



Risk Management Methods & Ethical, Legal, and Societal Implications of Nanotechnology

**Report of the National Nanotechnology Initiative Workshop
March 30–31, 2010**



About the Nanoscale Science, Engineering, and Technology Subcommittee

The Nanoscale Science, Engineering, and Technology (NSET) Subcommittee is the interagency body responsible for coordinating, planning, implementing, and reviewing the National Nanotechnology Initiative (NNI). The NSET is a subcommittee of the Committee on Technology of the National Science and Technology Council (NSTC), which is one of the principal means by which the President coordinates science and technology policies across the Federal Government. The National Nanotechnology Coordination Office (NNCO) provides technical and administrative support to the NSET Subcommittee and its working groups in the preparation of multiagency planning, budget, and assessment documents, including this report. More information is available at <http://www.nano.gov>.

About the National Nanotechnology Initiative

The National Nanotechnology Initiative is the Federal nanotechnology R&D program established in 2000 to coordinate Federal nanotechnology research, development, and deployment. The NNI consists of the individual and cooperative nanotechnology-related activities of 25 Federal agencies that have a range of research and regulatory roles and responsibilities. The goals of the NNI are fourfold: (1) to advance a world-class nanotechnology research and development program; (2) to foster the transfer of new technologies into products for commercial and public benefit; (3) to develop and sustain educational resources, a skilled workforce, and the supporting infrastructure and tools to advance nanotechnology; and (4) to support responsible development of nanotechnology.

About the Nanotechnology Environmental and Health Implications Working Group

The NSET Subcommittee and its Nanotechnology Environmental and Health Implications (NEHI) Working Group provide leadership in establishing the NNI environmental, health, and safety research agenda and in communicating data and information related to the environmental and health aspects of nanotechnology between NNI agencies and with the public. NNI activities support the development of the new tools and methods required for the research that will enable risk analysis and assist in regulatory decision making.

About this Report

This document is the report of a workshop held March 30–31, 2010. This was the final in a series of four workshops sponsored by the NSET Subcommittee to inform the NNI's long-range planning efforts for environmental, health, and safety research. Any ideas, findings, conclusions, and recommendations presented in this report are those of the workshop participants. This report was designed, assembled, and edited by NNCO staff.

About the Report Cover

Cover design is by Kathy Tresnak of Konzept, Inc. Book design is by staff members of the National Nanotechnology Coordination Office. *Center image right:* Illustration of platinum honeycomb structured with 10-nanometer-wide pores created through self-assembly by Cornell University. This hexagonal structure may transform the field of fuel cells and microchip fabrication (courtesy of Scott Warren and Uli Wiesner, Cornell University). The cover background is a false-color scanning tunneling microscopy image revealing the atomic-scale electronic perturbations caused by a lattice defect in bilayer graphene (courtesy of Joseph Stroscio, National Institute of Standards and Technology, <http://cnst.nist.gov>).

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Risk Management Methods, & Ethical, Legal, and Societal Implications of Nanotechnology

Report of the National Nanotechnology Initiative Workshop

March 30–31, 2010, Arlington, VA

Part IV of IV in the 2009–2010 NNI Environmental, Health, and Safety Workshop Series

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Acknowledgments

The many individuals listed below dedicated considerable time and expertise to make the NNI Risk Management Methods and Ethical, Legal, and Societal Implications of Nanotechnology Workshop a reality and to write and produce this report.

Workshop Organizing Committee:

- Jeff Morris, Co-chair (EPA/NEHI)
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The committee planned, organized, and ran this workshop and wrote and reviewed the report chapters.

Workshop Presenters: David Andrews, Mark Banash, Christopher Bell, Rosalyn Berne, Robert Blaunstein, Christopher Bosso, Steve Brown, Carolyn Cairns, Pat Casano, David Castner, Vince Castranova, Alta Charo, Elizabeth Corley, John Cowie, John Gannon, Charles Gause, Stacey Harper, Barbara Herr Harthorn, Jackie Isaacs, Tom Kalil, George Kimbrell, Rebecca Klaper, William Kojola, Kristen Kulinowski, Jennifer Kuzma, Greg Lowry, Gary Marchant, John Monica, Matthew Nisbet, Pilar Ossorio, Richard Pleus, Thomas Seager, Jeff Stevens, John Stone, Treye Thomas, and Amy Wolfe shared their expert perspectives with workshop participants on the state of the science in risk management methods and ethical, legal, and societal implications of nanotechnology research (for affiliations see Appendix B). Thanks are due to William Kojola for hosting the public comments, and Matthew Nisbet, Pilar Ossorio, and Thomas Seager for co-chairing breakout sessions; all four contributed to drafting the workshop report.

Support Staff: Staff members of the National Nanotechnology Coordination Office (NNCO) executed the planning and organization of the workshop and production of the report. In particular, Liesl Heeter and Heather Evans supported the organizing committee. Liesl Heeter handled workshop logistics along with Halyna Paikoush. Geoff Holdridge, Pat Johnson, Jim Kadtke, Mary Myers, Diana Petreski, Kristin Roy, and Ken Vest assisted at the workshop. Liesl Heeter was series editor of the report, Kristin Roy formatted the report, and Pat Johnson copyedited it.

Sponsor: The National Science and Technology Council Subcommittee on Nanoscale Science, Engineering, and Technology (NSET) sponsored the workshop and reviewed the draft report before its publication. Members of the NSET Subcommittee's Nanotechnology Environmental and Health Implications (NEHI) Working Group were particularly involved in planning and hosting the workshop and in vetting the report.

Thanks are due to all the workshop speakers, moderators, and participants in the March 30–31, 2010, workshop, held in Arlington, VA. The substance of the workshop depended upon their thoughtful engagement; their presentations and discussions at the workshop provided the foundation for this report.

Any opinions, findings, and conclusions or recommendations expressed in this material are those of the authors or workshop participants and do not necessarily reflect the views of the United States Government or the authors' parent institutions.

Preface

Nanotechnology holds the promise of exciting new solutions to critical scientific, industrial, and commercial challenges through the engineering of application-specific nanomaterials. With applications already on the market and others soon promised, there are questions about the potential risks as well as the potential benefits of nanotechnology to human health and to the environment. To foster greater scientific understanding to address these types of questions, the National Nanotechnology Initiative has made environmental, health, and safety research an essential component of its research and of U.S. efforts to be the world leader in nanotechnology.

Responsible development of nanotechnology, as with any emerging technology, depends upon a reliable scientific capacity to assess and manage potential risks. The realization of the benefits of nanotechnology can only come to fruition with responsible development and public acceptance of nanotechnology and nanotechnology-enabled products. Thus, consideration of any potential ethical, legal, and societal implications that may arise is essential.

Developing the scientific capacity to make informed decisions about risk and risk management requires a national effort that brings together scientists from many disciplines both within the Federal Government and without, through the Government's public-private partnerships with academia, industry, and public health and environmental advocates. To that end, the Nanotechnology Environmental and Health Implications (NEHI) Working Group of the National Science and Technology Council's Nanoscale Science, Engineering, and Technology (NSET) Subcommittee created an adaptive management process in its 2008 *Strategy for Nanotechnology-Related Environmental, Health, and Safety Research*, which called for holding public workshops on the state of the science.

This document reflects discussions from the Risk Management Methods and Ethical, Legal, and Societal Implications of Nanotechnology Workshop, held March 30-31, 2010. Organized by a multi-sector planning team, this workshop capped a four-part series of public workshops to examine environmental, health, and safety issues related to nanotechnology research. Participants from government agencies, academia, citizens, industry, nongovernmental organizations, and other stakeholders joined in robust discussions on the state of the science for risk management and for ethical, legal, and societal concerns. The proceedings from these workshops will inform the NSET Subcommittee and the NEHI Working Group in adaptively managing the process to refine the NNI EHS Research Strategy, which in turn informs the nanotechnology research agendas of the NNI's Federal agency members.

On behalf of the NSET Subcommittee, we thank the workshop co-chairs and the members of the planning team for organizing this workshop and leading the preparation of this report. Our sincere thanks also go to all the speakers, moderators, and participants for their many excellent contributions to the workshop and to this report.

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About the 2009–2010 NNI Series of EHS Workshops and Reports

From February 2009 to March 2010, the Nanoscale Science, Engineering, and Technology (NSET) Subcommittee of the National Science and Technology Council sponsored a four-part series of workshops to solicit stakeholders' input on the National Nanotechnology Initiative (NNI) strategy to address potential environment, health, and safety (EHS) implications of nanotechnology research, development, and deployment:

- Human and Environmental Exposure Assessment
February 24–25, 2009, Bethesda, MD
Website: <http://www.nano.gov/events/meetings-workshops/exposure>
- Nanomaterials and the Environment, & Instrumentation, Metrology, and Analytical Methods
October 6–7, 2009, Arlington, VA
Website: <http://www.nano.gov/events/meetings-workshops/environment>
- Nanomaterials and Human Health, & Instrumentation, Metrology, and Analytical Methods
November 17–18, 2009, Arlington, VA
Website: <http://www.nano.gov/events/meetings-workshops/humanhealth>
- Risk Management Methods, & Ethical, Legal, and Societal Implications of Nanotechnology (Capstone Meeting), March 30–31, 2010, Arlington, VA
Website: <http://www.nano.gov/events/meetings-workshops/capstone>

The interagency NSET Subcommittee's Working Group on Nanotechnology Environmental and Health Implications (NEHI) led the organization and management of the workshop series, with active participation from stakeholders in academia, industry, nongovernmental organizations, and the general public. Three documents released by the NEHI Working Group for public review provide a backdrop to the 2009–2010 EHS workshops; all are available at <http://www.nano.gov/publications-resources/>

1. *Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials* (2006) evaluated the state of the science and grouped EHS research into five categories: (1) Instrumentation, Metrology, and Analytical Methods; (2) Nanomaterials and Human Health; (3) Nanomaterials and the Environment; (4) Human and Environmental Exposure Assessment of Nanomaterials; and (5) Risk Management Methods. It also described principal research needs within each category.

2. *Prioritization of Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials: An Interim Document for Public Comment* (2007) was intended to elicit comments from the public, the scientific community, and other stakeholders on how the NSET Subcommittee proposed to approach prioritization of environmental, health, and safety research needs.

3. *Strategy for Nanotechnology-Related Environmental, Health, and Safety Research* (2008) incorporated input from the 2007 prioritization document. The 2008 strategy describes an adaptive management approach for interagency efforts to address EHS implications of nanotechnology, including identifying priority research needs, assessing existing research, analyzing strengths and weaknesses, and periodically updating and revising the strategy. It provides information to agencies that conduct and fund research on nanotechnology. It informs those agencies on critical research needs, and it facilitates collaborative research activities to address those critical research needs.

As part of its adaptive management of the NNI interagency nanotechnology-related EHS Research Strategy, the NSET Subcommittee's objectives were to review the state of the science, identify critical gaps, and inform the updating of the strategy, taking into account research advances made in the United States and abroad and the evolving needs of regulatory decision-makers. The goals of the NNI EHS strategy are to support nanotechnology risk assessment and risk management, to advance EHS research, and to develop adequate and timely EHS guidelines and regulations so that nanotechnology R&D is sustainable and of long-term benefit to the nation and the world. All four EHS workshops and their proceedings documents inform the 2011 update of the U.S. Federal Government's nanotechnology-related EHS Research Strategy.

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Executive Summary

Responsible development of nanotechnology depends upon managing the potential risks posed by this technology. The March 30–31, 2010, U.S. Federal Government-sponsored workshop, Risk Management Methods & Ethical, Legal, and Societal Implications of Nanotechnology addressed risk management methods, one of the five priority environmental, health, and safety (EHS) research needs for engineered nanoscale materials identified in the 2008 U.S. National Nanotechnology Initiative's (NNI) *Strategy for Nanotechnology-Related Environmental, Health, and Safety Research* (NNI EHS Research Strategy).¹ Ethical, legal, and societal implications (ELSI) of nanotechnology, which should be included in consideration of all five priority nanoEHS research needs, was introduced as a separate topic at the workshop.

In 2009, the Nanotechnology Environmental and Health Implications (NEHI) Working Group of the Nanoscale Science, Engineering, and Technology (NSET) Subcommittee of the National Science and Technology Council initiated an adaptive management process to assess the research goals and needs outlined in the 2008 EHS Research Strategy through a series of public workshops. The March workshop on Risk Management Methods and ELSI was the capstone of the series. These workshops, which took place 2009-2010, engaged various stakeholder groups (e.g., academia, industry, and nongovernmental organizations) and the general public in assessing the research goals in the 2008 EHS Research Strategy against the state of the science and in identifying gaps and barriers to further progress.

This capstone EHS workshop had two main objectives. The first was to discuss what information is available and what research is needed about risk management methods to inform decisions on the EHS implications of nanomaterials. The second objective was to broaden and enrich the NNI and public discourse on the ethical, legal, and societal implications of nanotechnology. These two objectives are interrelated, in that risk management methods are applied within a larger social context where decisions are made. An understanding of ELSI considerations can help ensure that specific risk management methods complement other societal responses to emerging technologies.

As the workshop progressed, discussion on risk management broadened to include risk assessment, and that broader discussion has been captured in this report. Workshop participants identified a number of important considerations for the development and application of risk management methods and risk assessment approaches:

- Risk management information needs should be integrated throughout the nanotechnology research agenda.
- Information should flow freely between physical sciences research, risk assessment, and risk management. As more is learned from assessment and management activities, that information should inform physical science activities, and vice versa.
- Information feedback loops from decision makers are needed to effectively implement and fully realize a research strategy. For example, researchers need to know the decision contexts within which the findings of their research will be

¹ <http://www.nano.gov>

applied, and whether the scientific information they gather is useful to decision makers.

- Although risk research related to nanomaterials has been focused heavily on characterization of dose-response, additional investment is needed in research on the impact of nanomaterials across the life cycle stages of product development, manufacture, commercialization, and disposal or end of life.
- Comparative risk assessment strategies should be encouraged. In generating information for such assessments, methods such as multicriteria decision analysis and life cycle analysis can help prioritize the needs for research and focus in the areas of highest uncertainty.

Participants also identified a number of key considerations for ELSI:

- To ensure that the revised NNI EHS Research Strategy is communicated to all stakeholders, include people from different publics, policymakers, nonprofits, and other organizations. Also, careful consideration should go into how to conduct nanotechnology outreach efforts and which groups of the public those efforts are reaching. Related to this, understanding localized knowledge can foster better communication to and from diverse publics.
- The ELSI and risk management and assessment communities need to communicate with each other and share data and methods. Funding institutions should provide mechanisms and infrastructure to facilitate cooperation between these communities.
- ELSI topics should be part of the next version of the NNI EHS Research Strategy. This step is important in that the NNI must make the case that ELSI is integral to and required for socially responsible research. This can be reinforced by making sure Federal sponsors of EHS research require grantees and contractors to consider ethical, legal, and societal concerns as they develop funding criteria, and by revisiting where necessary the NNI's societal dimensions goals.

Nanotechnology Terminology Used in this Report

Consistent with the 2006 NNI report *Environmental, Health, and Safety Research Needs for Nanoscale Materials*,¹ and for the purposes of this document, the term “engineered nanomaterials” (or “ENMs”)* refers to those materials that have been purposely synthesized or manufactured to have at least one external dimension of approximately 1–100 nanometers (nm)—the nanoscale—and that exhibit unique properties determined by this size. In this document, when the term nanomaterials is used alone, it refers to engineered nanoscale materials.

This definition also applies to *nanotechnology-enabled products* (NEPs), that is, intermediate products that exist during manufacture and final products.

* The term “engineered nanomaterial” is applicable to this workshop report and overall nanotechnology-related EHS research. This term does not necessarily apply to Federal regulatory statutes or policies relevant to nanotechnology.

1 NSET/NSTC, Washington, DC; http://www.nano.gov/NNI_EHS_research_needs.pdf.

- A common need for nanotechnology EHS decision support generally, one that encompasses both risk management and assessment and ELSI issues, is the need to apply a holistic approach to implementing a comprehensive risk research strategy. Developing useful tools to evaluate the development, progress, and success of such a research strategy may include consulting with the risk management/assessment and ELSI communities to track how the research agenda is progressing and what impact it is having on advancing the responsible development of nanotechnology.
- The proceedings of the capstone EHS workshop (see <http://www.nano.gov/events/meetings-workshops/capstone>), together with the reports from the three other EHS workshops in this series will inform the next version of the National Nanotechnology Initiative's strategy for nanotechnology-related EHS research.

1. Introduction

Background

Responsible development of nanotechnology depends upon managing the potential risks posed by this technology. One of the purposes of the Capstone Workshop on Risk Management Methods & Ethical, Legal, and Societal Implications of Nanotechnology was to discuss the information available and the research needed on risk management methods to inform decisions about the environmental, health, and safety (EHS) implications of nanomaterials. The other purpose was to explore the important role played by ethical, legal, and societal implications (ELSI) of nanotechnology. These two objectives are interrelated: risk management methods are applied within the larger social context where decisions are made. An understanding of ELSI considerations can help ensure that specific risk management methods complement other societal responses to emerging technologies.

About the Workshop

The National Nanotechnology Initiative (NNI) capstone workshop was held March 30–31, 2010, in Arlington, VA. It was sponsored by the Nanoscale Science, Engineering, and Technology (NSET) Subcommittee of the Committee on Technology of the National Science and Technology Council. The NSET Subcommittee implemented the workshop under the auspices of its Nanotechnology Environmental and Health Implications (NEHI) Working Group. The Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA), as the NNI coordinating agencies for risk management, played leading roles in organizing

the capstone workshop. This workshop was the last in the 2009–2010 four-part series of NNI environmental, health, and safety workshops aimed at furthering the development and application of the U.S. Federal Government strategy to responsibly and proactively address potential EHS implications of nanotechnology research and development.

This workshop on risk management addressed risk management methods, one of the five priority EHS research needs for engineered nanoscale materials identified in the 2008 NNI *Strategy for Nanotechnology-Related Environmental, Health, and Safety Research* (NNI EHS Research Strategy).¹ Ethical, legal, and societal implications of nanotechnology, which should be included in consideration of all five priority nanoEHS research needs, was introduced as a separate topic at the capstone workshop.

The open-forum workshop was designed to facilitate effective communication by bringing stakeholders together to address three overarching questions:

1. How can we make sure the NNI EHS Research Strategy communicates the status and research needs for effective risk management methods to all stakeholders (e.g., public, Federal Government, regulated industry, and academia)?
2. How can we ensure ELSI considerations are taken into account in the next generation of the NNI EHS Research Strategy?
3. What additional information should the Federal Government take into consideration when it updates its EHS Research Strategy?

The workshop was organized by a multisector planning team composed of representatives from

1 <http://www.nano.gov>

academia, industry, nongovernmental organizations, and the NEHI Working Group. More than 160 scientists and other stakeholders from state and national governments, industry, labor, academia, and other sectors attended. An additional 145 viewers joined remotely via the webcast.

The workshop opened with two perspectives on risk management, presented by Gary Marchant (Arizona State University) and Greg Lowry (Carnegie Mellon University), and two perspectives on ethical, legal, and societal considerations, presented by Pilar Ossorio (University of Wisconsin) and Barbara Herr Harthorn (University of California, Santa Barbara). These were followed by a presentation by Amy Jones (Lockheed Martin) of a hypothetical case scenario involving a new nanotechnology-enhanced paint or coating product and examination of that scenario using a typical industry product development protocol requiring the application of risk and ELSI considerations at all stages of product development, use, and end of life. The scenario was revisited in breakout sessions and plenary discussions on Day 2.

