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Flexibility, Clarity, and Legitimacy: Considerations for Managing Nanotechnology Risks

by Jonathan M. Gilligan

Editors' Summary: Risk assessment is one tool of legal and policy decision-making, and one that may play a large role in establishing nanotechnology policy and regulations. In this Article, Jonathan Gilligan analyzes different methods of risk assessment and applies these methods to nanotechnology. Gilligan challenges the notion that people perceive and react to risk in a logical way, postulating that both experts and laypeople are susceptible to irrationality when it comes to risk perception. He concludes with a determination that a singular approach to risk management of nanotechnology may not be enough; rather, multiple risk management methods should be utilized depending on qualitative assessments of different nanotechnologies.

I. Introduction

Environmental hazards associated with nanotechnology present particularly difficult problems for regulators. The classic stepwise approach of problem identification, quantitative assessment, and management[1] provides little guidance because both the quantity and variety of nanomaterials being produced by industry are growing exponentially and substantially outpacing our ability to identify potential hazards, much less to measure and characterize their effects. It is important to establish a risk-management regime that is flexible enough to achieve its goals in an atmosphere of great uncertainty and rapidly changing information. Before addressing the difficulties of identifying and assessing nanotechnological hazards, we must determine both the goals of a regulatory regime and the criteria for judging its success.

Whatever the goals of a government policy, a primary criterion for success must be public legitimacy.[2] If the public will not accept a policy, then no matter how sound the reasoning behind it, the policy will not work. The public may ignore a rule, change the rule through political pressure on legislators, or override the rule through referenda or action in the marketplace.[3]

But there is more to making policy than catering to public taste. Regulatory policy should also aid the smooth functioning of markets. Buyers and sellers require information, and where important information is not readily available, regulations may seek to provide it.[4] Producers and consumers must be able to plan for the future, so regulations should create clear and predictable responsibilities and liabilities, and buffer the effects of surprising new information.

Markets do well at managing many aspects of voluntary exposure to hazards, but regulations are necessary to manage the hazards of involuntarily exposure both by keeping the danger within acceptable limits and by ensuring that the

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1. Committee on the Institutional Means for Assessment of Risks to Public Health, Risk Assessment in the Federal Government: Managing the Process 19-20 (1983) [hereinafter Risk Assessment].

2. Deborah Stone, Policy Paradox: The Art of Political Decision Making 285 (Revised ed. 2002):

> Legitimacy is in some sense the political scientist's equivalent of the economist's invisible hand: we know it exists as a force that holds societies together, but we cannot give very satisfactory explanations of how to create it or why it is sometimes very strong and sometimes seems to disappear. Nevertheless, we can say that rules work best when they are perceived as legitimate.

See also Cass R. Sunstein, Risk & Reason: Safety, Law, and the Environment 294 (2002) ("[T]echnocrats tend to ignore the fact that to work well, a regulatory system needs one thing above all—public support and confidence. This is so whether or not a lack of confidence would be fully rational.").

3. *See* Sheila Jasanoff, The Fifth Branch: Science Advisers as Policymakers 123-51, 193-207 (1990) [hereinafter Fifth Branch]; Sheila Jasanoff, *Civilization & Madness: The Great BSE Scare of 1996*, 6 Pub. Understanding Sci. 221, 221-26 (1997) [hereinafter *Civilization & Madness*]; Sheila Jasanoff, *EPA's Regulation of Daminozide: Unscrambling the Messages of Risk*, 12 Sci. Tech. & Hum. Values 116, 116-18 (1987) [hereinafter *Regulation of Daminozide*].

4. *See* George A. Ackerlof, *The Market for "Lemons": Quality, Uncertainty, and the Market Mechanism*, 84 Q. J. Econ. 488, 499-500 (1970); George J. Stigler, *The Economics of Information*, 69 J. Pol. Econ. 213, 224 (1961).

risk is fairly distributed across the population—that certain identifiable groups of people are not unfairly exposed to disproportionate hazards.[5]

The goals of a regulatory policy should be: to create regulations acceptable to the public; to promote the smooth functioning of markets; and to protect people from excessive and unfair involuntary hazards. The last criterion is complicated by the fact that we should consider hazards of omission (deprivation) as well as commission (exposure). As well as potentially creating serious environmental hazards, nanotechnology can also potentially reduce pollution by permitting cleaner, more energy-efficient manufacturing.[6] Trade offs between two competing hazards are a staple of risk management, but in the case of nanotechnology, the competing hazards and benefits have so much overlap that they may be analogous to the Food and Drug Administration (FDA) balancing the active hazard of dangerous or ineffective drugs against the passive hazard of "drug-lag."[7]

A large part of recent debate over the regulation of environmental hazards takes place within a dichotomy between utilitarian (cost-benefit) and precautionary approaches with little apparent middle ground.[8] Strictly precautionary approaches to hazard management may give arbitrary, excessive, and unjustified weight to hazards of commission while neglecting hazards of omission.[9] However, utilitarian approaches, particularly the currently fashionable framework of quantitative cost-benefit analysis, function best when competing hazards can be assessed with great accuracy and precision. All too often, scientific uncertainty about hazards and difficulties precisely quantifying the value of life, health, fairness, and hedonic utility render the results of cost-benefit tests ambiguous and require tiebreaking procedures outside the utilitarian framework.[10]

