

Why Managing Research is Not Managing Science

UMass/Amherst
May 17, 2007

David Rejeski
Director, Project on Emerging Nanotechnologies
Woodrow Wilson International Center for Scholars
Washington, DC

Project on
Emerging Nanotechnologies
at the Woodrow Wilson International Center for Scholars



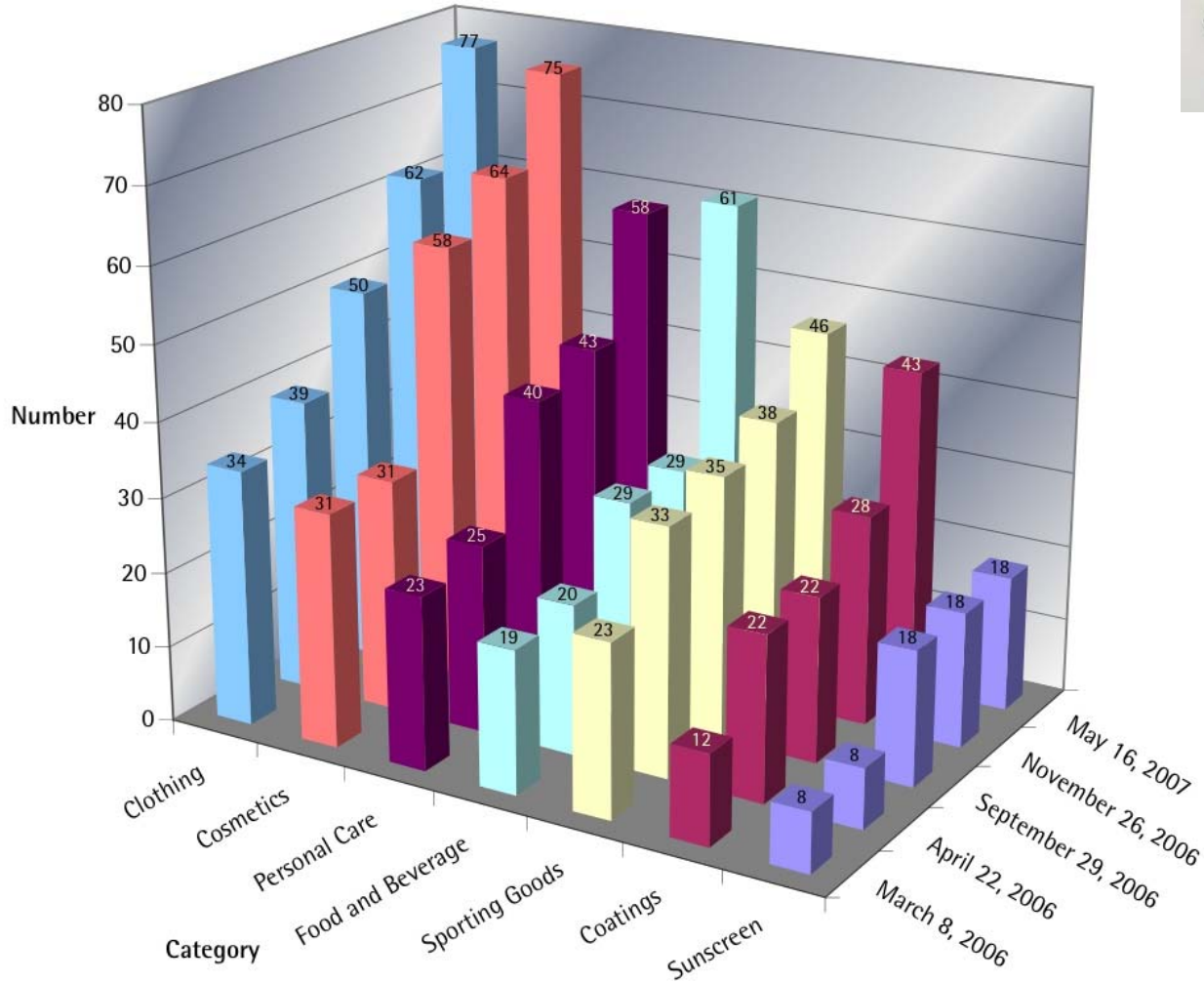
21st Century Nanotechnology Research and Development Act

