

THE FORUM

Regulate Nano Now

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We stand on the threshold of the next industrial revolution — the nanomaterials revolution. Those who want to commercialize nanoscale materials and maintain America's technological and economic leadership should learn the lessons of the biotech revolution and lobby the Bush administration to regulate nano now under the guidance of the National Academy of Sciences using existing EPA and FDA legal authority. A credible governmental program to protect health and the environment is crucial to public acceptance of this promising new technology.

The industrial and medical applications of nanotechnology are very exciting. Side effects of chemotherapy for cancer may become a thing of the past, for instance, as drugs can be attached to nanoparticles to kill cancer cells while leaving healthy cells alone. But some materials that are safe in ordinary sizes become toxic as nanomaterials. We already know that ordinary carbon formed into nanoparticles with spherical shapes, called buckyballs, can be toxic to fish. We currently lack techniques to find and clean up nanoscale chemical "spills" in the environment, so it is important to prevent problems before releases occur.

EPA correctly believes that it has existing statutory authority to regulate nanomaterials under the Toxic Substances Control Act by issuing a Significant New Use Rule but it has hesitated to act and instead is considering a voluntary program. Some are concerned that burdensome regulation may stifle this promising new technology. And EPA does not know how to prioritize or analyze the reams of data that might be produced if every new size or shape of par-

ticle were considered a separate "particular molecular identity" requiring pre-market testing and clearance under TSCA.

Without government guidance, some responsible companies are doing their best to test nanomaterials on their own. The American Society of Testing and Materials is developing consensus recommendations but as yet there are no established scientific protocols for either safety or environmental compatibility testing. Meanwhile, nanomaterials are already coming onto the market. Nanoscale oxides of zinc and titanium are in some suntan lotions and nanoscale fibers are used in some stain-resistant fabrics. Many more applications of nanotechnology are just around the corner.

Those of us who favor responsible development of nanotech should learn the lessons of the biotech revolution. One reason (among many) that consumers in the United States accepted biotechnology while the same products are still rejected by many consumers in Europe was the agility of the U.S. legal system to put a credible regulatory system in place quickly. The National Academy of Sciences made recommendations for screening techniques and testing priorities for genetically modified organisms, which EPA, FDA, and other agencies quickly adopted using their *Chevron* authority to interpret existing law. We should follow the same successful course for nanotech.

Lacking government guidance, some private companies are currently making important policy decisions about how to test nanomaterials. These decisions inevitably involve policy choices about where to focus scarce resources. For example, one company has concluded that nanomaterials that do not pass through the skin are probably safer and require a lesser degree of testing. These judgments may or may not turn out to be correct, but they should not be made by the private sector alone.

In this era of deregulation, we sometimes forget that one of the purposes of regulation is not

just to keep the public safe, but also to assure the public that new technologies are safe so that they will be accepted. As FDR said in 1933 when introducing the first federal law to regulate securities at the height of the Depression, "It should give impetus to honest dealing in securities and thereby bring back public confidence." A credible regulatory system can help industry win consumer acceptance of new technology. Timely and credible government regulation of biotechnology was implemented in the United States in the 1980s, but failed in Europe, leading to widespread public concern and a regulatory over-reaction by government, which is only now beginning to soften.

Like past technological revolutions, nanotechnology holds great promise, but also raises fears of possible risks to public health and the environment. Industry should not wait for the first scary headlines about a threatened nanodisaster, which are likely to lead to an over-reaction by government. Instead, industry and government should work together now to put in place a credible regulatory framework that will assure consumers that particular uses of nanotechnology are safe before they are put on the market.

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