The afternoon of the first day of the workshop consisted primarily of six concurrent breakout sessions focused on three risk management topics and three ELSI topics:

1. Risk Management and the Workplace
2. Risk Management and Product/Material Life Cycle
3. Risk Characterization Information
4. ELSI: What are Attitudes about Nanotechnology and How are They Formed?
5. ELSI and Risk Management Communications
6. Specific Ethical, Legal, and Societal Implications of Nanotechnology

Discussions on the second day of the workshop focused on sharing perspectives from the first day's breakout sessions with the entire workshop, followed by an expert panel discussion on the intersections between risk management and ethical, societal, and legal issues regarding nanotechnology. Another expert panel took on the task of applying the intersections between the two research areas to the previous day's case scenario; this was followed by an

audience discussion of the case scenario in light of what had been learned and discussed over the course of the workshop. Discussion topics addressed the questions, What information is required by the case scenario? Are there gaps? What recommendations would you make about information needs? Where do Risk Management Methods and ELSI intersect?

The workshop closed with a report of the findings of all four NNI EHS workshops and a discussion of the grand challenges ahead for nanotechnology and nanomaterials development and, in particular, for nanotechnology-focused EHS and ELSI research.

About the Report

This report summarizes the principal findings and recommendations from the presentations and discussions that took place during the March 30–31, 2010, capstone EHS workshop. The report is the principal output of the workshop; however, additional materials related to the workshop are available on <http://www.nano.gov>.

Chapter 2 provides the overarching themes and recommendations from the entire workshop followed by the major recommendations from each of the six breakout sessions in Chapter 3. Chapters 4–9 provide a statement of purpose and a summary of the general discussions and findings for each of the six breakout sessions. Chapter 10 summarizes both days' discussions of the case scenario. In the appendices are the agenda (Appendix A); participants' list (Appendix B); detailed reports of the breakout sessions (Appendix C), the case scenario (Appendix D), the grand challenges discussion (Appendix E); and a list of the acronyms used in the report (Appendix F).

The proceedings of the capstone EHS workshop (see <http://www.nano.gov/events/meetings-workshops/capstone>), together with the reports from the three other EHS workshops in this series were used to help guide the next iteration of the NNI EHS strategy. Ultimately, the report aims to inform the NNI Federal agencies and other parties working on nanotechnology about the critical nanotechnology environmental, health, and safety research needs and to facilitate collaborative research across the U.S. Federal Government.

2. Cross-Cutting Themes and Recommendations

This chapter summarizes the overarching themes that were raised in both the Risk Management Methods (RMM) and the Ethical, Legal, and Societal Implications (ELSI) breakout sessions on Day 1 and discussed further by all participants on Day 2 of the workshop. These overarching themes resonate with the discussions in all six breakout sessions and are provided for consideration in the next version of the NNI EHS Research Strategy.

Risk Management Methods Themes and Recommendations (Breakout Sessions 1–3)

RMM involves an approach for enhancing safety and for gathering information to reduce risk, in this case, for the responsible development of nanotechnology. The workshop breakout sessions 1–3 contributed a number of cross-cutting themes and recommendations in the area of RMM, based on the workshop dialogues among scientists, researchers, government officials, and other stakeholders concerning the entire life cycle of a nanotechnology-enabled product's use from research, prototyping, and manufacture to use and disposal. Participants said that, in the short term, more emphasis on RMM will enhance the prevention of potential hazards and the protection of society from safety concerns associated with nanomaterials and products that contain such materials. In the long term, RMM will help responsibly develop the emerging nanosciences.

The following are key themes raised in the RMM sessions:

- *Integrate risk management into the overall research agenda.* Integrate information needs that are specific to applying risk management approaches into a comprehensive nanotechnology research agenda.
- *Share information between research areas.* Do not separate physical science research (nanomaterial characterization, environmental transformations, chemical properties, etc.), risk assessment, and risk management. Rather, information should flow freely between physical science research, risk assessment, and risk management. What we learn from risk assessment and risk management activities that should inform nanotechnology-related science activities, and vice versa.
- *Improve communications between researchers and policy makers.* Information feedback loops from decision makers are needed to effectively implement and fully realize a research strategy. For example, researchers need to know the decision contexts within which the findings of their research will be applied, and whether the scientific information they gather is useful to decision makers.
- *Identify science questions at each stage of the risk chain* (i.e., source, fate and transport, exposure, effects, etc.) in order to effectively design and implement a nanomaterial risk research strategy. The research strategy must consider how information generated under the strategy will inform decision making.
- *Include life cycle approaches.* Although risk research related to nanomaterials has been focused on the characterization of dose response (i.e., effects), additional investment is needed in research on the impact of nanomaterials across their life

cycle stages: manufacture, fate and transport, consumer exposure, and end of life and disposal.

- *Implement comparative risk assessment strategies or strategies based on plausibility of risk as opposed to “absolute” risk assessment strategies.*
- *Use available methods to prioritize the need for research and focus in the areas of highest uncertainty.*

Ethical, Legal, and Societal Implications of Nanotechnology Themes and Recommendations (Breakout Sessions 4–6)

ELSI issues are essential to the responsible development of nanotechnology. How nanotechnology research and applications are introduced into society, how transparent decisions are, how sensitive and responsive policies are to the needs and perceptions of the full range of stakeholders, and how ethical, legal and social issues are handled will go a long way in determining the level of public trust and the future of innovation driven by nanotechnology. ELSI research seeks to generate knowledge and insights that can help society assess the potential impacts of nanotechnology and the possible responses. The following are themes and recommendations raised in the ELSI breakout sessions help achieve these goals:

- *Ensure that the 2011 EHS Research Strategy—both current status of research and research needs—is communicated to all stakeholders.* This involves defining and including all stakeholders from different publics, policymakers, nonprofits, and agencies within the NNI, and the ELSI and RMM communities, in sharing and communicating data consistently. Funding institutions should provide mechanisms and infrastructure to facilitate such cooperation. Emphasis should also be placed on a coordinating role for the NNI between ELSI and RMM, among agencies and other stakeholders, for building and maintaining trust and for avoiding inconsistent messages.
- *Conduct outreach.* Government agencies and ELSI researchers need to think carefully about how to conduct nanotechnology outreach efforts and which groups of the public those efforts are reaching. Outreach should be customized across different publics (e.g., across age groups and education groups) to ensure that existing nanotechnology knowledge gaps do not increase over time. Current research has shown that

outreach efforts focused on museum exhibits and public meetings are reaching the most educated groups of the public more than the least educated.

- *Consider the ELSI topics that should be part of the next version of the strategy.* This step is important in that the NNI must make the case that ELSI is integral to, and required for, socially responsible research.
- *Incorporate ELSI into contracts and grants.* Government agencies should make sure sponsors of EHS research require grantees and contractors are knowledgeable about ELSI issues, and agencies should consider ELSI as they develop their funding criteria, such as requiring public engagement activities of grantees and contractors or in Requests for Proposals (RFPs). NNI should consider funding primary research that focuses on ELSI topics. In addition, ELSI goals should be revisited and adjusted, where necessary, and include a description of how funding is spent, as well as making more transparent long-term planning efforts for different NNI funding areas.
- *Assess readiness to adjust as the field of nanotechnology evolves.* For example, the significance of the definition of nanotechnology may not be as useful as it could be where it depends on adherence to the size of components and where the definition does not touch on other relevant characteristics or properties associated with nanomaterials.
- *Take into account the importance of localized knowledge as an additional information source.* This includes interacting with many publics/populations to help guide scientists in designing, interpreting, and reporting their research.
- *Use appropriate language for discussing nanotechnology.* It is important to consider what is appropriate language for nanotechnology, for definitions provided in surveys and other evaluative research, and for communicating more generally. The language used should resonate with all stakeholders without creating bias.
- *Consult with RMM and ELSI communities when tracking the progress of the NNI research agenda as well as responding to what communities are thinking, evaluating the strategy’s impact, and how ELSI and RMM are evolving.* This

evaluation should not be ad hoc and isolated, but longitudinal, systematic, and complementary to other milestones such as PCAST reviews.

Common Overarching Themes in Both Topic Areas

- *Address barriers to pursuing RMM and ELSI in nanotechnology through innovative research models.* Challenges in implementing traditional approaches in RMM (e.g., considering physical research, risk assessment, and risk management as separate activities; the linear flow of information to enable risk management approaches and the lack of feedback loops during regulatory decision making to effectively implement a research strategy) and in ELSI (e.g., not including representative stakeholders from all sectors, and lack of regular cooperation and communication between ELSI experts and experts in other fields such as RMM) may
- require new approaches for addressing an emerging science area and for creating novel communication methods for bringing the right experts together.
- *Apply a holistic approach to designing and implementing a comprehensive risk research strategy.* RMM and ELSI must be viewed as integral components to, and requirements for, socially responsible research in the area of nanotechnology. Both areas require a thoughtful approach by which many subtopics are managed distinctly but viewed collectively.
- *Develop measurement tools to evaluate the development, progress, and success of a comprehensive nanotechnology research strategy.* This will involve consulting with RMM and ELSI communities when tracking the progress of the research agenda in terms of what communities are thinking, what the impacts are, and how ELSI and RMM are evolving.

3. Recommendations from Breakout Sessions

Session 1. Risk Management and the Workplace

- Develop guidance for workplace protective measurements.
- Identify standardized, validated exposure limits or reference concentrations to address exposure hazards, in light of the lack of consensus on levels, measures, and methods.
- Evaluate exposure limits by “binning” materials (possibly by mechanisms of action, as exposure limits are more applicable to manufacturing environments), using few materials at the same workstations every day. In addition, permissible exposure limits are less applicable to research environments with multiple materials.
- Use traditional industrial hygiene controls to control exposures once a target is established.
- Consider the control banding model. Biosafety levels are the equivalent of control banding, which is used in the pharmaceuticals industry. The suitability of control banding for nanotechnology is limited by information gaps. It will be necessary to develop exposure levels for individuals working with nanomaterials manually under laboratory conditions, including the methods to detect exposure and exposure limits.
- Develop a database of controls and exposure levels using validated, standardized controls.
- Establish data to set permissible exposure limits for key nanomaterials in the workplace, relevant to human health effects.
- Develop governance models that can be used to manage risk in the absence of adequate information (or “in situations where inadequate

information is available”), including how to inform the public about what is being done to reasonably manage risk, and how to build effective communications with researchers on the types of data and metrics needed.

Session 2. Risk Management and Product/ Material Life Cycle

Participants in the breakout sessions recommended rewording RMM Research Need #2, “examine product of material lifecycle to inform risk reduction decisions,” to read, “integrate life cycle analysis into the risk management decision process,” with the following sub-bullets:

- Establish nanotechnology-specific taxonomy for life-cycle stages.
- Develop new methods (i.e., multicriteria decision analysis [MCDA], life cycle assessment [LCA]).
- Develop case studies (e.g., green chemistry, nanomaterials selection, nanomaterials acquisition processes).
- Apply adaptive management tools based on monitoring/implementation (e.g., evaluate how well life cycle analysis is working; feedback loop).

In addition, the following *new* Research Needs were identified:

- Implement comparative risk assessment strategies or strategies based on plausibility of risk as opposed to “absolute” risk assessment strategies.
- Use methods such as MCDA and LCA for a gap analysis to prioritize the needs for research and to focus on the areas of highest uncertainty through a “value-of-information” analysis.

Session 3. Risk Characterization Information

- Develop a battery of tests, with particular emphasis on a standard set of tests with standardized reference materials.
- Develop a feedback loop from modes of toxicity to physico-chemical properties of nanoparticles to identify those characteristics that may not have been assessed during initial studies.
- Use traditional toxicology tests as a starting point to develop reliable and reproducible methods, although they may not be appropriate to test nanoparticle toxicity.
- Evaluate and validate toxicological tests and/or endpoints traditionally used to evaluate new chemicals to determine if they may be sufficient to cover new nanomaterials for appropriate use and limitations.
- Include a data repository for reporting both positive and negative results from the standardized tests.
- Develop predictive capability: toxicity of nanoparticles cannot, with the tools, data, and models currently available, be predicted based on their physico-chemical properties.
- Develop more data on additional characteristics of the nanomaterials, using interdisciplinary, integrated teams with multiple specialties.
- Determine what characteristics are important for various nanomaterials—do not just test a full range of characteristics—and harmonize biological and physical chemistry characterizations. In addition, consider the issues of contaminants and additives, because they can affect toxicity. In sum, this work needs to capture the full complexity of nanoparticle molecules and mixtures of nanoparticles.
- Conduct interlaboratory studies to define assay variability and error for protocols that could further be developed as standards. A parallel complementary approach is needed to establish rapid, high-throughput, accurate testing methods.
- Test/validate existing protocols typically used in chemical evaluation for use with nanomaterials, or develop new protocols where necessary. In addition, develop new rapid, high-throughput biological assays to address the many nanomaterial formulations that are, or will be, developed.
- Increase the pool of viable assays to allow us to move toward a truly weight-of-the-evidence approach on which guidance and regulation can be based, and identify those platforms that are most predictive of biological impact.
- Develop an iterative testing strategy (in which greener formulations are used as starting materials, are reformulated to improve performance and reduce toxic potential, and are retested to inform materials design) to further support the movement to a predictive environment in which material features can be altered to gain functionality in a predictable manner.
- Devise a strategy to develop short-term laboratory studies of biological effects of novel materials that will be predictive of the effects of low-dose and/or long-term exposure, the exposure scenario for most people. The studies can be used on a case-by-case basis until we have enough information to study general classes of nanoparticles.
- Use data on diesel particulates to devise studies and extrapolate the potency of nanomaterials using existing human health data, although more data are needed.

Session 4. Ethical, Legal, and Societal Implications: What Are Attitudes Toward Nanotechnology and How Are They Formed?

- ELSI researchers should continue to track public attitudes about nanotechnology and media–public interactions and their impact on attitudes over time. It will be important to continue data collection for a variety of different “publics” by making sure that data are collected across different demographic groups (e.g., gender, ethnicity, age, etc.) as well as across different education levels and geographic locations
- Ensure that consistent ELSI data collection occurs by adding ELSI research to all nanotechnology research proposal requests (including technical proposals)
- Government agencies and ELSI researchers should think carefully about how to conduct

nanotechnology outreach efforts. Outreach efforts need to be customized (e.g., across age groups or education groups) for the audience before communicating with audience members about nanotechnology.

- Since the NNI is a national consortium of Federal Government agencies, its membership needs to carefully develop an international perspective for U.S. nanotechnology policy, while simultaneously moving forward with national policy development.

Session 5. ELSI and Risk Management Methods Communications

- Promote effective public communication about nanotechnology, in part based on systematic empirical communication research, in which the NNI should play a much more prominent role than it has so far.
- Strengthen basic communication research to understand, develop, and utilize two-way channels of communication with different publics for the future of the NNI by helping develop, test, and assess innovative ways of reaching and engaging various publics through different forms of communication and informal science education.
- Continue to foster direct communication with government agencies, organizations, and industry in various public forums, including the news media, particularly newspapers in print and in digital form. Local newspapers, for instance,

remain a prominent source for original reporting on problems and policy debates, and they often drive the agenda of the rest of a community's media outlets, from local television to blogs.

- Increase use of social and other online media outlets for establishing two-way channels of communication and for closing various communication gaps identified by previous research, including informational gaps across socioeconomic groups.

Session 6. Specific Ethical, Legal, and Societal Implications of Nanotechnology Issues

- ELSI issues should be integrated into the application of life cycle approaches to nanotechnology-enabled products and both inform the process and use information from the process.
- Different types of nanomaterials applications trigger different ELSI issues, with different risks and benefits.
- The definition of nanotechnology based on size alone should be revisited and alternatives considered.
- Relevant nanotechnology stakeholders include diverse populations (e.g., in terms of race, gender, education, economic status, etc.).
- ELSI researchers and nanotechnology scientists and engineers should collaborate to ensure that ELSI research is informed by a realistic assessment of the state of the science.

4. Discussion Summary: Risk Management and the Workplace

Frank Mirer (Hunter School of Social Science) and
Charles Geraci (NIOSH)

Purpose

This breakout session focused on managing risks from engineered nanomaterials within the workplace.

Presentations

Dr. Jeffery Steevens presented his experience on developing guidance for working with nanomaterials in a laboratory setting. The early assumption at many labs was that nanomaterials should be treated as “nuisance dust”; nevertheless, he applied the principle of “as low as reasonably achievable” (ALARA) to minimize risk to his lab personnel. For example, he reasoned it would be safer to work with nanomaterials in solution, in solvents, and under hoods. The various EHS risk management principles he researched and developed were drawn up into appropriate protocols in his laboratory and are being shared with U.S. Army and other military nanotechnology labs. In sum, he stated that now is the time for guidance, given that people are already working with nanomaterials, and that creative solutions will be required to address exposure challenges.

Dr. Robert Blaunstein presented the insurance perspective on managing workplace risk: governance and regulations set expectations, allowing the insurance industry to manage risk. In particular, he noted it would be good to see specific requirements for the appropriate monitoring of

exposure and the mandating of protective clothing and procedures for workers.

An environmental lawyer, Christopher Bell, shared the perspective of working on developing standards at the international level through the International Standards Organization (ISO). He noted that the lack of data on exposure poses difficulties in writing these standards. Yet without standards in place to address current worker exposure, he felt the promise of engineered nanomaterials would be unrealized.

Discussion

Many in the group echoed the need to have guidance now to address current nanomaterial exposures by laboratory and manufacturing workers. But while the group agreed that conventional industrial hygiene controls would be useful, such as set limits to worker exposure to engineered nanomaterials, the group did not resolve how to determine those limits. Moreover, to determine exposure and set limits, it is not clear what should be measured and how it should be measured. Participants discussed whether the precautionary principle might be appropriate, that is, applying controls without having a formal risk assessment. Participants noted the need for databases to compile information. One question left unresolved was whether sufficient data from other sources existed (e.g., diesel particulates) that

could serve as proxies in setting personal exposure limits for similar engineered nanomaterials.

Findings

The group recommended the development of workplace guidance and ways to inform the public about whether an adequate job is being done to manage the risks from exposure to nanomaterials

in the workplace. The group also discussed the need to adapt conventional industrial hygiene standards for workplace guidance until the research data and metrics on engineered nanomaterials catches up to the needed exposure guidance; this includes the need to acquire the data and metrics needed to address exposure issues.

5. Discussion Summary: Risk Management and Product/Material Life Cycle

Igor Linkov (U.S. Army Engineer Research and Development Center) and Thomas Seager (Rochester Institute of Technology)

Purpose

This session focused on the development of risk assessment and risk management methods along with tools that could be used to assess life cycle risks and benefits and help in making management decisions.

Presentations

Dr. Thomas Seager presented *Uncertainty in Life Cycle Assessment of Nanomaterials: Towards a Decision-Driven Approach*. He noted that the high degree of variability and uncertainty with respect to novel engineering materials and threats greatly expands data needs with regard to dose–response relationships, environmental fate and transport, source terms, and life cycle environmental consequences. Therefore, it is essential to create and maintain a framework for interpreting available information, along with a strategy for prioritizing research efforts to reduce critically challenging uncertainties. The three analytic approaches he discussed were risk assessment, life cycle assessment, and multicriteria decision analysis. These approaches were discussed as an integrative framework for synthesizing both objective scientific information and subjective values-driven goals relevant in decision and policy contexts.

In his presentation, *Integrating Life Cycle Assessment, Risk Assessment and Decision Analysis for Nanomaterials*, Dr. Igor Linkov described an integrated risk assessment/life cycle analysis/multicriteria decision analysis (RA/LCA/MCDA) framework used to compare four different manufacturing processes for single-walled carbon nanotubes. In this work, an MCDA combined four criteria: energy and material efficiency at the manufacturing stage, life cycle score, health risks, and cost. The decision problem was modelled separately for 4 stakeholder groups (regulators, consumers, environmentalists, and manufacturers) and results were compared. A “value of information” analysis was conducted and showed that, for this case study, the decision to go ahead with manufacturing is robust, even with existing information.

