Pace Environmental Law Review

Volume 23
Issue 1 *Winter 2005-2006*

Article 3

January 2006

Who's Afraid of the Precautionary Principle?

Robert V. Percival

THE NORTH AMERICAN SYMPOSIUM ON THE JUDICIARY AND ENVIRONMENTAL LAW

Who's Afraid of the Precautionary Principle?

ROBERT V. PERCIVAL*

Although the precautionary principle is a relatively recent concept in the history of environmental law, it has been widely embraced throughout the world. As articulated in the Rio Declaration, signed in 1992 by representatives of 178 nations, the principle provides that a lack of scientific certainty should not preclude states from adopting cost-effective measures to control environmental risks.[1] The European Union (EU) has expressly endorsed the precautionary principle as part of its regulatory directives,[2] and some argue that the principle is so widely accepted that it should be recognized as customary international law.[3]

---

* Robert F. Stanton Professor of Law and Director, Environmental Law Program, University of Maryland School of Law. Professor Percival expresses his appreciation to Khushi Desai and April Birnbaum for their research assistance. He also would like to thank Dr. John D. Graham, Administrator of the Office of Management and Budget's Office of Information and Regulatory Affairs, and other participants in the Georgetown Environmental Research Workshop, for their valuable comments on a previous draft of this article.

1. "Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation." U.N. Conference on Environment & Development (UNCED), June 3-14, 1992, *Rio Declaration on Environment and Development, Principle 15*, U.N. Doc. A/CONF.151/26 (Aug. 12, 1992) [hereinafter *Principle 15*], *quoted in* ROBERT V. PERCIVAL ET AL., ENVIRONMENTAL REGULATION: LAW, SCIENCE & POLICY 1039 (4th ed. 2003).

2. *See* COMMISSION OF THE EUROPEAN COMMUNITIES, COMMUNICATION FROM THE COMMISSION ON THE PRECAUTIONARY PRINCIPLE (2000) [hereinafter COMMUNICATION], *available at* http://europa.eu.int/comm/dgs/health_consumer/library/pub/pub07_en.pdf.

3. *See generally* James Cameron, *The Status of the Precautionary Principle in International Law, in* INTERPRETING THE PRECAUTIONARY PRINCIPLE 262 (Tim O'Riordan & James Cameron eds., 1994).

Despite its growing popularity, the precautionary principle has come under fire in recent years. Its detractors generally have been drawn from the ranks of those who are well known critics of environmental regulation.[4] They argue that the precautionary principle is incoherent, potentially paralyzing, and that it will lead regulators to make bad choices.[5] Implicit (and sometimes explicit) in their argument is the notion that society faces greater peril from overly costly regulations adopted at the behest of a fearful public than from exposure to sources of environmental risks whose effect on human health and the environment is not fully understood at present.

This paper argues that, for the most part, critics of the precautionary principle are attacking a straw man. It maintains that they are confusing the precautionary principle with the separate question of how precautionary regulatory policy should be, both in the breadth of regulatory targets and the stringency with which they are regulated. While precaution has long been an important aspiration of much of United States environmental law, in practice, regulatory policy generally has been reactive, rather than truly precautionary. Only in rare circumstances—the most prominent example being the Montreal Protocol on Substances that Deplete the Ozone Layer[6]—have activities that generate environmental risks been subjected to strict regulatory action when the risks they generate were entirely theoretical. Although such truly precautionary regulation is rare, the essential notion embodied in the precautionary principle—that uncertainty should not be used as an excuse to eschew cost-effective preventive measures—is fundamental to modern environmental law's quest to transcend the limits of its common law legacy. The precautionary principle does not require that innovation come to a halt whenever any risks may be conjured. Properly understood, the precautionary principle is neither incoherent, paralyzing, nor a prescription for overregulation. Rather, it cautions that regulatory policy should be pro-active in ferreting out potentially serious threats to human health and the environment, as confirmed by the history of human exposure to substances such as lead and asbestos.

4. *See infra* notes 32-37 and accompanying text.

5. *Id.*

6. Montreal Protocol on Substances that Deplete the Ozone Layer, Sept. 16, 1987, S. Treaty Doc. No. 102-5, 1522 U.N.T.S. 3, *available at* http://hq.unep.org/ozone/pdfs/Montreal-Protocol2000.pdf.

The paper begins by examining the history of the precautionary principle and the criticisms levied against it by its critics. It then examines the role that precaution has played in the history of U.S. environmental law, focusing on the history of human exposure to lead and asbestos. The paper then concludes by assessing the precautionary principle in light of this experience. It concludes that even though the precautionary principle is not in itself a decision rule, it should still be considered an important element of modern environmental law.

I. HISTORY OF THE PRECAUTIONARY PRINCIPLE

Some have argued that the precautionary principle is thousands of years old because millennial oral traditions of indigenous people contain the concept of precaution.[7] Others trace it to a doctor's recommendation in 1854 to remove the handle of a water pump to stop a cholera epidemic,[8] or to the 1874 amendment of the British Alkali Act that imposed technology-based limits on emissions of noxious gases by certain factories.[9]

Although many examples exist of precautionary measures being undertaken prior to the twentieth century,[10] what has come to be known as the precautionary principle emerged only late in that century. The roots of the precautionary principle usually are traced to the concept of *Vorsorgeprinzip*, developed in Germany during consideration of legislation in the 1970s to prevent air pollution from damaging forests.[11] One translation of *Vorsorgeprinzip* into English is "foresight planning," though that phrase does not adequately capture its true meaning.[12] *Vorsorge* is "a word that combines notions of foresight and taking care with

---

7. Philippe H. Martin, *"If You Don't Know How to Fix It, Please Stop Breaking It!": The Precautionary Principle and Climate Change*, 2 FOUND. OF SCI. 263, 276 (1997).

8. THE PRECAUTIONARY PRINCIPLE IN THE 20TH CENTURY: LATE LESSONS FROM EARLY WARNINGS 5 (Poul Harremoës et al. eds., 2002).

9. Nigel Haigh, *The Introduction of the Precautionary Principle into the UK, in* INTERPRETING THE PRECAUTIONARY PRINCIPLE, *supra* note 3, at 229, 241.

10. *See, e.g., id.* at 241; Harremoës et al., *supra* note 8, at 5.

11. Sonja Boehmer-Christiansen, *The Precautionary Principle in Germany–Enabling Government, in* INTERPRETING THE PRECAUTIONARY PRINCIPLE, *supra* note 3, at 31, 36.

12. Timothy O'Riordan & James Cameron, *The History and Contemporary Significance of the Precautionary Principle, in* INTERPRETING THE PRECAUTIONARY PRINCIPLE, *supra* note 3, at 12, 16.

those of good husbandry and best practice."[13] It does not demand elimination of risk, regardless of its likelihood or the costs entailed in doing so.[14] Rather, *Vorsorge* encourages the incremental reduction of known adverse environmental impacts, without requiring scientific certainty of the links between specific pollutants and specific diseases.[15]

In 1984 the German Federal Interior Ministry explained the meaning of *Vorsorge* in the following terms:

> The principle of precaution commands that the damages done to the natural world (which surrounds us all) should be avoided *in advance* and in accordance with opportunity and possibility. Vorsorge further means the early detection of dangers to health and environment by comprehensive, synchronised (harmonised) research, in particular about cause and effect relationships, . . . it also means acting when conclusively ascertained understanding by science is not yet available. Precaution means to develop, in all sectors of the economy, technological processes that significantly reduce environmental burdens, especially those brought about by the introduction of harmful substances.[16]

The notion that environmental harm should be foreseen before it occurs was not new, nor was the realization that scientific uncertainty should not be an obstacle to taking sensible preventive measures. These concepts were reflected in many of the early environmental statutes adopted in various countries during the late 1960s and 1970s, including the Swedish Environmental Protection Act of 1969.[17] But during the 1980s these concepts came to be articulated more specifically as the precautionary principle, or precautionary approach,[18] which first was endorsed in a series of international agreements to protect the North Sea.[19]

---

13. NOGA MORAG-LEVINE, CHASING THE WIND: REGULATING AIR POLLUTION IN THE COMMON LAW STATE 11 (2003).

14. *Id.*

15. *See id.*

16. REPORT FROM THE GOVERNMENT TO THE FEDERAL PARLIAMENT ON THE PROTECTION OF AIR QUALITY (Germany 1984) (citation omitted), *quoted and translated in* Boehmer-Christiansen, *supra* note 11, at 37.

17. Environmental Protection Act of 1969 (Svensk författningssamling [SFS] 1969:387, *reprinted in* 1989:363) (Swed.).

18. The terms "precautionary principle" and "precautionary approach" have been used almost interchangeably, though the former seems to be preferred by those who are more enthusiastic about the concept. *See* NICOLAS DE SADELEER, ENVIRONMENTAL PRINCIPLES: FROM POLITICAL SLOGANS TO LEGAL RULES 92 (2002).

19. *See* International Conference on the Protection of the North Sea, *Bremen Ministerial Declaration* (1984) ("Conscious that damage to the marine environment can be

The most significant international endorsement of the precautionary principle occurred at the 1992 Earth Summit in Rio de Janeiro. The Rio Declaration, signed by the 178 nations participating in the conference, including the United States, stated in Principle 15: "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."[20] While the English translation of Principle 15 refers to "the precautionary approach," the official translation in several other languages refers to "the precautionary principle."[21]

The Rio Declaration's statement of the precautionary principle has been widely embraced in subsequent international agreements. Virtually identical language was incorporated into the 1992 Framework Convention on Climate Change[22] and the Preamble to the Convention on Biological Diversity,[23] which were adopted at the Rio Earth Summit. The Maastricht Treaty of 1992 adopted the precautionary principle without explaining what it

---

irreversible or remediable only at considerable expense and over long periods and that, therefore, coastal states and the EEC must not wait for proof of harmful effects before taking action . . . ."); Second International Conference on the Protection of the North Sea, *London Ministerial Declaration* (1987) ("In order to protect the North Sea from possibly damaging effects of the most dangerous substances, a precautionary approach is necessary which may require action to control inputs of such substances even before a causal link has been established by absolutely clear scientific evidence."), *quoted in* DE SADELEER, *supra* note 18, at 94 nn.4-5.

20. *Principle 15*, *supra* note 1.

21. Per Sandin, *Better Safe than Sorry: Applying Philosophical Methods to the Debate on Risk and the Precautionary Principle*, THESES IN PHILOSOPHY FROM THE ROYAL INST. OF TECH. 5 (2004) ("örsiktighetsprincipen," or "precautionary principle"), *available at* http://www.infra.kth.se/~sandin/dissintro.pdf.

22. The United Nations Framework Convention on Climate Change commits its parties "to take precautionary measures to anticipate, prevent or minimize the causes of climate change and mitigate its adverse effects." U.N. Conference on Environment & Development, June 3-14, 1992, *United Nations Framework Convention on Climate Change (UNFCC), Article 3(3), Principle 15*, U.N. DOC. A/AC.237/18 (1992), *quoted in* DE SADELEER, *supra* note 18, at 97. It declares:

> Where there are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing such measures, taking into account that policies and measures to deal with climate change should be cost-effective so as to ensure global benefits at the lowest possible cost.

Id.

23. 1992 Convention on Biological Diversity (CBD) ("where there is a threat of significant reduction or loss of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize such a threat"), *quoted in* DE SADELEER, *supra* note 18, at 97.

provides,[24] as did the 1997 Treaty establishing the European Community (EC), which declared that EC environmental policy "shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay."[25] As discussed below, in February 2000 the European Commission issued a Communication on the precautionary principle to explain in considerable detail its views concerning what the principle is and how it should be applied in EC environmental policy decisions.[26]

The United States government has been reluctant to embrace the precautionary principle, even though it is generally consistent with the thrust of most U.S. environmental laws, as discussed in Part III below. Disagreements over application of the principle have arisen in the context of trade disputes between the United States and the EU, regarding the importation of genetically modified food products.[27] In May 2003, the United States, with the support of Canada, requested World Trade Organization (WTO) consultations with the EC, charging that the "moratorium applied by the EC since October 1998 on the approval of biotech products has restricted imports of agricultural and food products from the US and Canada."[28] The United States and Canada argued that it was unlawful discrimination for "a number of EC member States [to] maintain national marketing and import bans on biotech products even though those products have already been approved by the EC for import and marketing in the EC."[29]

24. *See* The Maastricht Treaty, art. 130r, Feb. 7, 1992, *available at* http://www.eurotreaties.com/maastrichttec.pdf.

25. Treaty of Amsterdam Amending the Treaty on European Union, the Treaties Establishing the European Communities and Certain Related Acts—Consolidated Version of the Treaty Establishing the European Union, art. 174(2), Oct. 2, 1997 O.J. (C 340).

26. *See* COMMUNICATION, *supra* note 2.

27. *See* World Trade Organization Dispute Settlement: Dispute DS291, European Communities: Measures Affecting the Approval and Marketing of Biotech Products (July 1, 2005), http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds291_e.htm.