(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

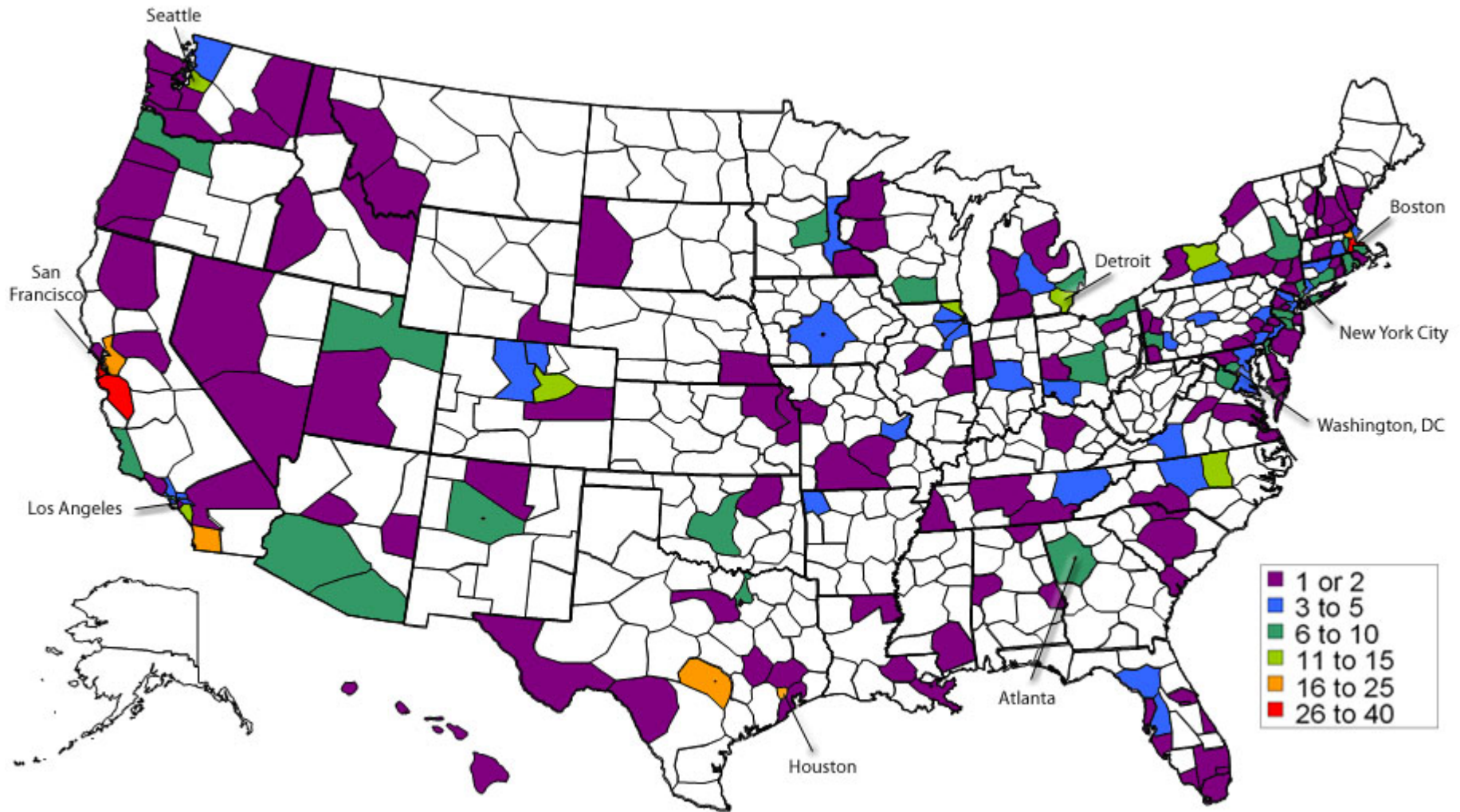
Number of Products



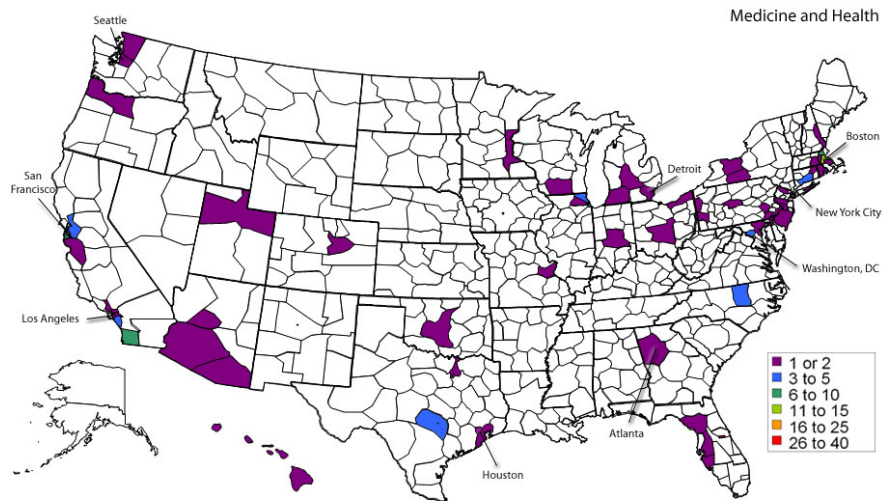
Date of Revision

Firms on the Map

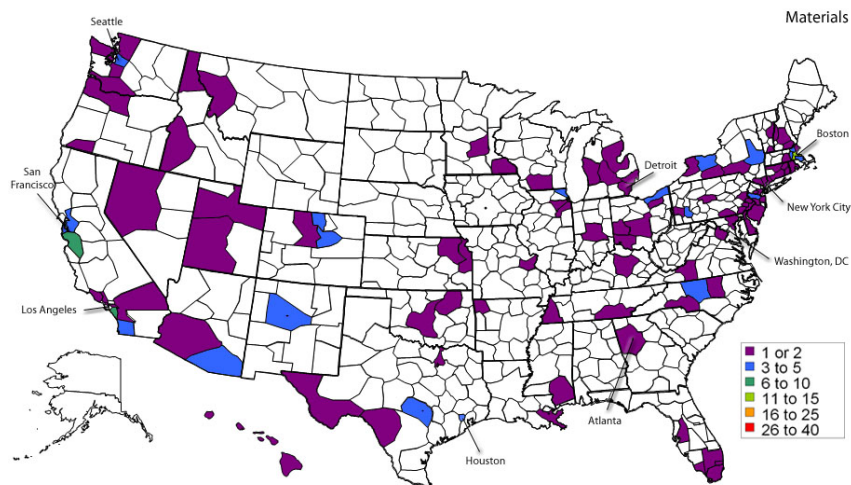
Nanotechnology Companies, Universities, Government Laboratories, and Organizations
