



Anticipation or Resilience?

Managing the health, safety, and environmental risks of nanotechnology

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stglobal.org

What's the fuss?

"You could never be **hungry**, never be **sick**, have all the **energy** you need, all the **water**, all the **food** and **no diseases**." -- Pat Mooney, director, ETC Group

"ETC Group today renewed its 2003 call for a global moratorium on nanotech lab research and a recall of consumer products containing engineered nanoparticles." -- ETC Group, press release, April 6, 2006

ETC's stance on biotechnology regulation has influenced policies of the European Parliament and the United Nations' Food and Agriculture Organization

Outline

- Nanotechnology: benefits & risks
- Approaches to risk management
 - Precautionary principle
e.g., ETC Group
 - Modify & extend existing regulations:
e.g., Royal Society of London
 - Competitive Discipline, voluntary standards
e.g., Foresight Institute (more or less)
- Anticipation or Resilience?
 - preparing for a harsh winter, or for an earthquake?
 - dictate methods, or measure results?

Nanotechnologies

US Nanotechnology Initiative:
\$1 billion per year in federal tax dollars

- Understanding and control of matter at dimensions of ~ 1 to 100 nanometers
- Unique phenomena enable novel applications.
- Imaging, measuring, modeling, & manipulating matter at this length scale.

Benefits and Risks

Potential Benefits *

- Meeting global energy needs with clean solutions
- Providing Abundant Clean Water Globally
- Increasing Health and Longevity of Human Life
- Maximizing Productivity of Agriculture
- Making Powerful Information Technology Available Everywhere
- Enabling the Development of Space

* *Foresight Nanotech Challenges*
www.foresight.org/challenges

Potential Risks

Physical, chemical, biological properties at nano-scale differ from bulk material and this could affect:

- health
 - increased toxicity
 - can more readily enter the body through skin, lungs, and digestive tracts
- safety
 - "risk of unexpected chemical reactions, fire and explosion"
(UK HSE exec)
- environmental
 - move more swiftly through aquifers than conventional pollutants ... ground water, food chain.

Risks Unknown

- National Institute for Occupational Health (NIOSH): "Occupational health risks associated with manufacturing and using nanomaterials are not yet clearly understood."
- Royal Society: "virtually no information available about the effect of nanoparticles on species other than humans or about how they behave in the air, water or soil, or about their ability to accumulate in food chains."

Risk Management—Precautionary Principle

strong version:

Prohibitory Precautionary Principle:

Prohibitions should be imposed on activities that have an uncertain potential to impose substantial harm, unless those in favor of those activities can show that they present no appreciable risk.

reverse onus: burden of proof on technologist

* Richard B. Stewart, *Environmental Regulatory Decision Making Under Uncertainty*, 2002

Precautionary Principle Critiques

Substitute Risks & Opportunity Costs

"risk also lies in technological stagnation...
disease, hunger, poverty and environmental
damage" – Ronald Bailey

Example: FDA regulations

Proving a negative

guilty until proven innocent: Apply to free speech?

Offers no guidance: apply the principle to itself

Risk Management—Regulations

Are Regulations appropriate for nanotech?

Important considerations:

- Paradoxes and unintended consequences
- Are regulations effective?
 - Burden of proof should be on those proposing regulation

Paradoxes of the Regulatory State*

- Overregulation produces underregulation
- Strong regulation of new risks increases aggregate risk levels
 - encourages continued use of potentially more dangerous technologies
- Costs of Regulations: >\$200 billion/year
 - richer is safer, wealthier is healthier
 - preventative expenditures
 - cost of a "statistical life": ~\$10-50 million
 - only 5 of 17 regs had positive lives-saved figure

