Feynman, Voltaire and Beckett on Nanotechnology

Nanopolicy Conference
National Press Club
December 3, 2007

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

Woodrow Wilson International Center for Scholars

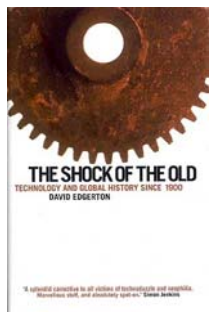
Project on Emerging Nanotechnologies at the Woodrow Wilson International Center for Scholars

“For a technology to succeed, reality must take precedence over public relations, for Nature cannot be fooled.”

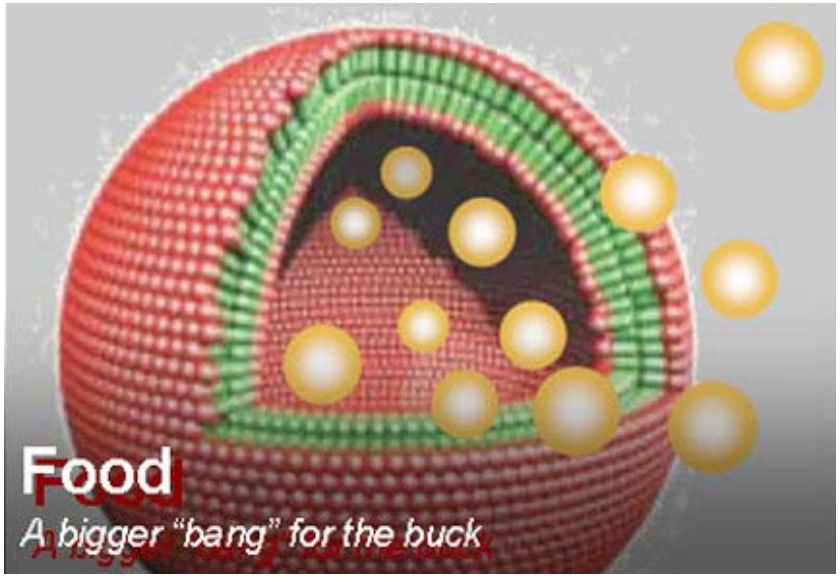
Richard Feynman

“Our understanding of technology is driven by an obsession with glamorous innovation…”

