the Nanoscale Science, Engineering, and Technology (NSET) Subcommittee of the Committee on Technology, National Science and Technology Council (NSTC)

Comments from:

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Washington, DC

January 4, 2007

1:15 p.m.

FDIC Auditorium, Arlington, Virginia

I would like to thank the National Nanotechnology Coordination Office (NNCO) for holding this public meeting on "Research Needs Related to the Environmental, Health, and Safety Aspects of Engineered Nanoscale Materials" on behalf of the Nanoscale Science, Engineering, and Technology (NSET) Subcommittee of the Committee on Technology, National Science and Technology Council (NSTC). I appreciate the opportunity to speak to you today about research strategies and prioritization criteria for addressing the environmental, health, and safety (EH&S) aspects of nanomaterials.

My name is Dr. Andrew Maynard. I am the Chief Science Advisor to the Project on Emerging Nanotechnologies at the Woodrow Wilson International Center for Scholars. I am an experienced researcher in the field of nanomaterials and their environmental and health impacts; and I have contributed substantially in the past fifteen years to the scientific understanding of how these materials might lead to new or different environmental and health risks. I was responsible for stimulating government research programs into the occupational health impact of nanomaterials in Britain towards the end of the 1990's and have spent five of the past six years developing and coordinating research programs at the Centers for Disease Control and Prevention (CDC) National Institute for Occupational Safety and Health (NIOSH) that address the safety of nanotechnologies in the workplace. While at NIOSH, I represented the agency on the Nanoscale Science, Engineering and Technology (NSET) Subcommittee of the National Science and Technology Council (NSTC), and was co-chair of the Nanotechnology Environmental and Health Implications (NEHI) Working Group from its inception.

The Project on Emerging Nanotechnologies is an initiative launched by the Woodrow Wilson International Center for Scholars and The Pew Charitable Trusts in 2005. It is dedicated to helping business, government and the public anticipate and manage the possible health and environmental implications of nanotechnology. As part of the Wilson Center, the Project on Emerging Nanotechnologies is a non-partisan, non-advocacy organization that collaborates with researchers, government, industry, non-governmental organizations, and others concerned with the safe applications and utilization of nanotechnology.

Our goal is to take a long-term look at nanotechnologies; to identify gaps in the nanotechnology information, data, and oversight processes; and to develop practical strategies and approaches for closing those gaps and ensuring that the benefits of nanotechnologies will be realized. We aim to provide independent, objective information and analysis that can help inform critical decisions affecting the development, use, and commercialization of responsible nanotechnologies around the globe.

In short, both the Wilson Center and The Pew Charitable Trusts believe there is a tremendous opportunity with nanotechnology to "get it right." Societies have missed this chance with other new technologies and, by doing so, have made costly mistakes. Because of the rapid commercialization and enormous potential impact of nanotechnologies, we must move forward quickly with a strategic, prioritized risk research framework for nanotechnology if we want the technology to succeed.

Researchers have been studying the potential risks of nanometer-scale particles and materials for many years. Seventeen years ago, scientists published some of the first nanotechnology risk research findings suggesting that nanometer-scale particles behave differently compared with larger particles in the lungs.[1] Fifteen years ago, the first concerns were raised about the potential health impacts of using carbon nanotubes in commercial products.[2] Over the last decade it has become increasingly clear that the impact of some nanoparticles is dependent on, not the usually measured mass concentration of material inhaled, but other properties such as the size and the surface of the particles.[3] Three years ago, the UK Royal Society and Royal Academy of Engineering set out a series of recommendations addressing uncertainty over the potentially unique risks associated with engineered nanomaterials.[4] And here we are at the beginning of 2007, at what I believe is the first public meeting held by the U.S. government to discuss how nanotechnology risk research might be prioritized. Some would say this is a meeting that is long overdue.

The U.S. government must move urgently to develop and implement a coordinated and systematic risk research effort addressing the potential risks posed by engineered nanomaterials if we are to see the long-term benefits of this technology. Many studies already have been published on what we do and do not know about the potential risks of nanotechnology—and engineered nanomaterials in particular—and how the many existing research gaps might be filled. I would therefore like to use my limited time here to make three specific points that will support NSET (and the broader National Nanotechnology Initiative, NNI) in developing effective research strategies:

1. Risk research has a purpose
2. Prioritizing risk research is not rocket science, and
3. Risk research needs a plan.

1. Risk research has a purpose.

The first point I would like to emphasize is that risk research has a purpose. That purpose is *to protect the health and the safety of people and the environment*. This may seem an obvious point, but it is often missed. The danger in missing it is that we end up investing millions of dollars in research, and only ask how that research might be useful after it has been completed. This model for exploratory research works well for developing new knowledge, but does not work so well for addressing specific questions related to safety and risk.