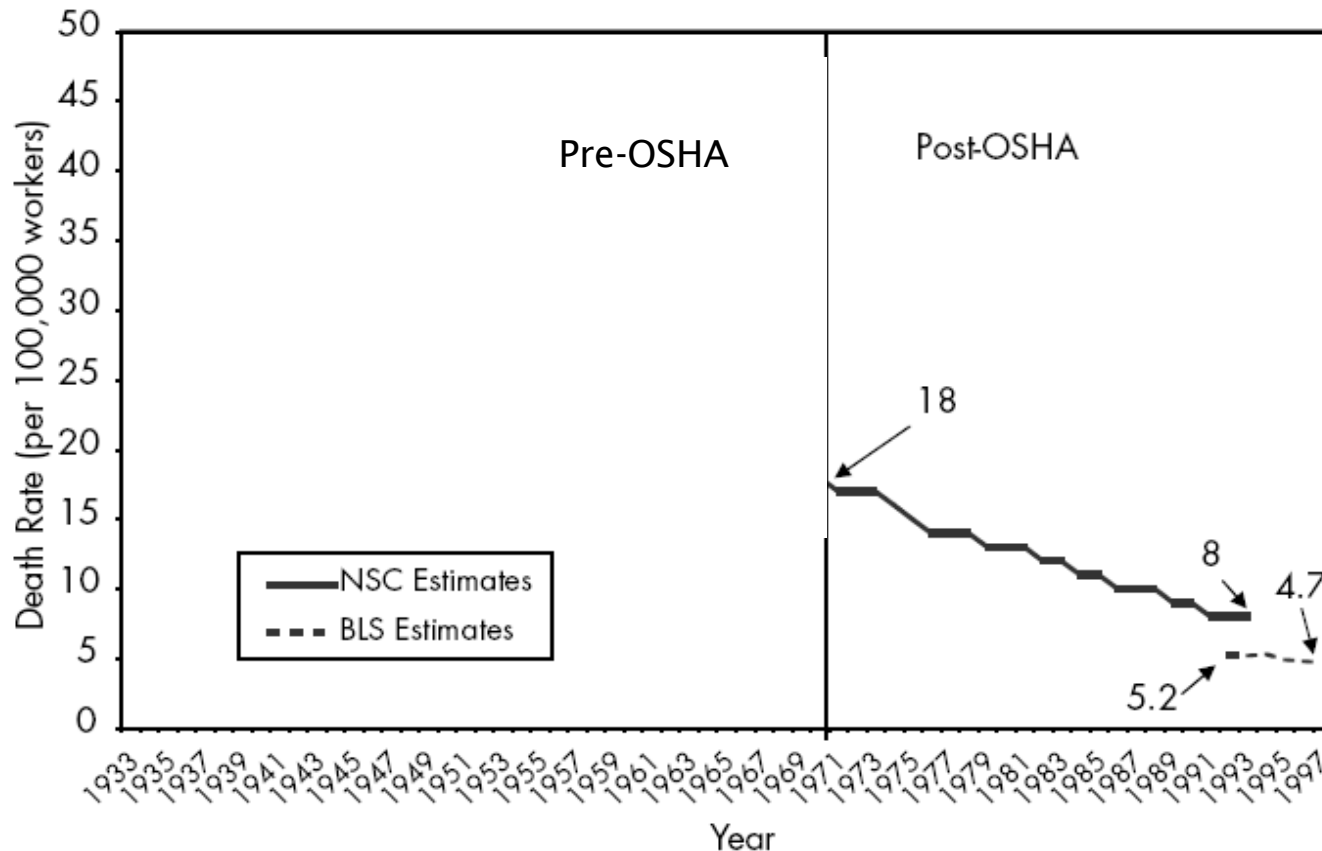
(Hahn, Lutter, Viscusi. 2000. Do Regulations Reduce Mortality? aei.brookings.org)

Regulations: other unintended consequences

- *Lulling effect*
 - e.g. anti-lock brakes (Viscusi, Wildavsky)
- *Bootleggers and Baptists, e.g., ETC?*
 - (Bruce Yandle at Clemson)
- *Regulatory capture*
 - agbiotech: Monsanto, Pioneer and Sygenta lobbied for strict regulations as "stamp of approval"
 - effectively a barrier to entry for competitors

Do Regulations work? OSHA

Figure 38.1
Workplace Fatalities, 1933–97



SOURCES: National Safety Council, *Accident Facts* (Itasca, Ill.: NSC, various years); and Bureau of Labor Statistics, *Occupational Injuries and Illnesses in the United States by Industry* (Washington: BLS, various years).

