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Nanotechnology: It's Knocking on FDA's Door
Food & Drug Administration Faces Growing Number of Nanotech Medical Products

WASHINGTON—"Thanks to the promise of nanotechnology, people will benefit from fantastic new prescription drugs and from better ways of getting existing pharmaceuticals into the body for more effective disease treatments. But new nano-enabled drugs and medical devices also place new burdens on an oversight agency that is already stretched extremely thin," said Project on Emerging Nanotechnologies Director David Rejeski in a presentation today at the Food and Drug Administration's first major public meeting on regulating products containing nanotechnology materials.

Both in his remarks and in the Project's written submission, available at www.nanotechproject.org, Rejeski stated that "there are currently 130 nano-based drugs and delivery systems and 125 biomedical devices in preclinical, clinical or commercial development—an increase of almost 70 percent just since last year. While FDA already has approved some products with materials in the nanosize range, prospects for future growth in this area—and the burden it will place on the agency's resources—are striking."

"The Project on Emerging Nanotechnologies—using information contained in the *2006 Nanomedicine, Device & Diagnostics Report*—recently examined just two sets of nanotechnology medical applications: cancer-relevant drugs (total: 77) and drug delivery applications (total: 56). While this was only a very preliminary assessment, the analysis shows the nanotechnology pipeline of medical products is growing and could pose a major challenge to the agency's resources and expertise in the near future," said Rejeski.

The Project's submission also highlighted nine currently available nanotechnology drug and drug delivery products already approved for use by FDA. They include:

- **Abraxane®**: a treatment for advanced forms of breast cancer using "nanoparticles made of the human protein albumin"
- **Acticoat®**: uses SILVCRYST™ Nanocrystals to create wound dressings that "offer powerful antimicrobial barrier protection"
- **Estrasorb®**: a topical estrogen therapy product based on a "patented and proprietary micellar nanoparticles drug-delivery platform"

More detailed information on these and other nanotechnology medical products can be found on the Project on Emerging Nanotechnologies website at www.nanotechproject.org.

“Nanotechnology is emerging rapidly as a transformative technology across virtually every product category FDA regulates,” stated Rejeski. “The stakes are extremely high—in terms of human health benefits, financial investments, and scientific progress. It’s up to FDA, with the strong support of Congress and industry, to ensure that these nanotechnology products are safe. Unless the FDA has the capacity to address potential nanotechnology risks now, public confidence in a host of valuable nanotechnology-based products could be undermined.”

The Project on Emerging Nanotechnologies just released a new report by former FDA Deputy Commissioner for Policy Michael R. Taylor, *Regulating the Products of Nanotechnology: Does FDA have the Tools It Needs?* This in-depth study of the FDA’s resource and legal capacity to safely regulate nanotechnology products—including dietary supplements, food, cosmetics and drugs—is also available on the Project’s website: www.nanotechproject.org

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.

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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