Discussion

Nanotechnology-related life cycle analysis needs to be streamlined toward specific technologies and products that are most relevant, as the analysis is too data-intensive to conduct for every case. Life cycle implementation needs to be coordinated, because individual agency missions are fragmented. (There was a recommendation that the NNI could serve in this capacity.) Increasingly, life cycle considerations are creeping into the purview of more agencies as

awareness about post-use environmental and health considerations evolves (e.g., therapeutics flushing into the water supply after clearance from the human body raises issues for FDA in addition to EPA).

Findings

Participants in the group recommended rewording of the 2008 RMM Research Need #2, from “examine product of material life cycle to inform risk reduction decisions” to “integrate life cycle analysis into the risk management decision process,” with the following sub-bullets:

- Establish a nanotechnology-specific taxonomy for life cycle stages.
- Develop new risk management methods (i.e., multicriteria decision analysis and life cycle assessment).
- Develop case studies, for example, in green chemistry, nanomaterials selection, and the nanomaterials acquisition process.
- Develop adaptive management tools based on monitoring and/or implementation (i.e., evaluate how well life cycle analysis is working, and implement feedback loops).
- In addition, the participants identified the following new research needs:
 - Implement comparative risk assessment strategies or strategies based on plausibility of risk as opposed to “absolute” risk assessment strategies.
 - Use methods, such as MCDA and life cycle analysis, for a gap analysis to prioritize the needs for research and focus in the areas of highest uncertainty through “value-of-information” analysis.

6. Discussion Summary: Risk Characterization Information

Michael Hansen (Consumers Union) and
Robert Bronaugh (FDA)

Purpose

This session focused on the development of risk characterization information that could be used to classify nanomaterials based on their physical and/or chemical properties.

Presentations

Dr. Vincent Castranova's presentation focused on research done by the National Institute for Occupational Safety and Health (NIOSH) on the inhalation of nanoparticles, which aims to: (1) develop and validate methods to quantify dose-response and structure-activity relationships, (2) translate *in vitro* test results to *in vivo* responses, and (3) extrapolate data to human exposures. The NIOSH work has shown that it is essential that test suspensions of nanoparticles contain structure sizes relevant to those measured in the workplace and that mechanistic information concerning *in vivo* bioactivity is needed to develop the proper *in vitro* screening test for each class of nanoparticles.

Dr. Stacey Harper's presentation addressed special consideration for nanomaterials in the context of hazard identification and dose-response and provided an overview of a path forward for nanomaterials risk characterization. She noted that the toxicological tests and endpoints traditionally used to evaluate new chemicals may be sufficient

to cover new nanomaterials, provided the tests are evaluated and validated for appropriate use and limitations. Although we currently cannot predict toxicity of nanoparticles based on physico-chemical characteristics, such prediction will be feasible in the future. A path forward for the next iteration of nanomaterials risk characterization would concentrate on: (1) leveraging ongoing research, (2) improving biological assessment, (3) improving characterization capacity, and (4) implementing an informatics infrastructure that facilitates data sharing.

Discussion

The group decided that present toxicology tests could be a useful starting point. There is a need for a battery of tests to be developed, with particular emphasis on a standard set of tests with standardized reference materials. For dose-response assessment, it's unclear which dose metrics (e.g., mass of the nanomaterial's core, mass of the core plus ligands, the number of atoms, the number of nanoparticles, the number of ligands, or the surface area) are most appropriate and whether the same dose metrics could be applied across different nanomaterial types.

The group also agreed that nanoparticles' toxicity could not, at present, be predicted based on their physico-chemical properties. More data are needed

on additional physico-chemical characteristics of nanoparticles and their relationship to biological activity; however, this work needs to capture the full complexity of nanoparticles and mixtures of nanoparticles. One potential approach involves an iterative testing strategy (in which “greener” formulations are used as starting materials, are reformulated to improve performance and reduce toxic potential, and are retested to inform materials design), which would further

support movement to a predictive environment in which material features can be altered to gain functionality in a predictable manner.

Findings

- Need a battery of standardized tests with standardized reference materials
- Need more data on additional characteristics of nanoparticles in order to better predict their toxicity

7. Discussion Summary: Ethical, Legal, and Societal Implications of Nanotechnology

What are Attitudes about Nanotechnology and How are they Formed?

Elizabeth Corley (Arizona State University) and Sally Tinkle (NIH/NIEHS)

Purpose

The fourth breakout session for the NNI Capstone Workshop was focused on ELSI issues and public attitudes about nanotechnology. The session participants discussed the importance of continuing to fund high-quality social science data collection that allows ELSI researchers to track changes over time related to public risk and benefit perceptions about nanotechnology, public trust in institutions that regulate nanotechnology, and public knowledge levels about nanotechnology. In addition, the session participants discussed the importance of collecting data that would enable researchers to compare public attitudes about nanotechnology with nanoscientists' and nanoregulators' perceptions about nanotechnology to identify areas where there are gaps and commonalities among these groups.

Group Discussion

The group discussed four general themes: (1) tracking public perceptions about nanotechnology over time, (2) the increasing focus of nanotechnology media coverage on specific application areas, (3) the widening nanotechnology

knowledge gaps across different groups within the public, and (4) the importance of analyzing attitudes about nanotechnology for a variety of "publics." For example, one topic that was discussed extensively during the breakout session was the focus of media content on nanotechnology often provides shortcuts for the public to use when they form attitudes. This is particularly important given the public's relatively low levels of knowledge about nanotechnology.

Findings

One overarching finding of the session was that ELSI researchers should continue to track public attitudes about nanotechnology and media effects on public attitudes over time. Several participants indicated that one way to ensure that this data collection happens is to add ELSI research to all nanotechnology research proposal requests (including technical proposals).

Second, the breakout participants discussed the importance of focusing ELSI research on nanotechnology application areas. The participants concluded that the public has different risk and benefit perceptions for different nanotechnology

application areas. For example, the public might have high benefit perceptions about nanomedicine for the treatment of diseases, but lower benefit perceptions for nanomedicine in the human enhancement area (i.e., for therapeutic versus non-therapeutic uses).

Third, the breakout group discussed knowledge gaps in detail, concluding that ELSI researchers need to think carefully about how to conduct nanotechnology outreach efforts and about which groups those efforts are reaching. The session participants indicated that outreach should be customized (e.g., across age groups or education groups) and that we should learn more about the audiences before we communicate with them about nanotechnology. There was concern among the session participants that nanotechnology knowledge gaps may increase over time if we are not more careful in outreach efforts.

Fourth, the group discussed the existence of more than one “public” for nanotechnology issues. The session identified the importance of collecting data for a variety of different “publics” by making sure that we collect data across different demographic groups (e.g., gender, ethnicity, age, etc.) as well as across different education levels and geographic locations.

Finally, a major challenge discussed during this session focused on the concept of the NNI being a “national” consortium of Federal Government agencies. The session participants concluded that the United States needs to think carefully about developing an international perspective for nanotechnology policy, while simultaneously moving forward with national policy development.

8. Discussion Summary: ELSI and Risk Management Methods Communications

Dietram Scheufele (University of Wisconsin–Madison) and Matthew Nisbet (American University)

Purpose

Recent public opinion data show widening communication gaps between science and the public on the topic of nanotechnology. This session addressed the questions, Where have we fallen short? How can better communication research and strategy help close these gaps, particularly on risk management methods (RMM)-related issues? And what outcomes of communication are particularly relevant?

Group Discussion

The discussion focused on at least four broad areas. First, participants saw a central role for the NNI in all communication efforts surrounding nanotechnology, based on three guiding principles:

1. Build long-term trust through openness
2. Respond in a timely manner to emerging issues
3. Facilitate two-way communication and engagement

Second, participants felt that working successfully with mass media and social media to set the agenda and contextualize the issues of nanotechnology in all their complexities is critical for building connections with the public. These communication efforts should be informed by systematic basic

research in communication and formative and post hoc evaluation at all stages of the product lifecycle (potentially in collaboration with existing NSF-funded social science efforts in this area).

Third, group discussions highlighted the importance of separating the foci on (and funding for) education and outreach from social scientific research on ELSI aspects (including communication research targeted at connecting with hard-to-reach publics).

Finally, discussions focused on the interplay of communication and education to help contextualize policy choices, build nanotechnology literacy, and develop long-term beliefs about the integrity of the scientific process.

Findings

Effective public communication about nanotechnology is not a guessing game; it is a science—a science in which systematic empirical communication research should play a much more prominent role as part of the NNI agenda than it has so far. Relying on basic communication research to understand, develop, and utilize two-way channels of communication with different publics will be critical for the future of the NNI by helping help us develop, test, and assess innovative ways of reaching and engaging various publics through different forms of communication and informal science education.

Direct communication on the part of government agencies, organizations, and industry continues to be important to public engagement, but news media, particularly newspapers in print and, now, their digital form, are necessary and vital intermediaries between experts and the public. Local newspapers, for instance, remain a prominent source for original reporting on problems and policy debates, and they often drive the agenda of the rest of a

community's media outlets, from local television to blogs. Participants also highlighted the increasing importance of social and other online media, in addition to traditional channels, for establishing two-way channels of communication and for closing various communication gaps identified by previous research, including informational gaps across socioeconomic groups.

9. Discussion Summary: Specific Ethical, Legal, and Societal Implications of Nanotechnology Issues

Mark S. Frankel (AAAS) and
Pilar Ossorio (University of Wisconsin–Madison)

Purpose

ELSI issues are deeply embedded in the “responsible development of nanotechnology.” How nanotechnology research and applications are introduced into society; how transparent decisions are, how sensitive and responsive policies are to the needs and perceptions of the full range of stakeholders; and how ethical, legal, and social issues are handled will go a long way toward determining levels of public trust and the future of innovation driven by nanotechnology. ELSI research seeks to generate knowledge and insights that can help society assess the potential impacts of nanotechnology and possible responses.

Group Discussion

Several broad themes surfaced during the session:

- Expected benefits
- Anticipated risks
- Safety
- Definition of nanotechnology
- Applications of nanotechnology
- Regulation

Research is needed on:

- The nature, quality, and scope of differences across the population with respect to people’s views about nanotechnology.
- How the benefits and burdens of nanotechnology R&D and its applications might be distributed across various sectors of the population and what ELSI issues are raised.
- What people believe they should know about nanotechnology in order to maximize benefits and minimize risks.
- What types of regulatory models for nanotechnology R&D and its applications are likely to be considered, with simultaneous study of the ELSI issues each model raises.

Findings

- ELSI issues should be integrated into the life cycle of nanotechnology-enabled products.
- Different types of nanomaterial applications trigger different ELSI issues, with different risks and benefits.
- The definition of nanotechnology based on size should be revisited and alternatives considered

- Relevant nanotechnology stakeholders should include diverse populations (e.g., race, gender, education, economic status, etc.).
- ELSI researchers and nanotechnology scientists and engineers should collaborate on the

study of ELSI issues to ensure that research is informed by a realistic assessment of the state of the science.

10. Case Scenario Summary: Bringing Risk Management and ELSI Together

Amy Jones (Lockheed Martin)

Purpose

The case scenario for the NNI Capstone Workshop asked the audience and invited panelists to consider and identify risk assessment and ELSI research needs associated with the introduction of a hypothetical paint or coating to market that would be used in manufacturing and consumer applications. The product under consideration contained a novel nanoparticle that improved product performance and was developed with the understanding that product safety and environmental stewardship were customer requirements.

Format

The case scenario was introduced on the first day of the workshop. The audience was provided a general overview of the hypothetical product and an outline of the product development protocol under which the new product was developed. A stage-gate approach¹ for product development was selected as the conceptual model to present the case scenario and frame the follow-on discussion. The stages consisted of the following: (1) idea build, (2) viability assessment, (3) prototype

¹ A stage-gate model is a project management approach in which each step (stage) is separated from the next by a decision gate. At each gate, continued project development is reevaluated based on inputs from risk assessments, business analysis, resource availability, etc.

build and test, (4) product optimization, and (5) commercialization. Workshop participants identified research needs to be addressed at each stage. Needs were summarized and discussed by the panelists on Day 2.

Day 1 Participant Questions

Research needs identified for each product development stage could be categorized into four general categories: manufacturing issues, environmental issues, consumer use issues, and regulatory issues. Gaps identified for the Stage 1 idea build were tools and protocols needed to characterize nanoparticle hazards, identification of the product's total life cycle environmental impact, anticipation of consumer risks and benefits, and identification of an appropriate regulatory framework. Stage 2 research needs focused on worker safety, analytical methods, risk assessment, product use and disposal, and waste management. Stage 3 research needs centered on toxicity testing, product stewardship, fate and effects modeling, anticipated consumer use and misuse, and regulatory interventions. The Stage 4 research needs identified were similar to Stage 3 with a continued focus on product stewardship and confirmation the product is indeed safe. Stage 5 research needs identified specific areas of data collection while the product is in manufacturing production and commerce. In particular,

participants were concerned about how regulators could track product performance and about life cycle issues.

Day 2 Panel Discussion

The invited panelists were recognized experts in research, consumer protection, product development and manufacturing, and legal and policy development. The discussants addressed each of the research needs identified by participants. The general themes were the need to

- Understand hazards presented by the nanoparticles under consideration for the new product and those that actually were incorporated into the product
- Develop reliable test methods for exposure monitoring and hazard characterization
- Develop methods for characterization of total life cycle impact

The discussants also addressed the need to engage small start-up companies, insurance companies, and regulators early in the product development process.

Findings

Companies large and small should begin the development of each new product with a focus on product stewardship and on gaining an understanding of the product's potential hazards early enough in the development process to design hazards out and safety in. Gaps noted were the reliability of current test methods, an unclear regulatory environment, life cycle assessments not being performed for all new products, and the need for a methodology to address RMM and ELSI questions.

Appendix A. Workshop Agenda

Day 1, Tuesday February 24, 2009, CPSC, Bethesda, MD

PROMENADE

7:30 a.m. Registration and continental breakfast

ROSSLYN BALLROOM

8:30 Welcome

Clayton Teague, National Nanotechnology Coordination Office

8:50 Workshop Scope and Goals & Charge to Participants

Jeff Morris, EPA

Carlos Peña, FDA

9:30 Two Risk Management Methods (RMM) Perspectives: Where we are? Where do we need to go?

Introduction–Igor Linkov, U.S. Army Engineer Research and Development Center

Gary Marchant, Arizona State University

Greg Lowry, Carnegie Mellon University

10:30 Break

10:45 Two Ethical, Legal, and Societal (ELSI) Perspectives: What is ELSI? How does ELSI apply to nanotechnology?

Introduction–Mark S. Frankel, AAAS

Pilar Ossorio, University of Wisconsin Law School

Barbara Herr Harthorn, University of California, Santa Barbara

11:45 Case Scenario: Breakout Discussions at Tables

Introduction–Amy Jones, Lockheed Martin

Discussion at tables among members

Facilitators

Mark S. Frankel, AAAS

Michael Hansen, Consumers Union

Igor Linkov, U.S. Army Engineer Research and Development Center

Jeff Morris, EPA

Carlos Peña, FDA

Dietram Scheufele, University of Wisconsin–Madison

12:30 Lunch (on your own - see packet for nearby eateries)

Please see Registration table for location of your breakout session

1:45 Concurrent Breakout Sessions

Session 1. Nanotechnology: Risk Management and the Workplace

Frank Mirer, Hunter College, and Charles Geraci, NIOSH

Subject matter experts: Christopher Bell, Sidley Austin, Robert Blaunstein, Nanotech Risk Management and Jeff Steevens, DOD

Session 2. Nanotechnology: Risk Management and Product/Material Lifecycle

Tom Seager, Rochester Institute of Technology, and Igor Linkov, U.S. Army Engineer Research and Development Center

Subject matter experts: Jackie Isaacs, Northeastern U., and George Kimbrell, ICTA

Session 3. Nanotechnology: Risk Characterization Information

Michael Hansen, Consumers Union, and Robert Bronaugh, FDA

Subject matter experts: Vince Castranova, NIOSH, Carlos Peña, FDA, and Stacey Harper, ONAMI

Session 4. Ethical, Legal, and Societal Implications: What are attitudes about nanotechnology and how are they formed?

Elizabeth Corley, Arizona State University, and Sally Tinkle, NIH/NIEHS

Subject matter expert: Jennifer Kuzma, University of Minnesota

Session 5. Nanotechnology: ELSI and RMM Communications

Dietram Scheufele, University of Wisconsin–Madison, and Matthew Nisbet, American University

Subject matter expert: Amy Wolfe, Oak Ridge National Lab

Session 6. Specific ELSI of Nanotechnology Issues

Mark S. Frankel, AAAS, and Pilar Ossorio, University of Wisconsin–Madison

Subject matter experts: Christopher Bosso, Northeastern University, Pat Casano, GE, Alta Charo, FDA, and John Stone, Michigan State University

3:45 Break

ROSSLYN BALLROOM

4:00 White House Perspective

Tom Kalil, White House Office of Science & Technology Policy

5:00 Closing Remarks

Jeff Morris, EPA

Wednesday, March 31, 2010

PROMENADE

7:30 a.m. Registration and continental breakfast

ROSSLYN BALLROOM

8:00 Welcome Back

Carlos Peña, FDA

8:15 Report Out from Tuesday's Breakout Sessions

Introduction–Robert Bronaugh, FDA

Frank Mirer, Tom Seager, Michael Hansen, Elizabeth Corley, Dietram Scheufele,

Mark S. Frankel

9:15 Case Scenario: Bringing Risk Management and ELSI Together

Introduction–Amy Jones, Lockheed Martin

Panel

Steve Brown, Intel

Carolyn Cairns, Consumers Union

John Monica, Porter, Wright, Arthur & Morris

Thomas Seager, Rochester Institute of Technology

10:00 Break

10:15 Risk Management and ELSI Information Needs

Breakout Discussions at Tables

Introduction–Michael Hansen

- How would you address the case scenario?
- What information do you need to address the case scenario?
- Are there gaps? What recommendations would you make about information needs?
- Where do Risk Management and ELSI intersect?

11:15 Breakout Reports from Audience

Key Themes from Case Scenario and Intersections Between Risk Management and ELSI

Moderator–Michael Hansen

(A volunteer from each table to present no more than 5 minutes of remarks summarizing the table's discussion.)

11:45 Public Comments

Moderator–William Kojola, AFL-CIO

12:00 Working Luncheon

Presentations on outcomes from previous nanoEHS workshops:

Introduction–Sally Tinkle, NIH/NIEHS

Human and Environmental Exposure Assessment

Charles Geraci, NIOSH, planning team member

Nanomaterials and the Environment & Instrumentation, Metrology, and Analytical Methods

Rebecca Klaper, Great Lakes WATER Institute, planning team member

Nanomaterials and Human Health & Instrumentation, Metrology, and Analytical Methods

Charles Gause, Luna Innovations, planning team member

1:30 Challenges for Nanotechnology and Nanomaterials

- How can we make sure the NNI Environmental Health and Safety (EHS) Research Strategy communicates the status and research needs for effective Risk Management Methods to all stakeholders (e.g., public, Federal Government, regulated industry, academia)?
- How can we ensure ELSI considerations are included in the next generation of the EHS Research Strategy?
- What additional information should the Federal Government take into consideration when it updates its EHS Research Strategy?

Moderator–Dietram Scheufele

Risk Management Methods

Frank Mirer, Thomas Seager, Michael Hansen

Ethical, Legal, and Societal Implications of Nanotechnology

Elizabeth Corley, Dietram Scheufele, Mark S. Frankel

2:30 Grand Challenges for nanoEHS Research Panel

Moderators–Charles Geraci, NIOSH and Treye Thomas, CPSC, Co-chair, Nanotechnology

Environmental and Health Implications (NEHI) Working Group

Panel/Presentations (20 minutes)

Open Discussion (40 minutes) for all workshop participants

(Please use the microphones provided for making your remarks.)