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[1] Ferin, J., G. Oberdörster, D. P. Penney, S. C. Soderholm, R. Gelein and H. C. Piper (1990). Increased Pulmonary Toxicity of Ultrafine Particles.1. Particle Clearance, Translocation, Morphology. *Journal of Aerosol Science* 21(3): 381-384.

[2] Coles, G. V. (1992). Occupational risks. *Nature* 359: 99.

[3] Oberdörster, G., J. Ferin, S. Soderholm, R. Gelein, C. Cox, R. Baggs and P. E. Morrow (1994). Increased pulmonary toxicity of inhaled ultrafine particles: due to lung overload alone? *Ann. Occup. Hyg.* 38(Suppl. 1): 295-302.

[4] RS/RAE (2004). Nanoscience and nanotechnologies: Opportunities and uncertainties. London, UK: The Royal Society and The Royal Academy of Engineering.

For instance, if we wanted to know how effective a specific disposable respirator is for preventing exposure to airborne nano-sized particles, we could scatter $40 million among the research community and hope that someone came up with an answer. Or we could frame our research efforts to answer that specific question, which is aimed at protecting the health and the safety of people working with nanomaterials. The point is that, while exploratory research has its place, it is not always the best model for providing workable answers to definite questions.

2. Prioritizing risk research is *not* rocket science.

The second point I would like to emphasize is that prioritizing risk research is not as complex or difficult as some might think. In a recent House Science Committee hearing, the Director of the National Science Foundation said:

> "I have to tell you that this area [of research] is so complex that I don't know of any person or a small group of people who would be smart enough to be able to identify all the risks, set priorities and lay out a so-called game-plan."[5]

Obviously, there are questions we need to ask that are difficult to answer, and questions we do not even know we should be asking yet. However, it is sometimes easy to get caught up in the complexity of a situation and miss the obvious answers—to use a well-worn cliché: *to miss the forest for the trees*.

I will illustrate this point with an example. Imagine I have a bottle of Dr. Gunderson's powdered nano calcium and magnesium dietary supplement—allegedly containing nano-sized particles that give superior absorption.[6] As I open the bottle, I can see—and smell—a fine plume of powder in the air. According to the directions, I should add one teaspoon of the powder to hot water or tea, and drink. These simple actions raise key questions:

- I have released nanoscale particles into the air: How many have I breathed in, how will the particles affect my lungs, and how could I measure the exposure?
- I have some of the powder on my hands—is that important, do nanoparticles penetrate the skin?
- How many particles are there in the glass of water—can we measure them?
- If I drink the liquid, how would those particles behave in my gastrointestinal tract?
- And when I pour the rest of the mixture down the drain, where will those particles enter the environment, and what will they do?

It does not take a degree in rocket science to see that these are obvious questions, and ones that the federal government must tackle when prioritizing and undertaking nanotechnology risk research.

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[5] Bement, Arden. Testimony to the U.S. House Committee on Science hearing "Research on environmental and safety impacts of nanotechnology: What are the federal agencies doing?" September 21, 2006.

[6] This is a commercially available product. For more information, see http://www.nanotechproject.org/index.php?id=44&action=view&product_id=1015, accessed December 29, 2006.

3. Risk research needs a plan.

My third and final point is that nanotechnology risk research needs a plan. We are here to talk about prioritization, but prioritization without the context of a strategic research framework will not get us anywhere. If risk research is to serve its purpose and support the development of safe nanotechnologies, we need to know:

a) Where we are now,
b) Where we want to be, and
c) How we are going to get there

Prioritization is a necessary part of this process, but it must be carried out in the light of current knowledge, existing research, and information about the introduction of specific nanotechnologies into commerce. To help with this process, I would like to close by briefly highlighting four resources.

Where we are now

First, consider *where we are now*—how nanotechnology is being used in the products we buy and use, and what research is being carried out to understand and address possible risks. The Project on Emerging Nanotechnologies has compiled two publicly accessible inventories to help with this baseline understanding.

Consumer Products Inventory

The first resource is an inventory of consumer products allegedly based on nanotechnology.[7] This inventory—which relies on manufacturer claims—does not capture *every* product on the market that uses nanotechnology, and undoubtedly contains some products that many people may not consider to be nanotechnology. Yet, with nearly four hundred entries which are fully classified and searchable, it is the perhaps the most comprehensive source of information available on where many people are first coming into contact with engineered nanomaterials.

