Nanotech Gamble

PART 3 of 4

Obsession with Nanotech Growth Stymies Safety Regulators

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(March 22) -- When the United States government formally acknowledged the world-changing potential of nanotechnology a decade ago, it was decided that America should lead the way. Almost immediately, 25 different federal agencies began scrambling to find uses for the engineered particles in medicine, energy, transport, weapons, protective devices and food, as well as thousands more real and dreamed-about applications.

Today, the U.S. is at the fore of worldwide nano-innovation. But when it comes to regulations and laws that will protect consumers and workers from the potential hazards, the country lags badly behind many other nations.

"The government agencies responsible for protecting the public from the adverse effects of these technologies seem worn and tattered," former Environmental Protection

Agency assistant administrator Clarence Davies wrote in a study for the Woodrow Wilson International Center for Scholars' Project on Emerging Nanotechnologies, where he is now a senior adviser. Davies, who while at the EPA authored what became its all-important Toxic Substances Control Act, adds that the gap between the capabilities of nanotechnology and those of the regulatory system "is likely to widen as the new technologies advance."

Advocates say the importance of establishing effective nano-safety guidance is difficult to overstate. But that effort is also dauntingly difficult.

"Get these rules wrong -- and we're not sure what they are yet -- or ignore them, and we may cause unnecessary harm to people and the environment," says Andrew Maynard, chief science adviser for the Wilson Center. "I don't think it will be the end of the world as we know it. But it will be a lost opportunity to get an exciting new technology right."

No One's in Charge

The U.S. government has no nano czar, no single entity responsible for setting priorities and doling out billions in research funds. But on paper, the National Nanotechnology Initiative comes closest to fitting that role.

Launched by the Clinton administration **in 2001**, the NNI was tasked with coordinating federal investment in

nanotechnology research and development. The official description of its mission mandates it to "advance a world-class nanotechnology research and development program, foster the transfer of new technologies into products for commercial and public benefit, and support responsible development of nanotechnology."

While that sounds somewhat czar-like, the reality is that who's in charge of America's nanotech policy is murky.

"Final authority resides in the [White House's] Office of Science and Technology Policy, the Office of Management and Budget, and with the president," says NNI Director Clayton Teague. At the same time, Teague's position is that there's no need for a central, government-wide coordinating entity on nanotechnology. "There is no nuclear 'czar,' no independent authority over information technology, electronic technology, or biotechnology for health and medicine," he says, adding that nanotechnology activities "claim less than 1 percent of the federal research and development budget" and therefore "simply don't require the special focus you are suggesting."

NNI's biggest shortcoming, say even the agency's supporters, is its failure to adequately fund basic research on the safety hazards of nanomaterial.

"The NNI has never effectively addressed environmental, health and safety issues surrounding nanotech with a comprehensive, interagency plan," Matthew Nordan,

president of technology forecasting firm Lux Research, told the Senate Committee on Commerce, Science and Transportation. Although his statement was made almost two years ago, committee investigators say there has been little or no improvement since.

The Obama administration's 2011 budget illustrates the scant federal resources devoted to nano-safety. It proposes spending $1.8 billion on nanotechnology overall, but just $117 million -- or 6.6 percent -- of that was earmarked for the study of health-related issues surrounding the engineered particles. "It's not a small amount," says Travis Earles, a nanotech adviser to the White House, defending the allotment.

Without a single office leading the charge, the task of guarding against potential nanotech risks falls to the four agencies most involved in protecting the public, workers and the environment: the EPA, the Food and Drug Administration, the U.S. Department of Agriculture and the Occupational Health and Safety Administration.

Many of the safety experts in those agencies told AOL News that the vital regulations for the use, production, labeling, sale and ultimate disposal of nanomaterial are not keeping pace with the rush of new products entering the marketplace.

"Consumers want to know what they buy, retailers have to know what they sell, and processors and recyclers need to know what they handle," Christoph Meili, of the Innovation

Society Ltd., said in a report on international nano regulations funded in part by the Swiss Federal Office for the Environment.

Some of the scientists involved in turning nanoparticles into new business opportunities, however, argue that such protocols would be premature.

"I don't think we have the scientific basis on which to establish regulations. And I think that right now a lot of the materials that are being produced are absolutely benign," says Stacey Harper assistant professor of nanotoxicology at Oregon State University.

"The Holy Grail," she says, "is figuring out what are those [hazardous] features that we need to avoid in engineering these newer materials."

'Do Nothing to Prevent Innovation'

The FDA makes stringent demands for safety information on nanomaterial used in medicine and medical devices, says Jesse Goodman, its chief scientist and deputy commissioner for science and public health. But the agency takes no specific measures to ensure the safety of the many costly cosmetics and dietary supplements boasting the benefits of the nano ingredients they claim to include, even though its own investigators say the public submits a constant stream of questions and complaints. "Nanotechnology products

present challenges similar to those the [FDA] faces for products of other emerging technologies," says an agency press officer, and "our existing regulations can pretty much handle these advancements."