Source: *Cato Handbook for 107th Congress*

Alternatives to OSHA Regulations

- Experience-rated workers compensation insurance
 - premiums decrease w/ fewer injuries
 - Regulations prescribe actions regardless of result. Insurance rewards results, allows for diversity of solutions.
- Wage-risk trade off
 - employees accept more risk for higher-paying jobs
 - Example: To work with asbestos, it's \$3-\$5K/year. (Viscusi, *Fatal Tradeoffs* 1992)
 - criticism: Ashford & Stone in *The Liability Maze*, 1991

Alternatives to product regulations

- FDA as a certification body, lift default bans
- Non-governmental certification bodies
 - electronics - Underwriters Labs
 - hotels and restaurants – AAA
 - Good Housekeeping, Consumer Reports
 - **nanotechnology – Foresight Guidelines for Responsible Nanotechnology Development**
6th Edition, April 2006
- Product liability insurance, torts

Potential Benefits of Insurance & torts

- Competitive pressures among insurers → continual improvements in the art of risk analysis.
- Cost of overestimating risk: lose business by setting premiums too high.
- Cost of underestimating risk: claims too high

– Martin Katzman

see also: Swiss Reinsurance Company. 2004. *Nanotechnology: Small Matter, Many Unknowns*.

- But: strict liability makes torts effectively regulatory, less *resilient* (Wildavsky, Huber)

Anticipation vs. Resilience

Aaron Wildavsky,
Searching for Safety 1988

Anticipation: "control by a central mind...predict & prevent potential dangers before damage is done."

Knowledge required:

- what to prevent
- how to prevent it
- remedy leaves us better off

Drawbacks: *rigid*, can forbid beneficial actions or lax rules that fail to protect

Examples: regulations

Resilience: "capacity to cope w/ unanticipated dangers before they become manifest, learning to bounce back"

Advantage: Accounts for wide range of hazards, only punishes behavior that leads to injury

Examples: torts, insurance, non-governmental certification

Conclusions

- reducing risk is "like squeezing a balloon"
- Precautionary Principle: what's the risk of applying it?
- new regulations – burden of proof on regulator
 - Are existing ones even effective?
 - Are they cost-effective?
- Anticipation vs. resilience: for nanotechnologies & other quickly-developing fields, resilience is more appropriate.

extra slides follow

Precautionary Principle

- **PP1. Nonpreclusion Precautionary Principle:** Regulation should not be precluded by the absence of scientific uncertainty about activities that pose a risk of substantial harm.
- **PP2. Margin of Safety Precautionary Principle:** Regulation should include a margin of safety, limiting activities below the level at which adverse effects have not been found or predicted.
- **PP3. Best Available Technology Precautionary Principle:** Best available technology requirements should be imposed on activities that pose an uncertain potential to create substantial harm, unless those in favor of those activities can show that they present no appreciable risk.
- **PP4. Prohibitory Precautionary Principle:** Prohibitions should be imposed on activities that have an uncertain potential to impose substantial harm, unless those in favor of those activities can show that they present no appreciable risk.

* Richard B. Stewart, *Environmental Regulatory Decision Making Under Uncertainty*, 2002

