Woodrow Wilson International Center for Scholars

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SUBJECT: *Prioritization of Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials: An Interim Document for Public Comment*: Comments on Process

The Project on Emerging Nanotechnologies, an initiative launched by the Woodrow Wilson International Center for Scholars and The Pew Charitable Trusts in 2005, 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 (NGOs), and others working towards 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 help develop practical strategies and approaches for closing those gaps and ensuring that the benefits of nanotechnologies will be realized while minimizing potential risks. 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.

We appreciate this opportunity to comment on *Prioritization of Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials: An Interim Document for Public Comment*, the latest document from the Nanotechnology Environmental and Health Implications (NEHI) Working Group of the Nanoscale Science, Engineering and Technology (NSET) of the National Science and Technology Council, Committee on Technology. Our comments are divided into two parts: the first section addresses the broader *process* issues that have emerged in the development of this research priorities list and the second section, written by Dr. Andrew. D. Maynard, Chief Science Advisor at the Project on Emerging Nanotechnologies, addresses the specific *content* of the document.

The results of this report are disappointing. Presumably the NEHI Working Group has been diligently working to improve on its initial *EHS Research Needs for Engineered Nanoscale Materials* report that it released on September 21, 2006 in light of the written and oral comments it received in conjunction with its public meeting held on January 4, 2007. That initial report was deemed "a very juvenile piece of work" by Congressman Bart Gordon (D-TN)[1], currently Chairman of the House Committee on Science and Technology, and there was hope that in the year following its release, improvements would be made to ensure that a real, targeted, and operational environmental, health and safety (EH&S) risk research strategy would be developed and implemented.

That sorely needed research strategy has yet to be presented and, so far, we are left with a simple—and even simplistic—list of priorities. In the intervening seven months since the January 2007 public meeting, NEHI seems to have taken what was a long laundry list of nearly seventy research activities and shortened it to a numbered laundry list of twenty-five research activities. In reference to this lack of substance, science journalist Barnaby J. Feder of *The New York Times* commented that "the title of the latest report from the Federal government's nanotechnology policy coordinators on safety concerns borders on self-parody," noting that "all it took to hatch this 12-page masterpiece of bureaucracy in action was 11 months of work following up the group's previous 80-page document."[2] Clearly, the nanotechnology community had higher expectations for NEHI's follow-on document, hoping that it would come closer to a real risk research strategy.

While page length rarely indicates the quality of the contents of a document, it is hard to consider how this prioritization list begins to offer any sense of vision, direction and coherence that are the hallmarks of a research strategy that delivers. The failings of this report raise an important question: Is NEHI—or more broadly, the National Nanotechnology Initiative (NNI)—capable of creating a strategy for addressing the environmental, health, and safety risks of nanotechnologies? The central components that would begin to constitute a strategy—defined by one web source as "an elaborate and systematic plan of action"—are certainly not present, and it is difficult to see how the current document could lead to the development of such components.[3] Important details like budgetary allocations, implementation timeframes, and assigned responsibilities are not even addressed here.

If we apply the government's own criteria under the Program Assessment Rating Tool (PART) to NEHI's effort, it would likely be rated "inadequate" because the program's purpose is not clear, is not designed to achieve objectives, is not supported by

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[1] Rick Weiss. "Nanotechnology Risks Unknown: Insufficient Attention Paid to Potential Dangers, Report Says," *The Washington Post*, September 26, 2006, p. A12. Available from http://www.washingtonpost.com/wp-dyn/content/article/2006/09/25/AR2006092501138.html, accessed September 4, 2007.

[2] Barnaby J. Feder. "No One Can Accuse Them of Acting Rashly," *The New York Times Bits Blog*, August 17, 2007. Available from http://bits.blogs.nytimes.com/2007/08/17/no-one-can-accuse-them-of-acting-rashly/, accessed September 4, 2007.

[3] Definition available from http://wordnet.princeton.edu/perl/webwn?s=strategy, accessed September 4, 2007.

a robust strategic plan with valid annual and long-term goals, and has no visible management component with financial oversight mechanisms. Finally, it does not focus on clear results that the NNI could report with accuracy and consistency. In short, NEHI has turned what should be a strategic activity, like a game of chess, into an elimination activity, like a game of checkers.

While this may be a "nano" step forward, it is one that was too long in the making in what is becoming a tediously long process. For instance, simply consider what significant events have happened in the nanotechnology policy and risk research landscape in the nearly year-long timeframe since the first EH&S needs document was released and, in comparison, how paltry the response indicated by the latest prioritization document appears.