David Edgerton
The Shock of the Old



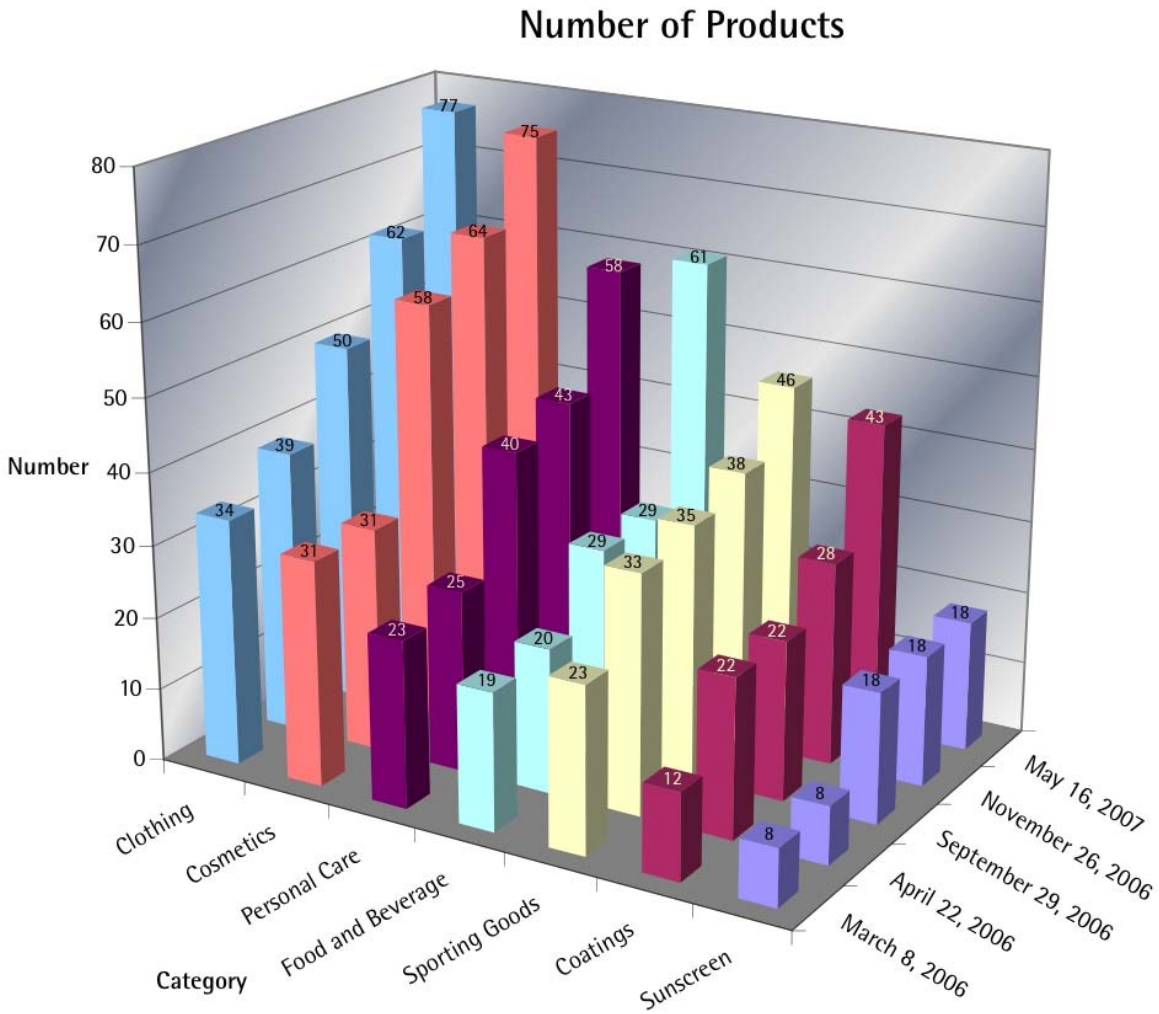
Nanotechnology: The Promise



Nanotechnology: The Reality

- Over 580 manufacturer-identified “nano” consumer products are commercially available from 22 countries.
- On-line inventory at http://www.nanotechproject.org/44

Product Introductions are Growing Rapidly



Significant increases in products using nano-engineered silver

Nano Teddy Bear

Number of products <u>doubled</u> in under 14 months

NGO Landscape Has Exploded

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

Friends of the Earth

FDA

Are We Safe?

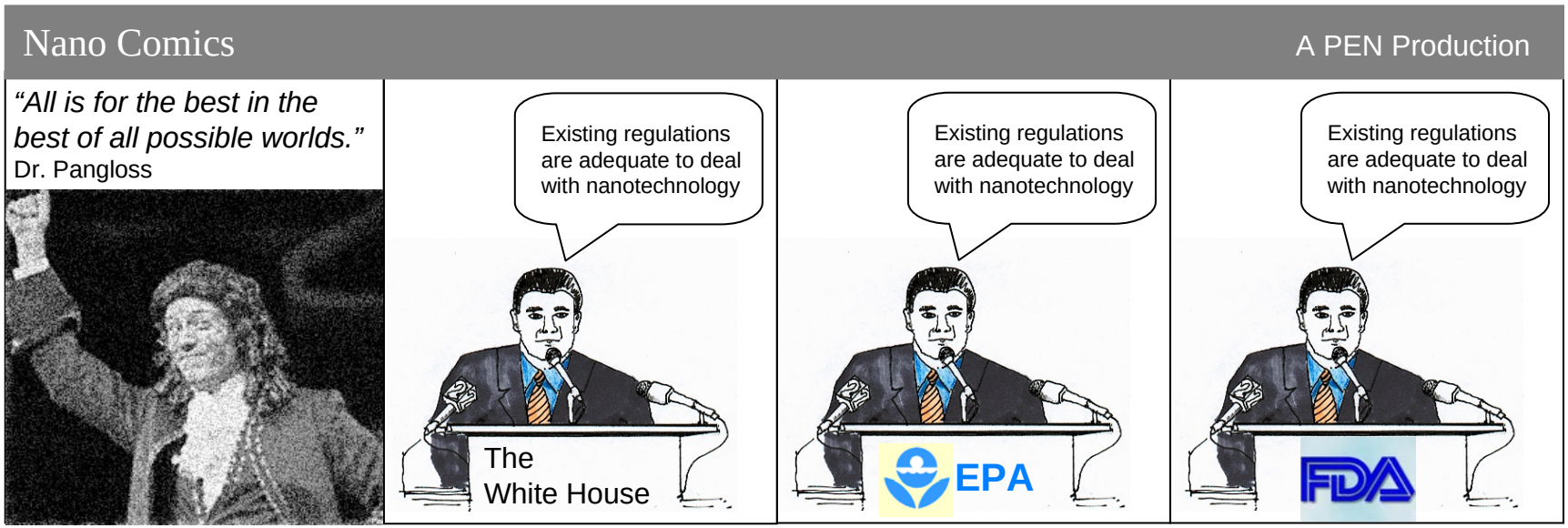
“The Federal government’s current understanding is that existing statutory authorities are adequate to address oversight of nanotechnology and its applications.”