That stated approach terrifies public health advocates, as well as some of the agency's own risk assessors.

"FDA is like ostriches with their heads in the ground, not looking for a problem so they do not see one. If they don't see one, they don't have to respond to a problem," says Jaydee Hanson, senior policy analyst for the Center for Food Safety.

The FDA does need better tools and expertise to predict the behavior of nanomaterial, Goodman concedes. But, he adds, "to get information needed to assess the safety of nano products, we do that in a way that doesn't cause a problem in terms of preventing innovation."

"Do nothing to prevent innovation" was former Vice President Dick Cheney's marching orders to the Office of Management and Budget during President George W. Bush's administration. "For years OMB acted as industry's protector," says Celeste Monforton, assistant research professor at George Washington University's School of Public Health. She is among the public health activists who cringe to hear the phrase still being used by President Barack Obama's regulators.

For all that, however, the FDA appears most AWOL in its

handling of nanomaterial in food. Food safety experts in the agency say it is doing little more than paying bureaucratic lip service to developing criteria for handling the anticipated avalanche of food, beverages and related packaging that is heading to store shelves. (The agency declined repeated requests to interview any of its food scientists or regulators.)

With the FDA largely punting, responsibility for ensuring the safety of the nanomaterial in the marketplace falls to the Consumer Product Safety Commission -- which raises additional problems. "If you take the nanoproducts that we know are out there and divide them up among the safety agencies, the CPSC is actually responsible for a majority of those," says David Rejeski, science director for the Technology Innovation Program at the Woodrow Wilson International Center for Scholars.

In an analysis of CPSC's ability to handle nanomaterial, Rejeski -- who has worked in the White House Office of Science and Technology Policy -- and his team identified many limitations. The CPSC has no method of collecting information on nano-products, and limited ability to inform the public about health hazards.

"Even if they find a product," Rejeski says, "they don't have much ability to do any research to determine whether it's dangerous."

Finding a Way Around the Roadblocks

Since 2008, the EPA has been attempting to impose some controls on carbon nanotubes, whose myriad industrial applications make them one of the most heavily used engineered particles.

In June, it seemed to have made significant progress toward that goal, issuing a final notice on a process called "Significant New Use Rules," which would have required companies to notify the agency at least 90 days prior to the manufacture, importing or processing of carbon nanotubes.

The move was cheered by the public health community: Studies have shown that multiwalled nanotubes are among the nanomaterials posing potential risks to humans, capable of damaging or destroying the immune system, creating asbestos-like lung disease and causing cancer or mutations in various cells. The advocates heralded the measure as the first clear sign that EPA was going to hold nano developers and users accountable.

Almost immediately, the Washington law firm of Wilmer Hale, while declining to say whom it represented, threw up procedural roadblocks, notifying the EPA that it planned "to submit adverse and/or critical comments on behalf of one or more clients." That was enough to force the EPA to withdraw the new rules.

The EPA resubmitted its proposal. But on Dec. 1, in an unprecedented move, the European Commission's

Directorate-General for Enterprise and Industry raised concerns on behalf of a British nanotube maker. Action on the new rule was put off for another three months, with the public comment period running through March. Nevertheless, the EPA believes that by year's end, its new nanotube requirements will be mandatory.

Efforts such as those undertaken by Wilmer Hale's client to stall or thwart new or enhanced safety regulations are legal. So is another practice used by many corporations to deny EPA access to health studies and other information crucial to assessing the risk of a new chemical or product: declaring that the data is confidential business information.

EPA Administrator Lisa Jackson has said she wants to put an end to the corporate maneuvering, especially as it applies to the new nanomaterial. While testifying before a senate committee in December attempting to add teeth to the Toxic Substances Control Act, Jackson explained the obstacles EPA risk assessors confront in trying to do their jobs.

Due to the legal and procedural hurdles in the law, over the past 30 years, the administrator said, EPA has only been able to require testing on about 200 of the more than 80,000 chemicals produced and used in the United States.

"EPA should have the clear authority to establish safety standards that reflect the best available science ... without the delays and obstacles currently in place, or excessive claims of confidential business information," Jackson told

the lawmakers. In February, the agency's assistant inspector general, Wade Najjum, issued a report that said "EPA's procedures for handling confidential business information requests are predisposed to protect industry information rather than to provide public access to health and safety studies."