- Federal agencies, such as the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA), have held public meetings and released reports on potential management strategies for nanotechnology. The EPA has continued discussion over the eventual implementation of its Nanoscale Materials Stewardship Program (NMSP)[4] and has released its analysis of how nanomaterials might be considered new chemical substances under its Toxic Substance Control Act (TSCA) Inventory.[5] The FDA has released the report of its Nanotechnology Task Force, which concluded that "nanoscale materials present regulatory challenges similar to those posed by products using other emerging technologies. However, these challenges may be magnified both because nanotechnology can be used in, or to make, any FDA-regulated product, and because, at this scale, properties of a material relevant to the safety and (as applicable) effectiveness of FDA-regulated products might change repeatedly as size enters into or varies within the nanoscale range."[6]

- Scientific and policy consensus from the academic, civil society and business communities is emerging around key risk research priorities and risk management strategies. Many of these efforts make an explicit point to tie together proposals for addressing scientific unknowns with concrete budgetary allocations and timelines for addressing such issues. For example:
    - In November 2006, the leading journal *Nature* published "Safe Handling of Nanotechnology," authored by 14 internationally renowned scientists

[4] *Concept Paper for the Nanoscale Materials Stewardship Program under TSCA*. Washington, DC: Environmental Protection Agency, July 12, 2007. Available from http://www.epa.gov/opptintr/nano/nmspfr.htm, accessed September 4, 2007.
[5] *TSCA Inventory Stats of Nanoscale Substance—General Approach*. Washington, DC: Environmental Protection Agency, July 12, 2007. Available from http://www.epa.gov/opptintr/nano/nmspfr.htm, accessed September 4, 2007.
[6] *Nanotechnology: A Report of the U.S. Food and Drug Administration Nanotechnology Task Force.* Rockville, MD: Food and Drug Administration, July 23, 2007. Available from http://www.fda.gov/nanotechnology/taskforce/report2007.html, accessed September 4, 2007.

who have identified, prioritized and mapped Five Grand Challenges for targeted research on nanotechnology's potential EH&S risks.[7]

- In December 2006, the consulting firm ICF International released its report, *Characterizing the Environmental, Health, and Safety Implications of Nanotechnology: Where Should the Federal Government Go From Here?*, analyzing the government's EH&S risk research portfolio and strategy and concluding that there is "an urgent need to chart a more aggressive course when it comes to answering such questions."[8]
- In June 2007, Environmental Defense and Dupont Corporation jointly released their *Nano Risk Framework* that outlines how researchers in laboratories and companies can organize and evaluate current information; assess, prioritize, and address data needs; and communicate clearly about mitigating risks.[9]
- In July 2007, a coalition of NGOs, including public interest, consumer, public health, labor, and environmental groups, released their recommendations for the oversight and risk management of nanotechnology. This document, "Principles for the Oversight of Nanotechnologies and Nanomaterials," illustrates the complexity of issues involved in managing potential risks as well as the range of organizations that are beginning to focus on the public implications of the lack of information regarding EH&S risks.[10]

- Local municipalities, such as the City of Berkeley, California, and the City of Cambridge, Massachusetts, have implemented or have begun to consider implementing oversight measures to regulate nanotechnology. In many respects, such local oversight activities have become necessary to ensure public confidence in nanotechnology primarily because of the slow response at the federal level to developing and implementing viable risk research and management strategies.[11]

- Consumer products are continuing to enter the market rapidly. As of June 2007, the Nanotechnology Consumer Products Inventory maintained by the Project on

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[7] Andrew D. Mayard, et al. "Safe Handling of Nanotechnology," *Nature* 444: 267-269, November 16, 2006. Available from http://www.nature.com/nature/journal/v444/n7117/full/444267a.html, accessed September 4, 2007.

[8] *Characterizing the Environmental, Health, and Safety Implications of Nanotechnology: Where Should the Federal Government Go From Here?* Fairfax, VA: ICF International, December 4, 2006. Available from Report; http://www.icfi.com/markets/environment/doc_files/nanotechnology.pdf, accessed September 4, 2007.

[9] *Nano Risk Framework*. Washington, DC: Environmental Defense and Dupont Corporation, June 21, 2007. Available from http://nanoriskframework.org/page.cfm?tagID=1095, accessed September 4, 2007.

[10] *Principles for the Oversight of Nanotechnologies and Nanomaterials*. Washington, DC: Friends of the Earth et al., July 31, 2007. Available from http://www.icta.org/doc/Principles%20for%20the%20Oversight%20of%20Nanotechnologies%20and%20Nanomaterials_final.pdf, accessed September 4, 2007.

