

FDA and Nanotechnology: Public Perceptions *Matter*

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Why do public perceptions matter?



Nano: On FDA's Doorsteps



Over **320** consumer products on the market from **17** countries, using a variety of nano materials (carbon, silver, zinc oxide, titanium dioxide).

Cosmetics: 58 cosmetics (largest category in our inventory)

Dietary supplements: 16 supplements of various kinds

Foods: 3 foods (canola oil, nano "slim" shake, and a "nanotea" from China)

Food contact items: 10 (this includes food storage containers, refrigerators, a nanosilver cutting board, and a "nano cleaning agent" for food from China)

Drugs & Biomedical Devices: At least 9 drugs currently on the market (for breast cancer, cholesterol-lowering, topical estrogen therapy, and anti-nausea for chemotherapy side effects).

New Japanese data: 200+ consumer products, with 87 cosmetics and 10 products listed as food

See: www.nanotechproject.org/inventories

Public perceptions matter because the public is coming in contact with more and more products that are, according to manufacturer's claims, based on nanotechnology. Many of these are under FDA purview.

Our inventory of nano-based consumer products now has over 320 products from 17 countries, an increase of 100 products in just six months.

- Largest increase is in cosmetics. - Dietary supplements are also up.
- Food is level, but products that come in contact with food have increased dramatically.
- Also, drugs and biomedical devices are emerging and we have launched a separate inventory to track these.

There is a new inventory in Japan that lists over 200 nano products with 87 cosmetics and 10 foods.

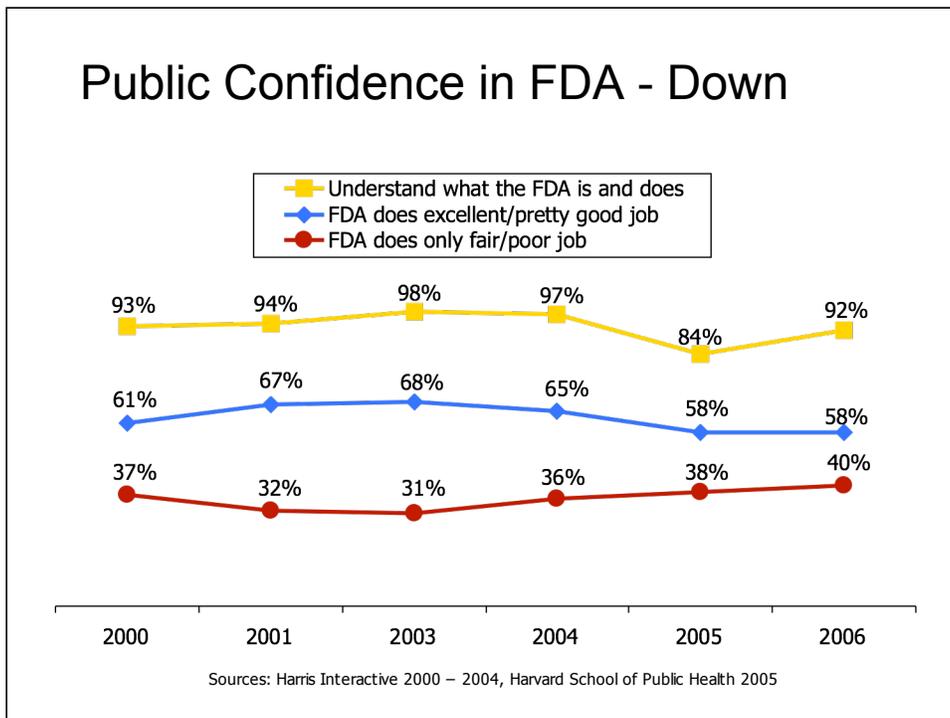
The Stakes Are High

- Worldwide public and private sector investment in nanotech R&D now exceeds \$10 billion annually.
- 2005 market size for nanotechnology drug delivery systems alone was estimated at \$980 million, expected to grow 54% annually over the next five years.
- Sales of nanotherapeutics, like nanosilver-based wound dressings, were \$28 million last year and are expected to increase every year by 62% through 2010.
- The number of nano-based drugs and biomedical devices in FDA's pipeline increased by 67% last year.
- Food industry experts project that nanotechnology will be incorporated into \$20 billion worth of consumer products globally by 2010.