3:30 Next Steps & Final Thoughts

Jeff Morris, EPA

Carlos Peña, FDA

Appendix B. Workshop Participants¹

Linda Abbott, USDA	Betty Bugusu, Institute of Food Technologists	John Cowie, AF&PA Agenda 2020 Technology Alliance
Norris Alderson		
David Andrews, Environmental Working Group	Kristin Bunker , RJ Lee Group, Inc.	Jeffrey Davis, Branch Health Clinic WNY
Charles Axten, Health Risk Solutions, LLC	Carolyn Cairns, Consumers Union	Jeffrey DePriest, Defense Threat Reduction Agency
Moslem Bahadori	Joe Carrier, Johns Hopkins University APL	Kapal Dewan, FDA
Tina Bahadori, American Chemistry Council	Chris Carroll, U.S. Army Public Health Command	Timothy Dole, EPA Office of Pesticide Programs
Mark Banash, Nanocomp Technologies	Janet Carter, OSHA	Travis Earles, OSTP
Jeffrey Barach, GMA	Ricardo Carvajal, Hyman, Phelps & McNamara, P.C.	Cynthia Ekstein, NSF
Timothy Barnett, SAIC	Patricia Kablach Casano, GE - Corporate Environmental Programs	Michael Ellenbecker, University of Massachusetts Lowell
Brenda Barry, American Chemistry Council	David Castner, University of Washington	Claude Emond , University of Montreal
John Bashaw, Day Pitney LLP	Vince Castranova, NIOSH	Garnet Erdakos, EPA
Chris Bell, Sidley Austin LLP	Gary Casuccio, RJ Lee Group, Inc.	Heather Evans, OSTP
Rosalyn Berne, University of Virginia	Alta Charo, FDA	Dorothy Farrel , NIH/NCI
David Berube, PCAST/NCSU	Samar Chatterjee, EPA/NOWCC	Mark S. Frankel, AAAS
Zbigniew Binienda, FDA/NCTR	Mitchell Cheeseman, FDA	Lisa Friedersdorf, nanoSTAR Institute, UVA
Robert Blaunstein, Nanotech Risk Management	Hongda Chen, USDA/NIFA	Pamela Fruechting
Esther Bleicher, FDA/HHS	Matthew Cho, Navy and Marine Corps Public Health Center	Jason Gallo, STPI
Fred Blosser, NIOSH	Shaun Clancy, Evonik Degussa Corporation	George Gamota, ITRI, Inc.
Christopher Bosso, Northeastern U	Lisa Corey, Intertox	Sumit Gangwal, EPA
Michael Boyles, DOC/Int'l Trade Admin	Elizabeth Corley, Arizona State University	John Gannon, DuPont
Robert Bronaugh, FDA	Charles Cottrell, North American Insulation Manufacturers Association	Charles Gause, Luna Innovations Incorporated
Steve Brown, Intel		Pat Gehrke, University of South Carolina
		Charles Geraci, NIOSH
		Sarah Gerould, USGS

¹ Affiliations are as of the date of the workshop.

Hilary Godwin, UCLA School of Public Health	Tom Kalil, OSTP	Nicholas Molen, Institute for Food and Agricultural Standards, Michigan State University
Jeffrey Grabill	Barbara Karn, EPA	John Monica, Porter Wright Morris & Arthur
Guillaume Gruere	George Kimbrell, ICTA	Jeff Morris, EPA
Nanda Gudderra, IBC Paradigm	Frederick Klaessig, Pennsylvania Bio Nano Systems, LLC	Mary Myers, NNCO
Bill Gullede, American Chemistry Council	Rebecca Klaper, UW-Milwaukee Great Lakes WATER Institute	Ritu Nalubola, FDA
Maureen Gwinn, EPA	Todd Kuiken, Woodrow Wilson International Center for Scholars	Clare Narrod, International Food Policy Research Institute
John Hadley, Owens Corning	Kristen Kulinowski, Rice University/ICON	Madeleine Nawar, EPA
Kate Hall, CropLife America	Jennifer Kuzma, University of Minnesota	Van Nguyen, DOE, Office of Science
Bill Hannah	Anjali Lamba, EPA	Matt Nisbet, American University
Jaydee Hanson, International Center for Technology Assessment	Igor Linkov, U.S. Army Engineer Research and Development Center	Janet Normandy, DOE
Stacey Harper, Oregon State University - ONAMI	Laurie Locascio, NIST	Thad Nosal, Insurance Services Online
Erin Heath, AAAS	David Loomis, Chubb Group of Insurance Companies	Pilar Ossorio, University of Wisconsin–Madison
Liesl Heeter, NNCO	Greg Lowry, Carnegie Mellon University	Martha Otto, EPA
Jon Hellerstein, CIH, CSP, MWV	Neil MacDonald, Federal Technology Watch	Halyna Paikoush, NNCO
Lori Henderson, NIH	Kosta Makrodimitris, FDA	Carlos Peña, FDA
Barbara Herr Harthorn, Center for Nanotechnology in Society, UCSB	Timothy Malloy, UCLA School of Law	Diana Petreski, NNCO
Robert Hershey, Robert L. Hershey, P.E.	Gary Marchant, Arizona State University	Martin Philbert, University of Michigan
Geoff Holdridge, NNCO	Daniel Marsick, DOE	Mark Philbrick, University of California, Berkeley
Mark Hoover, NIOSH	Brian Mayes, General Electric Global Research Center	Joseph Pickel, Center for Nanophase Materials Science
Nina Horne, University of California-Berkeley	Heather Meeks, DTRA	Rick Pleus, INTERTOX, Inc.
Jackie Isaacs, Northeastern University	Nancy Miller, Office of the Director, NIH	Bill Pritchard, BNA, Inc.
Joany Jackman, JHU APL	Franklin Mirer, Hunter College Dept of Urban Public Health	Mihail Roco, NSF
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Pat Johnson, Johnson Edits		Kristin Roy, NNCO
Amy Jones, Lockheed Martin		Nora Savage, EPA
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Dietram Scheufele, University of Wisconsin–Madison	Bruce Stockmeier, Center for Nanoscale Materials at Argonne National Laboratory	Thomas Umbreit, FDA
Paul Schulte, NIOSH	John Stone, Michigan State University	Louise Vallee, Chubb and Son, Inc.
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Molly Schwartz, STPI	Mellisa Theodore, Johns Hopkins University APL	Ken Vest, NNCO
Thomas Seager, Rochester Institute of Technology	Treye Thomas, CPSC	William Waissmann, Oswaldo Cruz Foundation
Robert Shelton, WTEC	Scott Thurmond, FDA	Greg Weatherman, The Solver Group
Jerry Smith, Intellegere Foundation	Sally Tinkle, NIH/NIEHS	Ronald White, JHU Risk Sciences and Public Policy Institute
Jeffery Steevens, U.S. Army ERDC	David Tobias, AAAS	Brenda Yamen, OSHA
		Felix Yeung, Beveridge & Diamond, P.C.

Appendix C. Detailed Breakout Session Reports

Session 1. Nanotechnology Risk Management and the Workplace

Frank Mirer (Hunter College) and Chuck Geraci (NIOSH)

Framing the Session

The session consisted of four brief presentations by subject matter experts, a period of discussion by workshop participants in three groups to discuss the questions listed in the “Research Needs” section below, and then a report back to the full workshop by a representative from each table. Among participants, it appeared that few were directly involved in the manufacture of nanomaterials. More represented were researchers and government agency employees.

A common theme of the subject matter experts was the need for some immediate guidance on protective measures for workers and researchers exposed to nanomaterials.

Research Needs

RMM 1—Understand and develop best workplace practices, processes, and environmental exposure controls

- Evaluate risk management approaches
- Evaluate risk reduction opportunities
- Understand the efficacies of personal protective equipment
- Process design and engineering control systems to reduce exposure

RMM 4—Develop nanomaterial-use and safety-incident trend information to help focus risk management efforts

- Flow in economy and uses
- Safety incident trends

Additional workshop questions

1. What are the advantages and disadvantages of the historical occupational approach, which is compliance with a permissible exposure limit (PEL) by engineering and process controls?

2. What are the advantages and disadvantages of a generic workplace control technology approach such as control banding?
3. What are advantages and disadvantages of the historical environmental permitting approach, which are reasonably, best or lowest achievable control technology, driven by a reference dose or concentration?
4. Is there a method to verify effectiveness of occupational or environmental controls other than a measurement of exposure compared to an exposure limit?
5. What information should be sufficient to set occupational and environmental exposure limits for common (e.g., carbon nanotubes, nano titanium dioxide, nanosilver) and uncommon nanomaterials?

State of the Science

The first speaker was Jeff Steevens (DOD/U.S. Army). His assignment was to laboratories working with military-relevant nanomaterials over 3-4 years. When these laboratories first started testing toxicity, there were questions about protection for the testers, safe handling, disposal, etc. On inquiry, lots of other laboratories indicated nanomaterials were handled as “nuisance dust” in the absence of an exposure limit. Dr. Steevens noted that he applied the “as low as reasonably achievable” (ALARA) principle. The assumption was that laboratory workers would be safer if they tried to keep the nanomaterials in solutions, solvents, and work under the hood. He started with a few nanomaterials, eventually reaching over 20 permutations. As a result, his laboratory developed a (U.S. Army) protocol, convinced that existing guidance was insufficient. Now his laboratory offers the U.S. Army protocol to others, and has developed an “almost” memo of understanding—a framework. It is getting some visibility from the armed services that are considering doing exposure assessment in their laboratories using the framework. Dr. Steevens summarized: we haven’t come far and we need to push hard; people are being exposed. On research and manufacturing, there is too much

complacency and an inadequate level of responsibility. We need to be creative regarding the solutions to address exposure challenges, and to set limits and controls.

Dr. Robert Blaunstein is a physicist working for the insurance industry. His particular focus is on environmental liability. He is concerned about nanotechnology and insurance implications for general liability, product liability, workers compensation, environmental liability, and professional liability. Are companies going to continue to offer coverage, or will they apply exclusions? Nanotechnology doesn't show up on any policy now, but it is being considered. Nanotechnology is a business, and the insurance business sells risk. The insurance industry loves regulation; it sets expectations. Industry wants to push some kind of governance, especially in the workplace—for example, monitoring A, B, and C, and mandating protective clothing and procedures to protect workers and the environment as much as possible. There is a need to get best practices into wider use, including in small companies.

Christopher Bell is an environmental lawyer working on the defense and management side of the issue. He is making progress now in the International Organization for Standardization (ISO) process of writing standards on nanotechnology issues. These issues are being wrestled with at the international level; there is an inherent problem with producing useful documents in the absence of data. It is important to have a good, prioritized plan; however, we need to get started now, as exposure is already happening. There may need to be some leaps of faith to keep efforts going—the alternative is to stop, which will not happen, as the unfolding promise of nanotechnology is already being realized.

Overarching Themes

Many participants echoed the subject matter experts on the need for guidance now on protective measures. An academic materials scientist stated that she had graduate students working with these materials now and needed some idea of whether protective measures such as fume hoods were working.

Another theme was that exposure limits or reference concentrations are the most familiar way to address hazards of exposures or evaluate control measures. But

there is no agreement on the level or what to measure and how to measure it.

Exposure limits may have to be developed by “binning” materials, hopefully by using mechanism-of-action. However, exposure limits are more applicable to manufacturing environments, in which a few materials are used at same workstations every day. Permissible exposure limits (PELs) are less applicable to research environments with multiple materials.

There was a general agreement that traditional industrial hygiene controls will work to control exposures once a target is established.

Control banding has a precedent in the pharmaceutical industry; this approach specifies controls based on hazard potential and physical characteristics of materials. Biosafety levels are equivalent to control banding.

The disadvantage of control banding in the nanotechnology arena is that we need information on the how much control this provides. For example, what is the exposure to an individual in a fume hood who is weighing materials manually? In order to gauge that, we need to know what to measure and how to measure it.

There was discussion of applying the precautionary principle—applying controls in the absence of an organized risk assessment. In the environmental arena, facilities are permitted based on requiring Reasonably Available Control Technology (RACT), Best Available Control Technology (BACT), and Lowest Achievable Emission Rate (LAER), without reference to specific risks of exposure. An individual site may permit the ratcheting of control upward. Perhaps that is applicable to the manufacture and use of nanomaterials and products?

One participant raised the issue of source environmental release; for example, what happens to materials after they pass through fume hoods and exhaust to the roof? But there was no discussion of this issue with regard to manufacturing facilities.

Participants discussed the need for a database of controls and levels of exposure using controls. That data, thus far, is not forthcoming, despite calls for the information. This indicates a need for a continuing effort in this area.

On the question of whether data exist to set permissible exposure limits (PELs) for key nanomaterials, it was noted that NIOSH has proposed a recommended exposure level (REL) for nano titanium dioxide of 200 $\mu\text{g}/\text{M}^3$ compared to a nuisance dust level of 5000 $\mu\text{g}/\text{M}^3$. This possibly could be done for some carbon nanotubes by using particle surface area converted back to a mass limit that can be measured with conventional equipment. Perhaps diesel particulate matter—a collection of combustion derived nanoparticles—could be an anchor for human health effects. But there is no PEL for diesel, and only a suggested reference concentration (5 $\mu\text{g}/\text{M}^3$) in EPA’s IRIS database, <http://www.epa.gov/iris/subst/0642.htm>.

Gaps and Barriers

Coming back to risk management approaches, in the nearmiddleterm, for most situations industry will face, we are operating absent direct observations of human health effects. Some have argued that there are enough data to draw strong inferences. So what can be done? Governance methods, even regulatory methods, process safety management, and certain kinds of materials and quantities, need to go through certain types of steps to create a soft governance model that still has some teeth. Among the challenges noted on the risk management side: What do we tell the public today with regard to doing a reasonably adequate job of managing risks? At the same time, we need a huge push on the research side—despite the inherently long timeline—with communication between the two sides to document the kinds of data and metrics needed.

Session 2. Risk Management and Product/Material Lifecycle

Igor Linkov (U.S. Army Engineer Research and Development Center) and Thomas Seager (Rochester Institute of Technology)

Framing the Session

In today’s society, emerging threats such as nanomaterials present a serious challenge to traditional models of risk assessment and risk management. The high degree of variability and

uncertainty with respect to novel engineering materials and threats greatly expands data needs with regard to dose–response relationships, environmental fate and transport, source terms, and life-cycle environmental consequences. Even massive expansions of risk or life cycle assessment efforts are unlikely to keep pace with rapid technological and social change. Therefore, it is essential to create and maintain a framework for interpreting available information along with a strategy for prioritizing research efforts to reduce critically challenging uncertainties.

Breakout session 2 focused on the development of risk assessment and risk management methods along with the tools that could be used to assess life cycle risks and benefits, which help in making decisions. The priority identified in the 2008 NNI EHS Research Strategy served as the starting point for our discussions. Ultimately, the three analytic approaches discussed were (1) risk assessment, (2) life cycle assessment, and (3) multicriteria decision analysis (MCDA). These approaches were discussed as an integrative framework for synthesizing both objective scientific information and subjective values-driven goals relevant in decision and policy contexts.

Research Needs

The group recommended a rewording of the 2008 research need bullet, from “examine product of material lifecycle to inform risk reduction decisions” to “integrate lifecycle analysis into the risk management decision process,” with the following sub-bullets:

- Establish nano-specific taxonomy for life cycle stages
- New methods development (i.e., MCDA, life cycle assessment)
- Develop case studies, for example: green chemistry, nanomaterials selection, nanomaterials acquisition process
- Adaptive management tools based on monitoring/implementation (i.e., evaluate how well life cycle analysis is working; feedback loop)

In addition, the following research needs were identified:

- Implement comparative risk assessment strategies as opposed to absolute risk assessment strategies
- Use methods, such as MCDA and life cycle analysis, for a gap analysis to prioritize the needs for research and focus in the areas of highest uncertainty through a value-of-information analysis

State of the Science

Uncertainty in life cycle assessment of nanomaterials: towards a decision-driven approach (Tom Seager)

When considering the life cycle of a product, there are a number of considerations to be made throughout the material's lifetime. Proper attention also needs to be paid to the energy and material inputs required to produce the new nanomaterial, along with their respective environmental profiles.

Stage in Life Cycle	Nanotechnology-Specific Points for Consideration
Raw Material Production	Careful characterization of materials is needed, including purity, aspect ratio, and agglomeration
Consumer Product Manufacturing	Upstream non-nanoscale sources may actually have the most important impacts in manufacturing
Consumer Use	Work backwards from a specific functional unit
End of Life	The quantity of nanomaterials to enter the environment may be exceedingly small on a mass basis
Human Population and Ecological Exposure	Appropriate equivalencies for characterization factors may not yet exist. An understanding of impact assessment is needed to prioritize knowledge gaps

In March 2007, the Woodrow Wilson International Center for Scholars convened a workshop on “Nanotechnology and Life Cycle Assessment: A Systems Approach to Nanotechnology and the Environment.” The resulting report from this workshop concluded that standard life cycle assessment is generally suitable for nanotechnology as a structured approach having a well-developed methodology.⁽¹⁾ However, this is only suitable if all of the required information is available. The existing data relating to human health and environmental impact needs to be organized and aggregated to identify what information is missing.

Another concern is that the standard life cycle assessment approach normalizes different criteria based on their relative importance. This normalization process is value-laden and potentially problematic. In cases with new nanomaterials, the input values for a full life cycle assessment have a high degree of uncertainty. An understanding of the context in which new nanomaterials are likely to be used is necessary in order to prioritize life cycle assessment input parameters.

Conducting a full traditional risk assessment (i.e., see the 1983 National Academies publication *Risk Assessment in the Federal Government: Managing the Process*[2]) is a very detailed and expensive process. Therefore, the characterization of risk should be a decision-driven activity and should be focused on the problems that are most important to our society. This concern is demonstrated in the 2009 National Academies publication *Science and Decisions: Advancing Risk Assessment* (2). According to a National Academies review⁽³⁾ of the 2008 NNI *Strategy for Nanotechnology-Related Environmental, Health, and Safety Research*,² the research being done in this area is not adequate to foster informative decision-making.

Example: Carbon nanotube (CNT) paper

There are many sources of potential risk along the manufacturing chain of CNT paper. These include the production of waste gas during synthesis and the release of waste acid along with dissolved metals during purification steps. It is important to also consider the resources required to make

1 http://www.nanotechproject.org/file_download/168

2 Available at www.nano.gov.

new materials. For example, a comparison of the manufacturing process for five different materials found that electrical energy requirements for the manufacture of nanotubes are substantially higher than values for steel, aluminum, polysilicon material, and wafer silicon.(1) This study also showed that nanomaterials have a higher uncertainty in toxicity and risk compared to the other bulk materials.

Data requirements for a life cycle analysis can be minimized by using a comparative approach along with a weighted impact assessment. As another example, the different required data and impact criteria for an electric car using CNT nanotechnology-enabled lithium ion batteries are stated below. Comparing different Li-ion batteries for the same use does not necessarily require a full assessment of the entire car, because in many areas the values would be the same, but just an assessment of a few targeted areas that would yield differing results (i.e., the method of CNT manufacture). A combined approach to understanding the risk of nanomaterials brings together life cycle assessment and risk analysis. The criteria for making a decision and their relative weights will always need to be determined. In the case of nanomaterials, in which not all parameters are known, new tools are being developed that model the desired data points as a probability distribution. (1) This research then uses a Monte Carlo analysis to identify favored alternatives and may help to reduce uncertainty of input parameters for risk and life cycle analyses.

Integrating life cycle assessment, risk assessment and decision analysis for nanomaterials (Igor Linkov)

Today the rapid emergence of nanotechnology-enabled products is far ahead of the generation of relevant EHS data, where data used by regulatory agencies is a small subset of all EHS data. There is a clear information gap that requires innovative risk management. One new approach links risk assessment, life cycle analysis, and multicriteria decision analysis (MCDA). This method was used to compare four different manufacturing processes for SWCNTs (2, 3). In this work, an MCDA combined four criteria: energy and material efficiency at the manufacturing stage, life cycle score, health risks, and

cost. Ideally, a link between life cycle data from the MCDA should be linked to risk assessment data.

