



Woodrow Wilson
International
Center
for Scholars

Contact: Colin Finan
Phone: (202) 691-4321 (work)
(202) 841-5605 (cell)
colin.finan@wilsoncenter.org

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Nanotech In Your Vitamins

Report highlights FDA's regulatory challenges posed by nanomaterials

Washington, DC – The ability of the Food and Drug Administration (FDA) to regulate the safety of dietary supplements using nanomaterials is severely limited by lack of information, lack of resources and the agency's lack of statutory authority in certain critical areas, according to a new expert report released by the Project on Emerging Nanotechnologies (PEN).

The report, *A Hard Pill To Swallow: Barriers to Effective FDA Regulation of Nanotechnology-Based Dietary Supplements*, details the main problems at FDA in regulating nano-enabled dietary supplements and offers a host of recommendations for improving oversight of such products.

"Historically, the regulation of dietary supplements has been a significant challenge for FDA, and the fact that some of those products are now being manufactured using nanotechnology creates an additional layer of complexity," says William B. Schultz, a co-author of the report and a former FDA official.

Little is known about the use of engineered nanoparticles in the dietary supplement market. Current law requires supplement manufacturers to disclose limited information about their products, and what information is available is a result of dietary supplement manufacturers touting the use of nanotechnology when marketing their products, according to the report.

"While it is not possible to precisely determine the prevalence of dietary supplements using engineered nanoparticles, it is likely that the public's exposure to these products will grow significantly in the next several years," says Lisa Barclay, also a co-author of the report.

According to an inventory of federal environmental, health and safety research on nanotechnology maintained by PEN, the U.S. government is spending less than \$1 million annually to study the direct impact of nanoscale materials on the gastrointestinal tract.

“It is not clear that the supplement industry is conducting the rigorous testing needed either to understand the effects of nanoscale ingredients in its products or to back up the product claims. This means that consumers are potentially exposed to unknown risks that should be balanced with the possible benefits of taking these supplements,” says David Rejeski, PEN’s director.

To obtain a copy of the new report, visit www.nanotechproject.org/supplements/.

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. In 2007, the global market for goods incorporating nanotechnology totaled \$147 billion. Lux Research projects that figure will grow to \$3.1 trillion by 2015.

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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