28. *Id.*

29. *See id.* In the "beef hormones dispute," the WTO had previously recognized that its Agreement on Sanitary and Phytosanitary Measures (SPS Agreement) provides that "when sufficient scientific evidence does not exist to permit a final decision on the safety of a product or process," members may take provisional precautionary measures. World Trade Organization, SPS Agreement Training Module: Chapter 8: Current Issues: The "Precautionary Principle," http://www.wto.org/english/tratop_e/sps_e/sps_agreement_cbt_e/c8s2pl_e.htm (last visited Nov. 5, 2005); World Trade Organization, Sanitary and Phytosanitary Measures: Introduction: Understanding the WTO Agreement on Sanitary and Phytosanitary Measures (May 1998) [hereinafter

II. CRITICISMS OF THE PRECAUTIONARY PRINCIPLE

As the precautionary principle has grown in popularity, it has come under fire from critics who believe that it could exacerbate what they perceive as a trend toward overregulation. Frank Cross argues that "the precautionary principle is deeply perverse in its implications for the environment and human welfare."[30] Complaining that the growing popularity of the precautionary principle threatens risk analysis, Gail Charnley criticizes the principle as anti-science and accuses its proponents of waging "the newest skirmish in the age-old battle between empirical science and anti-empirical ideology."[31] Aaron Wildavsky derides the precautionary principle as "a marvelous piece of rhetoric";[32] and Bjørn Lomborg maintains that if it is used to strengthen environmental protections, "the precautionary principle is actually all about making *worse* decisions than we need to."[33] More recently, Robert Hahn and Cass Sunstein have argued that "taken seriously, the precautionary principle can be paralyzing, providing no direction at all,"[34] in contrast to cost-benefit analysis, which they favor as a decision rule. Sunstein devotes much of his book, *Laws of Fear: Beyond the Precautionary Principle*, to attacking the principle as

---

Understanding the WTO Agreement], http://www.wto.org/english/tratop_e/sps_e/sps und_e.htm. It had also emphasized that the SPS Agreement expressly recognizes "the sovereign right of any government to provide the level of health protection it deems appropriate," excluding misuse. *Id.* Under the leadership of Director General Pascal Lamy, the WTO has placed renewed emphasis on the importance of incorporating environmental concerns into trade liberalization policy. Lamy recently has argued that, "Contrary to the perception of some members of the public, [trade] can be a friend, and not a foe, of conservation." Pascal Lamy, WTO Dir. Gen., Speech at the WTO Symposium on Trade and Sustainable Development within the Framework of Paragraph 51 of the Doha Ministerial Declaration (Oct. 10-11, 2005), *available at* http://www.wto.org/english/newse/sppl107-e.htm.

30. Frank B. Cross, *Paradoxical Perils of the Precautionary Principle*, 53 WASH. & LEE L. REV. 851, 851-52 (1996).

31. *President's Message*, RISK NEWSLETTER (Soc'y for Risk Analysis, McLean, Va.), Third Quarter 1999, at 2.

32. AARON WILDAVSKY, BUT IS IT TRUE? A CITIZEN'S GUIDE TO ENVIRONMENTAL HEALTH AND SAFETY ISSUES 428 (1995).

33. BJØRN LOMBORG, THE SKEPTICAL ENVIRONMENTALIST: MEASURING THE REAL STATE OF THE WORLD 350 (Hugh Matthews partial trans., Cambridge Univ. Press 2001).

34. Robert W. Hahn & Cass R. Sunstein, *The Precautionary Principle as a Basis for Decision Making*, THE ECONOMISTS' VOICE, 2005, Issue 2, Art. 8, at 1, 7.

indefensible, though he ultimately concludes that it can be useful in some circumstances.[35]

While arguing that the precautionary principle is dangerous, its critics also charge that it is so vague as to be incoherent. John Graham notes that the U.S. government considers the notion of "any universal precautionary principle . . . to be a mythical concept, perhaps like a unicorn."[36] In a recent lecture Cass Sunstein declared that "the precautionary principle is incoherent."[37]

Although there is no single, universally accepted formulation of the precautionary principle, the most widely embraced statement of it is that contained in the Rio Declaration, which was endorsed by nearly every country in the world.[38] Principle 15 of the Rio Declaration states that "[w]here there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."[39] Notice that this statement does not specify how precautionary regulatory policy should be. Rather it states only that if there are threats of significant harm, scientific uncertainty should not serve as an obstacle to taking cost-effective preventive measures. It does not specify how significant the harm must be, nor what particular cost-effective preventive measures should be undertaken. Thus, it should not be viewed as an effort to establish any particular, prescriptive decision rule.

Critics of the precautionary principle concede that the formulation articulated in the Rio Declaration is unobjectionable.[40] Referring to this as a "weak version" of the precautionary principle, Sunstein describes it as "important" and "necessary in practice only to combat public confusion or the self-interested claims of pri-

---

35. *See* CASS R. SUNSTEIN, LAWS OF FEAR: BEYOND THE PRECAUTIONARY PRINCIPLE (2005).

36. John Graham, Administrator, Office of Info. & Reg. Affairs, Office of Mgmt. & Budget, The Role of Precaution in Risk Assessment and Management: An American's View, Remarks at the Conference on the U.S., Europe, Precaution and Risk Management: A Comparative Case Study Analysis of the Management of Risk in a Complex World (Jan. 11-12, 2005), *available at* http://www.useu.be/RiskManagement/Jan1102GrahamUSRiskManagementPrecPrin.htm.

37. Cass Sunstein, Lecture, *Irreversible and Catastrophic: Global Warming, Terrorism, and Other Problems*, 23 PACE ENVTL. L. REV. 3, 4 (2005–2006).

38. *See* UN Department of Economic and Social Affairs Division for Sustainable Development, Documents (Dec. 15, 2004), http://www.un.org/esa/sustdev/documents/agenda21/.

39. *Principle 15*, *supra* note 1. The words "cost-effective" in Principle 15 were added at the insistence of the U.S. delegation to the Rio Earth Summit.

40. *See, e.g.*, LOMBORG, *supra* note 33, at 348-49; Cross, *supra* note 30, at 920.

vate groups demanding unambiguous evidence of harm, which no rational society requires."[41]

Rather than concentrating their fire on the Rio Declaration, critics of the precautionary principle focus on what they describe as a "strong version" that would require stringent regulation of anything that cannot be shown *not* to pose a possible risk to health, safety, or the environment.[42] For example, Frank Cross argues:

> Applied fully and logically, the precautionary principle would cannibalize itself and potentially obliterate all environmental regulation. Environmentalists would apply the principle to chemicals and industries, but why not apply it to the environmental regulations themselves? According to the burden of proof approach, advocates of regulation would be required to demonstrate to a certainty the absence of counterproductive effects on health resulting from the effects of the regulation itself. The practical consequences of regulation are so uncertain that advocates typically could not meet this burden, and the precautionary principle would preclude further regulation.[43]

Such an extreme version of the precautionary principle seems farfetched, but its critics, at times, seem intent on creating a caricature of it in an effort to defuse its growing popularity.[44] Their

---

41. SUNSTEIN, *supra* note 35, at 18, 23-24.

42. Critics of the precautionary principle frequently attempt to tie it to the "Wingspread Statement on the Precautionary Principle," drafted by a group of academics attending a conference in January 1998. *See* Global Development Research Center, Wingspread Statement on the Precautionary Principle, *available at* http://www.gdrc.org/u-gov/precaution-3.html; SUNSTEIN, *supra* note 35, at 19. The Wingspread Statement includes the sentence: "When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not established scientifically." *Wingspread Declaration, quoted in* SUNSTEIN, *supra* note 35, at 19. They use the Wingspread Statement as a straw man to imply that proponents of the precautionary principle seek to prohibit any activity that has the potential to cause harm. However, such an extreme interpretation has neither been embraced by the larger environmental community, nor adopted by regulatory policymakers.

43. Cross, *supra* note 30, at 861.

44. As John Applegate notes,

> [t]he precautionary principle is frequently caricatured as requiring the regulator to ban or forgo an activity or technology altogether, and sometimes it has been used to justify such action (for example, bans on genetically modified organisms ('GMO's)). However, none of the texts speaks in such absolute terms. The precautionary principle embraces a range of regulatory responses, taking into account a variety of factors (severity, cost, risk trade-offs) and a flexible degree of risk aversion.

primary objection is founded on the notion that precautionary regulation may create risks of its own, either by depriving society of "opportunity benefits" that could prevent even greater harm than that prevented by the regulation, or by inducing substitution of products or activities that pose even greater risks than those caused by the subject of regulation.[45] This objection is similar to the now-familiar "risk-risk" tradeoff argument made by critics of environmental regulation.[46] In the context of regulating well-known risks, the argument is highly problematic when it urges that such risks not be regulated because of the possibility that other, less well-understood risks may take their place and be even more significant.[47] Since history teaches that the most common way society becomes aware of risk is from the actual manifestation of harm,[48] it is dubious to assume that substitute activities or products necessarily will be more risky. Given the substantial barriers agencies face when engaging in risk regulation, theoretical risks that are taken seriously enough to generate precautionary regulation are unlikely to be systematically less harmful than unknown and unregulated risks.

Moreover, it has been shown that risk-tradeoff analysis is biased against environmental regulation because it focuses only on ancillary risks generated by regulation, and not on regulation's ancillary benefits.[49] Rascoff and Revesz note that many environmental regulations produce substantial ancillary benefits:

> For example, a more stringent standard for carbon monoxide emissions in automobile exhaust not only achieved its target of reducing air pollution, but also had the ancillary benefit of significantly reducing loss of life attributable to carbon monoxide-related accidents and suicides. Policies targeting greenhouse gas reductions can be expected to have the ancillary benefit of reducing conventional air pollutants. Policies favoring wastewater management through constructed wetlands have ancil-

---

John S. Applegate, *The Taming of the Precautionary Principle*, 27 WM. & MARY ENVTL. L. & POL'Y REV. 13, 19-20 (2002) (internal citations omitted).

45. *See* SUNSTEIN, *supra* note 35, at 26-32.

46. *See generally* RISK VERSUS RISK: TRADEOFFS IN PROTECTING HEALTH AND THE ENVIRONMENT (John D. Graham & Jonathan Baert Wiener eds., 1995).

47. *See* Cass R. Sunstein, *Foreword* in RISK VERSUS RISK: TRADEOFFS IN PROTECTING HEALTH AND THE ENVIRONMENT, *supra* note 46, at vii-xi.

48. This phenomenon is referred to as "the dilemma of preventive regulation" in PERCIVAL ET AL., *supra* note 1, at 343-45.

49. *See* Samuel J. Rascoff & Richard L. Revesz, *The Biases of Risk Tradeoff Analysis: Towards Parity in Environmental and Health-and-Safety Regulation*, 69 U. CHI. L. REV. 1763, 1763 (2002).

> lary benefits for public use and preservation of habitats. Medical interventions—most notably drug therapies—have been observed to have significant ancillary benefits.[50]

It is curious that some critics of the precautionary principle cite the difficulty of remediating existing environmental contamination as a reason for eschewing the precautionary principle. For example, Frank Cross cites as examples of risk-risk tradeoffs the fact that efforts to remediate asbestos and lead contamination occasionally make things worse by inadvertently releasing more of these toxic substances into the environment.[51] One would think that the great difficulty of remediating these contaminants actually would present an even stronger justification for enhanced precautionary measures to prevent their initial placement into the environment.

Drawing from the growing literature on the psychology of risk perception, Cass Sunstein maintains that there is reason to believe that the public will be overly fearful of certain immediate risks that are statistically far less dangerous than what would substitute for them if regulators responded to public demands for precaution.[52] David Dana has presented a strong counterargument that the precautionary principle is justified as a mechanism to counteract the same cognitive biases on which Sunstein relies.[53] Dana maintains that the public will be more inclined to avoid the immediate costs of compliance with precautionary regulations whose uncertain benefits will accrue only in the future.[54] Sunstein concedes that this criticism "is not implausible" and that the precautionary principle can "undoubtedly lead[ ] to some good results";[55] but he maintains that the same myopia that supports Dana's argument also would apply to the public's perceptions of the countervailing risks that would be incurred by the taking of precautionary action.[56] Thus, Sunstein's argument appears to rest largely on the notion that precautionary action is more likely to be counterproductive than beneficial because the public is incapable of knowing what statistically is in its best interests. He con-

50. *Id.* at 1766 (citations omitted).

51. *See* Cross, *supra* note 30, at 898-99.

52. *See* SUNSTEIN, *supra* note 35, at 36-49.

53. *See* David A. Dana, *A Behavioral Economic Defense of the Precautionary Principle*, 97 NW. U. L. REV. 1315, 1320-1330 (2003).

54. *See id.* at 1324, 1334-38.

