



**STATEMENT OF**

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**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**“RESEARCH ON ENVIRONMENTAL AND SAFETY IMPACTS OF  
NANOTECHNOLOGY: WHAT ARE THE FEDERAL AGENCIES  
DOING?”**

**BEFORE THE**

**COMMITTEE ON SCIENCE**  
**HOUSE OF REPRESENTATIVES**

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## **INTRODUCTION**

Mr. Chairman and Members of the Committee, thank you for the opportunity to speak with you today about nanotechnology programs and the work of the Nanotechnology Environmental and Health Implications (NEHI) Working Group. I am Dr. Norris Alderson, Associate Commissioner for Science, at the Food and Drug Administration (FDA or the Agency). As FDA's Associate Commissioner for Science, I am responsible for the management of the Office of Women's Health, the Office of Orphan Products Development, the Good Clinical Practices Staff, coordination of science issues across the Agency, and oversight of FDA-sponsored clinical studies and standards coordination.

## **OVERVIEW**

Nanotechnology is expected to contribute to scientific advances in medicine, energy, electronics, materials, and other areas. Many of the benefits of nanotechnology arise from the fact that nanomaterials exhibit properties and behavior different from those of materials at larger scales. These unique properties that enable new benefits, however, also could lead to nanomaterial-specific human health and environmental risks.

That a new technology could offer both benefits and, at the same time, potential risk, is not unique to nanotechnology. Other common examples are electricity, household cleaning supplies, gasoline, and medical X-rays. Learning more about risks of technologies provides information for their successful management and the realization of their benefits.

## **NANOTECHNOLOGY ENVIRONMENTAL AND HEALTH IMPLICATIONS (NEHI) WORKING GROUP**

I have been involved in the Nanotechnology Environmental and Health Implications (NEHI) Working Group since its inception. The Nanoscale Science, Engineering, and Technology (NSET) Subcommittee established the Working Group informally in late 2003 and formally chartered it in 2005.

The purpose of the NEHI Working Group is to provide for exchange of information among agencies that support nanotechnology research and those responsible for regulation and guidelines related to nanoproducts (containing engineered nanoscale materials); facilitate the identification, prioritization, and implementation of research and other activities required for the responsible research and development, utilization, and oversight of nanotechnology, including research methods of life-cycle analysis; and promote communication of information related to research on environmental and health implications of nanotechnology to other government agencies and non-government organizations.

One of the key objectives of the NEHI Working Group is to exchange information on the issues raised within the participating regulatory agencies by advances in nanotechnology. The NEHI Working Group assists in the development of information and strategies as a basis for the drafting by the regulatory agencies of guidance toward safe handling and use of nanoproducts by researchers, workers, and consumers. Further, the group is working to

support development of nanotechnology standards, including nomenclature and terminology, by consensus-based standards organizations.

In pursuit of these aforementioned objectives, activities of the NEHI Working Group over the past two years include:

- communication by participating regulatory agencies concerning their respective statutory authorities for regulating nanoproducts, and their approaches for carrying out those authorities;
- encouraging all the participating regulatory agencies to develop a position statement on how they are addressing nanotechnology (an effort that has resulted in the establishment of a nanotechnology website at most of the participating regulatory agencies);
- development of a preliminary “risk assessment influence diagram” to help guide the NEHI Working Group’s approach to thinking about potential risks from nanoproducts and services (this effort led to a peer-reviewed scientific publication);
- discussion with various relevant standards bodies regarding nomenclature and standards development for nanotechnology that will affect both regulators and researchers; and
- compiling the inputs from participating agencies on their perceived needs for Environmental, Health, and Safety (EHS) research and information and development of a draft document drawn from this compilation and inputs from industry and other similar documents from other countries and organizations.

A product of these activities is a report titled *Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials*.

## **THE NEHI WORKING GROUP REPORT**

The primary purpose of this document is to identify for the Federal government the EHS research and information needs related to understanding and management of potential risks of engineered nanoscale materials that may be used in commercial or consumer products, medical treatments, environmental applications, research, or elsewhere. In addition, industry producers and users of engineered nanoscale materials may use this document to inform their own research, risk assessment, and risk management activities.

The report is the first step in addressing the research needed to support informed risk assessment and risk management of nanomaterials. The document represents over a year of intensive work by the participating agencies.

In addition to gathering input from its members for the purposes of this report, the NEHI Working Group has considered a number of public documents on the subject of EHS research while drafting this report. Included were documents from the chemical industry, the Environmental Protection Agency (EPA), the National Institute for Occupational Safety and Health (NIOSH), the Royal Society/Royal Academy of Engineering in the United Kingdom, and the Scientific Committee on Emerging and New Identified Health Risks/European Commission.

Once the research needs were identified, they were grouped into five areas:

1. Instrumentation, metrology, and analytical methods
2. Nanomaterials and human health
3. Nanomaterials and the environment
4. Health and environmental surveillance
5. Risk management methods

Research on nanoscale materials is supported by each agency, respectively, based on its primary scientific mission. The National Institutes of Health (NIH) supports a broad spectrum of biological nanoscale research ranging from basic science to clinical and translational investigations and clinical trials; the National Science Foundation (NSF) supports basic research on interactions between engineered nanoscale materials and cells. The EPA looks at broader implications for both human health and the environment including how nanomaterials will potentially affect whole ecosystems containing many different organisms. In some cases, such as the EPA-NSF-NIOSH-National Institute of Environmental Health Sciences joint interagency solicitation on environmental implications of nanotechnology, agencies conduct joint review of proposals, and then allocate the top rated proposals among themselves according to their respective missions and program emphases.

The NEHI Working Group Report supports NSET's mandate to coordinate Federal nanoscale research activities. The document will serve as a uniform guide for all Federal

agencies in developing their plans to support environmental, health, and safety research on the implications of nanoscale materials.

## **NEXT STEPS**

With the completion of the report released today, issues that remain to be addressed in the future include:

- Further prioritize research needs. Priorities will be evaluated based primarily on the principles outlined in the document. Other factors that will be considered include the time frame for developing the information—because certain studies are inherently lengthy—and the availability of research tools.
- Evaluate in greater detail the current National Nanotechnology Initiative (NNI) EHS research portfolio.
- Perform a “gap analysis” of the NNI EHS research compared to the prioritized needs.
- Coordinate and facilitate among the NNI agencies research programs to address priorities. Agencies will work individually and jointly, where possible, to address research needs.
- Establish a process for periodically reviewing progress and for updating the research needs and priorities. Such a review must take into consideration advances made by entities other than U.S. government-funded bodies, such as advances by the private sector and foreign governments.

## **CONCLUSION**

I expect the NEHI Working Group to play an active role in all of the “next steps” mentioned above; although, the Working Group will serve only in an advisory capacity with respect to assisting agencies in setting their respective research priorities. Thank you again for the opportunity to testify today, Mr. Chairman. I appreciate the Committee’s continued interest in nanotechnology, and I am happy to answer any questions you may have.