There is obviously a lot at stake economically, with over \$10 billion dollars being invested annually by the public and private sectors in nanotech R&D.

Here are some of the market numbers and projections in areas that FDA regulates, such as drug delivery devices, therapeutics, and food.

Public Confidence in FDA - Down

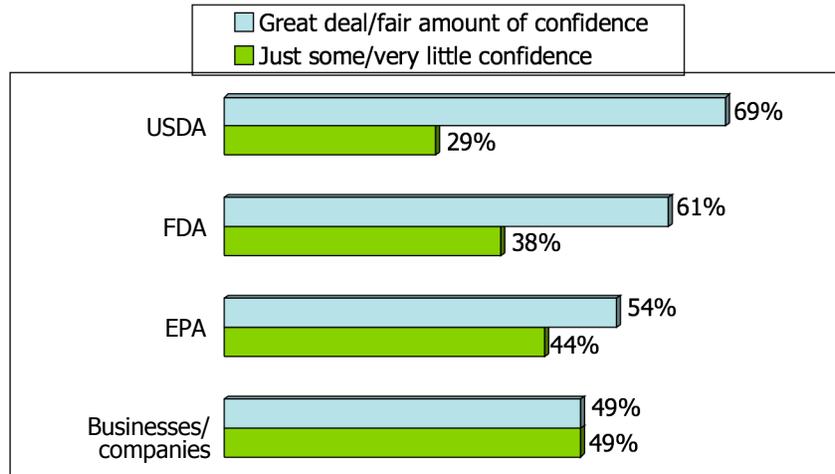


What can we say about the public perceptions of the FDA and nanotechnology.

The first important piece of data is that public confidence in FDA is down, and it is down precisely at the time when nanotech products are starting to penetrate the marketplace.

FDA versus Others

Confidence in Each to Maximize Benefits & Minimize Risks of Scientific/Technological Advancements



From: "Public Awareness of Nanotechnology: What do Americans know? Who do they trust?" Project on Emerging Nanotechnologies, 9/19/2006, www.nanotechproject.org

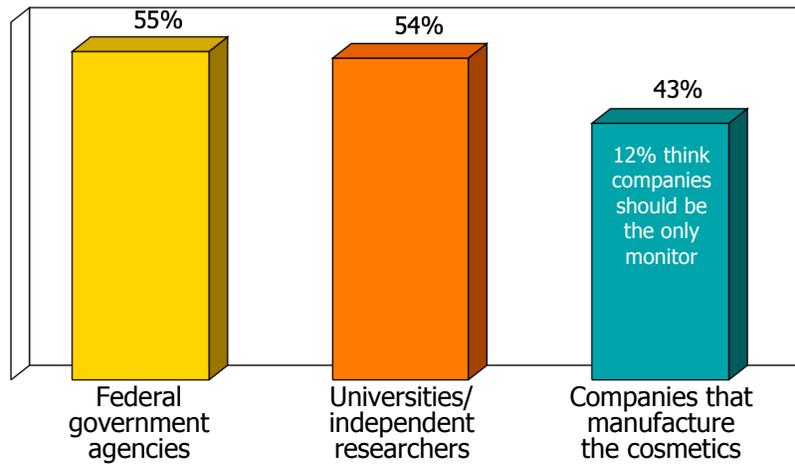
However, this story is more complicated.

In August, we conducted a national survey of over 1000 adults and asked people "who they trusted to maximize the benefits and minimize the risks of scientific advancements."

FDA came in below the Department of Agriculture, but above EPA, and far above industry, which people are very ambivalent about.

Trust in FDA is down, but the agency nevertheless has standing.

Who Should Monitor Cosmetics For Safety And Effectiveness?



We had a specific question about who should monitor cosmetics for safety and effectiveness. People chose the government and independent researchers above industry. In fact, only 12 percent trusted companies alone to monitor safety (which essentially is what happens now).