Environmental, Health and Safety Research Inventory

The second inventory I would like to draw to your attention addresses what research is currently being done to address potential risks.[8] I think that most reasonable people would agree that knowing what research is being carried out is a good thing when developing a strategic research plan. Indeed, in recent comments submitted to the U.S. House Science Committee, the chair of the NEHI working group stated that "An important next step is development of a more detailed inventory of the research currently

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[7] *The Nanotechnology Consumer Products Inventory*. Washington, DC: Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars. Available at www.nanotechproject.org/consumerproducts, accessed December 27, 2006.

[8] *Nanotechnology Health and Environmental Implications. An Inventory of Current Research*. Washington, DC: Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars. Available at www.nanotechproject.org/18/esh-inventory, accessed December 27, 2006.

being conducted by the National Nanotechnology Initiative."[9] The good news is that this inventory already exists—and has done so for over a year now.

There has been some confusion over the scope and nature of the Project on Emerging Nanotechnologies risk research inventory, and so it is worth highlighting its key points:

- The inventory lists all research we are aware of that has some degree of relevance to understanding the potential risks of nanotechnology. This includes research on nanotechnology applications that might conceivably lead to a greater understanding of possible implications. The inventory draws predominantly on the U.S. research portfolio, but also includes research from other countries. Most importantly, the information in the inventory is freely available for anyone to access, analyze, and, if they so desire, contest.
- In compiling the inventory, we used records published by federal agencies, together with information provided directly by researchers and funding agencies.
- The listed research is classified by various categories including: country, funding sector (e.g., government, industry), study relevance to understanding risk (on a scale of high to none), sources of nanomaterials addressed (e.g., engineered versus incidental nanomaterials), impact sectors (human health, environment, safety, and cross-cutting), and broad research categories (e.g., exposure, hazard, risk management, etc.). In this way, we were able to include research on ambient nanoparticles, and nanotechnology applications, and leave it to users of the inventory to extract the information that was relevant to them. This is key to the functionality of the inventory—rather than us deciding exclusively what is important and what is not. We provide the tools for others to make that decision.

There are many ways of analyzing and using the information in this inventory. For instance, it is relatively easy to estimate how much government agencies are investing in extramural research that is highly relevant to understanding the potential risks associated with engineered nanomaterials—an estimated $6 million in 2005. When estimates of intramural spending are included, this rises to $11 million,[10] compared to the unsubstantiated estimate from the NNI of approximately $40 million.[11] However, the important point is that, by developing and using a resource like this EH&S research inventory, it is possible to get a clear idea of where we are now in conducting research that will inform our future understanding of nano-risks and areas where further research efforts are needed. The U.S. government and the international community need such a tool—especially if government intends to build risk research collaborations with industry and with other countries.

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[9] Alderson, Norris. Testimony to the U.S. House Committee on Science hearing "Research on environmental and safety impacts of nanotechnology: What are the federal agencies doing?" September 21, 2006, Questions for the Record.

[10] Maynard, A. D. (2006). Nanotechnology: A Research Strategy for Addressing Risk. PEN 03. Washington, DC: Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars, July. Available at: http://www.nanotechproject.org/reports, accessed December 27, 2006.

[11] NSET (2005). The National Nanotechnology Initiative. Research and development leading to a revolution in technology and industry. Supplement to the President's FY2006 budget, Washington DC, Nanoscale Science Engineering and Technology subcommittee of the NSTC.

Where we want to be

Next, consider *where we want to be* in understanding and managing risks from nanomaterials.

Taking a long-term view of where we would like to be in this arena going forward, I would like to draw your attention to the recent paper published in the journal *Nature* entitled "Safe handling of nanotechnology."[12] This paper presents the perspective of fourteen international scientists on five of the major challenges facing the global research community as we look to develop safe nanotechnologies. These challenges are aimed at focusing attention on key components of a strategic research agenda that must be met if the technology is to reach its full potential. The Five Grand Challenges include:

1. Developing instrumentation to measure nanoparticles in air and water,
2. Evaluating the hazard of new nanomaterials,
3. Predicting the toxicity of emerging nanomaterials with models,
4. Assessing the possible impact of nanotechnologies across their lifetime, and
5. Developing strategic programs to enable risk-focused research.

These five challenges do not in themselves constitute a robust strategic research plan. However, they do lay a foundation for developing such a plan, and are beginning to be reflected in emerging research agendas, such as the European Union Framework Seven research agenda, published at the end of 2006.[13] The fifth challenge of creating a strategic research framework is particularly pertinent to today's meeting addressing research priorities. As the federal government begins to consider research priorities, I would encourage the use of these challenges as a framework on which to build a strong and relevant strategic research program.