in the United States



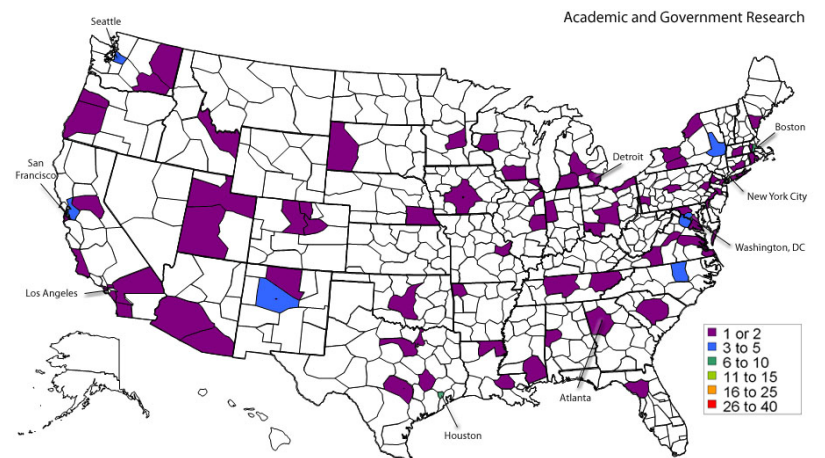
Industries, not an Industry



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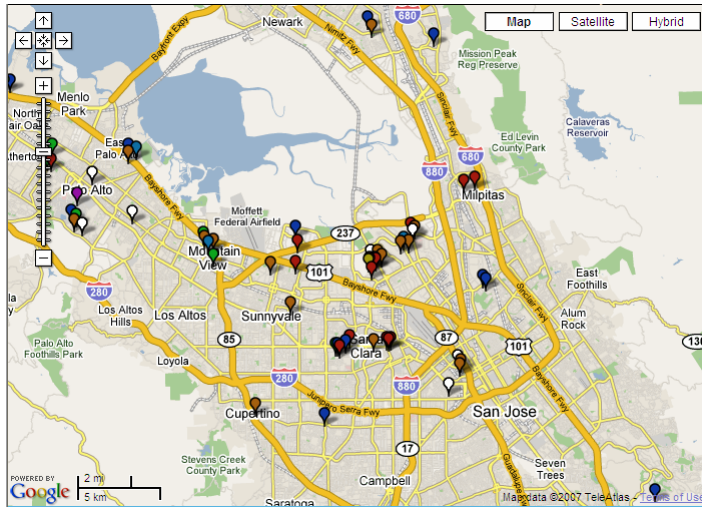


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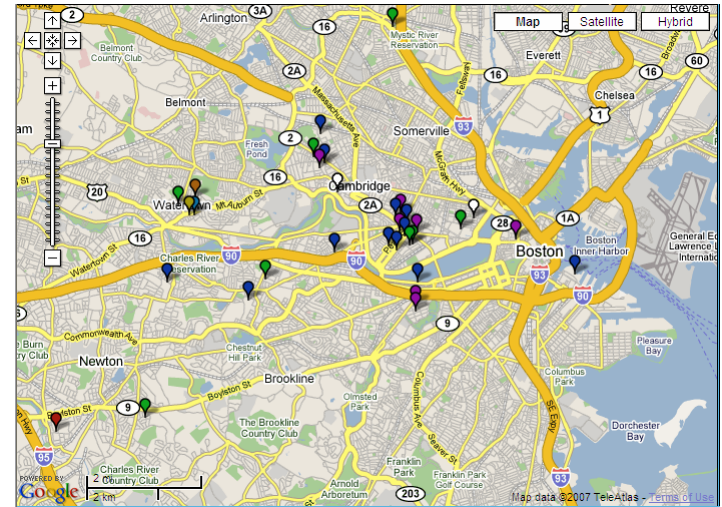