55. SUNSTEIN, *supra* note 35, at 52-53.

56. *See id.* at 52-55.

cludes that cost-benefit analysis offers one way out of this self-constructed conundrum,[57] without analyzing how efforts to quantify the costs and benefits of regulation may distort decision-makers' perceptions of the levels of uncertainty associated with them. Yet Sunstein ultimately concedes that for risks for which there are no satisfactory bases for balancing costs and benefits, such as catastrophic risks or the risks of species extinction, something akin to the precautionary principle makes good sense.[58]

Recently, Gary Marchant and Kenneth Mossman have sharply criticized the precautionary principle by characterizing it as a vehicle for justifying arbitrary and discriminatory trade measures imposed by members of the EU.[59] Based on an analysis of decisions by EU courts, Marchant and Mossman argue that the precautionary principle has been applied in an arbitrary and inconsistent manner.[60] They conclude that this "confirms the fears of many skeptics of the precautionary principle that it provides an open invitation for arbitrary and unreasonable decisions by both regulators and judges."[61] Ironically, this criticism of the precautionary principle—that it can be manipulated to promote arbitrary decision-making—echoes a major criticism of cost-benefit analysis that garnered substantial support because of the asymmetrical way in which it was employed by the Reagan Administration in a misguided effort to relax regulatory constraints on industry.[62]

Proponents of cost-benefit analysis who argue that acceptance of the precautionary principle is likely to lead to bad choices by regulatory authorities essentially are asserting that regulatory policy will be overly precautionary, generating social costs that exceed the benefits of regulation. Yet, as noted above, the precautionary principle does not purport to tell us how precautionary to be. Per Sandin has identified the four major elements of the precautionary principle: "(1) the threat dimension, (2) the uncertainty dimension, (3) the action dimension, and (4) the command dimen-

57. *See id.* at 63, 129-48, 225.

58. *See* Sunstein, *supra* note 37, at 16.

59. GARY E. MARCHANT & KENNETH L. MOSSMAN, ARBITRARY AND CAPRICIOUS: THE PRECAUTIONARY PRINCIPLE IN THE EUROPEAN UNION COURTS 1-3 (2004).

60. *Id.* at 1-3, 64-65.

61. *Id.* at 65.

62. *See* Robert V. Percival, *Checks Without Balance: Executive Office Oversight of the Environmental Protection Agency*, 54 LAW & CONTEMP. PROBS. 127, 184-89 (1991).

sion."[63] The "threat dimension" refers to the potential dangers of the activity, product, or substance that would trigger precautionary action.[64] The "uncertainty dimension" refers to the limits of knowledge concerning whether the regulatory target poses the hazard.[65] The "action dimension" concerns how regulatory authorities will respond to the threat, while the "command dimension" refers to their degree of discretion in doing so.[66] Sandin describes the four questions that must be answered to make the principle operative:

> 1. To what types of hazards does the principle apply?
> 2. Which level of evidence (lower than that of full scientific certainty) should be required?
> 3. What types of measures against potential hazards does the principle refer to?
> 4. With what force are these measures recommended (mandatory, merely permitted, etc.)?[67]

Applying these concepts to the Rio Declaration's statement of the precautionary principle—"Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation"—(1) the principle would apply to hazards "of serious or irreversible damage"; (2) where there is something short of full scientific certainty; (3) the actions that could be taken are cost-effective prevention measures; and (4) the command is not to use lack of scientific certainty as a reason to postpone taking such action.

In a very limited sense, this statement of the precautionary principle may tell us something about how precautionary to be by at least establishing that certain hazards should not be ignored entirely. As Sandin notes, the statement actually is directed only at deeming a particular argument ("lack of full scientific certainty") unacceptable as a reason for postponing undefined cost-effective actions to prevent the harm.[68] One should not postpone

---

63. Per Sandin, *Dimensions of the Precautionary Principle*, 5 HUM. & ECOLOGICAL RISK ASSESSMENT 889, 889 (1999).

64. *See id.* at 891-92.

65. *See id.* at 892-94.

66. *See id.* at 894-95.

67. Per Sandin et al., *Five Charges Against the Precautionary Principle*, 5 J. RISK RESEARCH 287, 290 (2002).

68. *See id.* at 289. Sandin calls this an "argumentative" version of the precautionary principle to distinguish it from "prescriptive" versions that provide more content concerning how precautionary regulatory policy should be in the face of uncertainty.

taking cost-effective measures to prevent serious or irreversible damage, though it is not clear how great the threat must appear to be in order to trigger application of the principle.

It certainly is appropriate for the precautionary principle not to attempt to dictate how precautionary regulatory policy should be. Decisions concerning how much protection to afford to public health and the environment are so fundamental to the relationship between governments and their citizenry that the products of democratic political processes must inform them. The environmental laws that these countries adopt are the authoritative declarations of how precautionary regulatory policy should be.

As debate continues over how precautionary regulatory policy should be, efforts are being made to develop more refined methods for incorporating the precautionary principle into decision-making processes in many of these countries.[69] For example, the Commission of the European Communities has issued a Communication outlining a detailed approach to using the precautionary principle and establishing guidelines for applying it.[70] As John Applegate notes, this Communication seeks "to fit the precautionary principle *into* the risk paradigm," rather than serve as an alternative to it.[71] The Communication undermines the notion that European regulators have adopted an "absolutist" version of the precautionary principle that requires stringent regulation of anything alleged to pose a threat. The Communication states in relevant part that:

> Recourse to the precautionary principle presupposes that potentially dangerous effects deriving from a phenomenon, product or process have been identified, and that scientific evaluation does not allow the risk to be determined with sufficient certainty.
>
> The implementation of an approach based on the precautionary principle should start with a scientific evaluation, as complete as possible, and where possible, identifying at each stage the degree of scientific uncertainty.
>
> [ ] Decision-makers need to be aware of the degree of uncertainty attached to the results of the evaluation of the available scientific information. Judging what is an 'acceptable' level of risk for

See id. at 289-90. As an example of a prescriptive version of the principle, Sandin cites the Wingspread Statement. *Id.* at 289.

69. See, for example, the mechanisms outlined in ADRIAN DEVILLE & RONNIE HARDING, APPLYING THE PRECAUTIONARY PRINCIPLE (1997).

70. *See* COMMUNICATION, *supra* note 2.

71. Applegate, *supra* note 44, at 61.

society is an eminently *political* responsibility. Decision-makers faced with an unacceptable risk, scientific uncertainty and public concerns have a duty to find answers. Therefore, all these factors have to be taken into consideration.

In some cases, the right answer may be not to act or at least not to introduce a binding legal measure. A wide range of initiatives is available in the case of action, going from a legally binding measure to a research project or a recommendation.

The decision-making procedure should be transparent and should involve as early as possible and to the extent reasonably possible all interested parties.

[ ] Where action is deemed necessary, measures based on the precautionary principle should be, *inter alia*:

- *proportional* to the chosen level of protection,
- *non-discriminatory* in their application,
- *consistent* with similar measures already taken,
- *based on an examination of the potential benefits and costs* of action or lack of action (including, where appropriate and feasible, an economic cost/benefit analysis),
- *subject to review,* in the light of new scientific data, and
- *capable of assigning responsibility for producing the scientific evidence* necessary for a more comprehensive risk assessment.[72]

The Communication emphasizes flexibility in responding to suspected risks. It permits both risk assessment and examination of costs and benefits, while recognizing the importance of reviewing interim regulatory measures in light of new scientific evidence. While it does not rule out banning products if that is the only possible way to control a risk, the Communication does endorse measures to require prior approval of potentially dangerous products and in certain cases shifts the burden of proof to the producer, manufacturer, or importer.[73]

---

72. COMMUNICATION, *supra* note 2, at 4.

73. Australia also has adopted its own refinements to the precautionary principle that are anything but absolutist. In May 1992, representatives of all levels of government in Australia signed the Intergovernmental Agreement on the Environment. It defines the precautionary principle as follows:

> Where there are threats of serious or irreversible environmental damage, lack of full scientific certainty should not be used as a reason for postponing measures to prevent environmental degradation. In the application of the precautionary principle, public and private decisions should be guided by:
>
> (i) careful evaluation to avoid, wherever practicable, serious or irreversible damage to the environment; and,

A comparison of risk regulation in Europe and the United States concluded that the EU is not systematically more precautionary in its regulatory policy than is the United States.[74] The United States has been more precautionary than the EU in responding to certain risks, including mad cow disease in blood, diesel engine exhaust, particulate air pollution, tobacco consumption, and terrorism.[75] Although this has been deemed a surprise because the precautionary principle has been much more influential in Europe than in the United States, it should not be that surprising in light of the fact that the principle does not dictate how precautionary regulatory policy should be. Yet most critics of the precautionary principle base their objections to it on the notion that it will inexorably produce bad policy choices weighted too heavily in the direction of preventing environmental harm.[76] It also should not be surprising when one considers that, even without expressly embracing the precautionary principle, U.S. environmental law has developed in a manner quite consistent with many elements of it, as discussed in the section that follows.

III. THE HISTORY OF PRECAUTION IN U.S. ENVIRONMENTAL LAW

A review of the history of U.S. environmental law can shed light on why Congress took a decidedly precautionary turn during the 1970s when it adopted comprehensive regulatory legislation to protect human health from environmental risks. Even before the precautionary principle took center stage in the 1990s, some of its harshest critics already were arguing that U.S. environmental policy had become unduly precautionary in response to public overreaction to environmental risks.[77] Yet, despite the regulatory statutes' commitment to preventative regulation, chemicals are

---

> (ii) an assessment of the risk-weighted consequences of various options.

DEVILLE & HARDING, *supra* note 69, at 13.

74. Jonathan B. Wiener, *Whose Precaution After All? A Comment on the Comparison and Evolution of Risk Regulatory Systems*, 13 DUKE J. COMP. & INT'L. L. 207, 261-62 (2003).

75. *Id.* at 225-29.

76. *See supra* notes 30-33 and accompanying text.

77. *See, e.g.*, MARY DOUGLAS & AARON WILDAVSKY, RISK AND CULTURE: AN ESSAY ON THE SELECTION OF TECHNICAL AND ENVIRONMENTAL DANGERS (1982); Peter Huber, *Safety and the Second Best: The Hazards of Public Risk Management in the Courts*, 85 COLUM. L. REV. 277 (1985); PHANTOM RISK: SCIENTIFIC INFERENCE AND THE LAW (Kenneth R. Foster et al. eds., 1993); Philip H. Abelson, *Toxic Terror: Phantom Risks*, 261 SCI. 407 (July 23, 1993) (book review).

still rarely regulated until after they have been released into the environment and damage to public health has become apparent.[78] This "dilemma of preventative regulation" reflects that it is always easier for scientists to identify hazards and to predict harm *after* it occurs, and that regulation is most politically salient when it responds to hazards that have become highly visible to the public. As a result, rather than realizing its promise of preventative regulation, environmental policy often is saddled with the far more difficult task of remediating environmental contamination after it has occurred.

Critics of the precautionary principle fear that if regulatory policy responds to what they view as excessive public fear of certain risks, the precautionary principle will lead to bad choices.[79] Yet the factors that influence how regulatory policy responds to environmental risks are not well understood. In particular, few retrospective studies have explored why society has in many instances failed to prevent pervasive environmental contamination from substances, such as lead and asbestos, that long were known to be extremely hazardous. Even as scientific knowledge concerning the hazards of lead accumulated over time, the legal system failed to avert widespread lead poisoning. The regulatory history of lead stands in sharp contrast to the response to the stratospheric ozone depletion problem, a rare instance in which truly precautionary regulation was undertaken solely in response to a seemingly compelling scientific theory before actual harm to public health had been detected.[80]

A. Lead Poisoning in Early America

Lead can serve some very useful functions, but, like asbestos and chlorofluorocarbons (CFCs), it ultimately has proven to be extremely hazardous to human health and the environment. While

78. The principal exceptions are new therapeutic drugs and pesticides, which cannot legally be marketed until after they have been approved by the Food and Drug Administration or EPA following extensive and specified testing. *See* PERCIVAL ET AL., *supra* note 1, at 334-35; Indus. Union Dep't v. Am. Petroleum Inst., 448 U.S. 607, 653 n.61 (1980). As the precautionary principle has grown in popularity, greater efforts now are being made to conduct testing of high-production volume chemicals in the United States, and to mandate pre-market testing protocols in the European Union through the Registration, Evaluation, and Authorisation of Chemicals (REACH) program. Europa, REACH, http://europa.eu.int/comm/environment/chemicals/reach.htm (last visited Dec. 16, 2005).

79. *See supra* notes 30-34 and accompanying text.

80. *See* SETH CAGIN & PHILIP DRAY, BETWEEN EARTH AND SKY: HOW CFCS CHANGED OUR WORLD AND ENDANGERED THE OZONE LAYER 189-207 (1993).

its chemical properties make it easy to use in a variety of products, lead performs no useful function in the human body.[81] Exposures from anthropogenic sources have caused lead to increase in the bodies of humans as a result of the use of lead in products, paint, plumbing, emissions from gasoline combustion and smelters, and lead in waste streams.[82] Levels of lead found in core samples in Greenland's icecap suggest that by the year 1750 lead-smelting activity had increased atmospheric deposition of lead to a level (0.0100 mg/kg) twenty times greater than the background level present in 800 B.C. (0.0005 mg/kg).[83] The Industrial Revolution and a massive increase in combustion of leaded gasoline have increased lead levels in icecap strata today to a level (0.21 mg/kg) more than 400 times natural background levels.[84]

As one of the most thoroughly studied toxic substances, lead has been found to cause a broad array of adverse health effects in humans. Exposure to high levels of lead can cause death.[85] At lower levels of exposure, lead can cause anemia, kidney damage, neurological injury, and reproductive and developmental dysfunction.[86] Lead also interferes with blood biochemistry and is associated with high blood pressure.[87] At a certain level of exposure to lead, "virtually all body systems will be injured or have a high risk of injury."[88] But lead is also particularly dangerous because of the apparently irreversible neurological and reproductive damage that it can cause, even at relatively low levels of exposure that are not uncommon even today.[89] Because many of the health effects

81. *See* COMMITTEE ON LEAD IN THE HUMAN ENVIRONMENT, LEAD IN THE HUMAN ENVIRONMENT 3-5 (1980) [hereinafter LEAD IN THE HUMAN ENVIRONMENT]; Agency for Toxic Substances and Disease Registry, Lead Toxicity Physiologic Effects, http://www.atsdr.dcd.gov/HEC/CSEM/lead/physiologic_effects.html (last visited Nov. 28, 2005).