Initial And Informed Impressions Of Risks/Benefits Of Nanotechnology

	Initial Impression		Informed Impression	
	Benefits outweigh	Risks outweigh	Benefits outweigh	Risks outweigh
All adults	16%	35%	26%	49%
Men	21%	39%	34%	45%
Women	10%	31%	19%	53%
Age 18 to 34	20%	41%	31%	45%
Age 35 to 49	18%	34%	25%	53%
Age 50 to 64	15%	36%	25%	52%
Age 65 and older	7%	26%	20%	47%
Men age 18 to 49	25%	40%	35%	44%
Men age 50 and older	17%	36%	32%	47%
Women age 18 to 49	12%	35%	21%	54%
Women age 50 and older	8%	28%	16%	52%
Income under \$30K	11%	38%	21%	48%
Income \$30K to \$50K	11%	34%	21%	56%
Income \$50K to \$75K	16%	39%	26%	53%
Income over \$75K	26%	34%	38%	41%

The survey also pointed to some important differences in risk/benefit perceptions that are relevant to FDA. The most important one being related to gender.

After we provided participants with information on nanotech applications and implications, women were far more likely to focus on risks than men.

This isn't new or surprising. As one expert in risk research once noted, "...a substantial percentage of white males see the world as so much less risky than everyone else sees it."

This is important because many of the nano-based products on the market that FDA has some oversight responsibility for -- such as cosmetics -- are purchased primarily by women. Women are also responsible for many of the food purchases in the home.

Public Comments



FDA and Cosmetics

- "I think it's definitely [the FDA's] **responsibility** or their job to, with cosmetics, make sure that it's safer for consumers...I think that if I had a product that was tested by the FDA, that I would feel more confident in using it."
- "I think [the FDA] needs to be **responsible**. They need to have the manufacturer report to them, and they need to test supplies and products."

FDA and Nanotechnology

- "I would ask the FDA to **oversee** the research of nanotechnology as well as **oversee** the cosmetics industry"
- I would ask them to take the time it needs to find out the results [of risk research] ... **Before letting [products] on the market**, before the risk to us."
- "I want a **watchdog**, you know, other consumer groups to be able to access [the FDA's risk research results]."

Nanotechnology and Industry

- "I think [manufacturers need] a **campaign to educate** people [saying]: 'This is a technology, we don't know everything about it. ... these are some risks, but we think it's a better product, and this is why you want to use it.'"
- "I would say they should make sure they are really improving the products before they take on this unknown technology that could actually do a lot of damage."

From focus groups run on Aug. 2, 2006, Baltimore, MD

In August we ran two focus groups with women to probe their attitudes toward nanotechnology, especially in relationship to cosmetics.

One of most stunning findings was that none of the women realized how little oversight FDA actually has over cosmetics.

At the end of the 2-hour sessions, we asked them what they would say to FDA or to industry and here are some of their responses.

You can see that they expect FDA to be responsible, to oversee, to play the role of the watchdog.

They expect industry to be honest, essentially to cut the hype.

Building Confidence in Nanotechnologies

Little public support for:

- A moratorium on nanotechnology research and development
- Industry self-regulation

When asked “How can public confidence in nanotechnologies be improved?” people converge around three recommendations:

- 1. Greater transparency and disclosure**
- 2. Pre-market testing**
- 3. Third-party testing and research**

We have now completed around 30 hours of focus group work on nanotech across the U.S. Here are the bottom-line messages.

Once people learn about nanotechnology, they show little support for a moratorium on nanotech R&D, they are excited about the potential, especially in the medical area. However, they also show little support for industry self regulation of this new technology.

They converge again and again around three recommendations...the most important one is disclosure and transparency.

A recent article stated: “Nanotech: Out of the Lab ... Onto the Store Shelves... There's a stealth revolution going on in nanotechnology today... As companies quietly integrate nanomaterials into more than \$32 billion worth of products worldwide.”

Stealth might be great for fighter jets but is not the strategy you want with a new technology like nano. Why? By avoiding disclosure you raise public suspicions and generate mistrust.

Trust: The Ultimate Currency

“If you once forfeit the confidence of your fellow citizens, you can never regain their respect and esteem.”

Abraham Lincoln

As we introduce nanotech into the marketplace, the most important variable will be trust. Trust is fragile. It can take years to build, and can be destroyed in days. Low levels of trust can effectively undermine attempts at communicating risks or benefits.

The question I ask today is this. “Is the FDA and the U.S. government doing enough to build public trust – to engage the public?” Because under-investing will surely cut the promise of nanotechnology short.

I’d like to thank FDA for inviting me to share some of our data and observations.

Much of the data I have cited can be found in reports on our website.

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