The goal of traditional risk assessment is to link exposure to health. The determination of adverse health effects are often based on limited and imprecise data with large uncertainties regarding toxicological effects in animals and epidemiological studies in humans. Benchmarks to help determine “acceptable risk” are often implemented, but these benchmarks do not exist for nanotechnology. However, some of these issues can be addressed by linking risk assessment with MCDA in an adaptive process.

One new approach involves the integration of quantitative measurements with expert judgment. A risk assessment looking at five different nanomaterials was compiled by using five risk categories ranging from very low (highly preferred) to extreme risk. Using available data and expert judgment, a value could be attributed to each of the nanomaterials to help highlight the comparatively safest materials.

A preference analysis is an important component in the assessment of risk, and different stakeholders are likely to weight criteria differently. In this instance, preference values from four stakeholder groups (manufacturer, end user, environmentalist, and regulator) can be used to highlight differences.

Several components are critical to decision making with regard to the safety of nanomaterials.

- People: Policy decision makers and stakeholders are important at the beginning and end of the analysis. Scientists and engineers help provide the needed information to make final decisions.
- Process: After defining a problem, alternatives need to be generated. Criteria for comparison of alternatives need to be identified and balanced with value judgments about their relative importance. After eliminating inferior alternatives, performance of the residual criteria needs to be determined so that a final ranking can be generated.
- Tools: Decision analysis is critical at the beginning and end of the decision process. Environmental assessment and modeling tools are important for determining performance.

There are clear benefits to advancing the use of new risk and decision analysis methods. These benefits would help explore the trade-offs among diverse objectives. New approaches would provide a quantitative framework to implement adaptive management, which is especially critical for the rapidly advancing field of nanotechnology. However, there are considerable issues in using these new approaches. A significant level of effort is required to accomplish effective deliberation required by a proper decision analysis. Equity in preference elicitation is very important and likely to affect results.

If these new approaches are explored and refined, the lack of nanotechnology-related risk assessment data should not stifle the future of nanomaterials and nanotechnology-enabled products. The decision analysis described here is still being developed but shows promising results. Furthermore, decision analysis has already been used in resolving community issues such as the case of sediment management problem in a New Hampshire estuary. In this case, decision analysis helped to identify a common, favored decision between disparate stakeholder groups and helped to bring the conflict to resolution.

Group Discussion

Life cycle thinking and implementation

Different from the formalized term “life cycle analysis,” life cycle thinking can help select technologies to meet needs. Choosing the “right” technology is ultimately a value choice. Further, there may be alternatives to some nanotechnologies that are not nanotechnology-based which should also be explored. Despite its use, life cycle analysis needs to be streamlined toward technologies and products that are most relevant, as the analysis is too data-intensive to conduct in every case. Life cycle implementation needs to be coordinated, because individual agency missions are fragmented. Increasingly, life cycle considerations are creeping into the purview of other agencies as awareness about post-use environmental and health considerations evolves (e.g., therapeutics flushing into the water supply after clearance from the human body raises issues for FDA as well as EPA).

Manufacturing environmentally benign materials

Generally speaking, using some level of precaution at the design stage of developing a new nanotechnology or nanotechnology-based product is a good idea. There are three material characteristics that historically have been associated with adverse environmental (toxic or abiotic) impacts:

1. **Persistence.** Long-lived materials are typically more problematic than short-lived.
2. **Mixing.** Highly mobile materials are typically more problematic than those that remain in place.
3. **Rarity.** Entirely novel anthropogenic materials (e.g., halogenated hydrocarbons) are typically problematic in comparison to those materials that occur naturally and for which natural attenuation, metabolic, or bio-geochemical cycling processes already exist.

Steering nanotechnology development and regulation towards materials that minimize these three qualities may prove advantageous. Nevertheless, there are hurdles to overcome when trying to encourage manufacturers to use environmentally benign materials. First, the science (including measurement and metrology tools) and toxicology of nanomaterials is not yet fully able to identify benign materials. Second, a number of issues also factor into the manufacturer’s decision inputs. Some of these include market forces, customer values, money for R&D, certification, liability, and the organization and priorities of the company overall.

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5. I. Linkov and T. P. Seager, Coupling multicriteria decision analysis and life cycle assessment for nanomaterials. *Journal of Industrial Ecology* **12**(3):282–285 (2008). doi: [10.1111/j.1530-9290.2008.00048.x](https://doi.org/10.1111/j.1530-9290.2008.00048.x).

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Session 3. Nanotechnology: Risk Characterization Information

Michael Hansen (Consumers Union) and Robert Bronaugh (FDA)

Framing the Session

Breakout session 3 focused on the development of risk characterization information that could be used to classify nanomaterials based on their physical or chemical properties. The priority identified in the 2008 NNI EHS Research Strategy served as the starting point for our discussions. The original risk management methods suggested that identification of nanomaterial (1) flammability/reactivity and (2) hazard information for risk management were sufficient to characterize risk. The breakout session started with presentations by Dr. Vincent Castranova (NIOSH) and Dr. Stacey Harper (Oregon State University and Oregon Nanoscience and Microtechnologies Institute)

After the two presentations, two groups were formed to discuss the research need and five additional questions. The original risk management methods priority identified in the 2008 NNI EHS Research Strategy suggested that identification of nanomaterial (1) flammability/reactivity and (2) hazard information for risk management were sufficient to characterize risk. Both groups agreed that these two characteristics were not sufficient to characterize nanoparticle risk.

Research Needs

Develop risk characterization information to determine and classify nanomaterials based on physical or chemical properties:

- Flammability/reactivity
- Hazard information for risk management

Additional questions

- Are the present toxicological tests/endpoints traditionally used to evaluate new chemicals sufficient to evaluate the toxicity of nanomaterials, or should new tests/endpoints (such as impact on gene expression or generation of reactive oxygen species generation, etc.) be considered? If so, what toxicological tests/endpoints should be required?
- Can you predict the toxicity of nanoparticles based on their physico-chemical properties? If the answer is “No,” what kind of information would be needed to predict toxicity? What types of physico-chemical characteristics will be needed to predict toxicity? Are size (surface area, size distribution), chemical composition (purity crystallinity, electronic properties, etc.), surface structure (surface reactivity, surface groups, inorganic/organic coatings, etc.), solubility, shape, and aggregation sufficient, or are other physico-chemical characteristics needed?
- Is there a strategy for extrapolating short-term laboratory studies of biological effects of novel materials to those points of departure?
- Are there human health data for exposure to nanometer-sized particles (for example, diesel particulate matter) that could serve as a point of departure for extrapolating potency?
- Are there chronic bioassay data that could serve as a point of departure for extrapolating potency?

State of the Science

Developing Risk Characterization Information to Determine and Classify Nanomaterials Based on Physico-chemical Properties (Vince Castranova)

“Developing Risk Characterization Information to Determine and Classify Nanomaterials Based on Physico-chemical Properties” focused mainly on

NIOSH testing involving inhalation of nanoparticles. He began by noting that the 2008 NNI EHS Research Strategy lists three research priorities for nanomaterials and human health: (1) Develop and validate methods to quantify dose-response and structure-activity relationships, (2) translate *in vitro* tests results to *in vivo* responses, and (3) extrapolate data to human exposures.

The challenges facing scientists in nanotoxicology include: (1) the need to obtain nanoparticle structure sizes in test systems which are relevant to those found in human exposure, especially workplace environments; (2) the need to develop predictive *in vitro* tests; and (3) relating animal model dose-response to anticipated human exposures.

Data from the NIOSH lab indicate that the degree of pulmonary inflammation measured 24 hours after intratracheal instillation of nano-sized carbon black in rats depends directly upon the degree of dispersion in the nanoparticle test suspension; the greater the dispersion, the higher the activity. Therefore, it is essential that test suspensions of nanoparticles contain structure sizes relevant to those measured in workplace air. A useful dispersion medium must be (1) effective, (2) biocompatible, (3) not mask the reactive surface of the particles, and (4) produce relevant structures sizes. A dilute artificial alveolar lining fluid (phosphate-buffered saline, and 0.01 mg/ml disaturated phosphatidylcholine, and 0.6 mg/ml albumin) meets the first three criteria. In addition, structure sizes of MWCNT in this dispersion medium are similar to those reported in air samples from production labs for MWCNT. Therefore, NIOSH suggests that a dilute artificial alveolar lining fluid maybe a useful dispersion medium for nanotoxicology research studies.

Nel et al. suggested that oxidant generation and oxidative stress may be useful paradigms to evaluate the bioactivity of nanoparticles. NIOSH in collaboration with the University of Rochester has shown that cellular generation of reactive oxidant species after *in vitro* exposure to a set of eight different types of nanospheres correlated well ($R^2 = 0.95$) with *in vivo* pulmonary inflammatory potency 24 hours after intratracheal instillation in rats. However, *in vitro* oxidant generation was not predictive of the *in vivo* pulmonary fibrosis reported after aspiration of single-walled carbon nanotubes

(SWCNT) or MWCNT purified to remove catalytic metals. In contrast, Wang et al. (2010) has reported that *in vitro* fibrogenicity tests (induction of fibroblast proliferation and collagen production) were predictive of *in vivo* response. Therefore, one needs mechanistic information concerning *in vivo* bioactivity to develop the proper *in vitro* screening tests for each class of nanoparticles. In addition, most *in vitro* studies have used relatively high exposure concentrations. NIOSH suggests using *in vitro* doses (μg / surface area of cells in culture) relevant to those used for pulmonary exposures (μg / surface area of alveolar epithelial cells) in a given model species.

When relating animal model responses to anticipated human responses to nanoparticle inhalation, NIOSH suggests a similar strategy to test relevant exposure levels, i.e., express lung burden as μg / surface area of alveolar epithelial cells. Stone et al. (1992) reports alveolar surface areas of 102, 0.4, and 0.05 m^2 / lung for the human, rat, and mouse, respectively.

Another challenge in relating animal model pulmonary responses to those anticipated in humans is that nanoparticle exposures in animals are bolus instillation or aspiration exposures or short-term inhalation exposures, yet human responses are likely to result from long-term inhalation of low airborne levels of nanoparticles. Resolution of this issue requires further investigation. However, the NIOSH lab has evidence that a given lung burden of nanoparticles achieved by bolus exposure or inhaled over 2–12 days results in qualitatively similar pulmonary and cardiovascular responses.

The information above indicates that progress is being made to overcome challenges facing nanotoxicology. Therefore, achieving the objectives set forth in the 2008 NNI EHS Research Strategy is a reasonable goal for the next few years.

Dr. Castranova's presentation led to three questions. Does the coating of nanoparticles change their bioactivity? He replied that yes, the coating, along with size, shape, and functionalization, all impact bioactivity. When asked about direct effects of nanoparticles on the brain, Dr. Castranova replied that NIOSH design methods only look at broad effects on the nervous system, not specifically on the brain. Finally, when asked if particle size effects are due to transport properties or active surface, he replied that

research suggests that the effects are due to the active surface area of the nanoparticle.

Hazard Identification and Nanomaterial Risk Characterization (Stacey Harper)

Dr. Harper's talk addressed special consideration for nanomaterials in the context of hazard identification and dose-response and provided an overview of a path forward for nanomaterial risk characterization.

Dr. Harper noted that toxicological tests/endpoints traditionally used to evaluate new chemicals may be sufficient to cover new nanomaterials; however, these tests need to be evaluated and validated for appropriate use and limitations. The unique physico-chemical properties of nanomaterials could very well extend to produce unique interactions or interferences with standard assays; thus, test protocols may need to be adapted. In addition, characterization should be considered throughout the exposure duration, or at least during the beginning and end of the assay, in order to capture the dynamic nature of nanomaterials that can readily change under certain conditions.

Dr. Harper argued that although we could not currently predict the toxicity of nanoparticles based on their physico-chemical properties, this would be feasible in the future and is a laudable goal to work towards. Current limitations to such predictive toxicology include the following:

- The relative importance of nanomaterial physico-chemical properties is altogether unclear, as is how these properties change in different media
- The expense, labor intensity, and variability of current nanometrology is insufficient to measure nanomaterial features in a high-throughput manner
- The sheer diversity of nanomaterials is akin to a third dimension of the periodic table in which size and geometry influence properties
- The lack of complex nanomaterial descriptors limits our ability to group like materials

Dr. Harper proposed a path forward for the next iteration of nanomaterial risk characterization. Four concentration areas were identified as necessary to rapidly expand our knowledge of the underlying features that dictate nanomaterial-biological interactions: (1) leverage ongoing research, (2)

improve biological assessments, (3) improve characterization capacity, and (4) implement an informatics infrastructure that facilitates data sharing.

Starting with a common need to understand nanomaterial-biological interactions, the path forward would leverage research on both the applications and implications of nanomaterials by establishing, enhancing, and supporting interdisciplinary communities. In the nanoinformatics community, an informal consortium has emerged from the interactions and common goals of many nanotechnology working groups, government agencies, academic institutes, standards organizations, and industry.

Two questions arose: When asked whether computational toxicology was useful, Dr. Harper said that it was an important area to focus work on. When asked about the utility of structure-activity characterization, Dr. Harper replied that it is very important.

Group Discussion

1. Are the present toxicological tests/endpoints traditionally used to evaluate new chemicals sufficient to evaluate the toxicity of nanomaterials, or should new tests/endpoints be considered?

Both groups felt that present toxicology tests, such as the standard battery of tests for pesticides required by EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), are insufficient but represent a good starting point. Some believe that the field is heading in the right direction, mentioning work on mode of action (MOA), Comptox, etc. Depending on the type of nanoparticle, a battery of tests may be needed. Toxicological tests/endpoints traditionally used to evaluate new chemicals may be sufficient to cover new nanomaterials; however, these tests need to be evaluated and validated for appropriate use and limitations. The unique physico-chemical properties of nanomaterials could very well extend to produce unique interactions or interferences with standard assays, thus, test protocols may need to be adapted. An example was given of OECD testing methods for nanoparticles, which are tiered, starting with the bulk material

and requiring modifications as we go. In addition, characterization should be considered throughout the exposure duration, or at least during the beginning and end of the assay, in order to capture the dynamic nature of nanomaterials that can readily change under certain conditions.

There is a need for a battery of tests to be developed, with particular emphasis on a standard set of tests with standardized reference materials. Thus, one needs to standardize and/or clearly characterize the nanomaterials used in the test and also to standardize the details and the protocol of the test guidelines. As part of the standardization/characterization of the nanomaterial, detailed sample preparation guidelines need to be developed. Once both the reference materials and the set of tests have been standardized, these various tests should be carried out by various laboratories to give a baseline of knowledge about the reference materials and to get interlaboratory comparisons. Furthermore, there needs to be a repository for reporting both positive and negative results from the standardized test.

With regards to dose–response assessments, appropriate dose metrics were discussed at length. It is unclear which dose metric (e.g., mass of nanomaterial core, mass of the core plus ligands, the number of atoms, the number of nanoparticles, the number of ligands, or the surface area) is most appropriate and if the same dose metrics could be applied across different nanomaterial types.

2. Can the toxicity of nanoparticles be predicted based on their physico-chemical properties? If not, what kind of information would be needed to predict toxicity? If so, what types of physico-chemical characteristics will be needed to predict toxicity? Are size (i.e., surface area, size distribution), chemical composition (i.e., purity, crystallinity, electronic properties, etc.), surface structure (i.e., surface reactivity, surface groups, inorganic/organic coatings, etc.), solubility, shape, and aggregation sufficient, or are other physico-chemical characteristics needed?

Both groups agreed that toxicity of nanoparticles could not, at present, be predicted based on their physico-chemical properties. More data are needed on additional characteristics of the nanomaterial, but these should be decided by more interdisciplinary,

truly integrative teams of multiple specialties. ISO has a list of 8 or 9 characteristics that could have an impact on nanoparticle toxicity, while OECD has a list of up to 14. For specific nanomaterials we need to be cautious in limiting data to just a few characteristics. Indeed, for certain nanoparticles, only 1 or 2 of the characteristics might be important. We need to determine what these characteristics are for various nanomaterials, and not just test a full range of characteristics. Ideally, one should look at toxicity of a specific nanoparticle while changing just one characteristic at a time. There also needs to be harmonization of the biological and physical chemistry characterization. In addition, the issue of contaminants and additives needs to be considered, as they can affect toxicity. In sum, this work needs to capture the full complexity of nanoparticle molecules themselves, and that of mixtures of nanoparticles.

One group recommended a two-pronged approach be utilized to rapidly gain information on potential biological impacts from nanomaterials. Interlaboratory studies should be conducted in order to define assay variability and error for protocols that could further be developed as standards. The International Alliance on NanoEHS Harmonization (IANH) and ASTM International are both actively engaged in running such interlaboratory studies, but more efforts will be needed. A parallel complimentary approach is needed to establish rapid, high-throughput, accurate testing methods. Existing protocols typically used in chemical evaluation need to be tested/validated for use with nanomaterials, or new protocols need to be developed where necessary. In addition, new rapid, high-throughput biological assays need to be developed to address the many nanomaterial formulations that are, or will be, developed. Increasing the pool of viable assays will allow us to move toward a truly weight-of-the-evidence approach on which guidance and regulation can be based, and identify those platforms that are most predictive of biological impact. An iterative testing strategy (in which greener formulations are used as starting materials, are reformulated to improve performance and reduce toxic potential, and are retested to inform materials design) will further support the movement to a predictive environment in which material features can be altered to gain functionality in a predictable manner.

3. Is there a strategy for extrapolating short-term laboratory studies of biological effects of novel materials to those points of departure?

The groups decided that there was not a current strategy, but also noted that the question may be much broader than just the field of nanotechnology. The problem with the high-dose, short-term exposure times used in laboratory studies is the extent to which they can or cannot be used to predict the impact of low-dose, long-term exposure, which is the exposure scenario for most people. It is possible that nanoparticles could amplify the problem, but that is not clear. What is clear is a need to design tests using weight-of-evidence, mode of action, etc. These tests should be used on a case-by-case basis until we have enough information to go from case-by-case to general classes of nanoparticles.

4. Are there human health data for exposure to nano-sized particles (for example, diesel particulate matter) that could serve as a point of departure for extrapolating potency?

5. Are there chronic bioassay data that could serve as a point of departure for extrapolating potency?

Some human health data can be used for extrapolating potency, but more data are clearly needed. Such data may be used to devise experiments for nanomaterials. It may be possible to obtain nanoparticle risk characterization by interpolating between data on molecular (e.g., nanoscale) properties and on bulk properties, but it is not clear where this strategy will work. Thus, data on diesel particulate matter could be used to devise studies and then extrapolate for nanomaterials in these studies, but such extrapolation would need to be confirmed.

Session 4. Ethical, Legal, and Societal Implications (ELSI) of Nanotechnology: Attitudes about Nanotechnology and Their Formation

Elizabeth Corley (Arizona State University) and Sally Tinkle (NIEHS/NIH)

Framing the Session

The fourth breakout session for the NNI Capstone Workshop focused on ELSI issues and public attitudes

about nanotechnology. The title for the session was, “What are public attitudes about nanotechnology and how are they formed?” Elizabeth A. Corley (Arizona State University) and Sally Tinkle (National Institutes of Health) served as the co-chairs of the session, and Jennifer Kuzma (University of Minnesota) was the subject matter expert. The breakout session explored public attitudes about nanotechnology, as well as the importance of continuing to track these attitudes over time.