82. *See generally* LEAD IN THE HUMAN ENVIRONMENT, *supra* note 81; Jerome O. Nriagu, *A History of Global Metal Pollution*, 272 SCI. 223 (1996).

83. Thomas D. Matte et al., *Occupational Lead Exposure, in* HUMAN LEAD EXPOSURE 155, 156 (Herbert L. Needleman ed., 1992).

84. *Id.* at 156.

85. EPA, Technology Transfer Network Air Toxics Website, Lead Compounds [hereinafter Lead Compounds], http://www.epa.gov/ttn/atw/hlthef/lead.html (last visited Nov. 17, 2005).

86. *Id.*

87. *Id.* Because lead is the oldest and most extensively studied neurotoxin, information about the adverse health effects associated with human exposure to lead is voluminous. One of the most useful summaries of this information is contained in Chapter IV of AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY, THE NATURE AND EXTENT OF LEAD POISONING IN CHILDREN IN THE UNITED STATES: A REPORT TO CONGRESS IV-1 (1988).

88. *Id.* at IV-3.

89. *See* Lead Compounds, *supra* note 85.

caused by exposure to lead do not have easily identifiable symptoms, lead poisoning is often difficult to diagnose,[90] particularly for physicians who have little knowledge or experience with the disease.

The use of high concentrations of lead in pewter is believed to have been responsible for considerable lead poisoning in colonial America.[91] Perhaps the most remarkable early legislative response to lead poisoning occurred in the Massachusetts Bay Colony in 1723. The colonial legislators enacted a law prohibiting the distillation of rum through leaden still heads or leaded pipes following complaints that colonists in North Carolina had become ill from drinking rum distilled in New England.[92] While the legislation probably reflects greater concern for preserving profitable trade than for protecting public health, it indicates that colonial authorities understood some of the potential hazards of lead.

Benjamin Franklin was the most important public figure to publicize the dangers of exposure to lead in colonial America. While working in England as a printer's apprentice in 1724, Franklin observed the maladies suffered by workers exposed to the heating of lead type during the cleaning process.[93] In 1745 he published Thomas Cadwalader's "Dry Gripes," an essay arguing that epidemics of "dry gripe," which most people associated with the drinking of rum, actually were caused by the use of lead materials in distillation equipment.[94] While in Paris in 1767, Franklin visited a hospital that had become famous for treating "what [he] call[ed] Dry Bellyach, or Colica Pictonum."[95] After obtaining a list of the occupations of the patients, Franklin noted that,

---

90. CONSUMER PRODUCT SAFETY COMMISSION, WHAT YOU SHOULD KNOW ABOUT LEAD BASED PAINT IN YOUR HOME: SAFETY ALERT, CPSC DOCUMENT #5054, *available at* http://www.cpsc.gov/cpscpub/pubs/5054.htm (last visited Nov. 20, 2005).

91. Carey P. McCord, *Lead and Lead Poisoning in Early America: Benjamin Franklin and Lead Poisoning*, 22 INDUS. MED. & SURGERY 393, 395, 396, 399 (1953).

92. An Act for Preventing Abuses in Distilling of Rum and Other Strong Liquors, with Leaden Heads or Pipes (enacted Sept. 3, 1723), *reprinted in id.* at 397. The Act declared that "the strong liquors and spirits that are distill(e)d through leaden heads or pipes are judged on good grounds to be unwholesome and hurtful." *Id.* It specified a fine of one hundred pounds for each violation and directed municipalities to appoint inspectors to enforce the prohibition. *Id.* Penalties collected under the Act were to be divided "one-half to the poor of the town where the offence is committed, and the other half to him or them that shall inform and sue for the same." *Id.*

93. McCord, *supra* note 91, at 394.

94. *Id.* at 393-94.

95. Letter from Benjamin Franklin to Benjamin Vaughan (July 31, 1786), *reprinted in id.*, at 398.

> all the Patients were of Trades, that, some way or other, use or work in Lead, such as Plumbers, Glaziers, Painters, &c., excepting only two kinds, Stonecutters and Soldiers. These I could not reconcile to my Notion, that Lead was the cause of that Disorder. But on my mentioning this Difficulty to a Physician of that Hospital, he inform'd me that the Stonecutters are continually using melted Lead to fix the Ends of Iron Balustrades in Stones; and that the Soldiers had been employ'd by Painters, as Labourers, in Grinding of Colours.[96]

These and other observations convinced Franklin of the hazards of lead. In a letter to a friend in 1786, Franklin described the sources of lead poisoning and questioned "how long a useful Truth may be known and exist, before it is generally receiv'd and practis'd on."[97]

Early in the nineteenth century, Congress responded to a series of spectacular boiler explosions on steamships by regulating the construction and maintenance of steamship boilers,[98] but health and safety regulation was otherwise left entirely to the states. In the late nineteenth century, state and local governments began to assume greater responsibility for protecting worker health and safety. Beginning with Massachusetts in 1877, twenty-three states enacted factory inspection laws.[99] In 1907, Illinois created a Commission on Occupational Diseases whose report helped enact an Occupational Diseases Act in 1911.[100] This legislation required employers to "'adopt and provide reasonable and approved devices, means or methods for the prevention of such industrial or occupational diseases as are incident to such work or process.'"[101] However, the preventative provisions in the law were largely unenforced until the 1930s when the Illinois Supreme Court struck them down as "an unwarranted and void delegation of legislative power."[102]

---

96. *Id.*

97. *Id.* at 399.

98. Robert L. Rabin, *Federal Regulation in Historical Perspective*, 38 STAN L. REV. 1189, 1196 (1986). Congress initially adopted legislation regulating steamship boilers in 1838 and then strengthened the law in 1852. *Id.*

99. DYING FOR WORK: WORKERS' SAFETY AND HEALTH IN TWENTIETH-CENTURY AMERICA 65 (David Rosner & Gerald Markowitz eds., 1987).

100. CLAUDIA CLARK, RADIUM GIRLS: WOMEN AND INDUSTRIAL HEALTH REFORM, 1910-1935 187-88 (1997).

101. *Id.* at 188 (quoting the Occupational Disease Act of 1911).

102. *See* Vallat v. Radium Dial Co., 196 N.E. 485, 487-88 (Ill. 1935) (citation omitted).

In 1906, Congress responded to public concern about the safety of the food supply by enacting federal meat inspection legislation[103] and the Pure Food and Drugs Act.[104] This legislation was animated more by concern over the economic impact of public fears than by concern for protecting public health. Rather than authorizing broad new regulations to protect health, the Pure Food and Drugs Act primarily prohibited fraudulent representations concerning food and drug products.[105] Similar concerns provided the rationale for enactment of the Federal Insecticide Act of 1910, which was designed to protect growers from being misled by false claims concerning the nature and efficacy of pesticide products.[106]

During the early twentieth century, two important developments occurred in the understanding of lead toxicity. Scientists discovered that children were highly sensitive to lead exposure[107] and that environmental, in addition to occupational, sources of lead could be significant.[108] Lockhart Gibson had established a link between use of lead-based paint and childhood lead poisoning in Australia in 1892.[109] In turn-of-the-century Hungary, children in the homes of "home industry" potters suffered from the symptoms of lead poisoning because the working and living conditions were appallingly contaminated.[110] These were important scientific developments for understanding the nature and scope of the hazards posed by lead. But they had little effect on regulatory policy toward lead until long after World War II.

B. Controversy over the Introduction of Tetraethyl Lead (TEL)

By the early 1920s, lead poisoning was well recognized as a major public health problem. A German publication in 1922 listed

103. Act of June 30, 1906, Pub. L. No. 59-382, 34 Stat. 669, 674 (1906) (authorizing meat inspection).

104. Pure Food and Drugs Act, Pub. L. No. 59-384, 34 Stat. 768 (1906).

105. Rabin, *supra* note 98, at 1228.

106. *See* Christopher Schroeder, *The Evolution of Federal Regulation of Toxic Substances*, *in* GOVERNMENT AND ENVIRONMENTAL POLITICS: ESSAYS ON HISTORICAL DEVELOPMENTS SINCE WORLD WAR TWO 263, 281 (Michael J. Lacey ed., 1989).

107. SIR THOMAS OLIVER, LEAD POISONING: FROM THE INDUSTRIAL, MEDICAL, AND SOCIAL POINTS OF VIEW 177-84 (1914).

108. *Id.* at 161.

109. Reaching Teachers to Teach Technology, Knowledge about the Health Effects of Lead (July 5, 2005), http://www.rst2.edu/ties/lead/university/resources/experts/book_appendix_info/timelines.htm.

110. OLIVER, *supra* note 107, at 76-82.

more than 3000 works about lead, including lead poisoning and lead-related regulations.[111] A medical monograph, published in the United States in 1926, described lead poisoning as "a preventable disease" that "is not only the most common poisoning in industry," but also the product of "diverse non-industrial sources" such as water supplies, drugs, and cosmetics.[112]

Despite widespread awareness of the hazards of lead, the use of lead in American industry increased dramatically in the early twentieth century. Ultimately, this resulted in the release of unprecedented quantities of lead directly into the environment,[113] generating some of the first expressions of concern over the public health implications of lead exposure outside the occupational context. Even before the development of gasoline lead additives, the growth of the automobile industry and its use of lead acid batteries had increased industrial use of lead. The discovery of tetraethyl lead (TEL) ensured that every street and highway in the nation would be dusted with substantial lead deposits.[114]

To facilitate the manufacture of cars with larger engines, General Motors (GM) sought to develop a new fuel additive that would enhance gasoline combustion and avoid engine knock.[115] After testing thousands of chemical compounds during years of trial and error experimentation, GM researcher Thomas Midgley, Jr. discovered in December 1921 that TEL had the properties GM desired.[116] GM joined with Standard Oil of New Jersey (Standard Oil) to form the Ethyl Corporation (Ethyl) to market the new lead additive.[117] The product initially was shipped directly to gas stations by DuPont, Ethyl's contractor, in small bottles that could be added to each tank of gasoline.[118]

On December 20, 1922, Hugh Cumming, the U.S. Surgeon General, sent a letter to Pierre du Pont that reflected an aware-

---

111. ELSE BLÄNSDORF, BLEILITERATUR: SCHRIFTEN AUS DEM GESAMTGEBIET DER GEWERBEHYGIENE (1922).

112. JOSEPH C. AUB ET AL., LEAD POISONING ix (1926).

113. Nriagu, *supra* note 82, at 223.

114. David Rosner & Gerald Markowitz, *A 'Gift of God'?: The Public Health Controversy over Leaded Gasoline during the 1920s,* 75 AM. J. PUB. HEALTH 344, 349 (1985).

115. *See* CAGIN & DRAY, *supra* note 80, at 27, 32-33.

116. *Id.* at 33-34. In addition to Cagin & Dray's book, the other comprehensive description of the history of the controversy over introduction of tetraethyl lead into gasoline is Rosner & Markowitz's article, *supra* note 114.