MEMORANDUM FOR THE HEADS OF
EXECUTIVE DEPARTMENTS AND AGENCIES

White House
Office of Science and Technology Policy
Council on Environmental Quality

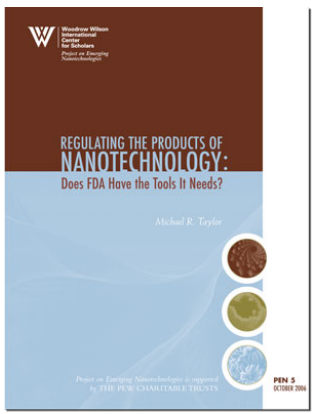
November 8, 2007

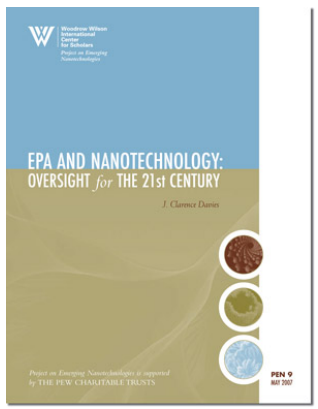
Voltaire on Nanotechnology

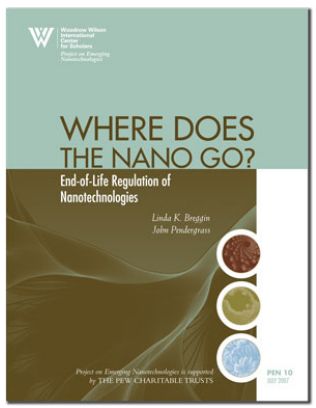


Oversight System is Inadequate

- Generic Deficiencies of Regulations
- Gaps in Regulatory Authority
- Lack of Resources (Financial and Human) and Expertise at Regulatory Agencies



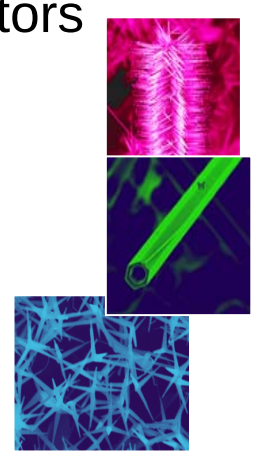




Generic Deficiencies in Regulations

• **Analogy** The creation of size- and structure-dependent novel properties using nanotechnology undercuts the ability of regulators to use analogy to predict the toxicity of new substances

• **Mass** Mass-based standards/thresholds of many regulations will not work (mass will not translate into toxicity; no adequate scientific basis for setting thresholds; no enough risk research)



All ZnO_2

• **Measurement** Reliable and inexpensive technologies do not exit to monitor emissions of nanomaterials (either in the workplace or the environment)

• **Thresholds** Reporting exemptions will exclude many nanotech manufacturing facilities with small production quantities (< 10,000 kg/year)

• **Control** Technologies for pollution control (BATs) are not available. May not even be in development.