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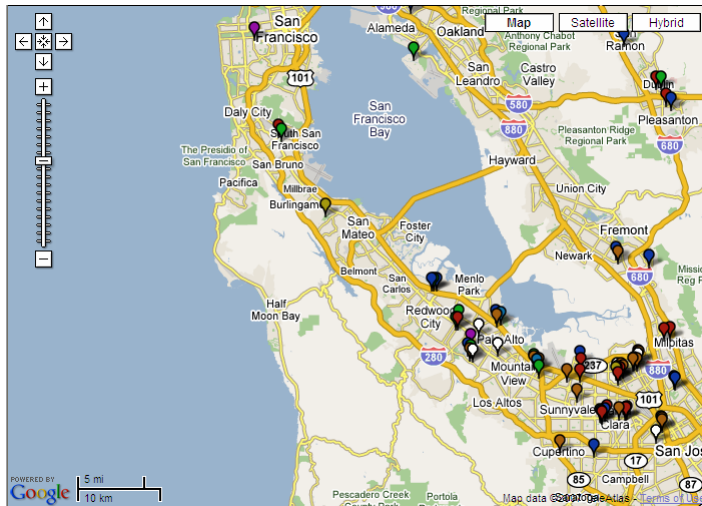
Top Nano Metro Areas



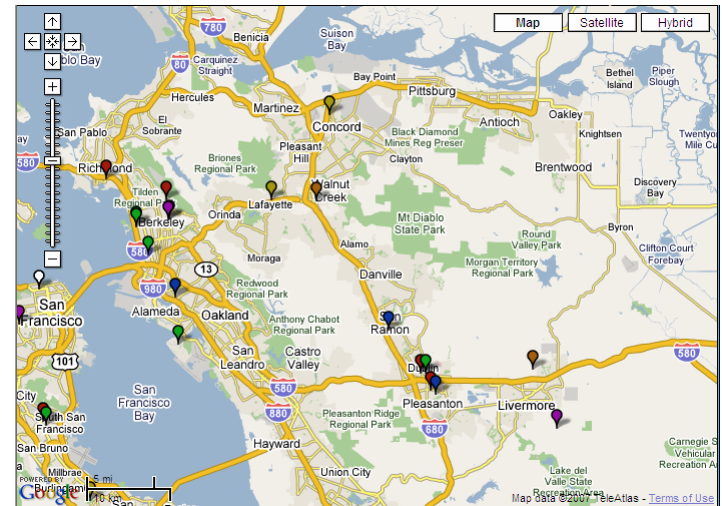
San Jose, CA – 38 entities



Boston, MA – 36 entities

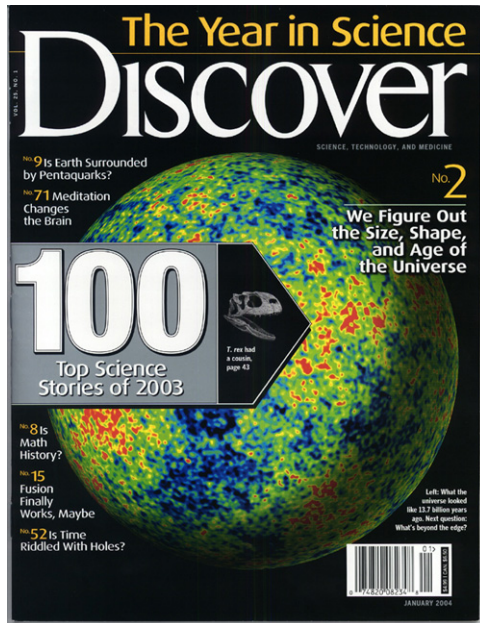


San Francisco, CA – 31 entities



Oakland, CA – 22 entities

Nano in the News: The Mass Media-zation 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