Cost-benefit studies of nanotechnology are particularly impractical because not only can we not measure the hazards and benefits of nanotechnology, it is too soon to have even identified in more than the vaguest sense what those hazards and benefits will be. We will not be able to establish now or in the near future a precise set of rules for governing nanotechnology. Rather, what is imperative is to establish a process for developing rules in the face of uncertainty and for adapting to the inevitable surprises that will come. This process must be able to maintain a broad sense of trust across all the stakeholders—government agencies, industry, consumers, and others—and be resilient in the face of the unexpected.

However, a purely precautionary approach to nanotechnology would deprive us of its potentially enormous benefits while we sort out our uncertainty about its potentially enormous dangers. Much nanotechnology does not promise to revolutionize industry or benefit the environment. Rather, it offers improved tennis racquets, better baseball bats, better colors for cosmetics, and similarly minor and evolutionary improvements in a broad range of products.[11] Applying a somewhat precautionary approach to such products will not deprive us of important breakthroughs. On the other hand, where nanotechnology offers truly important and revolutionary benefits, a more risk-acceptant position would be appropriate. I propose that we can find useful guidance in the way the Food and Drug Administration Modernization Act of 1997 balances costs, benefits, and precaution through the use of a fast track for important drugs within a default precautionary posture.[12] The FDA has been harshly criticized both for being too slow to get useful drugs to market, and for being unduly hasty, as in the case of Vioxx. Nonetheless, the FDA has not suffered a crisis of public confidence. While the implementation of the fast-track mechanism has been criticized, the general approach appears to retain legitimacy, so it seems feasible to approach nanotechnology with different levels of precaution for different substances based on the importance of their potential use.

II. Assessing Nanotechnology's Risks

One widely used rubric for assessing risks, laid out in a report of the National Research Council,[13] entails four steps: problem identification, dose-response assessment, exposure assessment, and risk characterization. First, we identify specific hazards: for instance, do inhaled nanoparticles cause lung cancer? Next, we measure the dose-response relationship: how much nanomaterial must someone inhale to double their risk of cancer? Third, we measure exposure: how much nanomaterial would a typical person inhale during the course of a day? Finally, we characterize the risk by combining three of the previous steps to describe the range of possible hazards and the degree of danger each poses.

This approach does not work well for nanotechnology for several reasons. First, the term "nanotechnology" is often used imprecisely, which makes it hard to clearly define which risks and benefits belong properly to the field. Nanotechnology refers to synthetic materials with particle sizes between one and a few hundred nanometers. However, nanotechnology is also a marketing buzzword. Many manufacturers suggest that products such as sunscreen, makeup, bicycles, and baseball bats are superior because they contain nanotechnology and promotional literature

5. *See, e.g.*, Robert V. Percival et al., Environmental Regulation: Law, Science, and Policy 85-95 (4th ed. 2003) (providing overview of environmental regulation); Sunstein, *supra* note 2, at 53-77 (outlining involuntary versus voluntary hazards and fair distribution of risks; defining acceptable limits); Exec. Order No. 12898, 59 Fed. Reg. 7629 (Feb. 16, 1994) (addressing unfair distribution of risks affecting minorities and the poor).

6. *See* Nanotechnology Research Directions: IWGN Workshop Report 143-52 (Mihail C. Roco et al. eds., 1999).

7. *See, e.g.*, Sam Peltzman, *An Evaluation of Consumer Protection Legislation: The 1962 Drug Amendments*, 81 J. Pol. Econ. 1049, 1067-68, 1089-90 (1973); Philip J. Hilts, Protecting America's Health: The FDA, Business, and One Hundred Years of Regulation 191-94, 244-54, 276-90 (historical overview of drug-lag, especially regarding HIV/AIDS drugs).

8. *See, e.g.*, W. Kip Viscusi, Rational Risk Policy 84-88 (1998); Sunstein, *supra* note 2, at 102-05; Stephen Breyer, Breaking the Vicious Circle: Toward Effective Risk Regulation 10-29 (1993); Frank Ackerman & Lisa Heinzerling, Priceless: On Knowing the Price of Everything and the Value of Nothing 117-22 (2004).

9. *See, e.g.*, Peltzman, *supra* note 7, at 1089-90; Viscusi, *supra* note 8, at 75-77, 94-100; Sunstein, *supra* note 2, at 133-52; Breyer, *supra* note 8, at 19, 23.

10. *See* Sunstein, *supra* note 2, at 153-90 (careful calculation of the costs and benefits of regulating arsenic in drinking water cannot determine whether costs greatly exceed benefits or vice versa).