Over the past 10 years, NNI funding of ELSI issues has been relatively small compared to the funding allocated for nanotechnology research focused on fundamental phenomena, nanomaterials, nanoscale devices, instrument research, research facilities, and nanomanufacturing. Given the smaller scale of funding, the session participants concluded that it is particularly important for funding agencies and the NNI to think carefully about how to most effectively fund ELSI research in this area. The session focused on the importance of continuing to fund high-quality social science data collection that allows ELSI researchers to track changes over time, in public risk and benefit perceptions about nanotechnology, public trust in institutions that regulate nanotechnology, and public knowledge levels about nanotechnology. In addition, the session participants discussed the importance of collecting data that would allow researchers to compare public attitudes about nanotechnology with nanomaterials scientists’ and regulators’ perceptions about nanotechnology to identify areas where there are gaps and commonalities between these groups.

Overarching Themes

- Many of the participants in the session believed that the way the media reports on the benefits or risks of nanotechnology would have an impact on public perceptions.
- Participants believed that it would be important to continue to track public attitudes about nanotechnology and media effects on public attitudes over time.
- Participants concluded that when we consider ELSI issues for nanotechnology, many of these distinctions in product type and product benefits will be increasingly important for researchers to consider.

State of the Science

Risk analysis is evolving towards a more integrated process that involves input from not only technical experts, but also stakeholders and citizens. More engaged and iterative models have been suggested by not only scholars (1,2), but also prominent scientific societies (3,4) and government agencies (5). There is growing recognition that values underpin risk analysis and, ultimately, environmental health and safety studies. Therefore, separation of discussion of values and risk assessment is artificial (1, 2). Until recently, risk analysis has been a somewhat closed process. There are normative, process-based, and effectiveness reasons for including public input in risk analysis (6). Thus, risk analysis and EHS studies as an integral part of risk analysis should take into account a wider range of stakeholder and public opinion than is currently considered.

The impetus for incorporating values in EHS and risk assessment work has arguably never been greater. We are at a crucial point in history where technological revolutions (e.g., nanotechnology, biotechnology) are no longer “seeable,” “knowable,” or controlled by the end users. Technologies are also converging and do not fit neatly into risk analysis or regulatory boxes. Public attitudes about nanotechnology are diverse and form based on multiple combinations of factors—trust, products being considered, culture, risk/benefit distribution, and risk perception factors like abilities to know, choose, and control one’s exposure to technological products. Public knowledge can also be used to better assess and manage risks (3). Given this climate, we are at an opportune time to better unveil the current values underlying risk analysis and decision making about nanotechnology, and to consider, incorporate, and empower a broader range of values.

There are multiple ways to incorporate public input into decision making about EHS issues. The most rigorous are analytical-deliberative engagement processes, in which people exchange views, ponder, and come to a shared understanding of each other’s perspectives, although their positions may still vary. Ideally, these processes would feed directly into decision making. However, in the absence of the resources, funding, and political impetus to conduct these more involved approaches, public perception studies are important as indicators of public opinion

that can be used in EHS-based decision making. As such, this session focused on public attitudes towards risk and benefits of nanotechnology, designed not as a way to manipulate the public, but rather to incorporate a diversity of public viewpoints.

Public Perceptions and Attitudes about Nanotechnology

Previous studies have suggested that the U.S. public has generally positive attitudes about nanotechnology and that they perceive the benefits of the technology as outweighing the risks (7-9). This research has also shown that in the absence of scientific knowledge about a technology, the public relies on a variety of heuristics to form attitudes about the technology. For example, we know that the public uses some of the following heuristics to form attitudes about nanotechnology:

- Media Effects
- Social Trust in Governmental Institutions
- Risk and Benefit Perceptions
- Social, Economic, and Political Values

Research has shown that this is an accurate assessment but that the media influences tend to be more positive than negative for nanotechnology. For example, Scheufele and Lewenstein (5) found that the media influences public attitudes toward nanotechnology by “emphasizing positive frames” (p. 665). The general positive coverage of nanotechnology in the U.S. media (9), therefore, indicates that the more attention the public pays to science coverage in these outlets, the more positive their attitude is about nanotechnology (5).

Over the last decade, a series of nationwide surveys have been conducted to examine the public’s perceptions about the risks and benefits of nanotechnology. According to many of these studies, the U.S. public generally holds positive attitudes toward nanotechnology benefits though they also express concerns about some potential risks (5, 10–12). In fact, some studies have demonstrated that nanotechnology might be one of the first emerging technologies where scientists are more concerned about some risks than the public, particularly in the areas of environment and health (13).

The development of biotechnology provides compelling arguments about the role that public acceptance and public support for an emerging technology can play in the successful commercialization of a new technology (14). Active and continuous communication between nanoscientists, policy-makers and the public about the risks and benefits of nanotechnology will remain an important part of both the regulation of nanotechnology and the commercialization of products that use the technology (15).

Transitioning from “Nanotechnology” to Specific Application Areas

Nanotechnology has been described as an enabling technology, which means that there are multiple application areas in a variety of disciplinary subfields. Previous research on the social and policy implications of nanotechnology has focused on public perceptions about the general risks and benefits of the technology. Yet, in the case of enabling technologies, recent research has demonstrated that it is increasingly important to consider specific application areas when asking the public to report their perceptions about risks, benefits, and regulation (2, 16, 17). For example, the public’s risk and benefit perceptions about the use of nanotechnology for medical applications might be quite different from their risk and benefit perceptions about nanotechnology use for national defense applications or applications in food and agriculture. Public and expert risk perceptions are particularly important to explore when attempting to make regulatory or policy decisions about nanotechnology, because several studies have shown that individual risk perceptions about an emerging technology are directly correlated with support for regulation of that technology (17, 18). Some previous research has demonstrated that both scientists (17) and the public (5) rely on their risk perceptions and values when they make policy or regulation decisions about emerging technologies.

Recent research has shown that the leading U.S. nanoscientists also think about application areas when they make statements about the need for regulation of the technology. For example, survey results have indicated that U.S. nanoscientists have a stronger sense of urgency for new nanotechnology regulations in the application areas of (1)

surveillance/privacy, (2) bioengineering/human enhancement, (3) medicine, and (4) environment and energy (17).

Widening Nanotechnology Knowledge Gaps

Despite large-scale nanotechnology outreach efforts over the past decade, studies have shown that general knowledge about the technology has remained about the same when the public as a whole is considered. Yet, recent research has explored differences in knowledge levels across formal education levels and found that those with the highest levels of education have seen slight increases in knowledge levels over time, while those with the lowest education levels have seen a drop in knowledge levels over the same time period. These results raise concerns that the group most in need of knowledge and information—those with the lowest levels of formal education—are not being reached by current outreach and education efforts. One silver lining in this study was that the results indicated that the Internet is the one media outlet that helps those with lower education levels catch up to higher education levels on nanotechnology knowledge. Therefore, the Internet might be one tool that could serve as a “leveler” of these knowledge gaps.

Analyzing Public Attitudes and Knowledge for a Variety of “Publics”

When we think about the public in analyzing attitudes and perceptions about nanotechnology, it is clear that there is more than one public. The session identified the importance of collecting data for a variety of different “publics” by making sure that we collect data across different demographic groups (e.g., by gender, ethnicity, age, etc.) as well as across different education levels and geographic locations. The importance of studying different publics is one part of the discussion noted above about widening knowledge gaps. Without collecting data across a wide range of educational levels, we would not know about the disparity in nanotechnology knowledge among those with the highest and lowest levels of formal education. Previous researchers have also found that demographic variables like ethnicity (11) and gender (5, 17) are correlated with public perceptions about nanotechnology risks/benefits as well as nanotechnology policy stances.

Research Needs

- The breakout session participants believed that it would be important to continue to track public attitudes about nanotechnology and media effects on public attitudes over time.
- Several participants indicated that one way to ensure that this data collection happens is to add ELSI research to all nanotechnology research proposal requests (including technical proposals).
- In addition to discussing nanotechnology application areas, the breakout group also brought up some additional ways of categorizing nanotechnology that would be important for ELSI researchers to pay attention to when collecting data about public attitudes.
- The participants indicated that the public's attitudes about nanotechnology commercial products might vary based on whether the products were luxury products or "core needs" products.
- Another distinction that was considered important was the difference between nanotechnology being used for therapeutic versus non-therapeutic medical uses (e.g., treatment of diseases versus human enhancement).
- In addition, the session participants believed that the public might have varying attitudes about nanotechnology products based on whether their benefit was directed largely to individuals (individual value) versus society (i.e., collective societal value). For example, the 2008 EU Code of Conduct for Responsible Nano Research³ says researchers should "not undertake research aiming for non-therapeutic enhancement of human beings leading to addiction or solely for the illicit enhancement of the performance of the human body." The session participants concluded that when we consider ELSI issues for nanotechnology, many of these distinctions in product type and product benefits will be increasingly important for researchers to consider.
- The breakout group discussed knowledge gaps in detail and concluded that in the future, ELSI

researchers need to think carefully about how we conduct nanotechnology outreach efforts and which groups we are successfully reaching with those efforts. The session participants indicated that outreach should be customized (e.g., across age groups or education groups) and that we should learn more about our audience[s] before we communicate with them about nanotechnology. There was some concern among the session participants that these types of knowledge gaps may increase over time if we are not more careful in our outreach efforts. One participant said, "We are setting ourselves up for these knowledge gaps."

Gaps and Barriers

- Many of the participants in the session believed that the way the media reports on the benefits or risks of nanotechnology would have an impact on public perceptions.
- The participants in the session also discussed the issue of the public's trust in policymakers who deal with nanotechnology.
- In general, research has demonstrated that the public's trust in governmental institutions' ability to manage risks is correlated with their perceptions about the risks and benefits of the technology (19).
- Also, public trust in decision makers is particularly important, given that some studies have found that public acceptance of a new technology depends more on the public's trust in regulating institutions than on the public's level of knowledge about the technology (20).
- The breakout participants discussed the issue of focusing on nanotechnology application areas extensively.
- The group discussion focused on how the public might have different risk and benefit perceptions for different nanotechnology application areas. For example, the group discussed how the public might have high benefit perceptions about nanomedicine for treatment of diseases, but lower benefit perceptions for nanomedicine in human enhancement (therapeutic versus nontherapeutic uses).

³ See http://cordis.europa.eu/fetch?CALLER=NEWSLINK_EN_C&RCN=29114&ACTION=D.

- Additionally, the group discussed how the public pays attention to “markers” in the media when reading stories about nanotechnology. For instance, several participants said that the public would pay attention to media keywords like “nano-food,” -medicine, -water, or -cosmetics.
- One of the major challenges discussed during this breakout session was focused on the concept of the NNI being a “national” organization. Several session participants asked, “Are we addressing nanotechnology as a national issue only?” They said that if we are addressing it as a national issue, this could have significant economic implications, because public acceptance, perceptions about moral acceptability of the technology, as well as regulations can differ across countries (19). The group indicated that if the NNI is not thoughtful in considering the role of the United States in the larger international discussion about nanotechnology then we might end up (as one participant said) “shipping the dirty nano jobs offshore.” The participants explained how some U.S. companies already collaborate with other countries if they cannot make certain products in the United States and that nanotechnology could head in this direction as well if we do not pay attention to the international context for nanomaterials and nanotechnology research and commercialization. The session concluded that we need to think internationally about policy issues and about developing an international perspective for nanotechnology policy.

Overarching Findings

- One topic that was discussed extensively during the breakout session was the fact that media content focused on nanotechnology often provides shortcuts for the public to use when they form attitudes. This is particularly true given the relatively low levels of knowledge that the public has about nanotechnology (19). Many of the participants in the session believed that the way the media reports on the benefits or risks of nanotechnology would have an impact on public perceptions.
- The participants in the session also discussed the issue of the public’s trust in policy-makers that deal with nanotechnology. In general,

research has demonstrated that the public’s trust in governmental institutions’ ability to manage risks is correlated with their perceptions about the risks and benefits of the technology (21). Also, public trust in decision-makers is particularly important given that some studies have found that public acceptance of a new technology depends more on the public’s trust in regulating institutions than on the public’s level of knowledge about the technology (20).

- The breakout session participants believed that it would be important to continue to track public attitudes about nanotechnology and media effects on public attitudes over time. Several participants indicated that one way to ensure that this data collection happens is to add ELSI research to all nanotechnology research proposal requests (including technical proposals). There is a need to “unpackage” nanotechnology for EHS, RA, and ELSI research, analysis, and discussions (22).
- The session concluded that we need to think internationally about policy issues and developing an international perspective for nanotechnology policy.

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Session 5. ELSI and Risk Management Methods Communications

Dietram Scheufele (U. of Wisconsin-Madison) and Matthew Nisbet (American University)

Framing the Session

- This fifth session of the Capstone Workshop focused on ELSI and Risk Communication. Drs. Scheufele and Nisbet gave presentations on the state of the science. Their talks were followed by a discussion of the following questions:
- What are the key risk management methods (RMM)-related issues from a scientific and a policy perspective that need to be part of an overall communication strategy?
- What outcomes are desirable (two-way exchanges, public information, awareness, adequate representation of scientific community in public discourse, etc.)?
- Given what we know about attitude formation and public knowledge,
- What are the best channels to connect with different publics (different interest and knowledge levels, etc.) without excluding some groups?

- How do audience characteristics determine what and how we communicate?
- What lessons can we learn from agricultural biotech etc.?
- What approaches make sense at different levels of the product lifecycle, policy process, etc.

Overarching Themes

- The NNI has a central role in all communication efforts surrounding nanotechnology.
- The point was raised that all communication should be based on empirical data about audiences, their informational needs, their concerns, and about the most effective ways of opening-two-way channels of information.
- A recurring theme was the need for a more “scientific” approach to communicating nanotechnology in the next decade of NNI funding.
- The discussions focused on the interplay of communication and education to help build scientific literacy and at the same time help develop long-term beliefs about the integrity of the scientific process.

State of the Science

The State of Nano Communication Research, (Dietram A. Scheufele)

Nanotechnology is the most recent example in a long line of emerging technologies that have produced applications with tremendous ethical, legal, and social implications. It is therefore particularly surprising that we continue to see communication gaps between science and the public (1). So where have we fallen short? And where are the most obvious contributions that social science research can make to the unresolved questions surrounding communication about emerging technologies in general, and nanotechnology in particular?

Surveys of the public have demonstrated that most Americans are largely unaware of the technology and that levels of actual knowledge about nanotechnology among the U.S. public, measured with a series of true/false questions, have remained low and overall stagnant since 2004 (2). These findings, of course, are not too surprising given how disengaged many

Americans are from science in general. During the 2004 election, for example, almost 7 out of 10 Americans (69%) reported that scientific findings are often “hard for people like me to understand,” and almost two thirds (60%) of the public thought that they did not know a lot about the issue of stem cell research, which was brought up by both presidential candidates during the debates (3). For issues such as nanotechnology, levels of self-reported knowledge are even lower, and 4 out of 5 Americans (81%) think that they are not well informed about nanotechnology, with about a fifth of all respondents (21%) thinking of themselves as “not informed at all” (4).

Part of the explanation for low levels of real and perceived knowledge lies in the lack of attention that the U.S. public pays to science as an issue. Half of all respondents (50%) in the same national survey (4) report that they watched “stories related to science, technology, and medicine” on TV only once or not at all during the past week. The numbers are similar for science stories read in newspapers (49%), and even higher for web content, where 4 out of 5 Americans (82%) report that they read “stories related to science, technology, and medicine” only once or not at all during the past week.

At the same time, recent U.S. surveys have shown that the public’s knowledge about nanotechnology, for instance, has few direct effects on attitudes or support for funding. The same research, however, has shown that the way audiences make sense of new information about nanotechnology by filtering it through a complex set of worldviews (5-7, religious beliefs (8), and emotional variables (9). Brossard and colleagues, for instance, found that higher levels of knowledge were significantly related to increased support for research among less religious respondents. For more religious respondents, however, there was no significant link. These findings suggest that predispositions serve as a “perceptual filter” that audiences use when they need to balance existing values and worldviews against what they know to be scientific facts.

Despite the limited levels of public literacy, a number of nano-based applications have received news coverage and policy discussions about the unforeseeable consequences of nanotechnology-related research. These concerns are driven in part by more general concerns about insufficient regulatory

structures for nanotechnology and its applications (10), and in part by worries about the specific risks to human health and the environment (4). In order to understand the emerging communication environment surrounding nanotechnology, it is important to examine some key insights from empirical communication research funded during the first decade of the NNI. At least three areas are worth highlighting.

Media Cultivation of Attitudes

Communication scholars have known for a long time that “cultivation effects” matter (i.e., the idea that public perceptions of how science functions are shaped heavily by media portrayals in popular culture) (11-12). Cultivation effects are particularly pronounced for issues where lay citizens have limited personal experience and where public perceptions are, therefore, shaped heavily by media portrayals. Given the limited experience that most citizens have with bench scientists and their daily work, it is not too surprising that their perceptions of science and science-related risks are shaped, in part, by television portrayals.

When it comes to data on real-world examples of cultivation effects in the emerging field of nanotechnology, evidence is limited. There have been speculative accounts of potential influences of popular novels such as Michael Crichton’s *Prey*, or motion pictures such as the Terminator series (14). At this point, however, there are no studies that have shown empirically that public views on nanotechnology are cultivated by exposure to popular media (i.e., that heavy exposure to popular media messages is significantly related to more negative perceptions). This may be due in part to the portrayal of nanotechnology in mass media so far, which appears to be mostly positive or neutral.

Widening Knowledge Gaps

Many of the previous attempts to connect wide cross-sections of the public with science have resulted in widening gaps between the already information-rich and the information-poor. This is partly due to likelihood of exposure. Almost 40% of college-educated respondents, for instance, visited a science or technology museum in 2006, compared to less than 10% for respondents with a high school education or less (15).

As a result, exhibits and similar outreach efforts may inherently favor elite audiences. Widening gaps between the information-rich and information-poor are also a function of the way issues like nanotechnology play out in public discourse. TV shows like NOVA or the “Science” section of the New York Times, for example, tailor their content to highly educated elite audiences. As a result, learning effects for mass audiences may be minimal, even if these audiences happen to tune in to NOVA or read an article in the New York Times. Consistent with this logic, Corley and Scheufele (16) found that highly educated respondents showed a slight increase in knowledge about nanotechnology over the last few years, measured as the number of correct responses on a series of six true/false quiz-type questions. The least educated respondents, however, showed a slight decrease in the number of questions they were able to answer correctly.

These findings also put a damper on the optimism with which some researchers have approached consensus conferences or town hall meetings on the issue of nanotechnology. These exercises are potentially very useful for tapping concerns of specific sub-publics upstream, but they are less useful as gauges of public reactions more generally. This is due to the fact that the volunteer participants in these meetings tend to differ significantly from lay publics in terms of interest in the topic, opinion extremity, and a host of other demographic characteristics.

Framing Nanotechnology

How can journalists and science communicators present issues in ways that resonate with audiences’ existing knowledge structures or value systems? And how does that help audiences to make sense of complex scientific issues, even though they are not experts? Some answers to these questions have been provided by communication researchers as part of the prominent communication subfield of “framing.”

Framing refers to how the presentation characteristics of information influence how individuals’ interpret that information. More specifically, frames are interpretative storylines that help communicate why an issue might be a problem, who or what might be responsible, and what should be done. The frame that is being used to describe a scientific or technological issue can serve as a

powerful heuristic when audiences are being asked to make judgments about associated risks or regulatory policies to attenuate the risks (17).

Greenpeace’s “Frankenfood” frame during the debates surrounding genetically modified organisms (GMOs) is a particularly good example. It resonates with culturally shared descriptions from Mary Shelley’s “Frankenstein” and visual images from various movie adaptations. It also activates an intuitive understanding of the dangers of “runaway science” and the risks of science going too far. And it does all of that simply by introducing a new label for GMOs and not by making a persuasive argument or offering new information.