 **Friends of the Earth**



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

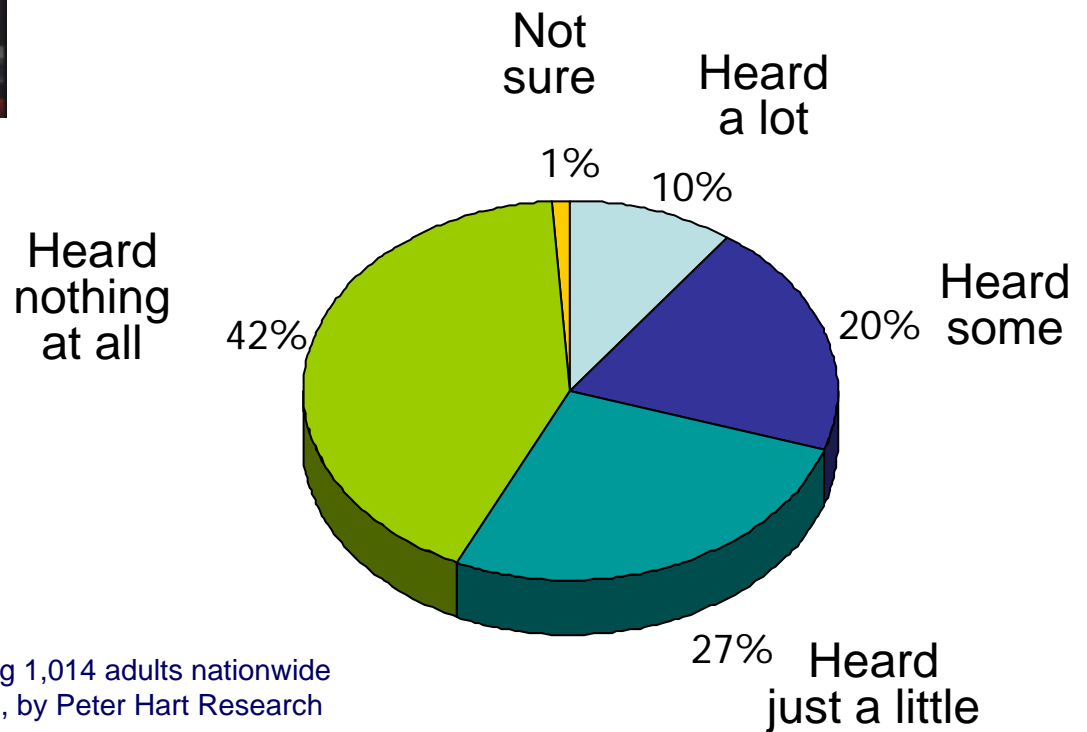


Comments on EPA's Voluntary Program for Nanotechnology, 2005

But Public Awareness is Still Low



How Much Have You Heard About Nanotechnology?



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

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

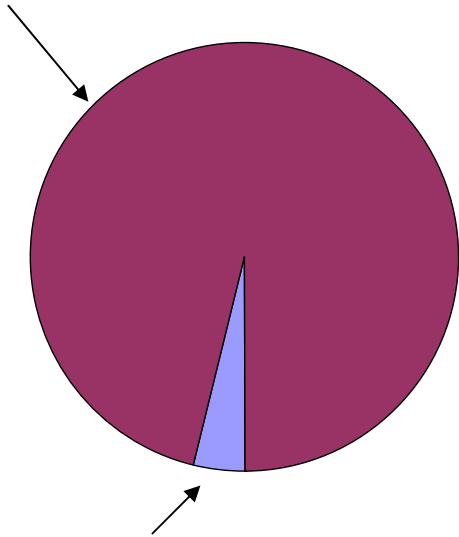
- “I would ask the FDA to **oversee** the research of nanotechnology as well as **oversee** the cosmetics industry”
- I would ask them to take the time it needs to find out the results [of risk research] ... **Before letting [products] on the market**, before the risk to us.“
- "I want a **watchdog**,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

Nanotechnology and Industry

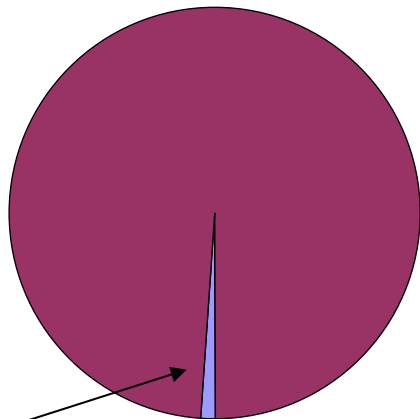
- "I think [manufacturers need] a **campaign to educate** people [saying]: ‘This is a technology, we don't know everything about it. ... these are some risks, but we think it's a better product, and this is why you want to use it.’“
- "I would say they should make sure they are really improving the products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

Dividing the Research Pie

Total Federal Nanotech Budget



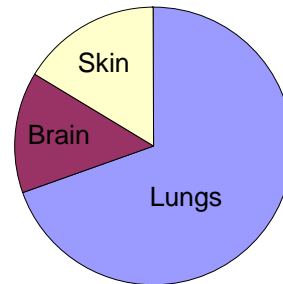
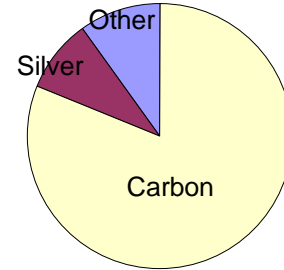
Environmental, Health and Safety Risk Research (4%?)



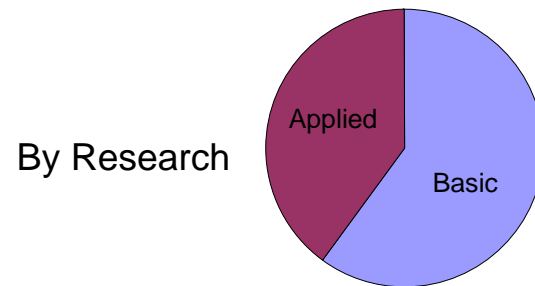
or 1%?

