Why Managing Research is Not Managing Science

UMass/Amherst
May 17, 2007

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Washington, DC
21st Century Nanotechnology Research and Development Act

(6) advancing the United States productivity and industrial competitiveness through stable, consistent, and coordinated investments in long-term scientific and engineering research in nanotechnology;

(7) accelerating the deployment and application of nanotechnology research and development in the private sector, including startup companies;
Products on the Market

Number of Products

<table>
<thead>
<tr>
<th>Category</th>
<th>May 16, 2007</th>
<th>November 26, 2006</th>
<th>September 29, 2006</th>
<th>April 22, 2006</th>
<th>March 8, 2006</th>
<th>Date of Revision</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clothing</td>
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<td>Cosmetics</td>
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<td>Personal Care</td>
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<td>Food and Beverage</td>
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<td>Sporting Goods</td>
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<tr>
<td>Coatings</td>
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<td>Sunscreen</td>
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</tbody>
</table>

Number
Firms on the Map

Nanotechnology Companies, Universities, Government Laboratories, and Organizations in the United States
Industries, not an Industry
Top Nano Metro Areas

San Jose, CA – 38 entities

Boston, MA – 36 entities

San Francisco, CA – 31 entities

Oakland, CA – 22 entities
Nano in the News: The Mass Media-ization of Nanotechnology
NGO Landscape Explodes

Natural Resources Defense Council
Greenpeace
Clean Production Action
United Steel Workers
Citizen's Environmental Coalition
Pesticide Action Network - N. America
International Center for Technology Assessment
Science and Environmental Health Network
Health Care Without Harm - Boston

Comments on
EPA's Nanotechnology White Paper, 2006

The Natural Resources Defense Council
Greenpeace
Science and Environmental Health Network
Beyond Pesticides/NCAMP
Environmental Health Project, Ecology Center
Rachel Carson Council, Inc.
ScienceCorps
The Endocrine Disruption Exchange, Inc (TEDX)
Institute for Agriculture & Trade Policy
Sierra Club
Environmental Health Fund
Maryland Pesticide Network
Environmental Research Foundation
ETC Group
Clean Production Action
Center for Environmental Health
Breast Cancer Fund
Friends of the Earth
International Center for Technology Assessment

Comments on EPA’s Voluntary Program for Nanotechnology, 2005
But Public Awareness is Still Low

Key findings from a survey among 1,014 adults nationwide
Conducted August 23 – 27, 2006, by Peter Hart Research

How Much Have You Heard About Nanotechnology?

- Heard nothing at all: 42%
- Heard a lot: 20%
- Heard some: 27%
- Heard just a little: 10%
- Not sure: 1%
Public Has Clear Expectations

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
Nanotechnology and Oversight

**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 assess [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."
Dividing the Research Pie

Total Federal Nanotech Budget

Environmental, Health and Safety Risk Research (4%?)
or 1%?

How to Prioritize?

By Material
- Carbon
- Silver
- Other

By Effect
- Lungs
- Skin
- Brain
- Other

By Research
- Basic
- Applied
State of Play

- No public, transparent accounting of nano-related risk research being done by the U.S. government.
- No comprehensive research strategy for environmental, health, and safety risks, either domestically or globally.

- No strategic/proactive public engagement process.
- No federal nano-specific oversight, even voluntary programs.
- Little consideration of broader social and ethical issues.
Managing the Science Enterprise

**Stage 1**
- Who's Involved: Scientists, Scientific journals
- Government

**Stage 2**
- Scientists
- Scientific journals
- Regulators
- Few NGOs
- Technical Press

**Stage 3**
- Scientists
- Scientific journals
- Regulators
- Many NGOs
- Lay press
- Public

**R&D**
- Basic
- Applied

**Products**
- # in Commerce

**Focus**
- Manage science
- Manage oversight
- Manage expectations
  
  *The social contract*
Meantime: Waiting for the “Killer” App
Voltaire on Nanotechnology

“All is for the best in the best of all possible worlds.”
Dr. Pangloss

Existing regulations are adequate to deal with nanotechnology

The White House

EPA

FDA

A PEN Production

Nano Comics

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## Gap Analysis: FDA Oversight

### Table 2. Capacity of FDA’s Legal Authority to Achieve the Primary Goals of Regulatory Oversight for Nanotechnology Products

<table>
<thead>
<tr>
<th></th>
<th>Cosmetic Ingredient</th>
<th>Whole Food</th>
<th>Dietary Supplement</th>
<th>GRAS Food Ingredient</th>
<th>Food Additive</th>
<th>Food Packaging</th>
<th>Medical Device</th>
<th>OTC Drug</th>
<th>New Drug</th>
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</thead>
<tbody>
<tr>
<td><strong>Pre-Market</strong></td>
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<tr>
<td>Obtain Early Information on Pipeline</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>Weak</td>
<td>Weak</td>
<td>Weak</td>
<td>Moderate</td>
<td>Weak</td>
<td>Moderate</td>
</tr>
<tr>
<td>Enforce Safety and Testing Requirements</td>
<td>Weak</td>
<td>None</td>
<td>Weak</td>
<td>Moderate</td>
<td>Strong</td>
<td>Strong</td>
<td>Strong</td>
<td>Strong</td>
<td>Strong</td>
</tr>
<tr>
<td>Place Burden To Prove Safety on Sponsor</td>
<td>Weak</td>
<td>None</td>
<td>Weak</td>
<td>Moderate</td>
<td>Strong</td>
<td>Strong</td>
<td>Strong</td>
<td>Strong</td>
<td>Strong</td>
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<tr>
<td>Review Safety Prior to Marketing</td>
<td>None</td>
<td>None</td>
<td>Weak</td>
<td>Weak</td>
<td>Strong</td>
<td>Strong</td>
<td>Moderate</td>
<td>Strong</td>
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<tr>
<td><strong>Post-Market</strong></td>
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<tr>
<td>Require Needed Monitoring and Testing</td>
<td>Weak</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>Weak</td>
<td>None</td>
<td>Strong</td>
<td>Weak</td>
<td>Moderate</td>
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<tr>
<td>Require Timely Adverse Event Reporting</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>Weak</td>
<td>None</td>
<td>Strong</td>
<td>None</td>
<td>Strong</td>
</tr>
<tr>
<td>Inspect Facilities and Safety Records</td>
<td>Weak</td>
<td>Moderate</td>
<td>Moderate</td>
<td>Moderate</td>
<td>Moderate</td>
<td>Moderate</td>
<td>Strong</td>
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<tr>
<td>Remove Unsafe Products from Market</td>
<td>Moderate</td>
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<td>Strong</td>
<td>Moderate</td>
<td>Strong</td>
<td>Strong</td>
<td>Strong</td>
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</tbody>
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Grove on Nanotechnology

“Only the paranoid survive”

House Science Committee
“Need for urgency…”

Freeman Dyson:
“The most dangerous technology is one that is not allowed to fail, and then fails.”
Nanotechnology: Some Possible Futures

1st Nano-based Blockbuster Drug
Cash in Stock

NO - NANO
Label Appears
Cut profits by 50%

Nanoparticle Spill in Los Angeles
Lose Face/Reputation

The NanoFood Battles Begin
Lose Sleep and Vacation
Need a Comprehensive Management Framework

Health & Environmental Risks
- Toxicity
- Life cycle impacts

Perception Risks
- What the public sees
- How the public responds

Structural Risks
- Regulatory system
- Industry structure

Wildcards
- Third rails
- Accidents
- Terrorists
- Hollywood

Level of effort by Policy Makers
For More Information

www.nanotechproject.org

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