117. CAGIN & DRAY, *supra* note 80, at 35.

118. *Id.*

ness of the severity of the lead poisoning problem.[119] It stated: "'Since lead poisoning in human beings is of the cumulative type resulting frequently from the daily intake of minute quantities, it seems pertinent to inquire whether there might not be a decided health hazard associated with the extensive use of lead tetra ethyl in engines.'"[120] Du Pont referred the letter to Midgley. Although Midgley had become severely lead poisoned as a result of his own research, he was convinced that the effects of his illness were reversible and that TEL posed no danger to the public because it would be sold in diluted form.[121] He claimed that virtually all the lead would remain in the car's engine. Midgley wrote the Surgeon General that while people working in tunnels might absorb "'a very small'" amount of lead, "'the average congested street will probably be so free from lead that it will be impossible to detect it.'"[122]

TEL went on sale in Dayton, Ohio in February 1923. To assuage public fears about TEL, GM and Ethyl funded a study of its safety by the U.S. Bureau of Mines in October 1923.[123] In October 1924, before the study was completed, news reached the public that four workers in a TEL manufacturing plant near Elizabeth, New Jersey had died from lead poisoning after suffering violent delusions.[124] Several dozen other workers had also been hospitalized.[125] Dubbed "loony gas" in the popular press, TEL subsequently was found to be responsible for the deaths of four other workers in a DuPont plant, two deaths in a GM facility, and many other hospitalizations.[126] With memories of chemical warfare in World War I still fresh in many minds, a public outcry ensued and several cities banned the sale of TEL.[127]

In March 1925, the Bureau of Mines released its study of the health effects of TEL.[128] The study was based on research exposing rabbits, dogs, guinea pigs, monkeys, and pigeons to exhaust from autos burning leaded gasoline for several hours on 188 differ-

---

119. *Id.* at 36.
120. *Id.* (quoting Letter from Hugh Cumming to Pierre Du Pont (Dec. 20, 1922)).
121. *See id.* at 35-36.
122. *Id.* at 36-37 (quoting Letter from Thomas Midgely to Hugh Cumming).
123. *Id.* at 37.
124. *See id.* at 46-47.
125. *See id.* at 47.
126. *See id.* at 49-50.
127. There were at least thirteen deaths from exposure to TEL in the various plants. *See* Willard F. Machle, *Tetra-Ethyl Lead Intoxication and Poisoning by Related Compounds of Lead*, 105 J. AM. MED. ASS'N 578, 578 (1935).
128. CAGIN & DRAY, *supra* note 80, at 50.

ent occasions.[129] It found no health risks from exposure to the exhaust fumes.[130] Public health officials criticized the study because the Bureau of Mines had little expertise on health issues and because GM and Standard Oil funded the study.[131] At the urging of Harvard professor of public health Alice Hamilton and others, the Surgeon General convened a conference in May 1925 to consider the health risks of TEL.[132] Seventy representatives of labor, industry, and the public health community participated in the conference, which ultimately resolved that the Surgeon General appoint a group of experts to complete a study of the health hazards of TEL by January 1, 1926.[133] The manufacturers of such additives agreed not to sell them until the panel convened by the Surgeon General completed its studies.[134]

In response to this resolution, the U.S. Public Health Service (PHS) examined 252 men, some of whom worked at gas stations where leaded gasoline was sold and others who did not.[135] In January 1926, the PHS released its study, which detected no difference in the health of the different groups of subjects.[136] It found that TEL posed no health risks to the general public, but rather that it was dangerous only when used in concentrated form during manufacturing and processing.[137] It proposed that workers in TEL plants could be protected by installing ventilation devices to prevent worker exposure to fumes.[138] Dangers to gas station attendants were deemed slight, and dangers to the general public were thought to be virtually nonexistent.[139] To control the risk of using leaded gasoline for cleansing or other purposes, it was agreed that ethyl gasoline should be dyed and clearly labeled as such.[140] The study provided little basis for evaluating the long-term health effects of emissions from leaded gasoline; and Alice Hamilton and other members of the public health community,

---

129. ENVIRONMENTAL CONTAMINANTS ENCYCLOPEDIA: LEAD ENTRY 70 (Roy J. Irwin ed., 1997), *available at* http://www.nature.nps.gov/hazardssafety/toxic/lead.pdf.

130. CAGIN & DRAY, *supra* note 80, at 50.

131. *See id.* at 50-51; Rosner & Markowitz, *supra* note 114, at 346.

132. CAGIN & DRAY, *supra* note 80, at 50-52.

133. *Id.* at 51-54.

134. *See id.* at 54.

135. *See id.*; Rosner & Markowitz, *supra* note 114, at 350.

136. *See id.*

137. *See* CAGIN & DRAY, *supra* note 80, at 54-55.

138. Public Health Service, *The Use of Tetraethyl Lead Gasoline in Its Relation to Public Health,* 163 PUB. HEALTH BULL. 118 (1926).

139. *See* Rosner & Markowitz, *supra* note 114, at 350-51.

140. *See* Public Health Service, *supra* note 138, at 118-19.

who wanted industry to develop a safe substitute for TEL, criticized it.[141] However, the conference procedure that had been used by the Surgeon General was widely applauded, and it was employed again in December 1928 to consider the problem of radium poisoning in workers painting luminous dials on watch faces and other instruments.[142] The Radium Conference produced results similar to the Tetraethyl Lead Conference—it was agreed that the problem would be studied further—but it provided a vehicle for publicizing the concerns of workers.[143]

Alice Hamilton, who had conducted the pioneering Illinois investigation of occupational diseases, ultimately expressed satisfaction with the use of the conference procedure. In 1929 she stated that she doubted "if any method of dealing with a new poison in industry would work more promptly and efficiently than does this entirely informal and extra-legal method that we Americans have devised, given a new and striking danger which lends itself to newspaper publicity."[144] However, she noted, "it cannot be used to combat old and familiar dangers, lead, silica dust, mercury, benzol. Nor can it be used for the newer poisons which do not produce spectacular effects; and these are much more numerous."[145] Hamilton thought the Tetraethyl Lead Conference had at least helped protect workers in TEL manufacturing plants from suffering from very severe lead poisoning. In her autobiography, published in 1943, she noted that "close watch is still kept to detect possible cases, but the precautions worked out . . . seem thus far to be so adequate that we do not fear any serious injury to the people employed" in occupations using tetraethyl lead.[146]

---

141. *See* CAGIN & DRAY, *supra* note 80, at 54-55.

142. *See generally* CLARK, *supra* note 100, at 151-57.

143. *See id.* at 154.

144. Alice Hamilton, *Nineteen Years in the Poisonous Trades*, HARPER'S, Oct. 1929, at 580, 587.

145. *Id.* at 587.

146. ALICE HAMILTON, EXPLORING THE DANGEROUS TRADES: THE AUTOBIOGRAPHY OF ALICE HAMILTON, M.D. 416-17 (1943). Hamilton's positive attitude has puzzled historians in light of the fact that the conference disregarded her plea that a substitute for tetraethyl lead be developed to protect public health. William Graebner states that her attitude's "overly sanguine character might be explained as the product of the nearly two-decade lapse between the event and its recollection," and by Hamilton's "ardent belief in cooperation and persuasion as problem-solving devices." *See* William Graebner, *Private Power, Private Knowledge, and Public Health: Science, Engineering, and Lead Poisoning, 1900-1970*, *in* THE HEALTH AND SAFETY OF WORKERS: CASE STUDIES IN THE POLITICS OF PROFESSIONAL RESPONSIBILITY 15, 38 (Ronald Bayer ed., 1988).

The Surgeon General actually had recognized that the PHS study was inadequate for assessing the long-term effect of lead additives on human health. His "blue-ribbon" committee's report, issued in 1926, warned that,

> it remains possible that if the use of leaded gasoline becomes widespread conditions may arise very different from those studied by us which would render its use more of a hazard than would appear to be the case from this investigation. Longer experience may show that even such slight storage of lead as was observed in these studies may lead eventually in susceptible individuals to recognizable or to chronic degenerative diseases of a less obvious character. In view of such possibilities the committee feels that the investigation begun under their direction must not be allowed to lapse . . . . It should be possible to follow closely the outcome of a more extended use of this fuel and to determine whether or not it may constitute a menace to the health of the general public after prolonged use or other conditions not now foreseen . . . . The vast increase in the number of automobiles throughout the country makes the study of all such questions a matter of real importance from the standpoint of public health . . . .[147]

However, in the decades to follow, the lead industry continued to control virtually all research, and the close monitoring recommended by the Surgeon General's committee was not undertaken.[148] The United States refused to sign the 1921 International Labour Organization agreement restricting the use of lead-based paint and, having acquiesced to the introduction of lead alkyls in gasoline, both government and industry appeared in alignment to promote expanded uses of lead.[149] Indeed, it was not until the 1970s that national regulatory attention focused on the chronic effects of exposure to lead on children's health.[150]

In the years prior to this shift, the lead industry worked hard to convey the impression that extensive scientific investigation had resolved all concerns about the health effects of lead emis-

147. DYING FOR WORK, *supra* note 99, at 134-35.

148. *See id.* at 134.

149. *See* International Labour Organization, List of Ratifications of International Labour Conventions, White Lead (Painting) Convention, 1921 (No.13), http://webfusion.ilo.org/public/db/standards/normes/appl/appl-byconv.cfm?conv=C013&1; *see also generally infra* note 150.

150. *See* Gerald Markowitz & David Rosner, *"Cater to the Children": The Role of the Lead Industry in a Public Health Tragedy, 1900-1955*, 90 AM. J. PUB. HEALTH 36, 44 (2000).

sions from gasoline combustion. Promoting the notion that most human lead exposure was part of a natural process, Dr. Robert Kehoe, medical director for Ethyl, argued that the human body excreted as much lead as it absorbed.[151] Thus, according to the industry, there was little cause for concern about the rapidly increasing use of lead in industrial products. There was, however, evidence that levels of lead in street dust had increased by almost 50 percent in the first decade after the introduction of TEL in gasoline.[152] Reports of widespread lead poisoning in children continued to mount during the 1950s. Julian Chisholm reported that some Baltimore children were excreting six times more lead than workers exposed to lead in occupational settings.[153] Physicians in Philadelphia reported that forty-one children had died from lead poisoning between 1956 and 1960 and that "control ha[d] not been accomplished."[154]

In 1958, the lead industry announced that it wanted to increase by one-third the concentration of lead additives in gasoline in order to accommodate cars with larger engines.[155] Without making any effort to evaluate the extent to which prior use of TEL had contributed to air emissions of lead, an advisory committee formed by the PHS decided that this would not pose a hazard to public health.[156] Efforts to monitor levels of lead in ambient air were launched in the early 1960s. In 1961, the PHS commenced a study that sampled levels of lead in the air of Cincinnati, Los Angeles, and Philadelphia. This "Three-City Study" provided data that permitted researchers to begin to link airborne lead with lead levels in human blood.[157] Governmental and research groups later conducted a "Seven-City Study" in cooperation with repre-

151. *Air Pollution—1966, Hearings on S.3112 and S.3400 before a Subcomm. on Air and Water Pollution of the Comm. on Public Works United States S.*, 89th Cong., 2nd Sess. 209 (1966) [hereinafter *Hearings on S.3112 and S.3400*] (statement of Dr. Robert A. Kehoe, Univ. of Cincinnati Coll. of Med).

152. Sidney Kaye & Paul Reznikoff, *A Comparative Study of the Lead Content of Street Dirts in New York City in 1924 and 1934*, 29 J. INDUS. HYGIENE & TOXICOLOGY 178, 178 (1947). This report was virtually ignored.

153. J. Julian Chisolm, Jr. & Harold E. Harrison, *The Exposure of Children to Lead*, 18 PEDIATRICS 943, 947 tbl.II (1956).

154. Theodore H. Ingalls et al., *Lead Poisoning in Philadelphia, 1955-1960*, 3 ARCHIVES ENVTL. HEALTH 575, 575, 576 tbl.1 (1961).

155. *See* CHRISTIAN WARREN, BRUSH WITH DEATH: A SOCIAL HISTORY OF LEAD POISONING 205 (2000).

156. *See id.* at 205-06.

157. J.R. Goldsmith & C.A. Hexter, *Respiratory Exposure to Lead: Epidemiological and Experimental Dose-Response Relationships*, 158 SCI. 132, 133 (1967).

sentatives of the lead industry.[158] As with previous studies involving the lead industry, the PHS continued to permit lead industry representatives to control the dissemination of information about the studies' results.[159] Based on these studies, the PHS declared in 1965 that existing levels of lead in the ambient air did not pose a significant threat to public health.[160]

In Senate hearings held in 1966, Dr. Robert Kehoe stated that "no other hygienic problem in the field of air pollution has been investigated so intensively, over such a prolonged period of time, and with such definitive results."[161] As a result of these studies, Kehoe declared, "this specific set of problems has been brought to such a point of understanding, in relation to the public health, as to remove it from the realm of urgency and to consign it into that group of hygienic problems on which a watchful and effective surveillance should be kept."[162]

Ironically, it was the elemental nature of lead, the very feature that makes it so hazardous, that the industry cited to promote the notion that some human exposure is inevitable.[163] In a finger-pointing theme that was frequently repeated in subsequent regulatory proceedings, Kehoe argued that humans were exposed to more lead in food and drink than from air emissions.[164] Kehoe maintained that this should not be of concern because studies

> have demonstrated clearly that the quantity of lead which is being absorbed daily by the average adult citizen of the United States who is not subjected to occupational or otherwise unusual types of exposure to lead, is balanced for all practical purposes by the excretion of a corresponding quantity of lead.[165]

Yet even Kehoe conceded that "[l]ead poisoning in industry is still one of the most frequent occupational diseases . . . despite the

---

158. Gregory S. Wetstone & Jan Goldman, *Chronology of Events Surrounding the* Ethyl *Decision, in* JUDICIAL REVIEW OF SCIENTIFIC UNCERTAINTY: INTERNATIONAL HARVESTER AND ETHYL CASES RECONSIDERED 3 (D.L. Davis et al. eds., 1981).

159. *Id.* at 4.

160. *See* WARREN, *supra* note 155, at 209-10.

161. *See Hearings on S.3112 and S.3400, supra* note 151, at 204 (statement of Dr. Robert A. Kehoe).

162. *See id.*

163. "We have known only for a relatively short time . . . that lead is an inevitable element in the surface of the earth, in its vegetation, in its animal life, and that there is no way in which man has ever been able to escape the absorption of lead while living on this planet." *Id.* at 206.

164. *Id.* at 209.

