United States House of Representatives
Committee on Science

Hearing on:

"Research on Environmental and Safety Impacts of Nanotechnology: Current Status of Planning and Implementation under the National Nanotechnology Initiative"

Testimony of:

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Summary

I am executive director of the multi-stakeholder International Council on Nanotechnology (ICON), and director of a federal research center in nanotechnology, and these roles have informed my opinions of the federal government's approach to nanotechnology risk research. I commend the Nanotechnology Environmental and Health Implications (NEHI) working group for its effort to identify and prioritize the research needs in this area. The urgency to nano-EHS research affects the entire NNI investment. This group should provide a full strategic plan within a year, and engage a broader community in authoring this document. The apparent agency boundaries that are currently used to classify the research needs should be removed, and instead these needs should be grouped and linked to larger unifying objectives – such as the development of predictive models for nanomaterial's impacts on the environment. These organizing goals should be described so that it is clear how they help transition us from a climate of uncertainty with regards to nanotechnology's risks to one of confidence. Finally, the NEHI prioritization misses the critical needs related to uniform methods, data structures and languages for nanotechnology risk researchers. There should be a clear plan to support the research harmonization activities so that the policymakers can extract – within a few years – consensus answers to key questions in this research area. These developments would create confidence that we're on a path towards understanding nanotechnology's risks, and keep the pipeline for nanotechnology wide open for innovations.

Thank you Mr. Chairman and members of the Committee for the opportunity to speak about the environmental, health and safety (EHS) research needs for nanotechnology. Today, I am providing my individual opinions, but they have been informed by my association with the International Council on Nanotechnology (ICON). ICON was established in 2004 by a coalition of academics, non-governmental organizations, industry and governments. This organization, based at Rice University, is a public-private partnership founded on the principle that multi-stakeholder, international collaboration is an essential ingredient for effective risk management of nanotechnology. As its executive director, it is my great honor to work with its director, Kristen Kulinowski, and our many volunteers from around the world on projects ranging from a free, searchable database of EHS research papers to a survey of current practices for nanoparticle handling in the workplace.

ICON's most recent effort is an international research needs assessment project – funded in part by the National Science Foundation (NSF). We have used the global reach of our volunteers to recruit diverse stakeholders to international workshops, where we asked them to assess the research needs for nanotechnology EHS. The first step in this process is to evaluate known information about these connections and identify where resources should be directed to address knowledge gaps. The ultimate goal envisioned by this project is the design of biocompatible and environmentally benign nanomaterials through the development of a framework that enables prediction of interactions based on physicochemical properties of engineered nanoparticles. The framework contains priorities to enable improved risk assessment over time as new nanomaterials or applications are developed. Armed with this knowledge, we can work together to develop safe applications of nanoscale materials or, in cases where the risks are too great, an alternative to their use.

Given this background, and my own experiences as a practicing nanotechnologist and director of the NSF Center for Biological and Environmental Nanotechnology, I will comment on the latest National Nanotechnology Initiative (NNI) document concerning nano-EHS research needs.

I commend the Nanotechnology Environmental and Health Implications (NEHI) working group for its effort to identify the research needs in this area; however, there is an urgency to nano-EHS research that affects the entire NNI investment. Innovation in nanotechnology is being threatened by the uncertainty about its risks and how government will manage them. We need this innovation more than ever right now. Nanotechnologies offer new approaches to treating cancer and cleaning water, and may enable energy independence for our country; but fewer of these transformative technologies will make it into commerce if the technology transfer pipeline becomes clogged by concerns about nanoproduct safety. This problem cannot be solved by increasing the inputs to the pipeline, nor should it be addressed by relaxing regulatory oversight. The only sure fix is high quality and intelligently packaged risk-related information.

A strategic plan needs several unifying objectives

The prioritization document provides 20,000 foot agency-specific views of this problem, but it never brings these together into a 50,000 foot view of exactly how each research need will transition us from a climate of uncertainty to one of confidence. I believe this disconnect may exist because of the silo approach to writing this report; this division is not a general feature of the NNI and risk research, and I note with great appreciation the productive coordination among EPA, NSF, NIOSH and NIH already with respect to current funding in the area. These agencies know how to work together, they just didn't convey that fact very effectively in this current report. As a result of this, the overall document left me without a sense of the shared objectives that will drive the program. The ultimate strategic plan must be structured by two, maybe three, overarching outcomes that stakeholders agree will give us more confidence in managing risks.

During our ICON workshops, we structured debate around the shared objective of predictive models for nanotechnology risk. There was great enthusiasm for framing the problem this way among scientists with research and regulatory missions alike. Nanotechnology throws a curve ball at conventional risk assessment, which is designed to evaluate the risk of a single substance like DDT. Its basic materials can be created with millions of possible variations of different sizes, shapes, surfaces and chemical type. Faced with such variety, we can't just apply a risk tool over and over again. Instead, we have to predict based on measurable properties how nanomaterials might move into organisms, and to then use informatics models to link their presence to an impact such as toxicity. Such a concrete outcome is the best starting point for the NNI's planning process.