[11] Hiawatha Bray. "Cambridge Considers Nanotech Curbs: City May Mimic Berkeley Bylaws," *The Boston Globe*, January 26, 2007. Available from http://boston.com/business/technology/articles/2007/01/26/cambridge_considers_nanotech_curbs/, accessed September 4, 2007.

Emerging Nanotechnologies contained over 500 manufacturer self-identified products.[12] These figures only include products that are self-identified by manufacturers as using nanotechnology and do not include the numerous industrial or intermediate product applications that use nanotechnology. This first generation of commercialization remains just the tip of the iceberg, as it is anticipated that products will continue to enter the market rapidly in the future. Similarly, issues associated with potential risks of using nano-engineered products, such as sunscreens and cosmetics, are being addressed more widely in publications like *Consumer Reports* magazine, which published a feature article on the subject in its July 2007 edition.[13]

- The lack of a substantial body of risk research remains, though there are a few published results that raise further concerns over the possible unconventional and scale-specific risks associated with engineered nanomaterials. For example:
    - A paper in the May 2007 edition of the Proceedings of the National Academy of Sciences concludes that certain nanomaterials may enhance the rate of amyloid protein fibrillation, which is associated with many human diseases, including Alzheimer's, Creutzfeld-Jacob disease, and dialysis-related amyloidosis.[14]
    - A November 2006 study sponsored by the International Council on Nanotechnology that focused on nanotechnology workplace safety practices concluded that "due in part to a lack of general information regarding nanomaterials risks, companies and labs have workers using conventional environmental, health and safety (EHS) practices while handling nanomaterials, even though the practices were developed to deal with bulk materials that can have markedly different chemical properties than their nano-sized counterparts."[15]

In short, the prioritization document lacks the coherence and big-picture view needed to allow the government to strategically address the challenges being faced—where stakes are high, clarity is needed, and decisiveness and speed are at a premium. These shortfalls include:

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[12] *A Nanotechnology Consumer Product Inventory*. Washington, DC: Project on Emerging Nanotechnologies, March 2006. Available from http://www.nanotechproject.org/consumerproducts, accessed September 4, 2007. Information available on the National Nanotechnology Initiative website—http://www.nano.gov/html/society/EHS.html, as of September 4, 2007—regarding the number of consumer products on the market remains considerably out of date, with reference to only 80 nanotechnology consumer products.

[13] "Nanotechnology: Untold Promise, Unknown Risk," *Consumer Reports*, July 2007. Available from http://www.consumerreports.org/cro/health-fitness/nanotechnology-7-07/overview/0707_nano_ov_1.htm, accessed September 4, 2007.

[14] Sara Linse, et al. "Nucleation of Protein Fibrillation by Nanoparticles," *PNAS*, May 7, 2007. Available from http://www.pnas.org/cgi/content/abstract/0701250104v1, accessed September 4, 2007.

[15] *A Survey of Current Practices in the Nanotechnology Workplace*. Houston, TX: International Council on Nanotechnology, November 13, 2005. Available from http://icon.rice.edu/projects.cfm?doc_id=4388, accessed September 4, 2007.

- ***Lack of integration within the risk research categories.*** For example, within four of the five research categories, the need for improved material characterization information is noted as a priority. The need for exposure research and transport research is also noted throughout many of the categories. How are these characterization, exposure, and transport research needs to be connected and integrated across multiple categories? How can research overlapping the environmental, the human health, and the worker safety categories be coordinated so that resources are not wasted or duplicated? The lack of such assessments makes the whole less than the sum of its parts.

- ***Lack of funding needs prioritization.*** If risk research budgets are only to increase incrementally over the coming years, where are these "dollars at the margins" most needed? It remains unclear where such additional money should be applied and how current disbursements can be reallocated to better address unanswered questions. The Project on Emerging Nanotechnologies maintains an inventory of ongoing risk research activities, and a search of that inventory illustrates that there is considerable need for a strategic assessment of research requirements to determine where the funding gaps may lie and whether important, yet easily overlooked topics, such as life-cycle assessment studies and risk management research, are adequately supported.[16] Presumably the findings of the upcoming analysis by the Government Accountability Office (GAO) will offer needed insight as to where such funds should be targeted.

- ***Lack of deadlines and timeframes.*** The prioritization document does not address when such research needs to be accomplished, let alone when a full EH&S strategy will be released. Setting such deadlines may be difficult, but it is not impossible: the authors of the *Nature* article "Safe handling of nanotechnology" outlined distinct timeframes within which certain questions need to be addressed. The lack of such deadlines also indicates a lack of appreciation that current and rapid commercialization of nanotechnologies requires urgent action to understand and manage potential risks. The public needs to be assured that risk research results will be made available in a timely manner so that they can be confident in the nanotech products that they buy.