165. *Id.* at 206, 220.

fact that we know how to prevent it."[166] However, Felix Wormser, former president of the Lead Industries Association (LIA), maintained at the same hearings that "occupational hazards can now be controlled and avoided" since all states had accepted a voluntary industry consensus standard for exposures to lead.[167] Wormser blamed "misdiagnosis" for "unduly increased public concern about lead."[168] He claimed that he had seen "case after case of press reports alleging lead as the cause of damage where lead was not even used or involved."[169] He praised the manufacturers of children's furniture and toys for eliminating the use of lead-based paints, and he noted that the American Standards Association had worked with LIA to specify "a limit on lead content for interior paints."[170] Wormser concluded that "more is known about the biological effects of lead than about almost any other air-borne substance."[171] He assured the committee that "[o]n the basis of this scientific knowledge, I can positively assert that lead constitutes no public health hazard in America today."[172]

Kehoe also sought to create the impression that further surveillance would be conducted to ensure that any public health problems would be detected before they became serious. When pressed as to whether or not it would be desirable to replace gasoline lead additives if a substitute could be developed that did not have toxic effects, Dr. Kehoe maintained that it would first be necessary to investigate the substitutes extensively because he believed "as a matter of principle, that we must investigate every material that we introduce into our environment . . . because there are unknown effects."[173]

Clair Patterson, a scientist with the California Institute of Technology, challenged Kehoe's claims. At the same Senate hearings in 1966, Patterson criticized public health officials and the academic community for defending and promoting "ideas that may be dangerous to the health of all Americans."[174] Based on his own

166. *Id.* at 205.

167. *Id.* at 233, 235-36 (statement of Felix E. Wormser, Consultant and Former President, Lead Indus. Ass'n, Inc.).

168. *Id.* at 235.

169. *Id.*

170. *Id.*

171. *Id.* at 239.

172. *Id.*

173. *Id.* at 207 (statement of Dr. Kehoe).

174. *Id.* at 312 (statement of Dr. Clair C. Patterson, Ph. D., California Institute of Technology).

calculations concerning lead levels near California freeways and human absorption of airborne lead, Patterson declared that existing levels of lead in the ambient air did pose a threat to public health.[175] Noting that residents of urban areas had significantly higher levels of lead in their blood than residents of rural areas, Patterson declared that this could only be explained by the significant increase in lead emissions from gasoline combustion.[176]

In response to these concerns, Congress in 1967 took a little-noticed but significant step when it adopted air quality legislation requiring that fuel additives be registered.[177] This legislation amended the 1965 Motor Vehicle Air Pollution Control Act,[178] which had initiated the process of establishing federal emissions standards for new motor vehicles. Regulatory action calling for reduced levels of hydrocarbons also reduced levels of lead in ambient air.[179] As the deadline for reducing hydrocarbon emissions approached, the only available technology to achieve it was the catalytic converter, a platinum-based device that increased the overall efficiency of gasoline fuel combustion.[180] Because the catalytic converter was "poisoned" by lead, vehicles using it required lead-free gasoline. In 1970, President Nixon asked Congress to promote the development of lead-free gasoline by imposing a federal tax on lead additives.[181]

C. The Asbestos Tragedy

Like the history of human exposure to lead, the history of asbestos exposure is replete with instances of early warnings of potentially catastrophic harm that failed to generate effective preventive regulation. Elevated levels of mortality among asbes-

175. *See id.* at 314.

176. *See id.* at 314-15. Subsequent research by Patterson and Settle suggested that modern levels of lead, in the environment and in humans, were far from a "natural" background, but rather represented an enormous contamination due to centuries of human use. *See* Dorothy M. Settle & Clair C. Patterson, *Lead in Albacore: Guide to Lead Pollution in Americans*, 207 Sci. 1167, 1170-73 (1980).

177. Air Quality Act of 1967, Pub. L. No. 90-148, § 210, 81 Stat. 485, 502 (1967).

178. Motor Vehicle Air Pollution Control Act, Pub. L. No. 89-272, 79 Stat. 992 (1965).

179. *See* V.M. Thomas, *The Elimination of Lead in Gasoline*, 20 Annual Rev. Energy Env't 301, 316-17 (1995).

180. For a brief description of the catalytic converter, see Carbon Monoxide Kills, Carbon Monoxide Emissions, http://www.carbonmonoxidekills.com/carbon_monoxide_emissions.htm (last updated Jan. 11, 2005).

181. Bureau of National Affairs, Inc., *President to Propose Congress Adopt Tax on Lead Additives in Motor Fuels,* 1 Env't Rep. (BNA) 71 (1970).

tos workers were reported in 1906, a few years after a London doctor, H. Montague Murray, had reported the first case of asbestosis, a deadly respiratory disease ultimately linked to asbestos exposure.[182] In 1924, the first case of a death clearly attributed to asbestosis appeared in the medical literature.[183] In the late 1920s, studies of elevated mortality rates among asbestos workers were published.[184] These studies inspired the British Parliament, in 1931, to enact legislation requiring improved ventilation and dust suppression in the asbestos-textile industry.[185]

The U.S. asbestos industry succeeded in suppressing evidence of elevated mortality rates among its workers during the 1930s, even as its insurers quietly moved to restrict coverage of workers exposed to asbestos.[186] Workers in other industries whose lungs were scarred through inhalation of silica filed tort suits in massive numbers during this decade.[187] The use of new, mechanical drilling and milling technologies early in the twentieth century had dramatically increased worker exposure to silica dust. Lawsuits seeking more than a billion dollars in compensation for silicosis were pending in 1934.[188] While many attributed the escalation of silicosis claims to the onset of the Great Depression, the claims created a crisis for the insurance industry, which responded by lobbying successfully for states to expand workers' compensation to cover occupational diseases such as silicosis and asbestosis, preempting tort litigation against employers.[189]

During World War II, 4.5 million Americans working in shipyards were exposed to dangerous levels of asbestos, which was widely used as a form of insulation.[190] Two decades later, in October 1964, Dr. Irving Selikoff's epidemiological studies of asbestos-insulation workers established that these workers were experiencing alarming rates of asbestosis and were dying of lung cancer at

182. PAUL BRODEUR, OUTRAGEOUS MISCONDUCT: THE ASBESTOS INDUSTRY ON TRIAL 11-12 (1985).

183. *Id.* at 13.

184. *See id.*

185. *Id.*

186. *See id.* at 13-14, 120.

187. *See* Andrew P. Morriss & Susan E. Dudley, *Defining What to Regulate: Silica & the Problem of Regulatory Categorization* 27 (Case W. Reserve Univ. Sch. of Law Case Research Paper Series, Mercatus Ctr. at George Mason Univ. Working Paper in Regulatory Studies, No. 05-21, 2005), *available at* http://ssrn.com/abstract=781684.

188. *Id.*

189. *See* BRODEUR, *supra* note 182, at 16-18.

190. *Id.* at 120.

seven times the expected rate.[191] The evidence associating friable asbestos insulation with troubling rates of asbestosis, mesothelioma, and lung cancer was so compelling that the Environmental Protection Agency (EPA) banned the use of such products shortly after it was given the authority to do so in the 1970s.[192] By the year 2000, an avalanche of tort litigation had been filed against manufacturers of asbestos products, including more than 600,000 lawsuits against more than 6000 defendants, resulting in $54 billion in damages and litigation costs.[193] More importantly, it is estimated that between 1979 and 2001, more than 230,000 deaths in the United States have been caused by exposure to asbestos.[194] EPA's difficulties in developing a coherent strategy for controlling the risks posed by huge quantities of asbestos in schools and buildings eventually convinced the agency to attempt to phaseout remaining uses of asbestos, as discussed below.

D. Precautionary Regulation by the Courts: The *Reserve Mining* Decision

While the hazards of lead and asbestos had become well known by the late 1960s, uncertainty over the health effects of a newly discovered hazard forced U.S. courts to address the question of whether a precautionary approach should be employed. The case, which arose in Minnesota, involved an effort to force the Reserve Mining Company (Reserve) to stop discharging 67,000 tons of taconite tailings daily into Lake Superior.[195] Following a

191. *Id.* at 30-31.

192. *See* Asbestos and Mercury: Proposed Amendments to National Emission Standards for Hazardous Air Pollutants, 39 Fed. Reg. 38,063, 38,064 (Oct. 25, 2974); National Emission Standards for Hazardous Air Pollutants: Asbestos, Beryllium, and Mercury, 38 Fed. Reg. 8819, 8820 (Apr. 6, 1973). Using its authority under the Clean Air Act, which had been enacted in 1970, EPA listed asbestos as a hazardous air pollutant on March 31, 1971. On April 6, 1973, EPA prohibited spray applications of products containing more than 1 percent asbestos by weight; and it prohibited any "visible emissions" in milling, manufacturing, or demolition. R.D. Brownson, *Current and Historical American Asbestos Regulations*, 53 MONALDI ARCHIVES CHEST DISEASES 181, 182 (1998).

193. Morriss & Dudley, *supra* note 187, at 61 (citing STEPHEN J. CARROLL ET AL., ASBESTOS LITIGATION COSTS AND COMPENSATION: AN INTERIM REPORT (2002)).

194. Environmental Working Group, Governmental Data on Asbestos Mortality, http://www.ewg.org/reports/asbestos/maps/government_data.php#moreinfo (last visited Oct. 18, 2005).

195. Much has been written about the history of this case. For a new review of its history, *see* John S. Applegate, *The Story of* Reserve Mining: *Managing Scientific Uncertainty in Environmental Regulation*, *in* ENVIRONMENTAL LAW STORIES 43 (Richard J. Lazarus & Oliver A. Houck eds., 2005) [hereinafter *Story of* Reserve Mining].

two-year interstate enforcement conference that heard hundreds of witnesses and compiled thousands of exhibits, the U.S. Department of Justice (DOJ) brought suit against Reserve in February 1972. The suit, which was joined by the States of Michigan, Minnesota, and Wisconsin, as well as several environmental groups, was brought under federal and state common law and for violations of the Refuse Act,[196] the Clean Water Act (CWA),[197] and state air and water pollution regulations.[198]

After an activist, a geologist, and a National Water Quality Laboratory scientist discovered that the taconite tailings released fibers structurally similar to asbestos in a source of drinking water serving Duluth, Minnesota, a city with an exposed population of 200,000, the case focused on whether ingestion of the fibers posed cancer risks similar to those associated with inhalation of asbestos.[199] The scientific evidence was inconclusive, despite court-sanctioned efforts to sample the tissues of recently diseased residents of Duluth. Federal District Judge Miles Lord ultimately determined that although there was no conclusive evidence of a hazard, the taconite tailings present in Duluth's drinking water posed a significant health risk because they were structurally similar to asbestos.[200] He then conducted a separate trial to determine the best means for halting the discharges. After becoming frustrated with the company's intransigence on the remedy issue, he issued an order requiring that the discharges cease immediately.[201]

Reserve appealed to the U.S. Court of Appeals for the Eighth Circuit, which issued, and later renewed, a stay of Judge Lord's order to avoid a shutdown of the plant.[202] In an opinion authored by Judge Myron Bright, a three-judge panel emphatically rejected the notion that precaution should take precedence in the face of scientific uncertainty:

---

196. Rivers and Harbors Appropriation Act of 1899, §13, 30 Stat. 1121 (codified as amended at 33 U.S.C. § 407 (2000)).

197. 33 U.S.C. §§1251-1387 (2000).

198. *Story of* Reserve Mining, *supra* note 195, at 57; United States v. Reserve Mining Co., 380 F. Supp. 11 (D. Minn. 1974); Reserve Mining Co. v. EPA, 514 F.2d 492, 492 (8th Cir. 1975).

199. *See Story of* Reserve Mining, *supra* note 195, at 44-45, 48-49, 58-61.

200. *See id.* at 60-61.

201. United States v. Reserve Mining Co., 380 F. Supp. 11, 21 (D. Minn. 1974), *modified and remanded by* 514 F.2d 492, 535-42 (8th Cir. 1975).

202. Reserve Mining Co. v. United States, 498 F.2d 1073, 1086 (8th Cir. 1974).

> [A]lthough Reserve's discharges represent a possible medical danger, they have not in this case been proven to amount to a health hazard. The discharges may or may not result in detrimental health effects, but, for the present, that is simply unknown . . . .
>
> We do not think that a bare risk of the unknown can amount to proof in this case. Plaintiffs have failed to prove that a demonstrable health hazard exists. This failure, we hasten to add, is not reflective of any weakness which it is within their power to cure, but rather, given the current state of medical and scientific knowledge, plaintiffs' case is based only on medical hypothesis and is simply beyond proof.
>
> We believe that Judge Lord carried his analysis one step beyond the evidence. Since testimony clearly established that an assessment of the risk was made impossible by the absence of medical knowledge, Judge Lord apparently took the position that all uncertainties should be resolved in favor of health safety. Since the appropriate threshold level for safe toleration of fibers was unknown, the district court tipped the balance in favor of attempting to protect against the unknown and simply assumed that Reserve's discharge presents a health hazard . . . . [T]he district court's determination to resolve all doubts in favor of health safety represents a legislative policy judgment, not a judicial one . . . .
>
> . . . .
>
> . . . Although we are sympathetic to the uncertainties facing the residents of the North Shore, we are a court of law, governed by rules of proof, and unknowns may not be substituted for proof of a demonstrable hazard to the public health.[203]

By rejecting a precautionary approach to regulation, the panel's decision alarmed federal and state environmental officials. In response, "[a] bill was introduced in Congress to shift the burden of proof to polluters to prove the safety of their discharges once it was shown that they presented a reasonable risk of being a threat to public health."[204] Russell Peterson, then Chairman of the Council on Environmental Quality, supported this proposed legislation, by arguing:

> Because of the latent health effects of carcinogens it will be more than 10 years before the magnitude of the health risk to the people of Duluth and Silver Bay will be fully realized, and

203. *Id.* at 1083-84.
204. PERCIVAL ET AL., *supra* note 1, at 353 (internal quotation marks omitted).