11. *See, e.g.*, Ellen Sheng, *Nanotechnology Hits the Tennis Court*, Wall St. J., Aug. 25, 2005, at D1; Rick Weiss, *For Now, Consumer Nanotech Concentrates on Little Things*, Wash. Post, Mar. 10, 2006, at A3; Joseph Ogando, *Nanotech Goes to Bat*, Design News, June 5, 2006, at 26.

12. 21 U.S.C. §356.

13. *See* Risk Assessment, *supra* note 1, at 19-20.

may stretch the term beyond its scientific definition.[14] Hazards from nanoparticles vary significantly with particle size, so imprecise boundaries on what constitutes nanotechnology obscures distinctions that are critical for accurate environmental and health risk assessment, and thus threatens to inflate estimates of the economic value of true nanotechnology—to compare the cost of apples and the benefit of oranges.

Some forecasts suggest that the market for products containing nanotechnology will reach tens of billions of dollars, even one trillion dollars or more within a decade and employ over two million people worldwide.[15] Nanotechnology may transform industry and benefit the environment by permitting cleaner manufacturing, creating new ways to clean up pollution in the environment, and increasing the efficiency with which we use energy and natural resources.[16] Nanotechnology could revolutionize medicine, allowing us to tinker with our bodies at a molecular scale, repairing defective genes, cleaning plaque from our arteries, and destroying cancerous tumors.

It is uncertain whether nanotechnology will deliver on all that has been promised in its name. At one time, the Internet was going to create a "long wave" of prosperity, make recessions obsolete, break America's dependence on foreign oil, and drive the Dow to 36,000.[17] Other technologies brought similar exaggerated promises: Nuclear energy would be too cheap to meter.[18] Antibiotics would permanently eliminate infectious disease.[19] The green revolution would eliminate hunger in the Third World.[20] Whether nanotechnology turns out to be truly revolutionary, a bust, or a modest, evolutionary success remains to be seen. Most of the benefits we are promised are still quite far from the marketplace and most current nanotechnology provides, at best, modest improvements to conventional products.[21]

It is also difficult to assess the risks of nanotechnology. Practically all nanotechnology in current products is "passive:" it doesn't actively manipulate its environment. In the future there will be great emphasis on "active" nanotechnology that does manipulate its environment. This may include small machines—particles that change their size or shape in response to external or internal stimulus—and one can even imagine the sort of microscopic robots beloved by science fiction writers. It has been proposed by the International Risk Governance Council that the hazards of nanotechnologies be divided into two "frames:" Frame 1 will treat hazards of passive technologies while Frame 2 will treat the hazards of active technologies.[22] Because active nanotechnologies are in their infancy, there is a much greater lead time to consider their hazards. Managing risks of passive nanotechnologies is more pressing, so this Article will focus primarily on Frame 1 hazards.

There is such a wide range in size that different types of nanoparticles present completely different hazards. Ten-nanometer particles can easily slip through membranes into the bloodstream or into cells while 100-nanometer particles generally do not.[23] The chemical properties can be significantly changed by altering the size and shape of the nanoparticle and experience with asbestos suggests that particle shape may be as important as size.

Assessments of the risk of small particulate matter in air pollution have repeatedly found that these particles are more deadly than previously believed, so there is good reason to worry about the effect of engineered nanoparticles.[24] On the other hand, one can ask whether there is any reason to pay special attention to nanotechnology when there are so many other sources of nanoparticles in the environment—notably diesel exhaust and industrial production of carbon black, both of which produce much greater amounts of nanoscale material than the nanotechnology industry.[25]

Hazards can involve the special chemical properties of nanoscale particles. Atoms at the surface of nanoparticles are often much more chemically active than they are on larger surfaces.[26] This is attractive to people who want to make more efficient catalytic converters to reduce pollution from combustion. It presents the possibility of using nanoparticles to clean up pollution from soil and groundwater. But the prospect of persistent catalysts in the environment may pose serious threats to the environment. Consider another persistent catalyst in the environment: stratospheric chlorine. In the 1930s, Thomas Midgley, fresh from inventing leaded gasoline, dealt the environment another blow by inventing chlorofluorocarbons (CFCs).[27] These compounds were miraculous because they allowed refrigerators to replace toxic or explosive coolants with something that was cheap, nontoxic, and nonflammable. Midgley demonstrated the safety of CFCs by inhaling it by the lungful and blowing

14. *See supra* note 11.

15. Mihail C. Roco, *International Perspective on Government Nanotechnology Funding in 2005*, 7 J. NANOPARTICLE RES. 707 (2005).

16. NANOTECHNOLOGY RESEARCH DIRECTIONS, *supra* note 6, at viii-xvii.

17. *See, e.g.*, *Untangling e-Conomics*, ECONOMIST, Sept. 23, 2000, at S5; JAMES K. GLASSMAN & KEVIN HASSETT, DOW 36,000: THE NEW STRATEGY FOR PROFITING FROM THE COMING RISE IN THE STOCK MARKET (2000); LAWRENCE KUDLOW, AMERICAN ABUNDANCE: THE NEW ECONOMIC AND MORAL PROSPERITY (1997).