- ***Lack of lead agency designation and responsibility.*** The prioritization list fails to identify which of the federal agencies will be responsible for addressing particular risk research needs. The public will increasingly ask "who is responsible?" and an answer to that question is not yet clear. Similarly, the prioritization list discounts the need that urgent and short-term questions be given special consideration. While such a decision might be appropriate if nanotechnology was a wholly futuristic technology, its impact on laboratories, companies, and consumers is already being felt. For that reason, there is a great need to shift resources and emphasis from basic science agencies, like the National Science Foundation, to

[16] *Nanotechnology Health and Environmental Implications: An Inventory of Current Research*. Washington, DC: Project on Emerging Nanotechnologies, November 2005. Available from http://www.nanotechproject.org/index.php?id=18, accessed September 4, 2007.

agencies with regulatory missions (or those that support such agencies), such as EPA, FDA, USDA, the National Institute for Occupational Safety and Health.

In the end, it is important to remember that time is not just running out, but that we are losing ground, as nanotechnology is commercialized without a robust and actionable risk research strategy. Hopefully, this interim prioritization report is merely a place-holder for what will be a more extensive risk research strategy output in the near future. While it is encouraging that more detailed, in-depth strategy development efforts are planned at individual agencies, as indicated by recent announcements at EPA, it is important to remember that an integrated, government-wide strategy for addressing risks is *not* simply the sum of individual agency strategies.[17] What these competing efforts indicate is that the federal nanotechnology risk research agenda is a bit like a ship without a captain, and it is unclear who has the responsibility to steer this ship in the right direction and make sure that it reaches its destination.

Unfortunately, if the suggested "next steps" are any true indication of future plans—from undertaking a gap analysis of ongoing activities and to formulating a strategy, all of which is work that has already been considered and developed by other organizations—the public and interested stakeholders may have to wait a long time before their concerns are addressed. If this document is truly meant to serve as a basis for a risk research strategy, there is a long way to go.

[17] Colin Finan. "Agency Research Chief Will Release Detailed Nanotech Study Plan This Fall," *Inside EPA*, September 5, 2007.

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SUBJECT:	*Prioritization of Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials: An Interim Document for Public Comment*: Comments on Content

Since publication of the document *EHS Research Needs for Engineered Nanoscale Materials* in September 2006, the Nanotechnology Environment and Heath Implications (NEHI) Working Group has faced the task of countering criticisms aimed at that report and of responding to invited comments. The current document, *Prioritization of Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials: An Interim Document for Public Comment*, further refines the prioritization principles established in the 2006 report and uses them to identify five research priority areas in each of the five categories listed in the initial report, giving twenty five research priority areas overall. Yet it remains hard to see how this report or subsequent planned activities will help to provide the information that industry, regulators, and the public need to ensure the safe development and use of nanotechnology.

With this report, NEHI has begun to set out a systematic process for guiding agency research efforts. But it seems the Working Group is in danger of mistaking methodology for strategy. While the current document focuses on prioritization, it appears to do so without a clear understanding of context: what the overarching issues are, what is needed to address them, when results are needed, and how the work will get done. Without this degree of vision, the resulting document is a *bureaucratic reaction to criticism*, rather than a *proactive statement of purpose*.

The stated principles for prioritizing environment, health and safety (EH&S) research do provide a means for sifting the many research "wants" into research "needs". But in the absence of a strategic overview, it is unclear how application of these principles will result in an effective research plan. And while the principles appear sound individually, it is difficult to understand how they can be applied together to identify a set of coherent research priorities.

The first principle—*prioritize research based on the value of information*—is a good first step towards developing a research strategy. Yet the document is curiously taciturn about what determines the value of information, beyond the rather vague criteria of reducing uncertainty, increasing knowledge, ascertaining degree of use, and ascertaining degree of exposure. It is unclear how these criteria have been interpreted in the prioritization process and whether the resulting research priorities respond to the needs of decision-makers. On a practical point, it is unclear whether there is any value (in the context of this document) given to information that *reduces the adverse impact* of nanotechnology, rather than simply *reducing uncertainty* over potential impact.

The second principle—*seek to leverage research funded by other governments and the private sector*—is an admirable principle for developing a research strategy. But it only applies to prioritizing research within the federal government *if research being conducted elsewhere is given low priority*. If the principle has been applied in this way, one must assume that research priorities being addressed in industry or other countries have been omitted from the document. If this is the case, how will this unlisted research be identified and integrated into future research strategies?