Gaps in Regulatory Authority: FDA

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	Mod-erate	Weak	Mod-erate
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	Mod-erate	Strong
Post-Market									
Require Needed Monitoring and Testing	Weak	None	None	None	Weak	None	Strong	Weak	Mod-erate
Require Timely Adverse Event Reporting	None	None	None	None	Weak	None	Strong	None	Strong
Inspect Facilities and Safety Records	Weak	Mod-erate	Moderate	Moderate	Mod-erate	Moderate	Strong	Strong	Strong
Remove Unsafe Products from Market	Moderate	Mod-erate	Moderate	Strong	Mod-erate	Strong	Strong	Strong	Strong

In areas of significant nano-product penetration:

-Cosmetics
-Dietary supplements

Gaps in Regulatory Authority: EPA

LEGAL ADEQUACY OF EPA PRODUCT PROGRAMS FOR NANOTECHNOLOGY OVERSIGHT

Function	TSCA	FIFRA	Fuel Additives
Requiring toxicity and use data	Weak	Strong	Strong
Placing burden to prove safety on manufacturer	None	Strong	Strong
Reviewing safety prior to marketing	Moderate	Strong	Strong
Requiring needed monitoring	Moderate	Moderate	Moderate
Requiring timely adverse event reporting	Strong	Moderate	Weak
Prohibiting initial marketing	Weak	Strong	Strong
Limiting uses or conditions of use	Weak	Strong	Weak
Requiring product withdrawal from market	Weak	Strong	Moderate

Note: TSCA = Toxic Substances Control Act; FIFRA = Federal Insecticide, Fungicide, and Rodenticide Act; Fuel Additives refer to section 211 of the Clean Air Act (CAA).

TSCA: "…a small step forward, but far too weak, giving the illusion of progress." Comment made in 1976 when the Toxic Substances Control Act was introduced.

Lack of Resources (Financial & Human)

- **Environmental Protection Agency:** EPA's budget today is *less* than EPA's budget in 1973, with inflation adjustments.

- **Food and Drug Administration:** FDA's budget is around 50 percent below 1996 levels while demands on the agency have increased.

- **Consumer Products Safety Commission:** 440 employees to oversee 15,000 types of products, one half the number the CPSC had in 1980.

- **Occupational Safety and Health Administration:** In 2005, OSHA had 2,200 employees, about 800 fewer than in 1980 to deal with issues of workplace safety and inspections.

You don't have to change laws to limit effective oversight, just cut budgets.

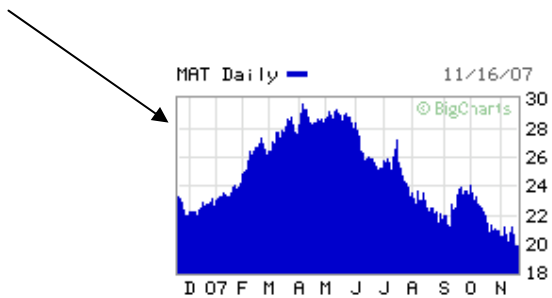
Oversight System is Already Failing

Rat Poison Found in Killer Pet Food That Sparked Nationwide Recall
March 23, 2007 (FDA)

Toxic Toothpaste Made in China Is Found in U.S.
June 2, 2007 (FDA)

