

FDA Gets Mixed Advice on Nanotechnology

by The Associated Press
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WASHINGTON (AP) -- The government must balance close oversight of the fast-growing field of nanotechnology against the risk of stifling new development, a Food and Drug Administration conference was told Tuesday.

These contrasting views emerged from a host of experts that the agency brought together to how it should regulate products containing tiny particles, some as small as one-millionth the width of the head of a pin.

Increasingly, those submicroscopic particles are being incorporated in the thousands of products overseen by the FDA, including drugs, foods, cosmetics and medical devices.

Those products account for roughly 20 cents of every dollar spent each year by U.S. consumers, giving the FDA a key role in both safeguarding the public and guiding the future development of nanotechnology.

"The success of nanotechnology will rely in large part on how FDA plays its regulatory role," said Michael Taylor of the University of Maryland's School of Public Health.

The key is to use science to weigh both the benefits and the risks of nanotechnology, said Matthew Jaffe of the U.S. Council of International Business. That's a balance the FDA already seeks to strike in assessing other products.

"We believe the regulatory process that is in place is significant and adequate to address the issues before the FDA," Jaffe said.

Nanotechnology involves the manufacture and manipulation of materials at the molecular or atomic level. At that scale, materials are measured in nanometers or billionths of a meter. Nanoscale materials are generally less than 100 nanometers in diameter. A sheet of paper, in comparison, is 100,000 nanometers thick. A human hair is 80,000 nanometers thick.

The FDA doesn't believe nanotechnology is inherently unsafe, but does acknowledge that materials at the nano scale can pose different safety issues than do things that are far larger.

The FDA wants to learn of new and emerging science issues related to nanotechnology, especially in regard to safety, said Randall Lutter, the agency's associate commissioner.

The topic vexes other countries as well.

'We cannot assume what we know about bulk-size substances applies to the nanotechnology-size substances,' Philippe Martin, of the European Commission, told the meeting.

Martin cited the ring he wears: it's made of gold, is yellowish and inert. But take a gold nanoparticle one nanometer in size, and it turns both blue and mildly reactive. Bump the size up to three nanometers, and the gold turns a reddish hue and now acts like a catalyst.

'How do we assess such a tremendous difference in property?' said Delara Karkan, of Health Canada, in citing the same example.

Kathy Jo Wetter, of the civil society organization ETC Group, told the FDA it was understaffed, underfunded and ill-equipped to deal with nanotechnology. Wetter said hundreds of nano products have already crept onto the market with little scrutiny.

'Unfortunately, so far the U.S. government has acted as a cheerleader and not as a regulator,' Wetter said.

Carolyn Cairns, a senior researcher at Consumers Union, told the FDA that nanomaterials should be regulated like any other new chemical substances and subjected to a full battery of tests before use.

Martin Philbert, a University of Michigan professor of toxicology, counseled the FDA to 'avoid overregulation while remaining vigilant.'

'The key is to manage the risk while deriving the maximum possible benefit from these materials,' Philbert said.

The Project on Emerging Nanotechnologies has cataloged more than 320 nanotech consumer products, including vitamin sprays, bedsheets and anti-bacterial food-storage bags.