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FDA IS NOT NANOTECH-READY

Former Official Says FDA Lacks Resources & Faces Legal Gaps

WASHINGTON—A new report released today, *Regulating the Products of Nanotechnology: Does FDA Have the Tools It Needs?* by Michael Taylor, a former Deputy Commissioner for Policy at the Food and Drug Administration (FDA), examines the agency's capacity to properly regulate new products containing nanotechnology materials—including food, drugs, medical devices, dietary supplements and cosmetics. Taylor's report comes days before FDA's first major public meeting on nanotechnology oversight, scheduled for October 10, 2006.

The report, commissioned by the Woodrow Wilson Center's Project on Emerging Nanotechnologies, finds FDA's resource base severely eroded. "The pressures of expanding regulatory responsibilities and the increasing cost of doing business, coupled with the failure of Congress and successive administrations to adequately fund even FDA's base operations, are a real threat to FDA's ability to effectively oversee nanotechnology," said Taylor. "But FDA's lack of 'nano-readiness' is about more than dollars," according to Taylor. "There are important gaps in FDA's legal authority that hamper its ability to understand and manage nanotechnology's potential risks. This is particularly true in the area of cosmetics and dietary supplements, and in the oversight of products after they reach the marketplace."

"Finally," argues Taylor, "there are over 300 manufacturer-identified nanotechnology consumer products being sold to Americans. FDA should take some immediate steps to gather information about this first wave of nanotechnology products and to set the criteria for determining when a nanoscale material is 'new' for legal, regulatory and safety purposes. By acting promptly, FDA will be in a better position to prevent regulatory and safety problems rather than having to react later, after the fact."

"Nanotechnology is emerging rapidly as a transformative technology across virtually every product category FDA regulates," stated David Rejeski, director of the Project on Emerging Nanotechnologies. "Its enormous potential to benefit consumers and patients will be realized, however, only if its safety is understood and reasonably assured. Consumers rely on the FDA to judge what is safe and unsafe. Unless the FDA addresses

potential nanotechnology risks now, public confidence in a host of valuable nanotechnology-based products could be undermined."

In his report, Taylor reviews Congress's and FDA's history of responding to new technologies and the public's longstanding expectation that FDA should be able to both ensure the safety of novel products before they enter the market and detect and swiftly correct problems that arise after marketing begins. "FDA has a leadership role to play on nanotechnology," Taylor said, "but it is incumbent on society, acting through Congress, to give FDA the legal tools and resources it needs to do the job."

Taylor hopes his report stimulates an active and necessary discussion about the tools FDA needs and the approach it should take to lead globally in bringing forward nanotechnology's potential benefits, as well as managing its risks. "In addition to addressing potential risks, FDA has an equally critical public health responsibility to foster timely introduction of the beneficial new medical products made possible by nanotechnology," Taylor said. "Business and health leaders alike should join in ensuring that FDA has the scientific tools and knowledge it needs to say 'yes' to safe and effective new products," Taylor remarked.

The Project on Emerging Nanotechnologies will release Mr. Taylor's report at a briefing today, October 5, from 12 Noon to 1:00 PM. ET at the Woodrow Wilson International Center for Scholars, located at 1300 Pennsylvania Avenue, N.W., Washington, D.C., 5th floor conference room.

The briefing will be webcast live at http://www.wilsoncenter.org/nano

About Nanotechnology
Nanotechnology is the ability to measure, see, manipulate, and manufacture things at an atomic and molecular scale, 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. Emerging 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 U.S. invests approximately $3 billion annually in nanotechnology research and development, which accounts for approximately one-third of the total public and private sector investments worldwide.

About the Author
Michael R. Taylor is a professor at the University of Maryland School of Medicine, where he conducts research on policy, resource, and institutional issues that affect the success of public health agencies in carrying out their prevention missions. Previously, he was a senior fellow and director of the Risk, Resource, and Environmental Management Division at Resources for the Future (RFF) and remains an RFF University Fellow. While at RFF, Taylor co-founded the Food Safety Research Consortium, which he chairs. Prior

to RFF, Taylor served in government, practiced law in Washington, and worked in private industry. He was administrator of the USDA's Food Safety and Inspection Service from 1994 to 1996; deputy commissioner for policy at the Food and Drug Administration from 1991 to 1994; and an FDA staff lawyer and executive assistant to the FDA Commissioner from 1976 to 1981. He practiced food and drug law as a partner in the law firm of King & Spalding for ten years and served as vice president for public policy at Monsanto Company. Taylor has served on several National Academy of Sciences (NAS) committees and currently serves on the Advisory Committee of the Partnership to Cut Hunger and Poverty in Africa and the Board of Trustees of Resolve, Inc. He received his law degree from the University of Virginia and his B.A. in political science at Davidson College.

The **Project on Emerging Nanotechnologies** is an initiative launched by the Wilson Center 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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