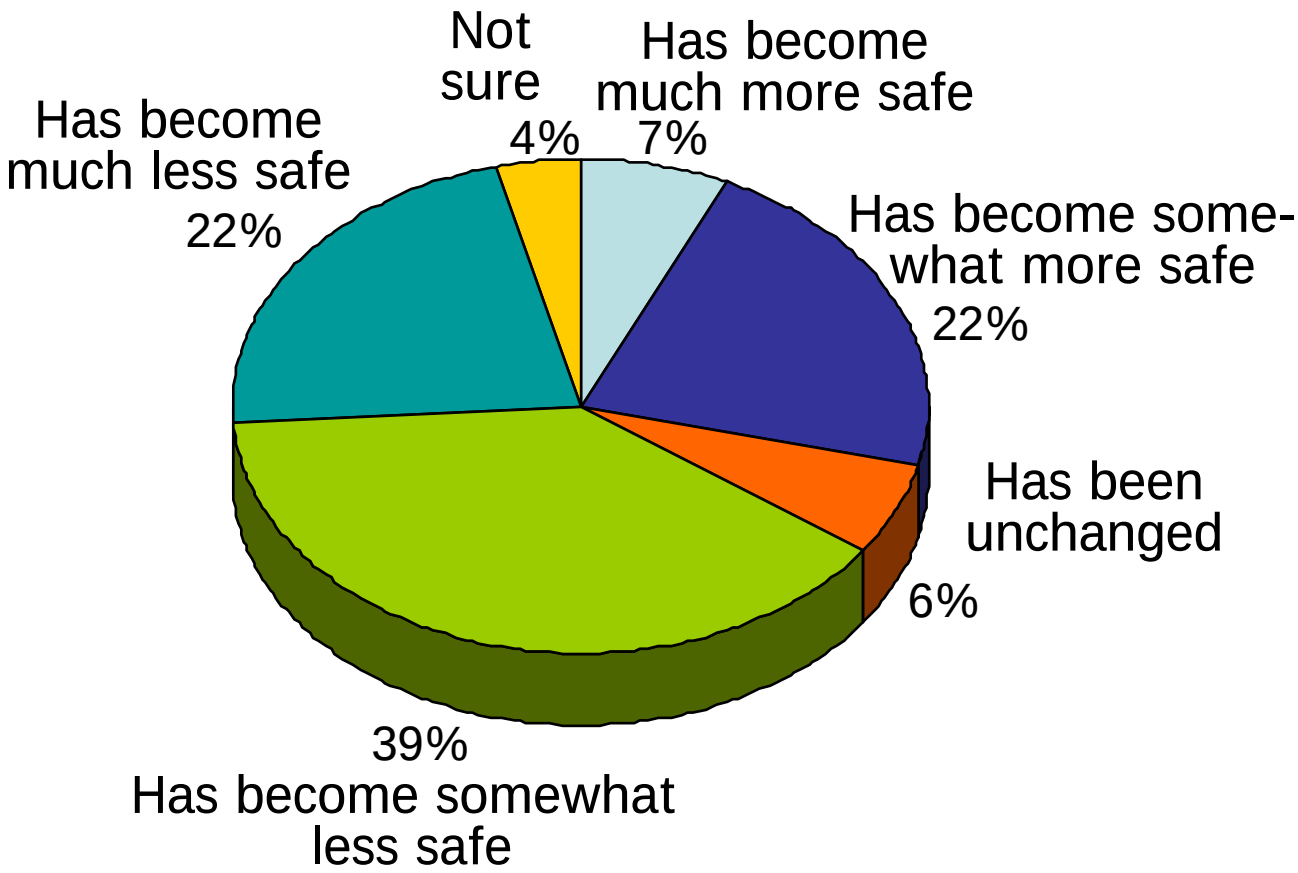
Meat Recall Expands Again on E. Coli Fears
June 9, 2007 (USDA)

Lead Paint Prompts Mattel to Recall 967,000 Toys
August 2, 2007 (CPSC)