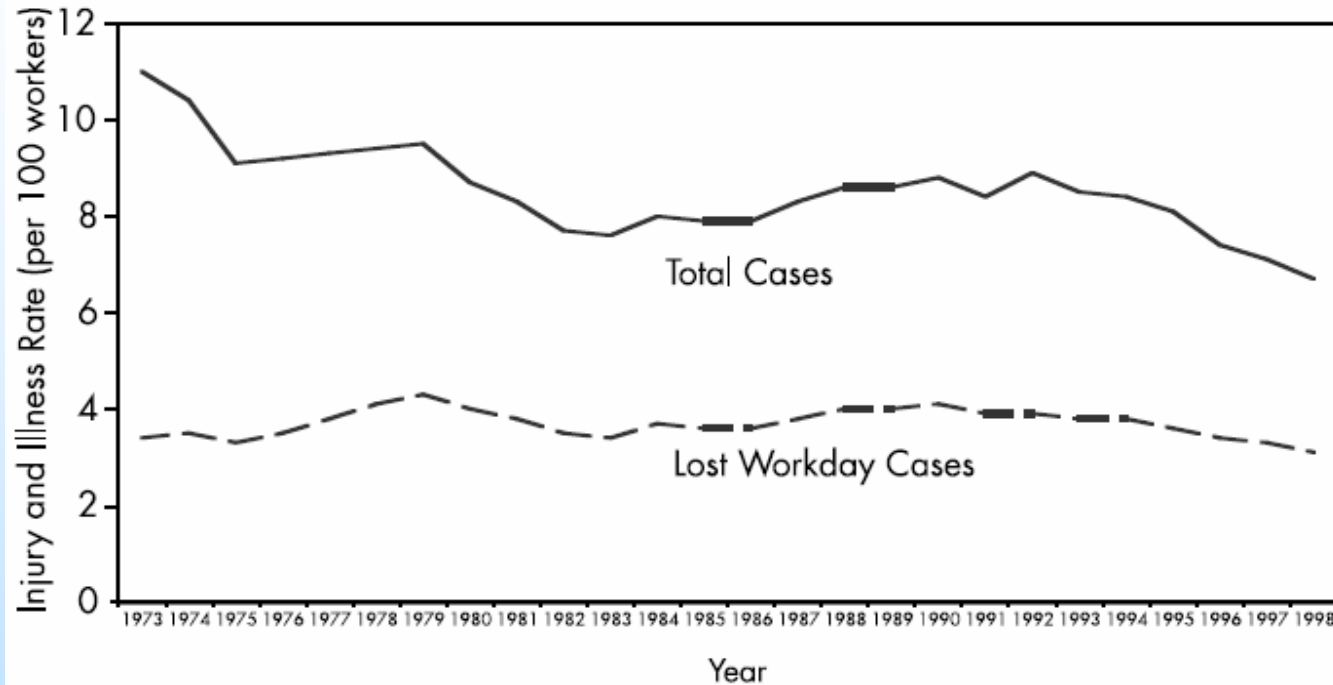
Costs of Regulations

- Richer is safer, wealthier is healthier
- Regulations make people poorer
 - enforcement & compliance costs
 - drives up costs of products
- Less \$ for *protective expenditures*
- Quantify this: measure net-lives saved
 - Of 16 federal regulations potentially related to nanotechnology, only 5 had a positive net-lives saved.

(Hahn, Lutter, Viscusi. 2000. Do Regulations Reduce Mortality? aei.brookings.org)