The final principle—*use adaptive management for nanomaterials EH&S risk research*—should be fundamental to any research strategy. Yet once again, it is difficult to conceive how this principle could be used to prioritize research now, rather simply just to keep the door open for future re-prioritization.

Out of these three principles for prioritizing EH&S research, only the first seems to be of practical use, and even this appears to lack the specificity to enable a coherent and integrated set of research priorities to be developed.

Moving on to the twenty-five research priorities themselves, these appear to reflect many of the recommendations that have been made by other groups and organizations over the past few years. Comparing them with the strategic research priorities published by the Project on Emerging Nanotechnologies in July 2006,[18] there appears to be substantial overlap. But this is in part because the NEHI priorities are open to broad interpretation in many cases. In contrast, the Project on Emerging Nanotechnologies' research priorities are more specific and reflect an underlying strategic perspective. Such a perspective is hard to identify in the NEHI priorities. In short, it is hard to see how following the NEHI priorities will provide the information decision-makers need to ensure the safety and sustainability of emerging nanotechnologies. Indeed, many of the priorities are sufficiently broad that they could be adequately addressed *without any progress being made towards ensuring the safety of nanotechnologies!*

- **Research Category: Instrumentation, Metrology, and Analytical Methods.** The research priorities identified in this area will ensure progress in identifying, assessing and managing the potential impacts of nanomaterials. However, further specificity would greatly help in ensuring the relevance of future research. For example, what are the specific challenges that need to be addressed for detecting nanomaterials in biological matrices, and what are the specific requirements for methods to monitor exposure in the workplace? Without this level of detail, it will be easy to justify research that, while of academic interest, is irrelevant to understanding and managing impact. As David Rejeski notes above, it also is not clear from the report how the research in this category—which is acknowledged

[18] Andrew D. Maynard. *Nanotechnology: A Research Strategy for Addressing Risk*. Washington, DC: Project on Emerging Nanotechnologies, July 2006. Available from http://www.nanotechproject.org/reports, accessed September 4, 2007.

as being relevant to the following four categories—is to be integrated across a coherent research strategy.

- **Research Category: Nanomaterials and Human Health.** Research priorities in this category show a sound appreciation of what is needed to develop a mechanistic understanding of nanomaterial-biological interactions and to lay a foundation for predicting nanomaterial health impact. The report's authors clearly understand the need for parallel and complementary research tracks, which are an essential part of a coherent research strategy. Yet these research priorities do not reflect more pragmatic and applied issues, such as how to screen for nanomaterials that are potentially toxic and how to relate nanomaterial properties to potential health effects.

- **Research Category: Nanomaterials and the Environment.** In contrast to the previous research category, research priorities for nanomaterials and the environment address practical issues, but do not lay a coherent foundation for developing a mechanistic understanding of nanomaterial behavior. Both are needed if immediate and longer-term challenges are to be addressed.

- **Research Category: Health and Environmental Exposure Assessment.** This is something of a schizophrenic category, lumping together exposure assessment and health impact evaluation/surveillance; separation of the two would make for a clearer assessment of priorities. The identified priorities are hard to fault, but the report gives little in the way of providing strategic direction for research in this area, or how these priorities integrate within other research categories. While the priorities of characterizing exposure among workers and characterizing health amongst exposed populations are laudable, no information is given to help researchers working in this area figure out what characterization research should be undertaken or what specific negative indications they should be looking for.

- **Research Category: Risk Management Methods.** In many ways this is a catch-all research category. The identified research priorities are sufficiently broad that they can accommodate research needs that are not covered elsewhere. Despite their breadth, the research priorities provide a useful framework for developing effective approaches to managing the potential risks of emerging nanotechnologies. Yet in the context of developing a strategic research program, more detail would be helpful. In particular, the first research priority covers a broad range of research needed to understand how to produce and handle nanomaterials safely. Given the importance of this kind of research in the short term, there is a danger that placing it all under one research priority out of twenty-five will obscure its place within a coherent research strategy.

As the commercialization of increasingly sophisticated nanotechnologies gathers pace, industry, regulators and the public need sound information, now more than ever, on which to base their decisions. They also need the assurance that there is a strategy in place to fill knowledge gaps as fast and efficiently as possible. This report suggests that

the federal government is out of touch with reality and that it is caught in a bureaucratic process that lacks the responsiveness and vision to address the questions that nanotechnology stakeholders need and want answered. It does not reflect the urgency with which new research is needed, nor the extent to which the economic success of emerging nanotechnologies will depend on this research. As it is an interim document, the hope is that the next installment will reflect a shift toward developing a coherent, well-funded, and top-down research strategy that addresses the questions nanotechnology stakeholders are asking—and soon.