Public Confidence Has Eroded

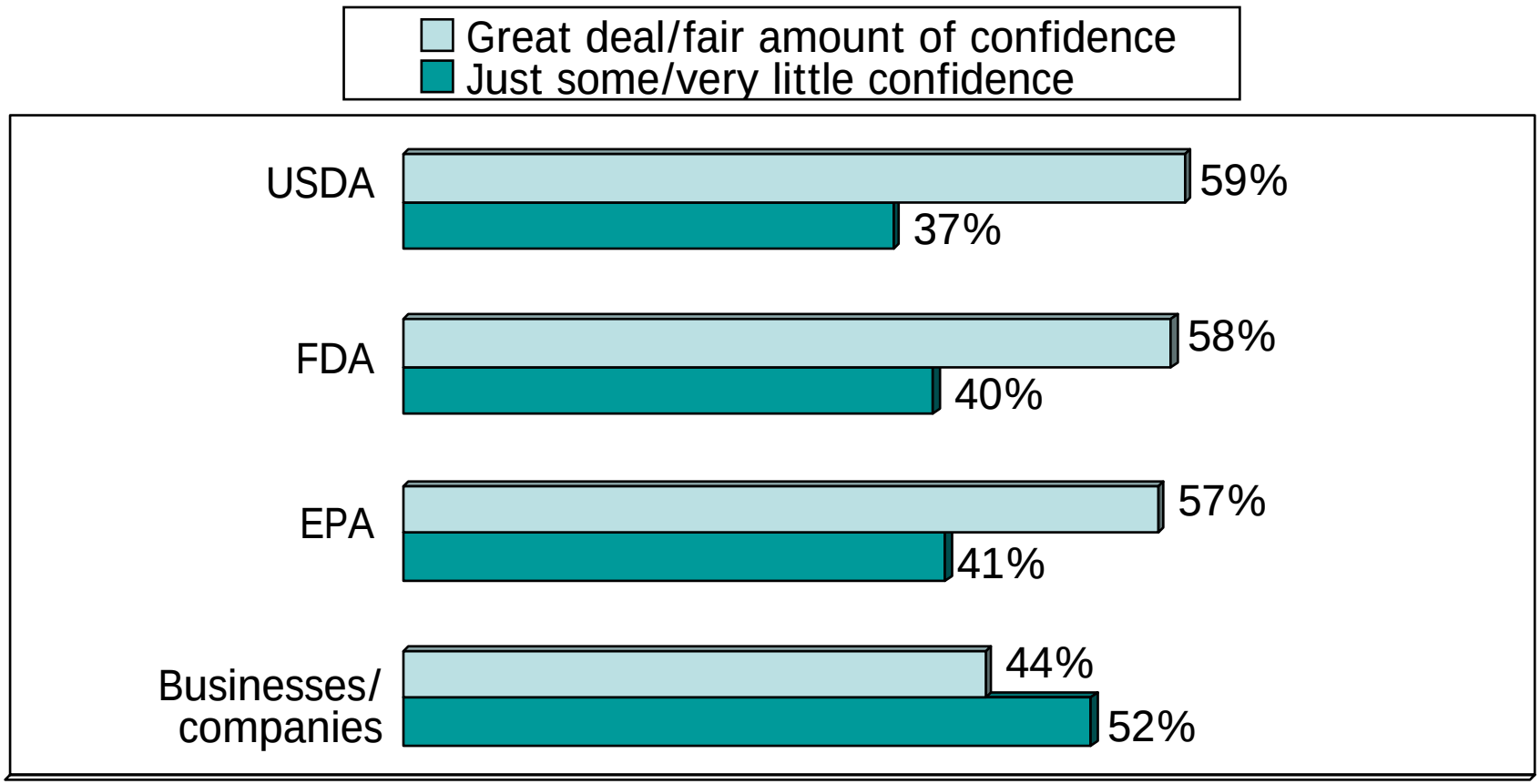
Over the past five years, the food supply:



From: "Public Awareness of Nanotechnology: What do Americans know? Who do they trust?" Project on Emerging Nanotechnologies, 9/2007, www.nanotechproject.org

Trust in Government and Industry is Weak

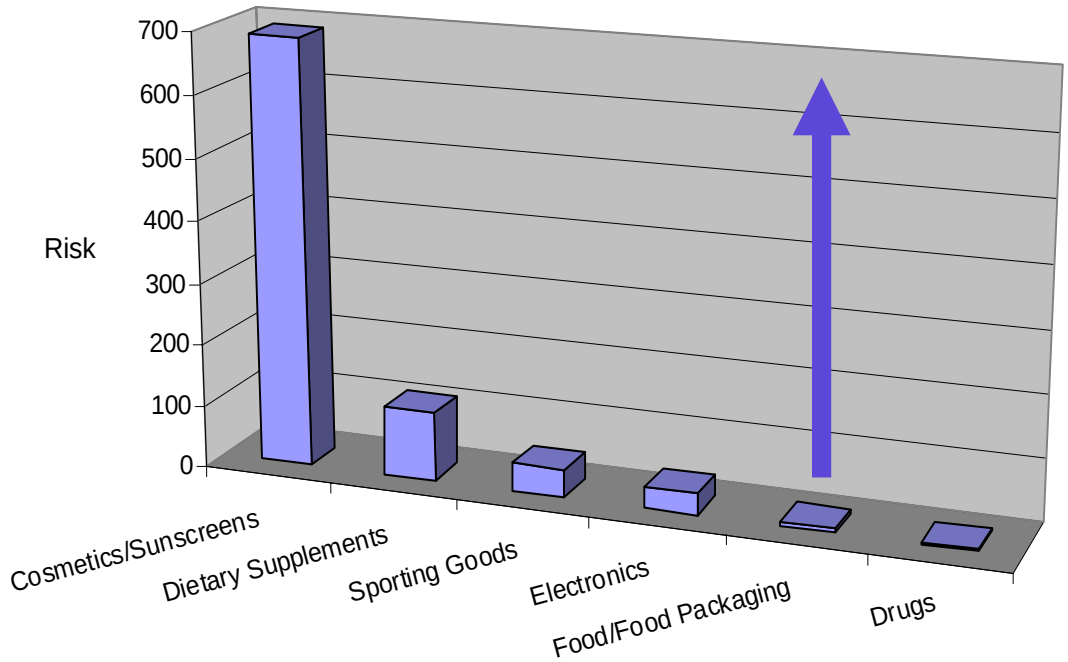
Confidence in Each to Maximize Benefits & Minimize Risks of Scientific/Technological Advancements