How to Prioritize?

By Material



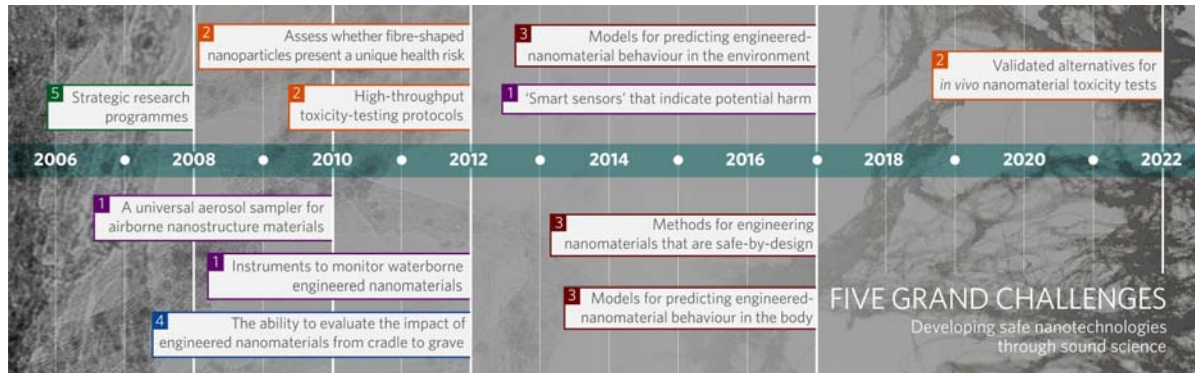
By Effect



By Research

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

Reality

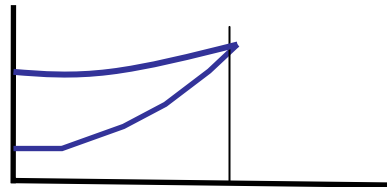
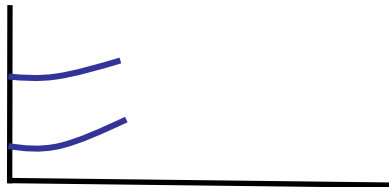


Stage 3

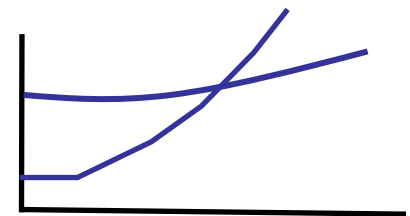
Scientists
Scientific journals
Regulators
Many NGOs
Lay press
Public

R&D

Basic
Applied

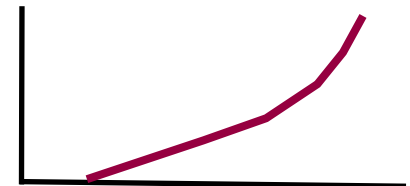
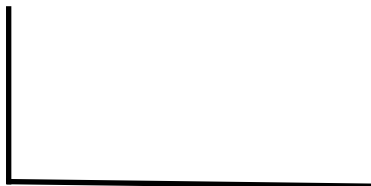