18. *Abundant Power From Atom Seen; It Will Be Too Cheap for Our Children to Meter, Strauss Tells Science Writers*, N.Y. TIMES, Sept. 17, 1954, at A5.

19. Kenrad E. Nelson & Carolyn F. Williams, *Early History of Infectious Disease*, *in* INFECTIOUS DISEASE EPIDEMIOLOGY: THEORY AND PRACTICE 17 (Kenrad E. Nelson & Carolyn F. Williams eds., 2006).

20. Norman Borlaug, *The Green Revolution, Peace, and Humanity*, *in* LES PRIX NOBEL EN 1970 225 (Frederick W. Haberman ed., 1971), *available at* http://nobelprize.org/nobel_prizes/peace/laureates/1970/borlaug-lecture.html.

21. *See supra* note 11.

22. ORTWIN RENN & MIKE ROCCO, INT'L RISK GOVERNANCE COUNCIL, NANOTECHNOLOGY RISK GOVERNANCE 14 (2006).

23. Andre Nel et al., *Toxic Potential of Materials at the Nanolevel*, 311 SCIENCE 622 (2006); Peter H.M. Hoet et al., *Nanoparticles—Known and Unknown Health Risks*, 2 J. NANOBIOTECH. 12 (2004); S. Moein Moghimi et al., *Nanomedicine: Current Status and Future Prospects*, 19 FASEB J. 311 (2005).

24. Michael Jerrett et al., *Spatial Analysis of Air Pollution and Mortality in Los Angeles*, 16 EPIDEMIOLOGY 727 (2005); R.B. Schlesinger et al., *The Health Relevance of Ambient Particulate Matter Characteristics: Coherence of Toxicological and Epidemiological Inferences*, 18 INHALATION TOXICOLOGY 95 (2006).

25. Ann M. Thayer, *Firms Find a New Field of Dreams*, CHEMICAL & ENGINEERING NEWS, Oct. 16, 2000; Michelle Bryner & Alex Scott, *Nanotechnology Entering the Commercial Phase*, CHEMICAL WK., Dec. 14, 2005, at 22.

26. Marie-Christine Daniel & Didier Astruc, *Gold Nanoparticles: Assembly, Supramolecular Chemistry, Quantum-Size-Related Properties, and Applications Toward Biology, Catalysis, and Nanotechnology*, 104 CHEMICAL REV. 293, 325-27 (2004).

27. SETH CAGIN & PHILIP DRAY, BETWEEN EARTH AND SKY 63-69 (1993).

out candles. Little did anyone know that CFCs in atmospheric concentrations of parts per trillion would be able to destroy almost all the stratospheric ozone over an area larger than the continental United States.[28] Such a small concentration of a pollutant could have a huge effect because chlorine atoms from the CFC molecules acted as catalysts, which allowed a single chlorine atom to destroy as many as 100,000 molecules of ozone.

Could environmentally persistent nanoscale catalysts pave the way to a similar surprise? Could nanocatalysts designed to helpfully catalyze the oxidation of hydrocarbon pollutants run amok and deplete natural organic matter from the soil, rendering farmland barren? Such a scenario might be a lower-tech version of the familiar "gray goo" story, but without requiring complex autonomous robots. It seems unlikely, but may fall into the category of low-probability/high-consequence risk for which even staunch utilitarians recommend a degree of precaution.[29]

As nanotechnology moves from passive (Frame 1) substances toward active (Frame 2) devices that exert some control over their surroundings, it becomes even harder to predict what the actual risks will be. The gray goo and superintelligence scenarios of science fiction, which worry Bill Joy and Richard Posner, among others, seem sufficiently improbable and sufficiently distant in the future that they need not concern nanotechnology regulations crafted for the next few decades. But one thing seems clear: the history of anthropogenic environmental hazards suggests that the most serious problems associated with nanotechnology are likely to be ones we have not yet imagined.

Once we identify potential hazards, assessing their magnitude—dose-response, exposure, and characterization—is similarly daunting. Obtaining good measurements of exposure and dose-response relationships is exceedingly difficult and uncertain. As we do these assessments, we must keep in mind the question of whether the risks of nanotechnology deserve special consideration, with greater scrutiny than other environmental risks. We only have detailed risk assessments for exposure to a handful of the tens of thousands of industrial chemicals in common use, so it is difficult to say whether some of these may be much more dangerous than most types of nanoparticles.[30]

Many hazardous substances become more hazardous in combination with one another than alone, as seen in synergetic interactions between asbestos and tobacco smoke or between fenfluramine and phentermine in Fen-Phen. If we consider the sheer number of possible hazardous combinations of nanomaterials, it might be statistically impossible to obtain valid epidemiology even from a population of hundreds of millions.