The changes to the Toxic Substances Control Act that Jackson is advocating would require mandatory reporting of the use of nanomaterials. EPA lawyers have told Senate investigators that the overhaul is vital due to the industry pressure spawned by the big business opportunities new nano-products can generate. Meanwhile, some nanotechnology players are pushing hard to get a resistant EPA to grandfather in nanomaterial already on the market. It's a significant point of dispute: One of the reasons the EPA is seeking the mandatory reporting requirement in the first place is that the agency is convinced the current voluntary system of submitting safety data doesn't work. In the fall, EPA assistant administrator Steve Owens told an international conference on regulating nanomaterial that about 90 percent of the various nanoscale materials already being used commercially, or thought to be used, were never reported to the government.

"EPA has determined that regulating existing nanoscale materials," explains press officer Dale Kemery, "is needed to ensure protection of human health and the environment."

A spokesman for the Senate Committee on Environment and

Public Works says two more hearings need to be held on revising the Toxic Substances Control Act, but they have yet to be scheduled.

Workers Require Extra Protections

If there is a frontrunner in the effort to institute meaningful safety regulations for nanomaterial, it is the National Institute for Occupational Safety and Health, the worker safety research arm of the Centers for Disease Control and Prevention. Physicians and scientists there have been scrambling to identify the risks that the nanotechnology industry's employees are encountering on the job. "Workers and employers can't wait for us to come up with all the answers before they unleash this technology. It's unleashed already," says Paul Schulte, manager of the NIOSH Nanotechnology Research Center.

Having published more than 170-peer-reviewed studies on the health effects from nano exposure, the agency has established exposure limits for nano titanium dioxide -- the heavily used material shown to damage and destroy DNA and chromosomes in studies at UCLA. The division has recommended that to ensure safety, the exposure limit for workers handling nano-titanium dioxide should be 15 times lower than that for the normal size of the chemical, says Vincent Castranova, the agency's chief of the Pathology and Physiology Research Branch.

The particles are believed to be used in more than 100 different manufacturing sites across the country. That's a lot workers.

NIOSH cannot pass laws, only make recommendations to the Occupational Safety and Health Administration. And because of all the tortuous, bureaucratic steps that still must be completed, as well as the anticipated blocking efforts from some industry interests, it could be two years before any regulations are instituted. OSHA leaders refused to respond to questions on what the agency will do in the meantime.

NIOSH has also almost completed recommendations for the handling of carbon nanotubes. And scientists at NIOSH's animal labs in Morgantown, W.Va., are now testing the toxicity of almost two dozen other nanoparticles, including the diesel additive cerium oxide; the metal hardening mixture of tungsten carbide and cobalt; the anti-microbial agent nanosilver; and the sun blocker zinc oxide.

Most significantly, NIOSH scientists have identified health risks from nanomaterials not previously documented by other researchers.

For example, says Castranova, when studying the potential impact of nano-titanium dioxide exposure on workers' lungs, they also found cardiovascular effects -- damage to the heart muscle.

Separately, the NIOSH team discovered that beyond the

well-documented lung damage that comes from inhalation of carbon nanotubes, those heavily used carbon structures were causing inflammation of the brain in the test animals.

"Everything we say could apply to a consumer. The big difference is that the consumer will likely see much lower concentrations, for much shorter periods of time," Castranova says, adding that the findings need to be viewed with the proper perspective.

Nanomaterials, Castranova says, are not anthrax, but they aren't Kool-Aid, either.

Other Countries Exercise Greater Caution

Consumer and safety watchdogs say Canada, the U.K. and the rest of the European Union are far ahead of the U.S. when it comes to nano safety requirements.

Canada became the first country to demand stringent reporting requirements of corporations and universities that import, manufacture or use more than 2 pounds of nanomaterial a year. The regulations -- necessary for proper risk assessment, the Canadian government said -- were crafted and would be enforced by Health Canada and Environment Canada. They require the reporting of the nanomaterial's chemical composition and physical description, toxicity and proposed use, along with other data.

French lawmakers have crafted legislation with similar stipulations. And the European Parliament voted last year that its 27 member states should consider nanomaterials as new substances, and not cover them under existing laws that do not take into account the risks associated with the technology. It also demanded that consumer products containing nanomaterials be clearly labeled as such, and that the manufacturers of new cosmetic products containing nanomaterials provide specific information to regulators six months before the product is placed on the European market.

In the U.K., the battle cry of nano-regulators is "No data, no market," especially with food products.

"Products will simply be denied regulatory approval until further [safety] information is available," the British House of Lords' science committee said in December. It concluded that there was too little research into the toxicological impact of eating nanomaterials, and too much secrecy on the part of the food industry.

"It's obvious that in some cases the U.S. has been a bit lax, though you could make the case that in some cases the EU requirements are a little bit too stringent," says Michael Holman, research director of Lux Research. "There's no regulatory regime that can give you 100 percent certainty that everything that comes to market is going to be perfectly safe."

But to Patty Lovera, assistant director of Food & Water Watch, that doesn't leave the U.S. government off the hook. The failure of the U.S. regulatory system to keep up with nanotechnology, she states simply, "puts consumers and the environment at risk."

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