How we are going to get there

The final resource I would like to draw your attention to addresses *how we might get to where we want to be*.

In July 2006, the Project on Emerging Nanotechnologies published a report entitled "Nanotechnology: A research strategy for addressing risk," which is an analysis of short-term strategic risk-risk research needs.[14] It has already been alluded to that prioritization can sometimes be complex but is not unachievable. This report suggests an approach to prioritization that addresses complex issues of parallel research tracks, balancing targeted and exploratory research and using various research funding mechanisms to best achieve the goal of protecting human health and the environment from any adverse effects caused by nanotechnology. The report also suggests research priorities for the next two years, including measuring nanomaterials exposure, evaluating

[12] Maynard, A. D., R. J. Aitken, T. Butz, V. Colvin, K. Donaldson, G. Oberdörster, M. A. Philbert, J. Ryan, A. Seaton, V. Stone, S. S. Tinkle, L. Tran, N. J. Walker and D. B. Warheit (2006). Safe handling of nanotechnology. *Nature* 444(16): 267-269.

[13] European Commission (2006). Framework Program 7: Cooperation: Theme 4: Nanosciences, Nanotechnologies, Materials and New Production Technologies – NMP. Brussels, Belgium: European Commission C(2006) 6839.

[14] Maynard, A. D. (2006). Nanotechnology: A Research Strategy for Addressing Risk. PEN 03. Washington, DC: Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars, July. Available at: http://www.nanotechproject.org/reports, accessed December 27, 2006.

toxicity, controlling releases of nanomaterials, and developing ways of working with and handling these materials safely.

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Nanotechnology is no longer a scientific curiosity. It is in the workplace, the environment and the home. But if people are to realize nanotechnology's benefits—in medicine, communications, and energy production—the federal government needs a master plan for identifying and reducing potential risks. This plan should include a top-down risk research strategy, dedicated and sufficient funding to do the job, and the mechanisms to ensure that resources are used effectively.

In closing, let me re-emphasize my first point: *Risk research has a purpose, and that purpose is to protect people and the environment from harm*. In the absence of anything else, this is a good test to apply when prioritizing research. Seventeen years ago, we were just beginning to realize how nanometer-scale materials might present new challenges to protecting our health and that of the environment. As we enter 2007, we have a pretty good idea of what the important questions are that we should be addressing. We now need to move forward and start providing answers to these questions as quickly and systematically as possible.

Biography of Andrew Maynard

Dr. Andrew Maynard serves as the Science Advisor to the Woodrow Wilson Center's Project on Emerging Nanotechnologies. He is internationally recognized as a research leader and lecturer in the fields of aerosol characterization and the implications of nanotechnology to occupational health. He trained as a physicist at Birmingham University (UK), and after completing a Ph.D. in ultrafine aerosol analysis at the Cavendish Laboratory, Cambridge University (UK) joined the Aerosols Research Group of the UK Health and Safety Executive.

In 2000, Dr. Maynard joined the National Institute for Occupational Safety and Health (NIOSH), part of the U.S. Centers for Disease Control and Prevention (CDC). At NIOSH, he established a groundbreaking research program in ultrafine aerosol analysis, and was instrumental in developing NIOSH's nanotechnology research program. This research was at the forefront of international scientific efforts to better understand the occupational health implications of nanomaterials, and to develop guidance on workplace exposures in this burgeoning industry. While at NIOSH, Dr. Maynard was a member of the Nanomaterial Science, Engineering and Technology subcommittee of the National Science and Technology Council (NSET). He also co-chaired the Nanotechnology Health and Environment Implications (NEHI) working group of NSET. Both are a part of the National Nanotechnology Initiative (NNI), the federal research and development program established to coordinate the U.S. government's annual $1 billion investment in nanoscale science, engineering, and technology.

Dr. Maynard was co-chair of the first two international conferences on nanotechnology and occupational health, and is affiliated with many organizations and initiatives exploring the responsible and sustainable development of nanotechnology. He is a member of the Executive Committee of the International Council On Nanotechnology (ICON), and until recently, chaired the International Standards Organization Working Group on size selective sampling in the workplace. He holds an Associate Professorship at the University of Cincinnati (OH), and is an Honorary Senior Lecturer at the University of Aberdeen (UK). His expertise covers many facets of scientific research and policy, from occupational aerosol sampler design to recommendations on strategic nanotechnology research, as reflected in over 70 professional publications. Dr. Maynard is a regular international speaker on nanotechnology, and frequently appears in print and on radio and television.