All of this means that any attempt to balance the risks of nanotechnology against the benefits it offers will be dominated by uncertainty. This uncertainty is clearest when we look at how the insurance industry views nanotechnology. The chief executive officer of SwissRe, a major reinsurance firm, identifies nanotechnology, global warming, and terrorism as the three great threats to the insurance industry and writes:

> Nanotechnology is not a manageable or even yet a definable field of risk. It is on the insurance industry's agenda because of concerns over "nano-toxicity" or "nano-pollution" and because nano-products are expected to become omnipresent across industry sectors and countries. This introduces the possibility of long-latent, widespread, and unforeseen claims.[31]

The great fear is that nanotechnology will produce the next generation of asbestos litigation.

Where science can provide clean and accurate answers to our questions, we can make policy in a fairly technocratic manner. Public interest groups are not clamoring for popular input into the selection of alloys to make cars or airplanes. Scientists and engineers enjoy a great deal of trust in these areas.

However, when science is uncertain—when hypotheses cannot be rigorously tested and when measurements are fraught with large error bars—the role of experts in making policy is much more complicated.

III. Risk Perception

One approach to risk assessment starts with a general definition that risk equals probability multiplied by consequence. However, people do not usually treat risk in their lives using mathematical formulations.[32] A more nuanced definition of risk might be that risk equals perceived probability times the sum of consequences plus outrage.[33] Risk is inherently an emotional concept, and while some people would like to divorce it from psychology and treat it as a cold calculation of net utility, this is not politically realistic and is not, in my mind, consistent with democratic respect for the public's concerns.

There is a voluminous literature on the psychology of risk perception which demonstrates that when people—experts or laypeople—face uncertain risks, they behave in predictably irrational ways.[34] Irrational thinking about risks poses two types of danger: First, people (including experts) may neglect or dismiss real risks and thus expose themselves and the public to danger. Second, they may exaggerate small or negligible risks, and in overreacting, deprive the public of important goods. If consumers distrust and reject a product, it will disappear from the market just as surely as if a regulatory agency banned it.[35]

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28. F. Sherwood Rowland, *Nobel Lecture in Chemistry*, *in* 3 Nobel Lectures, Chemistry 1991-1995 273 (Bo G. Malmstrom ed., 1996).

29. Richard A. Posner, Catastrophe: Risk and Response 35–37, 184-86, 253 (2004).

30. Stephen Breyer names this regulatory failing "random agenda selection." Breyer, *supra* note 8, at 19-20.

31. John R. Coomber, *Natural and Large Catastrophes—Changing Risk Characteristics and Challenges for the Insurance Industry*, 31 Geneva Papers 88, 93 (2006).

32. *See* Paul Slovic, *Beyond Numbers: A Broader Perspective on Risk Perception and Risk Communication*, *in* Acceptable Evidence: Science and Values in Risk Management 48, 55-62 (Deborah G. Mayo & Rachelle D. Hollander eds., 1991); *but see* Gerald J.S. Wilde, Target Risk 31-54 (1994) (people adjust behavior to maintain a constant level of perceived quantitative risk per hour).

33. Vincent Covello & Peter Sandman, *Risk Communication: Evolution and Revolution*, *in* Solutions to an Environment in Peril 164 (Anthony Wolbarst ed., 2001); *see also* Robin Gregory et al., *Technological Stigma*, *in* The Perception of Risk 341 (Paul Slovic, ed., 2000).

34. *See, e.g.*, Judgment Under Uncertainty: Heuristics and Biases (Daniel Kahneman et al. eds., 1982); Choices, Values, and Frames (Daniel Kahneman & Amos Tversky eds., 2000); The Perception of Risk, *supra* note 33.

35. *See infra* Part V.

A small sample of such irrational behaviors includes:

- People tend to focus on familiar risks. For instance, people spend a lot more time and money making sure their homeowner's insurance covers broken windows—a fairly minor hazard they could easily manage out of pocket—than making sure they are insured against catastrophic floods that could ruin them financially. People are usually more concerned whether their health insurance covers doctor visits for scrapes and allergies than long-term care for Alzheimer's or other disabilities.[36]

  This type of thinking applies particularly to the problem-identification step of risk assessment. There is a practically infinite number of possible hazards associated with any technology, and if we spent all our time making lists of novel ways to die, there would be no time to manage the real risks we already know about. Both laypeople and professional risk managers generally practice a form of bounded rationality: at some point they stop looking for new risks and start managing known risks.[37]

  This can be harmful, though. When engineers from Morton Thiokol, who manufactured the solid rocket motors for the space shuttles, warned the National Aeronautics and Space Administration (NASA) on January 28, 1986, not to launch the space shuttle *Challenger* in cold weather, NASA responded that careful studies had produced six thick volumes of risk-management procedures that constituted the flight readiness review, and that if the behavior of solid rocket motors in cold weather was not on the official list, it was not worth worrying about.[38] The result was the destruction of the spacecraft and the deaths of seven astronauts. Officials charged with managing floods tend to plan for the last flood instead of treating a variety of flood hazards.[39] We have not yet begun to scratch the surface of identifying possible hazards associated with nanotechnology, and it is important not to shut the door prematurely on problem identification, nor to become overconfident that we have identified all the important risks.