> unfortunately it will be based upon the fate of over 200,000 people. Even a few more days of additional exposure pose an unnecessary and unacceptable risk to the residents of the area.[205]

Although Congress did not enact this proposed legislation, Reserve ultimately was forced to end its discharges into Lake Superior. The Eighth Circuit panel refused to endorse the district court's precautionary approach to respond to a potential health hazard, but it concluded that the company was likely to lose on the claims that its discharges violated the terms of its permit.[206] Thus, the court conditioned its stay "upon assurances that there will be a speedy termination of Reserve's discharges into Lake Superior and control of its emissions into the air."[207]

After negotiations with Reserve failed to produce agreement on a plan to abate the discharges, the Eighth Circuit announced a briefing schedule for hearing Reserve's appeal en banc. The court's en banc decision upheld Judge Lord's issuance of an injunction to require abatement of the discharges into Lake Superior; but rather than requiring that they be halted immediately, it gave Reserve "reasonable time" to abate them "on reasonable terms."[208] The court stated that "[t]he United States and the other plaintiffs have established that Reserve's discharges into the air and water give rise to a potential threat to the public health. The risk to public health is of sufficient gravity to be legally cognizable and calls for an abatement order on reasonable terms."[209] However, it noted that "[n]o harm to the public health has been shown to have occurred to this date and the danger to health is not imminent."[210]

But the court justified its decision to require abatement of the hazard on the ground that "[t]he evidence calls for preventive and

205. *To Promote and Protect the Free Flow of Interstate Commerce Without Unreasonable Damage to the Environment; To Assure that Activities Which Affect Interstate Commerce Will Not Unreasonably Injure Environmental Rights; To Provide a Right of Action for Relief for Protection of the Environment from Unreasonable Infringement by Activities Which Affect Interstate Commerce and to Establish the Right of All Citizens to the Protection, Preservation, and Enhancement of the Environment: Hearing on S. 1104 Amendment No. 1814 Before the Subcomm. on Environment of the Comm. on Commerce*, 93rd Cong. 8 (1974) (letter from Russell W. Peterson to Hon. Wallace H. Johnson).

206. *Reserve Mining Co.*, 498 F.2d at 1074, 1084.

207. *Id.* at 1084-85.

208. Reserve Mining Co. v. EPA, 514 F.2d 492, 500 (8th Cir. 1975).

209. *Id.*

210. *Id.*

precautionary steps."[211] Finding no reason to require Reserve to shut down immediately, the court granted it "a reasonable opportunity and a reasonable time period to convert its Minnesota taconite operations to on-land disposal of taconite tailings and to restrict air emissions at its Silver Bay plant, or to close its existing Minnesota taconite-pelletizing operations."[212] Because the court believed that the "evidence suggests that the threat to public health from the air emissions is more significant than that from the water discharge," it directed Reserve to "take reasonable immediate steps to reduce its air emissions."[213]

The Eighth Circuit's en banc decision in *Reserve* serves as an important precedent for the application of the precautionary principle in the United States. It represents an explicit recognition by the court that in circumstances where science simply cannot resolve the question whether something poses an environmental risk, it still may be appropriate to require precautionary measures to be taken. Thus, the court agreed that it was reasonable to require abatement of the tailings discharges even in the face of uncertainty concerning their actual impact on human health. Therefore, the Eighth Circuit upheld the trial court's order directing Reserve to phaseout disposal of taconite tailings in Lake Superior.[214]

After bitter battles between Reserve and Judge Lord continued on remand, the Eighth Circuit ultimately removed Judge Lord from the case for exhibiting what it deemed to be pro-plaintiff bias and substantial disregard for its mandate.[215] In decisions from May and July 1976, Judge Devitt found Reserve to have violated the law, fined the company heavily, imposed sanctions for its misconduct during discovery, and gave it one year to halt all discharges.[216] The Eighth Circuit basically upheld these decisions in full.[217]

211. *See id.*

212. *Id.*

213. *Id.*

214. *Id.* at 499-500 (8th Cir. 1975).

215. Reserve Mining Co. v. Lord, 529 F.2d 181, 185 (8th Cir. 1976).

216. United States v. Reserve Mining Co., 412 F. Supp. 705, 713-14 (D. Minn. 1976) (May decision); United States v. Reserve Mining Co., 417 F. Supp. 789, 791 (D. Minn. 1976) (July decision).

217. United States v. Reserve Mining Co., 543 F.2d 1210, 1211 (8th Cir. 1976).

E. Legislation Authorizing Precautionary Regulation and the *Ethyl* Decision

During the 1970s, Congress adopted far-reaching legislation establishing comprehensive programs to protect the environment.[218] These laws—the National Environmental Policy Act (NEPA),[219] the Clean Air Act,[220] the CWA,[221] and the Toxic Substances Control Act (TSCA)[222]—represent a sharp departure from the common law approach to environmental protection by endorsing precautionary measures to prevent environmental damage before it occurs. The first major federal statute adopted during this period—the National Environmental Policy Act—directs federal agencies, before undertaking any major actions, to prepare and consider detailed assessments of their environmental impacts and of alternatives to them.[223] This environmental assessment requirement has been widely emulated throughout the world, and it has become a central element of the environmental protection infrastructure in many countries.[224] By requiring agencies to carefully examine the prospective consequences of their actions, NEPA enhances the ability of decision-makers to take precautionary action.

The first major federal regulatory statute Congress adopted was the Clean Air Act Amendments of 1970.[225] This legislation endorsed precautionary regulation by requiring the newly created EPA to set national ambient air quality standards to protect public health, with a margin of safety built into the standards.[226] This legislation also directed EPA to set standards that would require at least a 90-percent reduction in hydrocarbon and carbon monoxide emissions from new motor vehicles.[227] Congress also

---

218. A superb history of these developments is presented in RICHARD J. LAZARUS, THE MAKING OF ENVIRONMENTAL LAW (2004).

219. 42 U.S.C. §§ 4321-4347 (2000).

220. 42 U.S.C. §§ 7401-7671q (2000).

221. 33 U.S.C. §§ 1251-1387.

222. 15 U.S.C. §§ 2601-2692 (2000).

223. 42 U.S.C. § 4332.

224. More than eighty countries and twenty-five states have adopted some form of environmental impact assessment requirement. COUNCIL ON ENVIRONMENTAL QUALITY, THE NATIONAL ENVIRONMENTAL POLICY ACT: A STUDY OF ITS EFFECTIVENESS AFTER TWENTY-FIVE YEARS (1997), *available at* http://ceq.eh.doe.gov/nepa/nepa25fn.pdf.

225. Clean Air Act Amendments of 1970, Pub. L. 91-604, 84 Stat. 1676.

226. *Id.* § 109(b)(1), 84 Stat. at 1680 (codified at 42 U.S.C. § 7409(b)(1) ("standards the attainment and maintenance of which in the judgment of the Administrator, based on such [air quality] criteria and allowing an adequate margin of safety, are requisite to protect the public health")).

227. *Id.* § 202(b)(1)(A), 84 Stat. at 1690.

authorized the EPA to control or to prohibit the use of any fuel additive whose emission products "will endanger the public health or welfare."[228] To meet the required 90-percent reduction in conventional pollutants, new automobiles had to be equipped with catalytic converters.[229] Because lead additives in gasoline render catalytic converters ineffective in controlling exhaust emissions, the use of leaded gasoline in the new vehicle fleet had to be prohibited.[230]

In January 1971, the EPA announced that it was considering controls on lead additives in gasoline not only because of lead's incompatibility with catalytic converters, but also because of concern over the effects of lead emissions on public health.[231] In February 1972, the EPA proposed regulations to require a phased reduction in the lead content of leaded gasoline to 1.25 grams per gallon (gpg) by 1977.[232] The EPA based its proposed limits on the lead content of gasoline on a health assessment document that concluded that airborne lead levels exceeding 2 ug/m^3 were associated with a sufficient risk of adverse physiological effects to endanger public health.[233] However, in January 1973, when the EPA adopted regulations requiring the use of lead-free gasoline in cars with catalytic converters, it deferred adoption of limits on the lead content of gasoline because of uncertainties concerning its assessment of the evidence of the health effects of airborne lead.[234]

The EPA Administrator determined that it was "difficult if not impossible" to identify the precise level of airborne lead that would endanger health.[235] However, he re-proposed the 1.25gpg limit based on a new health assessment document that considered the cumulative effect of airborne lead exposure on total human exposure to lead.[236] The Administrator emphasized that there

228. *Id.* § 211(c)(1)(A), 84 Stat. at 1698 (codified as amended at 42 U.S.C. § 7545(c)(1)(A)).

229. *See* PERCIVAL ET AL., *supra* note 1, at 554-55.

230. *See* Thomas, *supra* note 179, at 316-17.

231. Advance Notice of Proposed Rule Making, Regulation of Fuel Additives, 36 Fed. Reg. 1486 (Jan. 30, 1971).

232. Regulation of Fuels and Fuel Additives: Lead and Phosphorus Additives in Motor Vehicle Gasoline, 37 Fed. Reg. 3882, 3883 (proposed Feb. 17, 1972) (to be codified at 40 C.F.R. pt. 80).

233. *Id.* at 3882; EPA, HEALTH HAZARDS OF LEAD 8-9 (1972).

234. Regulation of Fuels and Fuel Additives, 38 Fed. Reg. 1254, 1254 (Jan. 10, 1973).

235. Regulation of Fuels and Fuel Additives: Notice of Proposed Rule Making, 38 Fed. Reg. 1258, 1258 (Jan. 10, 1973) (to be codified at 40 C.F.R. pt. 80).

236. *Id.* at 1259.

was evidence that human exposure to airborne lead occurred not only through direct absorption of lead in the lungs, but also as a result of atmospheric deposition on soil, another source of significant exposure to children.[237] The EPA's new proposal required phased reductions in the lead content of gasoline beginning in 1975 and culminating in 1978 with the 1.25gpg limit.[238]

In response to a lawsuit by environmentalists, the Court of Appeals for the District of Columbia ordered the EPA in October 1973 to decide within thirty days whether or not lead additives in gasoline should be regulated for health reasons.[239] In November 1973, the EPA issued a revised health assessment document that determined lead emissions from gasoline "will endanger the public health."[240] In December 1973, EPA adopted the proposed limit on the lead content of gasoline after modifying it to base the standard on grams of lead per gallon of *all* gasoline produced.[241] This modification was designed in part to encourage greater production of unleaded gasoline because it would permit a refinery to increase the lead content of the leaded gasoline it produced as it expanded production of unleaded gasoline.[242] The standard required large refineries to begin phased reductions in lead usage on January 1, 1975, with small refineries to follow on January 1, 1977.[243] By January 1, 1979, all refineries were required to comply with a standard of 0.5 gpg for all gasoline produced,[244] which was equivalent to the 1.5-grams-per-leaded-gallon standard.

Lead-additive manufacturers challenged EPA's decision in court. In December 1974, a three-judge panel of the U.S. Court of Appeals for the District of Columbia Circuit struck down the regulations by a two-one vote, with Judge J. Skelly Wright dissenting.[245] In a majority opinion by Judge Wilkey, the court held that there was insufficient evidence to prove that lead emissions "will endanger the public health or welfare," as required by the Clean

---

237. *Id.*

238. *Id.* at 1260.

239. *See* Ethyl Corp. v. EPA, 541 F.2d 1, 10 (D.C. Cir. 1976) (citing Natural Res. Def. Council, Inc. v. EPA, No. 72-2233 (D.C. Cir. 1973)).

240. *See Ethyl Corp.*, 541 F.2d at 10 (discussing EPA'S POSITION ON THE HEALTH IMPLICATIONS OF AIRBORNE LEAD (Nov. 28, 1973)).

241. Regulation of Fuels and Fuel Additives, 38 Fed. Reg. 33,734, 33,734 (Dec. 6, 1973) (codified at 40 C.F.R. pt. 80, as amended).

242. *See id.* at 33,739.

243. *Id.* at 33,739-40.

244. *Id.* at 33,741.