Frames therefore have very little to do with actual information. Rather, their effects are very subtle and work by activating cognitive schema that increase or decrease the likelihood that audiences interpret the issue in certain ways (e.g., as an issue of “morality” or “economics”). Nanotechnology, in a similar fashion, was described early on in its issue cycle mostly in terms of its economic and scientific promise, and attitudes toward the new technology were shaped mostly by these positive frames offered by mass media (18).

Summary

In sum, effective public communication about nanotechnology is not a guessing game; it is a science—a science in which systematic empirical communication research should play a much more prominent role than it has so far. Public opinion and communication research allows us to get a very accurate picture over time of exactly what different groups in society want to know about nanotechnology and other emerging technologies, about potential implications for their daily lives, about what their concerns are and whom they are looking to for answers. Relying on basic communication research to understand and develop two-way channels of communication with different publics will therefore be critical for the future of the NNI by helping help us develop, test, and assess innovative ways of reaching and engaging various publics through different forms of communication and informal science education.

New Tools for Engagement (Matthew C. Nisbet)

Direct communication on the part of government agencies, organizations, and industry is important to public engagement, but the news media, particularly newspapers in print and now their digital form, are necessary and vital intermediaries between experts and the public.

Through several different mechanisms, news coverage enables experts, policymakers, and the public to recognize and learn about the relevance of nanotechnology, how to become involved, and how to partner with others around defining and pursuing collective and individual actions.

News coverage provides members of a community with information, interpretation, analysis, and debate that can bring to light policy options, benefits, risks, and trade-offs, and that builds social and economic connections. Newspapers in particular can and should play a central coordinating and capacity-building function in society’s response to nanotechnology. Even as the media system rapidly evolves, studies find that local newspapers remain at the core of a community’s news ecology, serving as the major source for original reporting on problems and policy debates, with this reporting driving the agenda of the rest of a community’s media outlets from local television to blogs.

Guiding Public Attention and Evaluations

Research on the agenda-setting effect of the media has provided overwhelming evidence that the issues portrayed in the media subsequently shape the issue priorities of the public, determining the problems that the public perceives as the most pressing and most important. The agenda-setting influence of the media is relevant to public participation on nanotechnology in two fundamental ways.

First, the news media builds general awareness and agenda status for nanotechnology, so that it reaches a decision status for consumers, organizations, and governments.

Second, and perhaps most importantly, research on priming shows that the issues that receive the greatest amount of news attention are frequently used as the criteria by which the public is likely to judge, reward, or punish government officials, agencies, and corporations.

Policymakers and government organizations, therefore, have a strong intuitive, if not formal, sense of how the news media can prime public evaluations. Therefore, if and when news attention to nanotechnology increases, in order to protect their public image, key decision makers from across the public and private sector will become more likely to take action to address questions related to nanotechnology. In short, news coverage promotes public accountability on the part of elected officials, corporations, and organizations. As one recent report defined it: “People behave better if they are being watched.”

Framing the Relevance of the Issue and Creating the Context for Decision Making

Closely related to generating attention and accountability, the media also frames the definition and interpretation of nanotechnology, creating the context for public debate and for consumer decisions.

Facilitating Learning, Participation, and Coordination

Media coverage, especially on the part of newspapers, is also important for public participation in community and national-level decision making. On complex issues such as nanotechnology, studies find that newspaper coverage—whether in print or online—is the best and most readily available source of informal learning for the public. Moreover, studies conclude that the more the public learns about the technical and social dimensions of an issue such as nanotechnology, the more likely they are to directly participate with others in working towards solutions. Learning promotes feelings of efficacy about addressing the problem, which additionally boosts the likelihood of participation, along with overall trust.

Newspaper coverage also typically provides readers with so-called mobilizing information, details about how to connect with community members and organizations, where to turn up for events and activities, and how to get involved in decision making about nanotechnology.

As newspapers have moved their content and coverage online, the digital context has enabled more opportunities to provide mobilizing information. In turn, online newspaper content fuels additional attention from blogs and digital media sites, which

often combine news and commentary with digital tools that enable readers to influence their friends and to contact decision makers directly. Finally, while newspapers and online media are likely to differentially benefit higher educated audiences, to the extent that print and online newspaper coverage of a problem increases the likelihood of attention from national and local television news, the availability of quality TV coverage can promote learning and participation from lower socio-economic segments of the public.

Factors Shaping News Coverage of Nanotechnology

If generating greater print and online newspaper coverage is central to increasing overall public engagement with nanotechnology, then it is important to understand the factors that shape journalistic decision making on the issue. “Media agenda building” is the term that media scholars use to refer to the process by which news organizations and journalists feature, emphasize, and/or select certain events or issues to cover over others.

A common thread in this research is that news coverage is rarely a direct reflection of reality, but rather a process that involves the professional judgment of journalists, the influence of key sources, and economic and political pressures on news organizations.

Information subsidies and agenda-building strategies. In covering a complex topic such as nanotechnology, journalists also rely on so-called “information subsidies” from sources. Scientific studies (and their news releases), reports, briefings, and staged events literally subsidize the cost of news production, reducing the time, effort, and expertise that journalists require to cover a complicated issue such as climate change.

Information subsidies become even more important in an era where few journalists remain who have experience and expertise covering the nanotechnology or emerging technology beat.

Apart from focusing events and political, regulatory, or industry actions, subsidies that organizations control include release of studies or reports, public meetings, op-eds and editorials, coalition press conferences, and news events.

Economic pressures and down-sizing. The economic capacity of news organizations is likely to be another major factor that influences news attention to the health impacts of climate change. The news media and newspapers are currently in a unprecedented state of economic distress, forcing dramatic cuts over the past decade in coverage of science, the environment, and health, cuts that have escalated over the past year. Consider that in 1989, there were 95 U.S. newspapers that carried weekly science sections. As of 2005, there were only 35, and today there are estimated to be less than 20. This suggests the potential for diminishing coverage of nanotechnology in general and even more limited news about the public health relevance of climate change, especially at regional and local newspapers. For a detailed overview on issues discussed in previous two sections, see Nisbet and Scheufele (19).

Research Needs

What outcomes are desirable (two-way exchanges, public information, awareness, adequate representation of scientific community in public discourse, etc.)?

Many session participants highlighted a central role for the NNI in all communication efforts surrounding nanotechnology. They felt that such a central coordinating role would also provide the infrastructure necessary to equip the NNI's member agencies to deliver relevant and consistent information to various audiences.

Session participants also emphasized the need for a more fine-grained understanding of outcomes (knowledge, attitudes, and behaviors) and their interrelationships, as well as a distinction between nanotechnology more generally and more context-specific applications with potentially very different communication dynamics surrounding them.

Session participants also identified at least three guiding principles for the NNI as part of these communication efforts:

1. Build trust through openness: Transparency emerged as a key theme throughout all discussions. Session participants felt that there was a tremendous opportunity to further build the NNI's reputation as an objective, nonpartisan clearinghouse that citizens, journalists, and

other stakeholders all trust equally. Participants emphasized that this role does include explaining the benefits and the risks of nanotechnology to various audiences.

2. Toward that end, discussions also focused on the importance of timely responses by the NNI to emerging issues in the public arena. This includes providing online background materials for citizens and expert input on public debates. But it also requires establishing processes for timely responses to media and other public inquiries.
3. Finally, the discussion focused on two-way dialogue and engagement as key components of any communication effort. Rather than promoting a one-way transfer of information, session participants described NNI's role ideally as a facilitator of dialogue.

What are the key RMM-related issues from a scientific and a policy perspective that need to be part of an overall communication strategy?

The discussion in this context focused largely on the idea of widening the audience for any communication effort surrounding RMM and ELSI related to nanotechnology. Most comments focused on the need to expand the idea of what relevant audiences are and to include all stakeholders in the societal discourse about nanotechnology. Session participants felt that the NNI can play a leadership role in facilitating these discussions and bringing all stakeholders to the table, including public consumers, NNI's member agencies, etc.

Session participants also felt that any communication effort by NNI should not be mistaken for a propaganda campaign with the goal of promoting nanotechnology. Concerns was raised about being able to provide truly balanced information, given tensions between scientific assessments and potentially biased lay understandings of risks and benefits related to nanotechnology, and given increasingly episodic and controversy-focused media coverage.

Finally, the point was raised that all communication should be based on empirical data about audiences, their informational needs, their concerns, and about the most effective ways of opening-two-way channels of information sharing. One discussion group referred

to a new paradigm of communication for the next decade of the NNI. They referred to the 2001 risk framework as “all about informing” and to the 2011 risk framework as “all about creating dialogues.” Framing was emphasized as setting the context and points of discussion for any dialogue efforts. Research is needed on which frames help bring disparate or specific groups together into conversation and mutual learning about nanotechnology.

What are the best channels to connect with different publics without excluding some groups?

The breakout discussions on this topic cautioned against abandoning traditional news channels, which are still critical venues for setting agendas and for contextualizing or framing public debates. In other words, public debates about nanotechnology do not occur in a vacuum. Rather, objective scientific arguments often compete with partisan messages put forth by interest groups and other newsmakers. And these partisan players often promote frames that favor particular regular stances or particular interpretations of benefits and risks. Working successfully with mass media to set the agenda and contextualize the issue of nanotechnology in all its complexities is therefore critical for building connections with the public.

In addition to traditional channels, however, the discussions also highlighted the importance of social media for establishing two-way channels of communication. Many participants felt that social media could play a particularly important role for closing various gaps identified by previous research, including knowledge gaps across socioeconomic groups (16) and communication gaps in international contexts. In this context, the group also urged the NNI to examine new initiatives in (documentary) films and new projects in journalism with an eye toward developing communication strategies that can help close widening rifts between groups with different educational levels and reach hard-to-reach segments of the public.

Finally, the discussions focused on the continued importance of education (K through gray) for helping to build scientific literacy for current breakthroughs, but also for developing long-term beliefs about the integrity of the scientific system (5).

What approaches make sense at different levels of the product lifecycle, policy process, etc.?

A final recurring theme was the need for a more scientific approach to communicating nanotechnology in the next decade of NNI funding. Group discussions echoed a distinction made in the March 2010 PCAST report⁴ and highlighted the importance of separating the foci on (and funding for) education and outreach (which are important areas) from social scientific research on ELSI aspects (including communication research targeted at connecting with hard-to-reach publics).

Participants suggested that communication efforts should be informed by systematic formative and post hoc evaluation at all stages of the product lifecycle (potentially in collaboration with existing NSF-funded efforts in this area). This includes long-term tracking of media, various publics, etc., in line with recommendations from the 2010 PCAST report that asked for “[a]n effective program in societal implications [that] would have well-defined areas of focus, clearly articulated outcomes as well as plans for assessing and evaluating those outcomes.”

Overarching Findings

- The discussion highlighted a central role of the NNI in all communication efforts surrounding nanotechnology, and identified three guiding principles for the NNI:
 - Build trust with all stakeholders through openness
 - Respond in a timely manner to emerging issues
 - Facilitate two-way communication and engagement.
- Working successfully with mass media and social media to set the agenda and contextualize the issue of nanotechnology in all its complexities is critical for building connections with the public.
- Group discussions echoed a distinction made in the March 2010 PCAST report and highlighted the importance of separating the focus on (and

⁴ President’s Council of Advisors on Science and Technology, *Report to the President and Congress on the Third Assessment of the National Nanotechnology Initiative* (EOP/PCAST, Washington, DC, 2010; <http://www.whitehouse.gov/sites/default/files/microsites/ostp/pcast-nano-report.pdf>).

funding for) education and outreach (which are important areas) from social scientific research on ELSI aspects (including communication research targeted at connecting with hard-to-reach publics).

- Participants suggested that communication efforts should be informed by systematic basic research in communication, and formative and post hoc evaluation at all stages of the product lifecycle (potentially in collaboration with existing NSF-funded social science efforts in this area).
- In addition to recognizing the importance of traditional news channels, the discussions highlighted the importance of social media for establishing two-way channels of communication.
- The group also urged the NNI to examine new initiatives in (documentary) films and new projects in journalism to help close the widening rifts between groups with different educational levels and to reach hard-to-reach segments of the lay public.
- Finally, the discussions focused on the continued importance of education (K through grad) for helping to build scientific literacy for current breakthroughs, but also for developing long-term beliefs about the integrity of the scientific system.

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Session 6. Specific Ethical, Legal, and Societal Implications of Nanotechnology

Mark S. Frankel (AAAS) and Pilar Ossorio (University of Wisconsin School of Law)

Framing the Session

ELSI issues are deeply embedded in the responsible development of nanotechnology. How nanotechnology research and applications are introduced into society; how transparent decisions are; how sensitive and responsive policies are to the needs and perceptions of the full range of stakeholders; and how ethical, legal, and social issues are handled will go a long way to determining public trust and the future of innovation driven by nanotechnology.

At the outset of this session, participants stressed the importance of defining the goals that should guide social policy for nanotechnology. Achievement of those goals, i.e., the benefits of nanotechnology,

must be balanced against potential adverse events. Considering ELSI issues provides tools for assessing how well we are doing in reaching some acceptable balance of benefits and risks.

At the heart of that assessment will be a range of values that can facilitate or impede the responsible development of nanotechnology. Several such values were identified by the group, including innovation, safety, transparency, equity, effective governance, scientific freedom, and economic progress; the list is by no means exhaustive. When those values conflict, as, for example, when innovation is tempered by concerns for safety, society, or one or more of its major social institutions, society faces challenging choices. ELSI research seeks to produce knowledge and insights that can help society assess those challenges and identify potential responses. This session moved from these more general considerations to specific ELSI issues that are likely to be associated with nanotechnology research and applications.

Overarching Themes

Several broad themes surfaced during the session:

- **Expected Benefits.** One should not expect societal support, whether in the form of funding, favorable policies, or freedom of inquiry, unless there are tangible benefits to be gained. These benefits may be society-wide, or affect a subset of the population; they may be short-term and/or long-term; they may be unique or expand upon existing advancements.
- **Anticipated Risks.** Risks will be a major factor affecting public support for nanotechnology. Risks can be expected in research involving human and animal subjects, exposure to new materials during the development and production of the technology, and use by consumers. As a general rule, benefits of some new advancement should outweigh whatever risks can be anticipated
- **Safety.** While absolute safety is unachievable and not a realistic basis for public policy, the question of how much safety is enough, when balanced against risks, was central to the discussion. Like risk, safety has several dimensions—people desire physical and emotional safety, they want

their economic status and relationships with others to be safe, and they want their safety at some acceptable level of cost.

- **Definition of Nanotechnology.** There was considerable uneasiness with defining nanotechnology according to its size characteristics. Both good policies/regulation and effective analysis of ELSI issues would benefit from a definition that focuses on the purpose and impact of nanotechnology-aided products.
- **Applications of Nanotechnology.** Uses of nanotechnology raise significant social issues. Among those raised at the session included the use of public vs. private investment for nanotechnology R&D, consumer rights to access and the benefits access confers, as well as protection from potential harms, and how new nanotechnologies might be used for national security purposes.
- **Regulation.** Regulatory policy can impose caution until greater knowledge of impacts is acquired. It serves as a mechanism for pursuing some priorities over others. It can be used to protect the most vulnerable populations in society. But regulation also poses challenges for society. It imposes restrictions on freedom of inquiry, it can slow down development and production of a highly valued product, keeping it out of the hands (at least longer than might otherwise be the case) of people who need it, and it can complicate access and use by the average citizen.

Gaps and Barriers

- There are many stakeholders engaged in R&D and policy related to nanotechnology. Some will fear it, while others will embrace it. Until we learn more about how different subpopulations (e.g., based on gender, ethnicity, education level, etc.) view nanotechnology and why, it will be virtually impossible to develop sound public policy.
- Small vs. large companies, and start-ups vs. internationally recognized corporations pose a potential barrier to nanotechnology R&D and its widespread application. Do small companies, many of which are at the cutting edge of research and innovation, but which plan to be acquired within a few years, have the capacity for assessing

risks and providing a safe workplace? Do we know what would constitute a safe laboratory environment when working with nanomaterials? How can we motivate the private sector to adopt safe practices?

- Differences among stakeholders on an adequate definition of nanotechnology will be a barrier to research and the development of appropriate and effective policies.

Current Research Needs

- There is a need for research on the nature, quality, and scope of differences across the population with respect to people's views about nanotechnology.
- Research is needed on how the benefits and burdens of nanotechnology R&D and its applications might be distributed across various sectors of the population and what ELSI issues are raised.
- Data are needed on what people believe they should know about nanotechnology in order to maximize benefits and minimize risks. What methods of informing various publics are likely to be most helpful? What should be the nature and scope of information provide to research subjects? To consumers? To employees?
- Research is needed on what types of regulatory models are likely to be considered for nanotechnology R&D and its applications, with simultaneous study of the ELSI issues each model.
- A nanotechnology research portfolio on ELSI issues should include assessment of the roles and responsibilities of the private and public sectors in matters related to access, privacy, and managing risks.

Future Research Needs

- Research is needed on the role of insurance in managing risk and liability costs of a fledgling industry.
- Study of what, if any, changes in patent law should be considered in response to the emergence of a nanotechnology manufacturing sector.

Additional Considerations

- Participants in the session identified several features of ELSI research that should be considered when developing a research portfolio:
- Successful ELSI work begins with good information. Transparency and data-sharing among stakeholders is critical to designing studies and to building a body of literature that is based on a realistic and competent understanding of the state of the science of nanotechnology.
- ELSI issues should be integrated into the life cycle of nanotechnology-enabled products. From hypothesis/idea to development to usage and to everything in between, possible ethical, legal, and societal implications should be evaluated at each stage.
- Different types of nanomaterial applications trigger different ELSI issues, with different risks and benefits. Research priorities and policies should take into account such differences, for example, when assessing the potential benefits

and risks of new nanomaterials for clothing or those of nanomaterials that are intended for placement in the human body.

Overarching Findings

- The definition of nanotechnology based on size needs to be revisited and alternatives considered.
- Relevant nanotechnology stakeholders include diverse populations (e.g., according to race, gender, education, economic status, etc.). ELSI research should take that diversity into account.
- ELSI researchers and nanotechnology scientists and engineers should collaborate on the study of ELSI issues to ensure that research is informed by a realistic assessment of the state of the science.

Appendix D. Case Scenario for a New Nanotechnology-Enabled Paint or Coating

Dr. Amy C. Jones (Lockheed Martin Corporation)

Framing the Session

The purpose of the case scenario was to obtain direct attendee input on overarching and cross-cutting Risk Management Methods (RMM) needs and Ethical, Legal, and Societal Implications (ELSI) of introducing new nanotechnology-enabled products. In order to facilitate audience input into research questions that should be asked to foster safe product development, a fictitious case scenario for development of a paint or coating was selected. The audience was asked to consider a paint or coating that could be used in both manufacturing and consumer applications. Audience members were asked to consider a product that contained a novel nanoparticle to improve its product performance. The audience was asked to frame research questions with the understanding that enhanced product capability, product safety, and environmental stewardship were customer requirements.

Case Scenario

The case scenario was developed using a gated product development model that is commonly used in industry to take products from conceptual ideas to full commercialization. Gated development enables companies to design products consistent with ISO 9000 quality standards.¹ It enables companies to down-select from a multitude of good ideas, to select a few products that fill a need and are commercially viable.

The first stage of product development is “Idea Build.” The business case is evaluated, but most importantly for EHS, this is the opportunity to screen new concepts for early identification and evaluation of EHS issues/risks. This stage allows the team to systematically plan for elimination, mitigation, minimization, and

¹ The ISO 9000 family of standards represents an international consensus on good quality management practices. It consists of standards and guidelines relating to quality management systems and related supporting standards. See http://www.iso.org/iso/iso_9000_essentials.

management of potential hazards posed by new product forms under consideration.

The second stage of product development is “Viability Assessment” wherein candidate products are tested for functionality and commercial viability. One or two product forms are evaluated and a strategy is developed for managing total risk (e.g., elimination, mitigation, or reduction of hazards and/or hazardous practices) early in product development. At this stage, any additional risk(s) are identified that is (are) not yet managed or eliminated. This “residual risk” is tracked and removed as the product moves through the next stage of development.