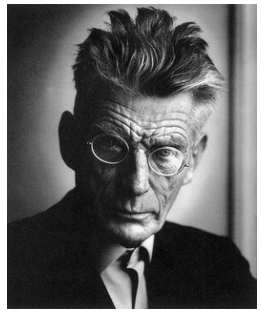
From: "Public Awareness of Nanotechnology: What do Americans know? Who do they trust?" Project on Emerging Nanotechnologies, 9/2007, www.nanotechproject.org

Investments at Risk

$$\left[\frac{P \times E}{G \times S}\right]^{Ps} = Risk$$



	Cosmetics/ Sunscreens	Dietary Supplements	Sporting Goods	Electronics	Food/ Food Packaging	Drugs
Number of Products (P)	78	36	45	49	7	10
Potential for Exposure (E)	2	2	1	1	2	3
Government Oversight (G)	1	1	1	1	2	3
Industry Stewardship (S)	2	1	1	2	2	3
NGO/Public Scrutiny (Ps)	1.5	1.1	1	1.1	1.5	1
Risk	689	110	45	34	7	3



“We wait…”

Waiting for Godot

Waiting for the Killer App

"The potential for **medical advances** is the most important benefit."

"Save for medical applications, all the other uses of nanotechnology rate a '0'."

"The technology may be used to develop **new drugs** and may help in the medical field."

"The most important thing would be to **combat illness**."

"The **environment and medicine** have the most to gain from [nanotech]. Both could change the shape of the debate."

"The most benefit would be for **national security**."

Results of focus groups conducted by Hart Research for the Project on Emerging Nanotechnologies on August 15, 2007, in Baltimore, MD

Waiting for Guidance and Clarity

"At this point in time we don't understand what regulatory requirements may be uniquely applicable to nanotechnology and nanoparticles."
Senior Safety Manager for a large manufacturing company in Massachusetts

"I need environmental, health and safety risk management information …in preparing responses to anticipated customer inquires about nanotechnology content when we bring our products to market."
Director for Technology for a Massachusetts nano manufacturer

"We need clarity concerning testing protocols, standards, and regulations. Our funding will run low within the next six months."
CEO of a nano start-up

"We need different regulation than we have now. It's a new technology and we need a different set of people to set up a system to see if it's safe. The current system fails at some points."
Public comment, Focus group, 2005

Waiting for Federal Action

"Without U.S. Rules, Biotech Food Lacks Investors"
New York Times, Front page, July 30, 2007

"In Turnaround, Industries Seek U.S. Regulations"
New York Times, Front page, September 16, 2007

"Food Makers Get Appetite for Regulation"
Wall Street Journal, September 17, 2007

"The Brave New Risks of Nanotechnology"
Financial Times, September 19, 2007

"If the Federal government isn't going to do anything, it's up to us to step up."
Mayor Tom Bates, Berkeley California

California Sues EPA Over Auto Emissions
November 8, 2007

Observations

- Next 2-3 years will be crucial to the long-term success of nanotechnologies (success is not preordained).
- Social oversight (based on an emerging social contract) will be more important than government oversight during this period (and possibly beyond).
- How the public learns about nano, from whom, and with what message(s) could have large downstream impacts on consumer confidence and market growth.
- Industry will have to deal with both real and perceptual risks; brand equity and firm reputations will be at stake; countries like China will undermine standards.
- Risk management and oversight are easier now.
- An accident involving nano could change the equation.

For More Information

www.nanotechproject.org

David Rejeski
Phone: (202) 691-4255
Email: david.rejeski@wilsoncenter.org