- Certain hazards, such as shark attacks or terrorism, evoke such dread that people take disproportionate measures to avoid them, even if the probability of those hazards is small. This leads to irrational responses. For instance, if some people are offered airline flight insurance that covers death from any cause during the trip and others are offered insurance that covers only against death from terrorism or mechanical failure, people are willing to pay more for the latter policy even though the former would cover both named hazards as well as any other, such as pilot error.[40] This seems to happen because the mention of specific dreaded causes produces a mental picture which causes greater anxiety than the more general and abstract hazard.

  Substances, such as nuclear waste, that evoke dread response can acquire "stigma."[41] Public response to stigma is often to demand that exposure be reduced not just to a safe level but to zero, with no tolerance. This can be very disruptive and lead to inefficient regulation, a breakdown of consensus among stakeholders, and a disappearing market for what might be reasonably safe and efficient products or services.[42]

- When considering very improbable risks with catastrophic costs, people often confuse "very small probability" with "zero probability" and thus discount the risk altogether.[43] The risk of the entire human species being killed by an asteroid hitting the earth is unbelievably small, about one chance in 50 million in any given year, so most of us act as though such a thing could not possibly happen during our lifetime. But the consequences should this happen are so great that a number of scholars believe humankind is making a grave mistake by neglecting this hazard.[44]

IV. Experts and Risk

We might hope that expert judgment would be less subject to irrationality than that of laypeople, but a large body of research on expert opinions about uncertain technical questions finds a number of common patterns of false reasoning or irrationality. When experts or laypeople make guesses or estimates of uncertain quantities, both tend to be overconfident and underestimate the uncertainty of their estimates. A panel of seven prominent engineers was asked to estimate a range of answers to a basic question about how high a retaining wall could safely be built, so that they were confident that there was a 90% probability that the correct answer lay within this range. While the basic guesses were not bad, the 90% confidence intervals were uniformly much too small and not one of the engineers had the correct answer within his interval.[45] This means that while their basic estimates were not bad, the engineers were much too confident in these estimates and did not understand how far off they might be.

This overconfidence combines with another observed tendency: when experts give their opinion about scientifically uncertain matters that have even indirect connections to political controversies, their opinions tend to be strongly influenced by their politics. A study of a number of experts on nuclear power in the early 1980s asked three completely unrelated questions: How much would demand for electric-

36. Paul Slovic et al., *Preference for Insuring Against Probable Small Losses: Insurance Implications*, *in* The Perception of Risk, *supra* note 33, at 51.

37. *See* Paul Slovic et al., *Decision Processes, Rationality, and Adjustment to Natural Hazards*, *in* The Perception of Risk, *supra* note 33, at 1.

38. Diane Vaughn, The Challenger Launch Decision: Risky Technology, Culture, and Deviance at NASA 6 (1996) ("Mulloy stated that since no Launch Commit Criteria had ever been set for booster joint temperature, what Thiokol was proposing to do was to create new Launch Commit Criteria on the eve of a launch.").

39. *See* Slovic, *Decision Processes*, *supra* note 37, at 194-95.

40. Eric J. Johnson et al., *Framing, Probability Distortions, and Insurance Decisions*, *in* Choices, Values, and Frames, *supra* note 34, at 224, 228.

41. *See* Roger E. Kasperson et al., *Stigma and the Social Amplification of Risk: Toward a Framework of Risk Analysis*, *in* Risk, Media, and Stigma: Understanding Public Challenges to Modern Science and Technology 9 (James Flynn et al. eds., 2001).

42. *See* Robin Gregory et al., *Technological Stigma*, *in* Risk, Media, and Stigma, *supra* note 41, at 3; *see also* Jeanne X. Kasperson et al., *The Social Amplification of Risk: Assessing Fifteen Years of Research and Theory*, *in* The Social Amplification of Risk 13 (Nick Pidgeon et al. eds., 2003).

43. Howard Kunreuther et al., *Making Low Probabilities Useful*, 23 J. Risk & Uncertainty 103, 105 (2004); Posner, *supra* note 29, at 168.

44. *See* Posner, *supra* note 29, at 92-138.

45. Paul Slovic et al., *Facts Versus Fears: Understanding Perceived Risk*, *in* Judgment Under Uncertainty, *supra* note 34, at 463, 475-77.

ity grow in the next 20 years? How much high-quality uranium ore was there in the ground? How quickly would the cost of producing solar electricity fall in the next 20 years? Each of these questions was scientific, meaning that there was a definite answer that could ultimately be found (by waiting 20 years and looking at electricity consumption, uranium supplies, and solar energy prices).[46] There is no good reason to think that the answer to any of these questions has anything to do with the answer to another; the demand for electricity cannot affect how much uranium is in the ground.

The experts' answers to these questions fell into two groups. Most of those who believed that energy demand would rise sharply tended to think that uranium resources were scarce and that solar energy would remain expensive. Those who believed that energy demand would not rise very much tended to think that uranium was plentiful and that the cost of solar power would drop. Very few respondents fell outside this polarized pattern.