The third stage of product development is “Prototype Build and Test.” Product developers move a single promising candidate product form to pilot production or its equivalent. Manufacturing processes are identified or optimized and final hazardous material substitutions are made. Previously identified residual risks are removed. The product stewardship plan for the final product form begins to take form at this stage and covers all aspects of manufacturing, commercialization, and end-of-life management.

The fourth stage is “Product Optimization.” This is the point at which the product is transferred to manufacturing and unanticipated EHS issues are identified and managed. The final product stewardship plan is adopted during this stage.

The fifth and final stage of development is “Commercialization.” EHS support is provided prior to product launch and throughout the life of the product. Data is collected on product performance and the product stewardship plan is updated as needed.

Session Structure

The session occurred in two parts. The case scenario was introduced on the first day. Attendees were provided a general overview of the “new product” and an outline of a typical industry product development protocol that included the following steps: idea build, viability assessment, prototyping, product optimization, ending with product commercialization.

After the overview, attendees participated in table talk discussions identifying RMM and ELSI research needs to be addressed at each stage of product development. The second part occurred on Day 2 where subject matter experts formed a panel to discuss the overarching themes identified on Day 1 in the table discussions.

Overarching Themes from Table Discussions

- During the idea build or conceptualization of the new product, developers should identify, evaluate, and plan to eliminate any EHS issues. Developers should look broadly to identify RMM and ELSI issues not otherwise addressed by regulations.
- While assessing product viability, developers should strive to fully characterize nanomaterials with regards to physical, chemical, and other properties relevant to RMM decisions. Risk/benefit, use/misuse, and other total life cycle management questions should be answered during early phases of development.
- Prior to and during prototyping, focus should be on manufacturing safety and mitigating potential for worker exposure. Testing prototypes for potential to release nanoparticles should occur at this stage along with total life cycle analysis that assesses hazards at every stage of the product life cycle. In addition, communication plans and public perceptions should be addressed.
- By the time the product manufacturing process is being optimized, most RMM and ELSI concerns should be identified and addressed.
- After commercialization, the manufacturer should continue to evaluate product as use/misuse and environmental data become available.

Panelist Discussion

Audience members used flip charts during table discussions and identified over 200 research questions. Many of the questions were repeated, and many focused on major themes. The questions were therefore consolidated into a smaller set of questions for the panelists to address. Research questions for each stage of product development were categorized into four main areas: (1) Manufacturing, (2) Environmental, (3) Consumer Use, and (4) Regulatory.

Idea Build

The EHS objective of the idea build stage of new product development is early identification and evaluation of potential EHS issues. The main question posed by attendees for manufacturing considerations was: What tools or protocols are needed to evaluate hazards posed by nanoparticles under consideration for the new paint or coating? The environmental questions were consolidated to one question: Could the nanoparticle be released during the product life cycle? The consumer questions had an ELSI component: How should risk/benefit be addressed in the early stages of product development? What type of data would warrant a stop to product development? Finally, the regulatory questions were consolidated into one question: What statutes will the paint or coating fall under?

Steve Brown from Intel provided an overview of how industry typically manages the idea build stage, including literature searches, evaluation of hazards posed by the macro-form of the particle, and possibly, developing protocols to assess new hazards posed by the nano-form. An NNI research contribution could be the development of new test protocols.

Tom Seager pointed out that the initial stage of product development is the one with greatest uncertainty, but which presents the greatest freedom to develop research ideas. He further indicated that it is a good time to introduce life cycle thinking. He discussed four representative life cycle stages: production, manufacturing, consumer use, and end of life. Evaluating these stages early on could enable developers to create products that are environmentally benign and possibly save developers hundreds of hours and thousands of dollars.

Carolyn Cairns addressed risk/benefit. She indicated that developers should take a hard look at their business case to determine if the new material provides sufficient benefit to warrant introducing a substance into commerce with unknown or poorly characterized toxicological properties. She noted that risk/benefit analysis is often a long, complex, and often difficult process, but it is worth the effort.

Product Viability Assessment

The EHS objectives of the second stage of product development are generally focused on developing a

strategy for managing EHS risk early in the project. The timing is after preliminary formulae or product forms are selected and prior to scale-up and consumer testing. Questions from attendees for manufacturing were focused on exposure controls: What worker exposure controls will be employed for research and development? Will controls developed for research and development be transferable to high-volume manufacturing? Environmental questions addressed risk. Are existing analytical techniques sufficient to detect releases of nanoparticles into the environment? What type of product-specific risk assessments should be conducted? Consumer use issues were summarized into one question: How are consumer needs for personal safety and product disposal being considered during formula selection or finalization of product form? The regulatory issues for this stage of development were summarized into one question: How should manufacturing waste for nanoparticles be managed?

Panelist Steve Brown started the discussion by pointing out that in manufacturing, the controls put in place for research and development set the stage for controls to be implemented downstream in manufacturing. He indicated that research into effective exposure controls is carried out at this stage. An NNI research need is to evaluate and develop better analytical techniques in exposure monitoring while products are still in the R&D stages of development.

John Monica addressed the question of regulatory controls of manufacturing waste. He indicated that the best practice is to manage the waste as hazardous until the hazards associated with the nanomaterial of interest are known. He also addressed the regulatory framework for the entire product development process. His advice to all was to consider the evolving regulatory framework at every step of product development and not wait until after the product has been developed and placed into commerce. Throughout the process ask, What is the benefit of the product, why is it important, what special characteristic sets it apart, how can it be used and misused, how will the product be disposed of at the end of life, what are you communicating to regulators and downstream customers? NNI research should help companies and consumers be able to answer those questions.

Prototype Build and Test

The objectives of the third stage of product development are to develop and optimize manufacturing processes. The formal product stewardship plan may also be developed at this time. This timing of this effort is after the formula or product form passes functional and initial EHS testing. Attendee questions on manufacturing, environment, consumer use, and regulatory issues were summarized into the following questions: Does sufficient information exist on the novel nanoparticle to develop a formal product stewardship plan? What type of environmental effects data should be generated prior to transferring the product to production? Could the novel nanoparticle be released during anticipated use, misuse, or disposal, and how would we know? What regulatory interventions should be required before the novel nanoparticle moves into production? The most important NNI research questions involved sufficient information for developing a product stewardship plan: How will all the toxicity characteristics and exposure potential for new products be identified? What tests need to be developed? What existing tests can be used or modified? An overriding theme was, How would we know the testing was meaningful?

Tom Seager indicated that many of the students at Rochester Institute of Technology who work in the NanoPower Research Labs have also entered the sustainability program wherein they are exposed to classes about how to evaluate products in environmental and societal contexts. This could change the way the students think about their material science and physics research. Students receiving this multidisciplinary education are already putting sustainability principles to work, striving to develop processes that use less energy and less hazardous starting materials. The students have demonstrated that it is possible to consider and make design changes to accommodate environmental stewardship in the early stages of product development.

Carolyn Cairns added that during prototype build and test, developers should take manufacturing by others into account when evaluating risks. She stressed developing communications at this stage. She pointed out that risk and perception of risk must be addressed along the entire material chain. She also pointed to

another potential NNI research need; that is to be able to identify materials interactions. In the example of the case study paint or coating, will it react safely with other materials and the environment?

John Monica added context to the use and misuse questions and added the question, How is a company to anticipate reasonably foreseeable misuse? That is already a legal obligation, but nanotechnology may add complexity to this obligation. How could the NNI research assist companies and the public identify the realm of misuses? With regard to the question of what regulatory interventions could be used, Mr. Monica indicated that EPA's authority under the Toxic Substances Control Act (TSCA) was a sufficient intervention at this stage of product development and that EPA is modifying its approach under TSCA to address the novel properties of nanoparticles and new chemical substances.

Steve Brown weighed in stressing the importance of topics that panelists and attendees raised. He discussed the need for manufacturers to have enough toxicological and information on the potential to release nanoparticles into the environment before proceeding to the next step of transferring the product from R&D to manufacturing. He also pointed out that this step is the one in which modifications to product and process can still be made. NNI research into toxicity and particle release detection methods could greatly aide in this process.

Product Optimization

Product optimization is the transfer of a product from R&D to manufacturing. The EHS objective is to manage anticipated and unanticipated EHS issues that arise from high-volume manufacturing. The attendee input on this stage was considerably less than on the previous 3 stages. That may be due to the perception that once a manufacturer reaches this stage, the questions about toxicity, exposure, and life cycle management should already be answered. The manufacturing, environmental, consumer, and regulatory questions were essentially repeats of questions asked about earlier stages: Are exposure control measures effective? Is the product stewardship plan complete with all EHS issues identified and managed? Are consumer safety data and communication with consumers adequate? Are regulatory reviews complete?

The panelists gave examples of products that have gone through sufficient review and those that had not. The take-away message was that responsible companies must work with regulators and other government agencies to assure procedures and tests are in place to enable companies to provide safe products. Panelists also discussed the importance of communication with the consumer. In particular, they noted that some paints on the market are already being labeled and sold as "nanotechnology-enabled." In the context of the case study, the panelists questioned what that actually meant. They placed an emphasis on having a sufficient product stewardship process and communication plan to enable consumers to actually know what they are buying and how to manage any risk associated with use.

Product Commercialization

The EHS objective of product commercialization is to provide EHS support after the product is introduced into commerce. Attendee questions related to product performance: What type of information is the manufacturer obliged to collect after the product is introduced? Is the product being used as anticipated? What type of data is necessary and sufficient to warrant a product recall? How should regulators track product performance and life cycle issues?

Tom Seager took this opportunity to point out that nanotechnology presents a challenge, because to his knowledge, life cycle assessments of products have not been developed for this new technology. He proposed that NNI research be directed toward developing a screening life cycle tool.

John Monica reminded the audience of the manufacturer's obligation to foresee areas of misuse. He suggested companies develop a tracking system for incident reports and complaints so that manufacturers can anticipate trends and identify early in a product's life if it will have long-term EHS issues. Whether and how regulators track product performance and lifecycle was identified as an evolving issue that warranted further discussion.

Steve Brown reiterated the need to understand life cycle and product stewardship issues during the R&D stage of development. He suggested that NNI research may include the development of databases that contain life cycle information that includes toxicity assessment and hazard analysis results. Those

databases could then be used in the development of new products. Could the NNI develop rapid decision-making tools that could give researchers and product designers an early indication of the safety of the product they are developing and steer them to more environmentally friendly designs?

Carolyn Cairns requested research into refining methods for identifying where products are in their life cycles so that if a problem is identified, a product can be recalled. She also called upon industry to develop contingency plans for the event that a product must be recalled due to EHS issues.

Conclusions

The panelists and attendees agreed that the NNI can play a significant role in addressing research

needs to ensure that products that are introduced into commerce are safe to use and safe for the environment. All companies should begin the development of each new product with a focus on product stewardship and on gaining an understanding of product hazards early enough in the development process to design hazards out and safety in. Research gaps that were identified were the lack of test methods for both toxicity tests and exposure assessments and the lack of a standard life cycle analysis assessment protocol.

The panelists were all positive on the role NNI research could play in the development of robust product stewardship plans and of data needed to aide regulators in developing a clear regulatory framework for nanotechnology.

Appendix E. Summary of Grand Challenges for Nanotechnology EHS Research

The final session of the Capstone Meeting was dedicated to identifying grand challenges for nanotechnology EHS research. These grand challenges were intended to address overarching questions that, if answered, would materially improve our understanding of the EHS implications of nanomaterials and, therefore, would augment our ability to regulate their use in a safe and scientifically informed fashion. The grand challenges discussion was intended to integrate all four of the EHS workshops and furnish a cross-disciplinary perspective to provide a set of broad issues for potential inclusion in the 2011 update of the 2008 NNI EHS Research Strategy.

The session opened with four keynote speakers from different backgrounds representing the perspectives of industry, labor, and academia, and of both technical researchers and researchers focused on the ethical, legal, societal, and international (ELSI) implications of nanotechnology. After a brief public comment period, conference attendees were asked to anonymously submit their own suggestions of Grand Challenges for the EHS and ELSI communities; both these anonymous suggestions and the comments of the keynote speakers are summarized below.

Keynote Speaker Perspectives

Richard Pleus, a toxicologist and pharmacologist at Intertox, was the first invited speaker. His comments focused on the technical side of EHS research needs: he highlighted the difficulty of physico-chemical characterization of nanomaterials and nano-objects. Pleus posited three major questions that need to be answered for each new material: “What does it look like?” “What is it made of?” and “Which of these (and beyond these) influence interactions?” The last of these questions is currently answered on a chemical-by-chemical or a material-by-material basis; however, Pleus stated that in the future we will want to be able to both predict toxicity based on physico-chemical properties and to redesign products to reduce toxicity in order to safely integrate nanotechnology into society. He noted three major challenges to address in moving toward that capability: (1) improvement in analytical methods and metrology, (2) a more

systematic method of assessing properties to predict toxicity, and (3) a better understanding of when within the life cycle of the material to determine its physico-chemical properties. Throughout this process, Pleus emphasized the need for multidisciplinary collaboration: research of this kind will require close collaborations between materials scientists, metrologists, toxicologists, and other disciplines.

Bill Kojola of the AFL-CIO spoke next. His focus area was on the safety of workers and on the design of regulations and of processes to protect workers from exposure to hazardous chemicals and materials. Kojola stated that the challenge from labor’s perspective is to design a regulatory system to act preventively rather than reactively. He noted the late recognition of the dangers of asbestos as a prime example of our tendency to respond to workplace hazards only after deaths and illnesses have occurred. Therefore, Kojola posited, a grand challenge for nanotechnology is to, “with the help of EHS research, make nanotechnology an example or a model of cautionary and preventive efforts to protect workers from becoming ill when working with nanoparticles.” The obstacles to achieving this grand challenge, he stated, were societal and governmental in nature: he listed society’s tendency to react dismissively to concerns about safety until evidence of harm accumulates, an overreliance on soft law and voluntary initiatives, and the lack of regulatory mechanisms to deal with uncertainty as major barriers to workplace safety. Kojola advocated a change from a chemical-by-chemical regulatory focus to the development of a crosscutting set of standard tests to be required for all products and procedures, including generic requirements for premanufacture exposure assessment and medical surveillance of workers.

The third speaker was Jackie Isaacs of Northeastern University, who addressed the ELSI perspective. She began by discussing the interdisciplinary nature of ELSI work and stated that one of the major challenges moving forward will be to engage the full spectrum of researchers who have expertise to impart in nanotechnology, from biologists to physicists and from lawyers to industrial hygienists. She then moved on

to discuss methods for improving industrial hygiene (and attendant workplace safety). Isaacs saw promise in training students in EHS best practices, perhaps by reaching out through professional societies: this could route around some of the longer regulatory processes in order to start improving educational and workplace safety immediately. She noted that developing regulations to ensure that workers are not exposed to dangerous levels of nanomaterials would require a better understanding of what overexposure actually is, as well as less expensive methods of measuring exposure. Next, Isaacs discussed public engagement, specifically referring to the need to train scientists to communicate effectively, pointing out efforts by museums and informal science education foundations to improve the public's understanding of nanotechnology. Finally, Isaacs turned to the science of decision making: she recommended the development of a strategic case study that, through an iterative process, could help target data collection and modeling to help reach decision end points more swiftly.

The final speaker was Mark Banash of Nanocomp Technologies, who presented the industrial perspective on EHS issues. He began his discussion by detailing several technical innovations at Nanocomp manufacturing facilities, including double containment facilities protected by vacuum and filtration and a complex set of sensors coupled to emergency shutdown safeguards. From the industrial perspective, he stated, metrology is the area in most need of innovation: real-time data would enable business expansion by allowing worker protection programs to scale with the size of the facility.

Summary of Public Input

The participants in the EHS Capstone meeting submitted 59 suggestions for Grand Challenges for nanotechnology EHS research. While most participants did not submit research challenges *per se*, they did comment on major EHS issues that will need to be considered as nanotechnology moves further into the commercialization process. Issues raised by participants spanned a range of scientific topics and regulatory considerations, some of which fall outside the scope of a research-oriented entity like the NNI; however, all comments are reflected here (and also indicated in various other parts of this report) in order

to give a sense of the spectrum of issues surrounding nanotechnology EHS concerns.

The suggestions covered a range of topics, but fell broadly into two main categories: research issues and governance issues. Within these categories, comments generally focused around a few themes, such as exposure and education. In addition, a number of comments focused on crosscutting issues, such as regulation and risk. Table E-1 provides a summary of the number of comments in each thematic area.

Table E-1: Public Comments on Nanotechnology EHS Grand Challenges*

Category	Theme	Comments
Research	Particle characterization	9
	Exposure issues	8
	ELSI	7
Governance	Education	2
	Transparency	11
Crosscutting	Regulation	12
	Risk	8
	Multidisciplinary	9

*Note that some comments touched on multiple categories and are therefore double-counted.

Webcast of Session

The Grand Challenges for Nanotechnology EHS Research was webcast and is available at <http://www.nano.gov/events/meetings-workshops/capstone>.

Closing Remarks

Nanotechnology allows scientists to create, explore, and manipulate the biological and material worlds measured in nanometers. The end goal of EHS research is to use knowledge about the safety implications of novel materials and processes to make informed decisions about whether and how to proceed. As a result, risk analysis and risk management as well as ELSI considerations have a strong relationship to EHS research. The opportunity to bring ELSI discussion into risk management methods is important moving forward in the research and development of this emerging technology. ELSI is becoming an important area of interest, especially now that it can be factored into risk management methods discussions. It will

be helpful to continue to clarify its importance in science in a larger context for the purpose of making informed decisions towards the responsible development of nanotechnology. EHS considerations should also be evaluated in a larger societal context, which has a key role in advancing nanotechnology.

Industry, academia, and public stakeholders will be valuable in promoting this discourse, and when needed, contributing additional considerations. Input from this RMM and ELSI workshop was intended to contribute to the development of the 2011 NNI EHS Research Strategy.

Appendix F. List of Acronyms

AAAS	American Association for the Advancement of Science	NIOSH	National Institute for Occupational Safety and Health (CDC)
CDC	Centers for Disease Control and Prevention	NIST	National Institute of Standards and Technology
CPSC	Consumer Product Safety Commission	NNCO	National Nanotechnology Coordination Office
DOC	Department of Commerce	NNI	National Nanotechnology Initiative
DOD	Department of Defense	NSET	Nanoscale Science, Engineering, and Technology Subcommittee of the National Science and Technology Council's Committee on Technology
DOE	Department of Energy	NSF	National Science Foundation
EHS	Environment(al), health, and safety	NSTC	National Science and Technology Council
ELSI	Ethical, Legal, and Societal Implications	OECD	Organisation for Economic Co-operation and Development
ENM	engineered nanomaterial(s)	OSHA	Occupational Safety and Health Administration (DOL)
EPA	U.S. Environmental Protection Agency	PCAST	President's Council of Advisors on Science and Technology
EU	European Union	PEL	permissible exposure limits
FDA	Food and Drug Administration	RA	risk assessment
HHS	U.S. Department of Health and Human Services	R&D	Research and development
ISO	International Organization for Standardization	REL	recommended exposure level
LCA	life cycle analysis	RMM	Risk Management Methods
MCDA	multicriteria decision analysis	SWCNT	single-walled carbon nanotube
MWCNT	multiwalled carbon nanotube	TLV	Threshold limit value
NEHI	Nanotechnology Environmental and Health Implications Working Group of NSET	TSCA	Toxic Substances Control Act (1976)
NGO	Nongovernmental organization	USDA	U.S. Department of Agriculture
NIEHS	National Institute of Environmental Health Sciences (NIH)	USGS	U.S. Geological Survey
NIH	National Institutes of Health		

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