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Nanotechnology Oversight Requires Thinking Outside the Box Former EPA Official Says Now Is Time to Consider Regulatory Questions, Mechanisms

WASHINGTON, D.C.—With hundreds of nanotechnology-enabled products already on the market and many more in the commercial pipeline, a new report by a former senior Environmental Protection Agency (EPA) official urges policymakers to give greater attention to the challenges of crafting an oversight system that can effectively address health and safety issues particular to nanoscale materials and devices.

"It is time for government, industry, the scientific community, non-governmental organizations and other interested parties to begin a more systematic discussion about the core elements of an oversight framework for nanoscale materials" writes Mark Greenwood in *Thinking Big About Things Small: Creating an Effective Oversight System for Nanotechnology*. Greenwood worked for EPA for over 16 years and was director of EPA's Office of Pollution Prevention and Toxics from 1990 to 1994.

The report was released at an event sponsored by the Project on Emerging Nanotechnologies at the Woodrow Wilson International Center for Scholars. The Project is a partnership between the Wilson Center and The Pew Charitable Trusts.

"Public discussions of nanotechnology oversight over the last few years have been dominated by two topics: research priorities and the potential jurisdiction of various health and environmental statutes over nanoscale materials," said Greenwood. "Not enough attention is being given to the policies that should be used to define acceptable and unacceptable risk and to determine appropriate management practices."

Greenwood distills three sets of issues that he proposes as the defining elements of an effective oversight system: risk criteria, information reporting requirements and risk management tools. The report identifies, in each of these three areas, some of the key policy questions that will be particularly important to consider, regardless of the form of oversight. Greenwood also emphasizes that the policies established in these three areas will "shape the overall social and economic trajectory of nanotechnology and determine what kinds of nanoscale products and companies can prosper in the future."

"Ultimately," suggests David Rejeski, director of the Wilson Center's Project on Emerging Nanotechnologies, "existing regulatory approaches likely will prove to be suboptimal. Novel problems require novel solutions, and the oversight of nanotechnology will require 'out of the box' thinking. As an alternative, this report suggests that a number of statute-independent questions need to be answered by government, industry, non-governmental organizations and other stakeholders."

"There is much at stake," said Rejeski. "How the oversight system evolves at this early stage will have significant impacts on industry structure, the competitive strategies of firms, and approaches to intellectual property. It can ultimately define who can 'play' or not, especially if the costs of testing and data submissions are high. These impacts have not received the attention they deserve but need to be addressed as soon as possible."

Greenwood also emphasizes the importance of openness in the risk-management decision-making process. "While recognizing the need to protect intellectual property and to be sensitive to other business concerns, efforts to devise an effective nanotechnology oversight system should explore ways to assemble information so that the public feels it is adequately informed," said Greenwood. "Stakeholders must engage in pragmatic discussions about the ground rules for transparency. The need for this discussion is no more distant than nanotechnology itself. And this means that this discussion should start now."

About the Author

Mark Greenwood is currently a partner in the Washington, D.C., office of Ropes & Gray, where he practices environmental law. Before joining Ropes & Gray in 1994, Mark worked for the U.S. Environmental Protection Agency for over 16 years. He held a variety of senior positions in the Office of General Counsel, managing legal issues in areas as diverse as pesticides, toxic chemicals, hazardous waste management, Superfund, and environmental reporting. From 1990–1994, he was director of the EPA's Office of Pollution Prevention and Toxics.

About Nanotechnology

Nanotechnology is the ability to measure, see, manipulate and manufacture things usually between 1 and 100 nanometers. A nanometer is one billionth of a meter; a human hair is roughly 100,000 nanometers wide.

The market opportunity for nanotechnology is substantial. Nanotechnology was incorporated into more than \$30 billion in manufactured goods in 2005—more than double the previous year. In 2014, Lux Research projects that \$2.6 trillion in global manufactured goods will incorporate nanotechnology, or about 15 percent of total output.

The **Project on Emerging Nanotechnologies** is an initiative launched by the Woodrow Wilson International Center for Scholars and The Pew Charitable Trusts in 2005. It is dedicated to helping business, government and the public anticipate and manage possible health and environmental implications of nanotechnology. For more information about the project, log on to www.nanotechproject.org.

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