Engage external stakeholders in developing Grand Challenges for Nano-EHS Research

The NEHI's work would benefit greatly from a more open process that engaged external advisors not only as commenters on the document, but also as authors. This report was made available for public comment for one month, and comments were restricted to the 'principles used for prioritization,' not the actual priorities. The NEHI would benefit greatly from convening external advisors for the next stage of the process; in the least, this engagement could accelerate the drafting of the full plan. I would point to the NNI grand challenge workshops (2000 – 2003) as a model for this activity. These events drew researchers from all sectors together to draft the language of 'grand challenges' in area of nanotechnology related to information sciences, biology, materials and manufacturing as well as environment. Reports from these meetings often included prioritization of issues and in some cases rather detailed plans about how best to proceed with research in the area. I think especially for this topic that engagement of multiple stakeholder groups is essential. The NNI should hold 'Grand Challenge for Nanotechnology Risk Research' workshops and structure them in such a way as to directly input into their planning – and convey that structure to the participants. Engaging external advisors as real partners in the planning process should accelerate the pace of this activity and ensure the planning document is well integrated with other global efforts.

the few academics actively involved in nanotechnology standardization and I cannot see that changing. Second, research harmonization could in principle happen over the span of nine months and several workshops; even a straightforward ASTM standard could take two years. Third, there are real issues with international participation in either ASTM or other standard developing organizations, including the International Organization for Standardization (ISO). US scientists can only write standards by being on ASTM (unless they are nominated to the US technical advisory group to ISO), and foreign scientists are usually expected to participate in their national standards activities – to which ASTM is a competitor. Fourth, international standardization is highly politicized and any document takes on legal and commercial scrutiny that is out of place when researchers are discussing the nitty gritty details of evaluating cell death, for example. Finally – and most problematic – standards documents from ASTM and ISO are copyrighted and expensive. The research harmonization documents need to be freely available to anyone with a computer – they have to be easy to use and access.

It may be that the research harmonization documents could serve as starting points for more formal standardization in ASTM, ISO or elsewhere. In this model, research harmonization activities would be a precursor not a competitor for formal standardization processes; in this way, they could better serve the immediate needs of the research community.

Conclusion

In conclusion, I hope that the NNI can quickly, with external input, develop a detailed strategic plan. Breaking down risk research into several concrete outcomes – such as predictive simulations – will help to rally the scientific community and create public confidence in existing and new nanoproducts. Perhaps the first step will be programs that catalyze the research community to develop and adopt common practices for nanotechnology risk research. These developments would create confidence that we're on a path towards understanding nanotechnology's risks, and keep the pipeline for nanotechnology innovation flowing.

International NanoEHS Research Needs Assessment:

A Preview of Reports from Two Workshops

ICON sponsored two workshops this year to discuss the research needed to enable prediction of nanomaterial impacts. The first workshop, held at the National Institutes of Health campus in Bethesda, MD in January, tested whether nanomaterial composition was a reasonable way to begin classifying nanomaterials for predictive purposes and where in the lifecycle of a given class of nanoparticle there might be high exposure potential. However, the dynamic nature of nanomaterials throughout their lifecycle presents challenges for using physicochemical properties as predictors of biological behavior. Workshop participants identified the need for a set of screening tools to correlate the functional properties of nanomaterials—i.e., how they behave rather than what they are made of—to determine potential for bio-interaction. These tools do not exist today.

The second workshop, held at the Centre for Global Dialogue in Rüschlikon, Switzerland in June, focused on the mechanisms by which engineered nanomaterials interact with biological organisms—including oxidative stress, inflammation and immune response, protein misfolding, apoptosis and necrosis, genotoxicity and mutagenicity, and developmental effects—and interactions between engineered nanomaterials and in vitro and in vivo systems at the level of biological molecules, target cells, tissues and whole animals. Workshop participants identified a need to understand what happens to a nanoparticle when it enters a biological organism and becomes coated with biomolecules in a complex and dynamic manner that is still poorly understood. Tools for characterizing these coatings, for tracking certain types of nanoparticles throughout the body, and for correlating cell-culture studies with impacts in whole organisms are all outstanding challenges.

Some themes that cut across both workshops were the need for standard terminology, a robust library of standard reference materials for use in nano-EHS research, a set of toxicology tools that have been validated for use with nanomaterials, and a better understanding of how dose and dose rate impact toxicity for nanomaterials. All these needs were seen as limiting the research community's ability to develop predictive models for the interactions of nanomaterials with humans and the environment.

The workshops were enabled by funding from the National Science Foundation (BES-0646107) with generous in-kind support from the National Institutes of Health and the Swiss Reinsurance Company. The final report is in preparation and will be made available at http://icon.rice.edu.

Vicki Colvin, Ph.D.

Dr. Vicki Colvin received her Bachelor's degree in chemistry and physics from Stanford University in 1988, and in 1994 obtained her Ph.D. in chemistry from the University of California, Berkeley, where she worked under the guidance of Dr. Paul Alivisatos. During her time at the University of California, Berkeley, Colvin was awarded the American Chemical Society's Victor K. LaMer Award for her work in colloid and surface chemistry. Colvin completed her postdoctoral work at AT&T Bell Labs.

In 1996, Colvin was recruited by Rice University to expand its nanotechnology program. Today, she serves as Professor of Chemistry and Chemical & Biomolecular Engineering at Rice University, as well as Director of its Center for Biological and Environmental Nanotechnology (CBEN). CBEN was one of the nation's first Nanoscience and Engineering Centers funded by the National Science Foundation. One of CBEN's primary areas of interest is the application of nanotechnology to the environment.

Colvin has received numerous accolades for her teaching abilities, including Phi Beta Kappa's Teaching Prize for 1998-1999 and the Camille Dreyfus Teacher Scholar Award in 2002. In 2002, she was also named one of Discover Magazine's "Top 20 Scientists to Watch" and received an Alfred P. Sloan Fellowship. Her research in low-field magnetic separation of nanocrystals was named Top Five (no. 2 of 5) Nanotech Breakthroughs of 2006 by Forbes/Wolfe Nanotech Report.

Colvin is also a frequent contributor to Science, Advanced Materials, Physical Review Letters and other peer-reviewed journals, having authored/co-authored over 75 articles, and holds patents to four inventions.