These patterns were explained by asking a fourth question: the first group (high demand for electricity, scarce uranium, expensive solar energy) tended to support a political program to build nuclear fast-breeder reactors, while the second group opposed building these reactors. The answers to the scientific questions about energy demand and so on tended to fall in line with what would support the political position of the respondent.

Where science is uncertain, scientists who favor developing nanotechnology quickly may similarly tend to produce high estimates of the beneficial aspects of nanotechnology and low estimates of the negative aspects, while scientists who prefer to go slowly with nanotechnology may believe the opposite. The influence of personal preferences on estimates of purely scientific questions about nanotechnology might be a fruitful area for research.

V. Science and Trans-Science

To better manage uncertainty in politically important scientific questions, two prominent scholars of science policy, Harvey Brooks and Alvin Weinberg, introduced a distinction between science and what Weinberg named "trans-science."[47] Trans-science refers to questions that are formally scientific—they contain hypotheses that can, in principle, be tested empirically—but unlike in regular science, trans-scientific hypotheses cannot be tested in practice. Performing the tests may be too expensive, too time-consuming, or unethical. The hypothesis that global warming will raise the average surface temperature of the earth by 2.7 degrees in the year 2100 is trans-scientific because in 2100 we will know unambiguously whether the hypothesis was true or false, but it is not possible to test it empirically today.

Brooks and Weinberg suggest that we would manage disputes over technological policy issues better if we clearly distinguished scientific questions, which can be resolved with empirical tests by the experts, from trans-scientific questions, which call for personal judgment and may require greater participation by the public.

When public policy decisions center on trans-scientific questions, debates can become rancorous and divisive. People's political interests tend to influence their scientific opinions so that the usual method of settling disputes with empirical tests is not possible. In such cases, Brooks recommends distinguishing between two modes of resolving disputes: consensus-building and adversarial contests.[48] Consensus-building follows the standard scientific model of gathering evidence and debating with an eye toward establishing broad agreement on factual matters. It is possible if both sides of the dispute can agree on criteria that would cause either side to concede its position. Then, even if the trans-scientific question cannot be answered with certainty, both sides can agree on the terms of discussion. So long as experts on either side of a technically complex policy question can seek consensus, it makes some sense to follow a technocratic approach.

On the other hand, if the two sides cannot even agree on how they would seek consensus, the dispute must be handled in an adversarial manner, analogous to a courtroom trial.[49] When scientists are engaged in adversarial debate about policy, Brooks suggests that there is no good reason to give them a privileged position. Without an empirical resolution to the argument, someone must serve as jury, and there is no good reason why that should not be representatives of the informed public. If the public is the ultimate arbiter of the legitimacy of regulatory policy, then it is imperative that debates be conducted with public participation.[50]

We can learn from the mistakes of the past. Three examples of how not to manage uncertain risks are the way the British Ministry of Agriculture, Fisheries, and Food handled the mad cow crisis of 1996, the way the U.S. Environmental Protection Agency (EPA) handled the Alar scare in 1989, and the way the Nuclear Regulatory Commission (NRC) handled public concern about reactor safety in the late 1970s. In all three cases, scientific experts sacrificed their credibility by claiming expert privilege and certainty for what were in fact mere opinions and guesses.

When mad cow disease was first reported in British cattle in 1988, and for many years thereafter, the British government assured the public that British beef was perfectly safe.[51] In 1996, scientists reported that at least a few people were catching incurable fatal brain disease by eating tainted beef. Some warned of an epidemic that could kill hundreds of thousands. As Sheila Jasanoff describes the result, "[T]rust in government vanished and people looked to other institutions—the high street butcher, the restaurant, the media, the supermarket—for information and advice to restore their security. It was as if the gears of democracy had spun loose, causing citizens, at least temporarily, to disengage from the state."[52]

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46. Harvey Brooks, *On the Resolution of Technically Intensive Public Policy Debates*, 9 Sci. Tech. & Hum. Values 39, 40 (1984) [hereinafter *Policy Debates*]; *cf.* Alan S. Manne & Richard G. Richels, *Probability Assessment and Decision Analysis of Alternative Nuclear Fuel Cycles*, *in* National Energy Issues—How Do We Decide? 241 (Robert G. Sachs ed., 1980).

47. Alvin Weinberg, *Science and Trans-Science*, 10 Minerva 209, 209 (1972); Harvey Brooks, *Science and Trans-Science*, 10 Minerva 484, 484 (1972).

48. *Policy Debates*, *supra* note 46, at 40-41.

49. *Id.* at 41-44; *see also* Arthur Kantrowitz, *A Proposal for an Institution for Scientific Judgment*, 156 Science 763 (1967) (original proposal for a "science court").

50. *Policy Debates*, *supra* note 46, at 45-49.

51. *Civilization & Madness*, *supra* note 3, at 222.

52. *Id.* at 223.

Subsequent epidemiology showed the warnings of widespread epidemics to be just as baseless as the government's reassurances. Current estimates of the human toll conclude that there will be a total of around 200 deaths from the British epidemic.[53] But once government had squandered its credibility with baseless assurances, it was in no position to moderate the panic and prevent the public from overreacting to this genuine but very small risk.