OSHA

Figure 38.2
Workplace Injuries and Illnesses, 1973–98

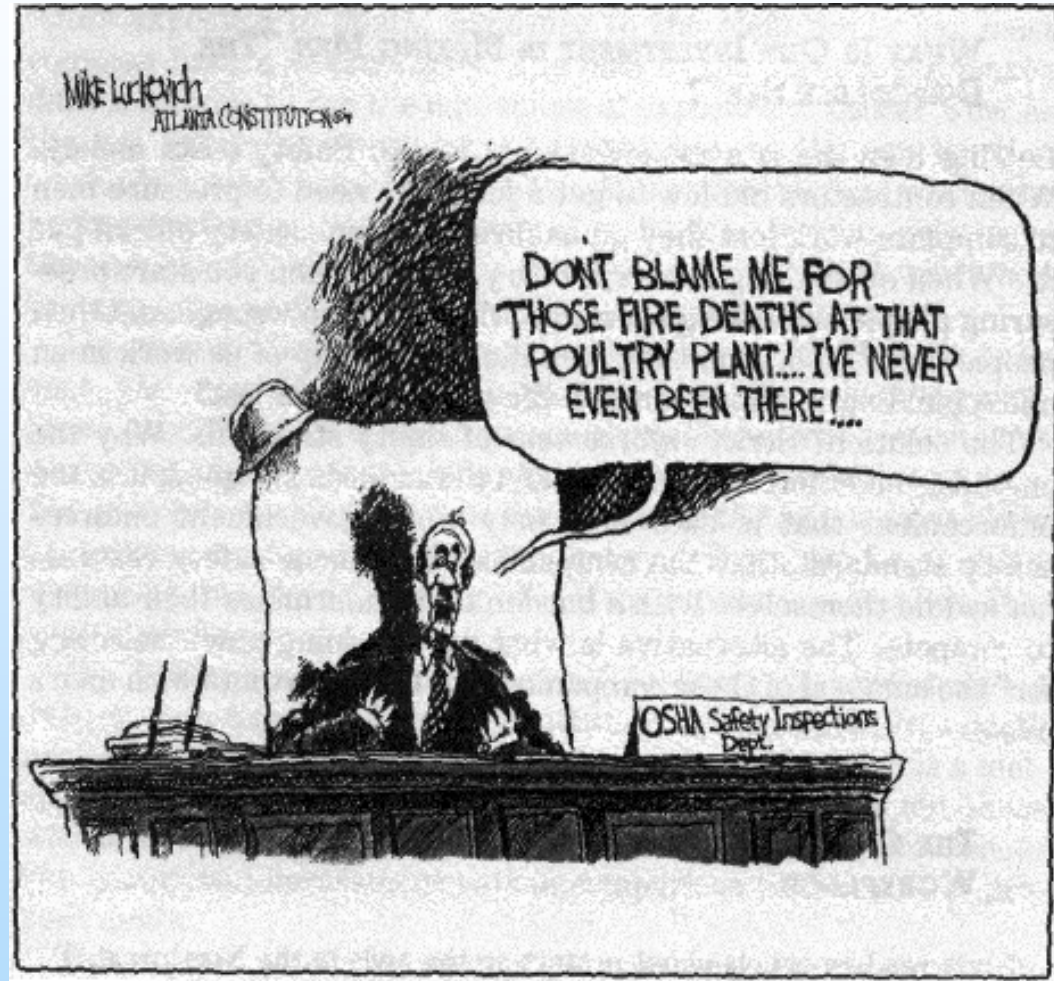


SOURCE: Bureau of Labor Statistics, *Occupational Injuries and Illnesses in the United States by Industry* (Washington: BLS, various years).

Source: *Cato Handbook for 107th Congress*

OSHA

- overregulation produces underregulation
 - discretionary non-enforcement
 - enforcement-caused diversion



Effectiveness of FDA

- Opportunity costs for pre-approval bans
 - beta blockers, heart medication, 7-year delay
119,000 Americans, dead. (L. Lasagna, Tufts)
 - Interleukin-2, kidney cancer, 3-year delay,
25,000 Americans died
drug had been approved in nine other countries.
- Cost of approval stifles innovation
- errors of commission vs. omission
- comprehensive critique w/ references:
FDAreview.org

Regulations: environmental, EPA

- Relevant Regulation:

Toxic Substances Control Act (TSCA)

- Env. Defense Fund: "testing of existing chemicals under [the] TSCA ... modest dent in backlog of untested chemicals."
- Alternative: "toxic torts"
 - If victim can demonstrate harm, company is liable
 - Challenges: can be difficult to trace harm to source, difficult to insure against

(W. Kip Viscusi, *Cutting the Green Tape*, 2000)

Calculating Cost of Regulations

1. Net cost of regulation compliance
2. Monetized benefits
3. Stat. life saved – agency estimates
4. cost per stat. life saved, ~\$300K/life-year
5. fatalities induced by cost of rules
6. net lives saved by rules: 5+3

net cost per statistical life saved is the net cost divided by the discounted reduction in population mortality risk.

Do Regulations Reduce Mortality?

TABLE 2

Regulatory Costs on Health

Summary of expenditures per life saved that lead to the loss of a statistical life

Author	Income loss per statistical life (\$ millions*)	Methodology
Keeney (1990)	12.5	Mortality rate-income relationship for the United States
Lutter and Morrall (1994)	9.3	International data on mortality-income relationship.
Viscusi (1994)	50	Value of life coupled with marriage propensity to spend on health.
Lutter, Morrall, and Viscusi (1999)	15	Same as Viscusi '94 but including harmful health-related expenditures coupled with marginal propensity.

* For comparability, the results from Keeney and Lutter and Morrall have been put in 1992 dollars, which is the same as Viscusi.

SOURCES: "Mortality Risks Induced by Economic Expenditures," by Ralph L. Keeney, *Risk Analysis*, Vol. 10 (1990); "Health-Health Analysis: A New Way to Evaluate Health and Safety Regulation," by Randall Lutter and John F. Morrall III, *Journal of Risk and Uncertainty*, Vol. 8 (1994); "Mortality Effects of Regulatory Costs and Policy Evaluation Criteria," by W. Kip Viscusi, *RAND Journal of Economics*, Vol. 25 (1994); and "The Cost-per-Life-Saved Cutoff for Safety-Enhancing Regulations," by Randall Lutter, John F. Morrall III, and W. Kip Viscusi, *Economic Inquiry*, Vol. 37 (1999).

Source: Viscusi and Gayer, "[Safety at Any Price?](#)", *Regulation*, Fall 2002.