Woodrow Wilson International Center for Scholars

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FDA Nanotechnology Task Force Takes a Step Forward
Agency Sees Nanotech Challenges in Every Product Category It Regulates

WASHINGTON, DC—According to Project on Emerging Nanotechnologies Director David Rejeski, "Today, FDA took a step forward in fulfilling its responsibilities for nanotechnology oversight. If nanotechnology regulation was a baseball game, FDA has scored the first run in the first inning. But the agency must act rapidly to adopt and fully implement the Nanotechnology Task Force's recommendations. Without moving quickly and building on the recommendations in the Task Force report, FDA will not be able to keep pace with today's rapidly developing nanotechnology market or engender consumer and investor confidence in emerging products."

Just released, this is the first report from the Food and Drug Administration's Nanotechnology Task Force about the agency's regulatory approach toward nanotechnology—an exciting new field of engineering and science that is estimated to grow to $2.6 trillion in manufactured goods globally by 2014. As the Task Force report highlights, nanotechnology impacts every area of FDA responsibility—drugs, drug delivery systems, cosmetics, medical devices, and food products. Overall, the agency regulates products that are worth nearly $1.5 trillion annually and that account for almost 25 percent of US consumer spending.

"Today, there are more than 500 manufacturer-identified nanotechnology consumer products being sold. These can be found in an online inventory maintained by the Wilson Center's Project on Emerging Nanotechnologies (see: www.nanotechproject.org/consumerproducts)," said Rejeski. "The number of listed products has more than doubled in a year. It does not include nanotech consumer products which companies do not identify as such, or the hundreds of nano raw materials, intermediate components, and industrial equipment items currently used by manufacturers."

"In light of this fast-rising commercialization, FDA needs to make certain that it has the tools, resources and information necessary to ensure the safety of novel products before they enter the market, and to detect and move swiftly to correct any problems that may arise. Given the agency's insufficient resources—which for two decades have not kept pace with inflation—making sure that FDA has the capacity to safely manage nanotechnology must be the shared responsibility of Congress and our political leaders," argued Rejeski. "The agency must be 'nano-ready' for the products on the market today and able to deal with the more advanced nanotechnology applications expected in the next 5-10 years."

"Many of the first generation of nanotechnology products now on the market are in sectors where FDA's statutory authority is weakest—areas like cosmetics and dietary supplements," stated Project on Emerging Nanotechnologies Chief Science Advisor Andrew Maynard. "The Task Force report clearly states that size matters in making risk management decisions. Because the chemical, physical and biological properties of nanoscale materials are often different from their larger counterparts, they potentially lead to different safety issues. The report's recommendations that FDA provide clear nanotechnology-associated guidance for manufacturers in all areas of agency responsibility are an important move towards ensuring the benefits of nanotechnology are realized without undue risk,"

Dr. Maynard said. "FDA is limited in its oversight of nanotechnology by the dearth of available risk research data on nanomaterials. Because the agency is resource-starved, there are scant funds for FDA to conduct its own regulatory-relevant risk research. It is critical that FDA—and other regulatory agencies—have the means necessary to evaluate which nanomaterials are harmful and which are not. This is an issue that Congressional leaders from both parties have called on the federal government to address urgently," said Maynard.

For an in-depth analysis of FDA's nanotechnology readiness, see the October 2006 report, ***Regulating the Products of Nanotechnology: Does FDA Have the Tools It Needs?*** This report was commissioned by the Project on Emerging Nanotechnologies, and is available at http://www.nanotechproject.org/82

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 **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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