A similar case occurred in the United States in 1989.[54] Apples were frequently treated with the chemical daminozide (trade name Alar) to extend their shelf life. EPA had proposed banning daminozide and then reversed itself when its Science Advisory Panel concluded there was insufficient evidence to support the ban. EPA opened its scientific review hearings on Alar to representatives from Uniroyal, the principal manufacturer of Alar, but not to environmental or consumer safety groups. This convinced large segments of the public that EPA had been captured by industry interests. Consumers did not trust reassurances from EPA and industry and refused to buy Alar-treated apples. This forced growers to abandon Alar and Uniroyal to withdraw it from the market.

Finally, the accident at the Three Mile Island nuclear reactor in 1979, after years of assurance from the NRC that such accidents were absurdly improbable, irreparably damaged public trust in the safety of nuclear power.[55] Regardless that no one was injured or killed in the accident, that only negligible amounts of nuclear radiation were released, or that coal-fired power plants are millions of times more deadly, public opposition to nuclear power became strong enough that no new nuclear power plants have been built since.

VI. Trust, Regulation, and Uncertainty

A common thread of these regulatory disasters is the loss of public trust in scientific experts and in regulatory agencies. When the public stops trusting experts and government to provide accurate and honest assessments of risk, the resulting backlash can be very destructive. Similarly, when a trusted company or industry loses its good name and good will, the loss can be catastrophic. In regulating nanotechnology, it is important to avoid repeating these mistakes, because if the public loses trust in expert assurances of nanotechnology's safety, even safe, effective, and environmentally friendly nanotechnology may disappear in the face of consumer backlash.

Studies of expert opinion about risk suggest that scientists and engineers conducting risk analyses of new technologies tend to focus on the risks that lie in their areas of expertise and particularly on those risks that are commonly discussed in the scientific literature, while giving little care either to the prospect of serious unanticipated types of risk, or to economic and political risks to the industry's market.[56]

In considering how to balance the benefits of nanotechnology against its largely unknown risks and how to weigh those risks against the known risks of conventional technologies, it is worth considering whether a cost-benefit approach might provide guidance as to when a modified precautionary principle would be an appropriate response to uncertain risks of the new technologies. Many applications of nanotechnology today represent luxuries or minor improvements to existing goods. Delaying a new cosmetic product in order to more thoroughly assess its safety is not comparable to lags in the release of potentially life-saving medicines. Increasing the strength-to-weight ratio or the stiffness of a tennis racquet, a ski, or a bicycle frame is not comparable to reducing noxious effluents from manufacturing plants. There is no good reason not to apply more precautionary regulations to the less essential uses of nanotechnology while accepting greater exposure to novel hazards if the prospective benefits are revolutionary.

Quantitative tests of prospective costs and prospective benefits are likely to be of little use and may indeed be harmful because assigning numbers, however qualified by uncertainty, tends to raise false expectations of precision and accuracy in public debate. However, some simple qualitative tests may be useful. If nanotechnology merely provides incremental improvements in the qualities of an existing product, there is no compelling case to rush the technology to market before carefully assessing health and environmental impacts. In these cases, a precautionary approach, similar to that taken in approving new drugs, is appropriate. On the other hand, in those places where nanotechnology offers a revolutionary change, creating goods qualitatively different from what is currently available and which fill important niches in the national interest, then a more lenient regulatory regime, as with the FDA's fast track for essential drugs, seems wise. To maintain public trust over the long term, it will also be important to engage all stakeholders in the process of managing nanotechnological hazards. Consistently clear, open, and reciprocal communication between public, regulators, industry, and other stakeholders is essential to avoiding crises of confidence when problems arise.

Today, nanotechnology enjoys high esteem with consumers. Marketing departments prominently advertise the presence of nano-anything in products. There is no sign that consumers make any emotional connection between nanoparticles in their makeup and the gray goo of science fiction. However, overconfidence on the part of industry or regulators and blithe assurances that there is no risk associated with nanotechnology would not be wise. Eventually, there will be serious environmental and health effects from some kind of nanotechnology, probably in ways that we have not yet imagined, and how successfully scientists, industry, and regulatory agencies manage that crisis depends on the groundwork developed now and in the next few years for communicating honestly and clearly about risk and uncertainty.

53. Jerome N. Huillard d'Aignaux et al., *Predictability of the UK Variant Creutzfeldt-Jakob Disease Epidemic*, 294 Science 1729, 1729-30 (2001).

54. Fifth Branch, *supra* note 3, at 141-51; *Regulation of Daminozide*, *supra* note 3, at 117-18.

55. *See* J. Samuel Walker, Three Mile Island: A Nuclear Crisis in Historical Perspective 239-44 (2004).

56. Martin P.K. von Krauss et al., *Elicitation of Expert Judgments of Uncertainty in the Risk Assessment of Herbicide-Tolerant Oilseed Crops*, 24 Risk Analysis 1515, 1526 (2004).