2004



Products

in
Commerce



Focus

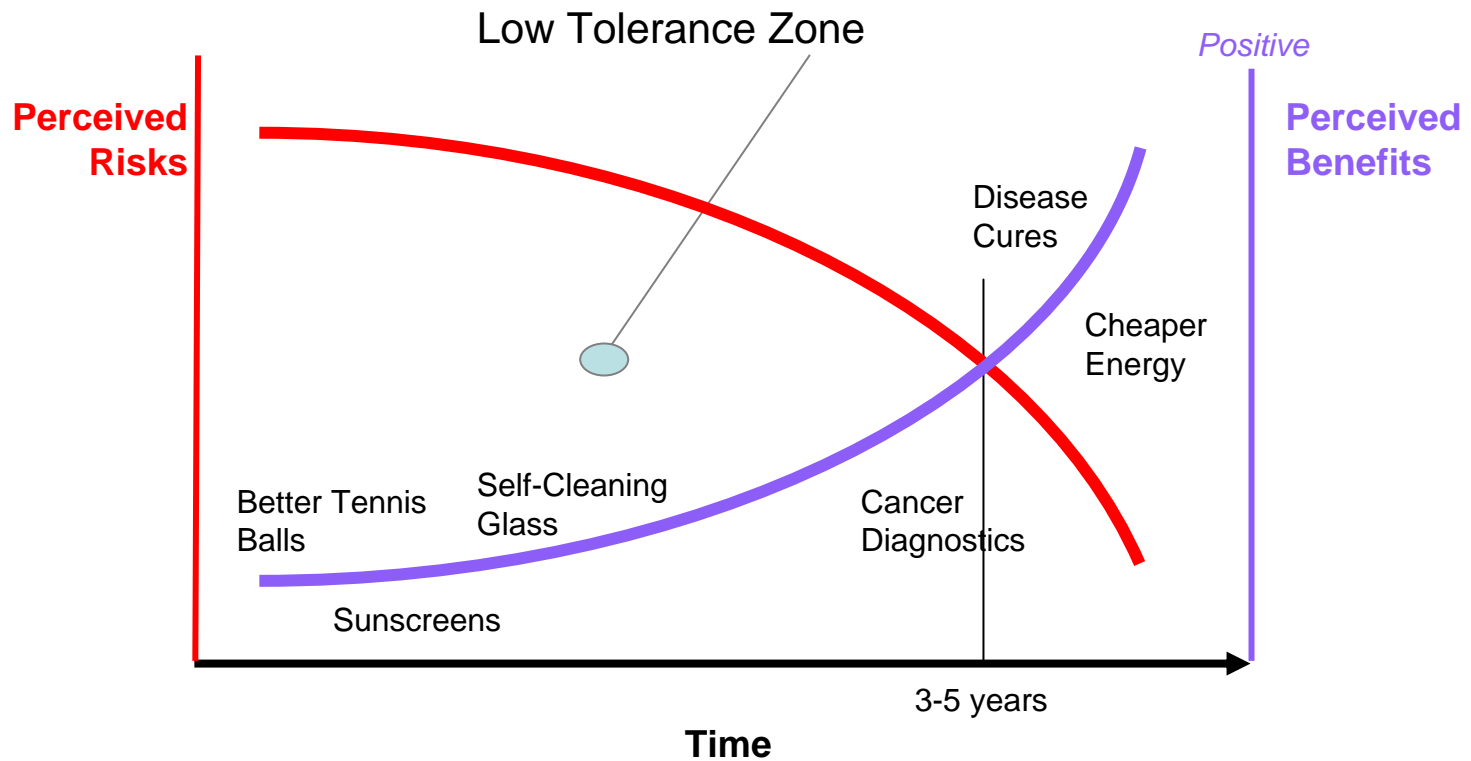
Manage science

Manage oversight

Manage expectations

The social contract

Meantime: Waiting for the “Killer” App



Voltaire on Nanotechnology

Nano Comics

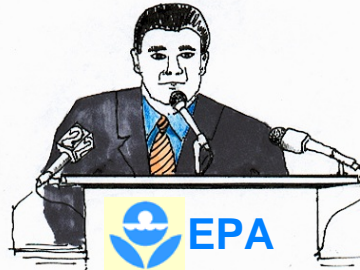
"All is for the best in the best of all possible worlds."
Dr. Pangloss



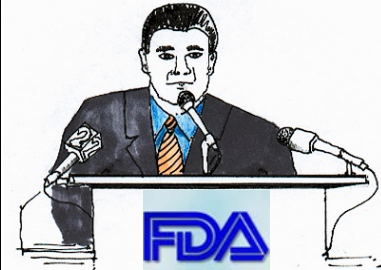
Existing regulations are adequate to deal with nanotechnology



Existing regulations are adequate to deal with nanotechnology



Existing regulations are adequate to deal with nanotechnology



A PEN Production

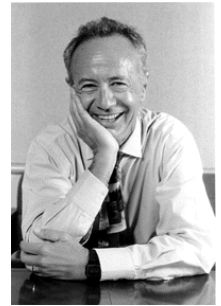
Gap Analysis: FDA Oversight

TABLE 2. CAPACITY OF FDA'S LEGAL AUTHORITY TO ACHIEVE THE PRIMARY GOALS OF REGULATORY OVERSIGHT FOR NANOTECHNOLOGY PRODUCTS

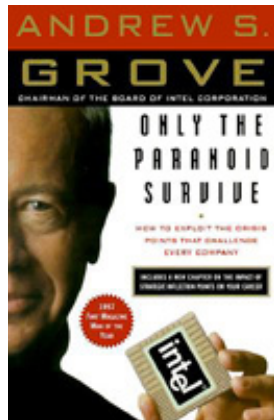
	Cosmetic Ingredient	Whole Food	Dietary Supplement	GRAS Food Ingredient	Food Additive	Food Packaging	Medical Device	OTC Drug	New Drug
Pre-Market									
Obtain Early Information on Pipeline	None	None	None	Weak	Weak	Weak	Moderate	Weak	Moderate
Enforce Safety and Testing Requirements	Weak	None	Weak	Moderate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

From: Taylor, Michael (2006). "Regulating the Products of Nanotechnology: Does FDA Have the Tools It Needs," Washington, DC: Project on Emerging Nanotechnologies.

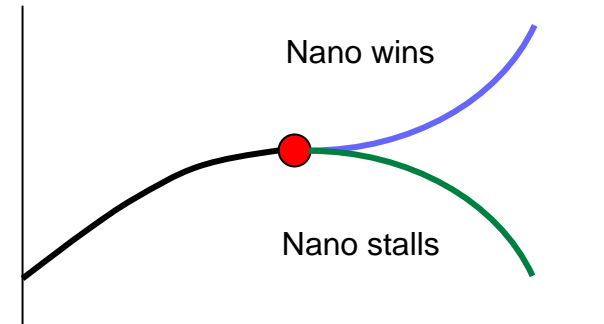
Grove on Nanotechnology



“Only the paranoid survive”



“
An inflection point
occurs where the *old*
strategic picture
dissolves and gives
way to the *new*.
”



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

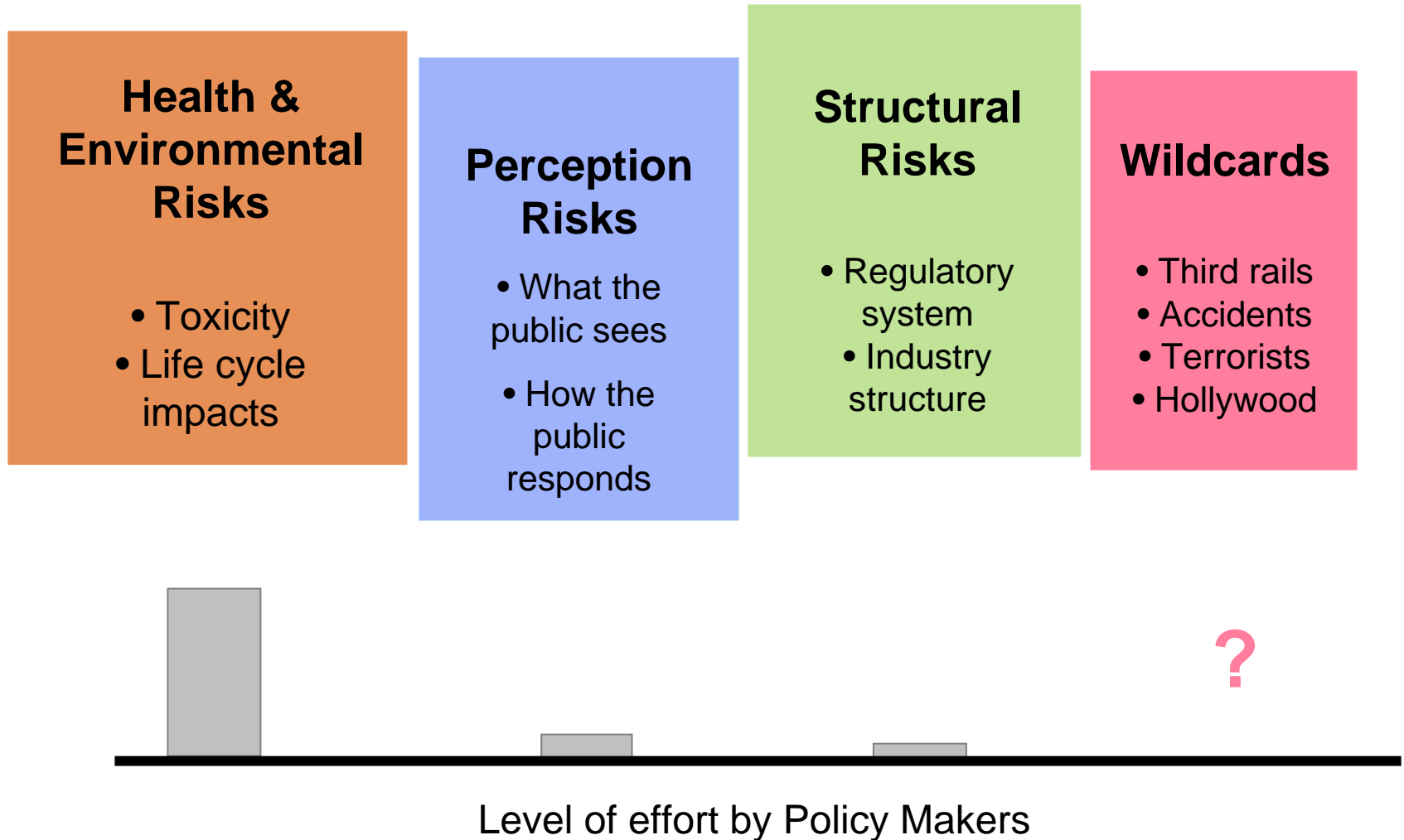
NO - NANO Label Appears
Cut profits by 50%



Nanoparticle Spill in Los Angeles
Lose Face/Reputation

The NanoFood Battles Begin
Lose Sleep and Vacation

Need a Comprehensive Management Framework



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www.nanotechproject.org

David Rejeski

Phone: (202) 691-4255

Email: david.rejeski@wilsoncenter.org