245. Ethyl Corp. v. EPA, 5 Envtl. L. Rep. (Envtl. Law Inst.) 20,096, 20,096-97 (D.C. Cir. 1978).

Air Act.[246] The court agreed that "the case against auto lead emissions is a speculative and inconclusive one at best."[247]

The EPA appealed this decision to the full court, which agreed to rehear the case. In March 1976, the court reversed the three-judge panel's decision by a five-four vote and upheld the lead standard.[248] In a decision that stands as a landmark in its endorsement of precautionary regulation, the court ruled that there was sufficient evidence to regulate lead additives, even though it could not be proven with certainty that they endanger public health.[249] In his majority opinion, Judge Wright noted the precautionary nature of the Clean Air Act's regulatory mandate: "Regulatory action may be taken before the threatened harm occurs; indeed the very existence of . . . precautionary legislation would seem to *demand* that regulatory action precede, and, optimally, prevent, the perceived threat."[250]

The TEL manufacturers argued that there was no definitive proof that emissions of lead from gasoline caused harm.[251] They maintained that EPA was required to present some "dispositive study" to demonstrate that lead additives in gasoline had caused lead poisoning in individuals.[252] The court acknowledged the lack of "hard proof of any danger," but it rejected the notion that such proof was necessary before precautionary regulation could be implemented.[253] "Undoubtedly, certainty is the scientific ideal to the extent that even science can be certain of its truth. But certainty in the complexities of environmental medicine may be achievable only after the fact . . . . Awaiting certainty will often allow for only reactive, not preventive regulation."[254]

After reviewing the 10,000-page record, the court focused on three EPA conclusions that the lead additive manufacturers had challenged:

> (1) that, based on a preliminary determination that blood lead levels of 40 μg are indicative of danger to health, elevated blood lead levels 'exist to a small but significant extent in

246. *Id.* at 20,114-15.
247. *Id.* at 20,097.
248. Ethyl Corp. v. EPA, 541 F.2d 1, 6, 11, 55 (D.C. Cir. 1976).
249. *See id.* at 17.
250. *Id.* at 13 (emphasis added).
251. *See id.* at 12.
252. *See id.* at 37.
253. *Id.* at 8, 17.
254. *Id.* at 25 (footnote omitted).

> the general adult population and to a very great extent among children' . . . ; (2) that airborne lead is directly absorbed in the body through respiration to a degree that constitutes a significant risk to public health; and (3) that airborne lead falls to the ground where it mixes with dust and poses a significant risk to the health of urban children.[255]

The court observed that while no specific blood lead level could be identified as the threshold for danger, the 40μg level was a conservative standard; and that studies, including those of the blood lead levels of workers in various occupational groups who work outside and whose only exposure to lead is through the ambient air, justified EPA's first conclusion.[256] The court found that theoretical, epidemiological, and clinical studies supported the second conclusion; and it upheld the third conclusion as a hypothesis that is consistent with known information about high lead concentrations in dust in urban areas and the behavior of children.[257]

The court rejected the industry's claim that a "dispositive study" had to support EPA's determination, noting that "[b]y its nature, scientific evidence is cumulative."[258] The court noted the difficulties inherent in determining whether or not lead emissions endanger health, including the existence of multiple sources of human exposure to lead and the difficulties of conducting controlled experiments on humans.[259] However, it upheld EPA's regulation by emphasizing the precautionary purpose of the statute:

> Where a statute is precautionary in nature, the evidence difficult to come by, uncertain, or conflicting because it is on the frontiers of scientific knowledge, the regulations designed to protect the public health, and the decision that of an expert administrator, we will not demand rigorous step-by-step proof of cause and effect. Such proof may be impossible to obtain if the precautionary purpose of the statute is to be served.[260]

The *Ethyl* decision remains a landmark in environmental law because of its endorsement of the precautionary principle long before it became a staple of global environmental policy. The deci-

255. *Id.* at 38 (citation omitted).
256. *Id.* at 38-41.
257. *Id.* at 41-46.
258. *Id.* at 37-38.
259. *See id.* at 9.
260. *Id.* at 28 (footnote omitted).

sion established that precautionary regulation could be based "on the inconclusive but suggestive results of numerous studies," suggesting that exposure to a substance was likely to endanger health even in the absence of conclusive proof that such adverse health effects actually had occurred.[261] It also indicated that courts would be deferential in reviewing the judgment of the EPA Administrator in assessing the significance of scientific evidence.

Shortly after the *Ethyl* decision, Congress amended the Clean Air Act to change the standard for regulating fuel additives from "will endanger public health or welfare" to "may reasonably be anticipated to endanger the public health or welfare."[262] This essentially codified the *Ethyl* court's approach and confirmed EPA's authority to regulate fuel additives on the basis of information that they are *likely* to produce harm, without first requiring that they be shown to have produced such harm.

In his dissent, Judge Wilkey argued that,

> If there can be found potential harm from lead in exhaust emissions, the best (and only convincing) proof of such potential harm is what has occurred in the past (either in 50 years of practical usage or in laboratory experimentation), from which the Administrator can logically deduce that the same factors will produce the same harm in the future.[263]

Under his view, the fact that lead has been emitted from automobiles for so many years would require some showing that harm has actually been caused by them, even if a more relaxed standard might be applicable when considering regulation of new substances.

Even though the Seven-Cities Study had found that only a very small percentage (0.15 percent) of adults had elevated blood-lead levels, EPA argued that the study was methodologically flawed, and had relied on evidence of elevated lead levels in occupational groups (e.g., mailmen, service station employees) whose only exposure to lead would be through air emissions.[264] While Judge Wilkey asserted that EPA was simply "picking and choosing" data to support its conclusion, the majority supported EPA's

261. *Id.* at 37-38.

262. Clean Air Act Amendments of 1977, Pub. L. No. 95-95, § 401(e), 91 Stat. 685 (codified at 42 U.S.C. § 7545(c)(1)(A)).

263. *Ethyl Corp.*, 541 F.2d at 95 (Wilkey, J., dissenting).

264. *See id.* at 40-41.

approach.[265] As discussed in Section H below, subsequent events have decisively confirmed the wisdom of EPA's precautionary approach.

F. Action to Phaseout Chlorofluorocarbons (CFCs) and Other Ozone-Depleting Substances

Although it was well known that exposure to lead could harm humans, the true uncertainty in *Ethyl* concerned the degree of human exposure to lead caused by combustion of lead additives in gasoline. The most dramatic instance in which U.S. regulatory policy has responded to purely theoretical risks is its response to the theory that CFCs could damage the earth's ozone layer. In 1974, two scientists from the University of California—Sherry Rowland and Mario Molina—published a paper suggesting that the ozone layer could be damaged by a family of chemicals once hailed as a miracle of modern science.[266] CFCs, chemicals used in a wide variety of industrial applications including aerosol propellants, foam blowing, air conditioning, and solvents, were discovered in the 1920s by Thomas Midgely, the same chemist who discovered TEL.[267] At the time of Midgely's discovery, CFCs were considered to be a marvelous advance for public health and safety because they could be used to replace highly toxic materials that formerly had been used to insulate refrigeration equipment.[268] Beginning in the 1950s, CFCs had become widely used, particularly as propellants in popular aerosol spray deodorants. Rowland and Molina hypothesized that CFCs would reach the upper atmosphere, where they could be broken apart by the intense energy of the sun, releasing chlorine.[269] The chlorine would then act as a catalyst, converting ozone (O_3) to oxygen, destroying the Earth's protective ozone shield.[270]

Rowland and Molina's study sparked considerable research that confirmed that their hypothesis was theoretically sound, though at the time it was not possible to prove definitively that CFCs actually were destroying the ozone layer. As publicity focused on potential harm to the ozone layer, American consumers stopped buying aerosol sprays (including those without CFCs); in

265. *See id.* at 37-38, 103.
266. *See* CAGIN & DRAY, *supra* note 80, at 171, 178, 185, 188-89.
267. *See id.* at 64-66.
268. *See id.* at 66-67.
269. *Id.* at 180-81.
270. *Id.* at 181.

less than two years the market for products with such sprays dropped by two-thirds without any government regulation.[271] Competing manufacturers began advertising that their products did not contain chemicals thought to harm the ozone layer. While disputing the notion that CFCs threatened the ozone layer, industry eventually agreed, after several states initiated regulatory proceedings,[272] that federal regulation would be preferable to potentially conflicting state standards. In March 1978, EPA (under TSCA), the Food and Drug Administration, and the Consumer Product Safety Commission jointly issued regulations to limit the use of CFCs in "nonessential" aerosol propellants (military and medical uses were exempted).[273]

Even before international research could pinpoint the role of CFCs in ozone depletion, discovery of an ozone "hole" demonstrated the vulnerability of the ozone layer. This contributed to a heightened sense of urgency that spurred international negotiations based on the framework established by the Vienna Convention. Four negotiating sessions, beginning in Geneva in December 1986, culminated in the signing of the Montreal Protocol on Substances that Deplete the Ozone Layer in September 1987.[274] The Protocol called for a freeze on production and consumption of CFCs and halons at 1986 levels, followed by a 50-percent reduction in CFC use by industrialized countries over a ten-year period.[275]

G. The Supreme Court's Benzene Decision

Congress often has mandated that technology-based standards be promulgated to reduce environmental and occupational risks. The Clean Air Act requires EPA to establish technology-based standards that must be met by new or modified major stationary sources and by companies that emit hazardous air pollutants.[276] The Clean Water Act requires EPA to set technology-based effluent limits on discharges of water pollutants on an in-

271. *See id.* at 205-06.

272. *Id.* at 206.

273. *See id.* at 213; Chlorofluorocarbons in Various Products as Propellants in Self-Pressurized Containers, 43 Fed. Reg. 11,301, 11,301-02, 11,316, 11,319-20 (Mar. 17, 1978).

274. Richard Elliot Benedick, Ozone Diplomacy: New Directions in Safeguarding the Planet 69-76 (1991).

275. *Id.* at 87.

276. 42 U.S.C. §§ 7411, 7412.

dustry-wide basis.[277] The Occupational Health and Safety Act requires the Occupational Safety and Health Administration (OSHA) to promulgate an occupational health standard that "most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity," even if exposed to the hazard throughout his working life.[278] Because technology-based standards are not based on assessment of the extent of likely harm caused by regulated pollutants, they often are viewed as an example of precautionary regulation.[279]

Fears that judicial endorsement of precautionary regulation in both *Ethyl* and *Reserve Mining* could spawn overregulation were calmed somewhat when the U.S. Supreme Court issued its "benzene decision" in 1980. A plurality of the Court concluded that a statutory command to establish a standard that "'most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity,'" even if exposed to the hazard throughout his working life, did not automatically require reducing exposure to carcinogens to the lowest feasible level.[280] Instead it held that OSHA must first perform a risk assessment to establish that the risk is "significant" and that it could be appreciably reduced by the standard it ultimately promulgated.[281] Thus, the Court conditioned precautionary regulation on the making of threshold findings that such regulation would appreciably reduce risks that appear to be substantial.

The Court's plurality decision did not represent a wholesale rejection of the precautionary approach to regulation. Rather, it expressly endorsed the notion that precautionary regulation could be undertaken in the face of uncertainty, while the Court developed its own common law concerning what evidence was necessary to trigger regulatory action under the Occupational Safety and Health Act. The plurality also endorsed the use of conservative default assumptions in risk assessment ("so long as they are supported by a body of reputable scientific thought"), and it speci-

277. 33 U.S.C. § 1314(b).

278. 29 U.S.C. § 655(b)(5) (2000).

279. *See generally* MORAG-LEVINE, *supra* note 13 (arguing that greater acceptance of the precautionary principle in Europe is reflected in greater emphasis on technology-based regulation in European countries than in the United States).

280. Indus. Union Dep't v. Am. Petroleum Inst., 448 U.S. 607, 612, 615 (1980) (quoting 29 U.S.C. § 655(b)(5)).

281. *Id.* at 653, 659.

fied that risk assessment need not be quantitative in circumstances where such analysis was not possible given the extent of uncertainty.[282]

By requiring OSHA to assess risks and to determine that they are "significant" enough to warrant regulation, the Supreme Court placed a greater burden on agencies seeking to adopt precautionary regulation. While this regulatory threshold in itself does not appear to be a significant barrier to regulation, the Court's decision created yet another obstacle for an agency already having great difficulty setting standards.[283] It also meant that workers had to tolerate exposure to dangerous levels of benzene for nearly a decade longer than OSHA initially had intended when it promulgated an emergency temporary standard in 1977, which was invalidated in court.[284] It was not until 1987 that OSHA ultimately lowered the permissible exposure limit for benzene to the very level it had sought to adopt on an emergency basis a decade earlier.[285]

OSHA currently is considering a new permissible exposure limit for silica to replace the now-woefully outdated national consensus standard it initially adopted.[286] Despite periodic assertions that the problem of worker exposure to silica has been solved, today between 200 and 300 workers die of silicosis each year.[287] Thus, a problem that commanded national attention seventy years ago when the Gauley Bridge disaster was publicized remains serious due to regulatory policies that have been insufficiently precautionary.[288]

H. The Phaseout of TEL from Gasoline

Despite the *Ethyl* decision endorsing precautionary regulation, a serious attempt to repeal lead phasedown came shortly af-

282. *See id.* at 656. These aspects of the Court's decision have been criticized by opponents of the precautionary principle. *See, e.g.*, Cross, *supra* note 30, at 856 n.29.

283. THOMAS O. MCGARITY & SIDNEY A. SHAPIRO, WORKERS AT RISK: THE FAILED PROMISE OF THE OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION 57 (1993). (OSHA has been able to update only a small fraction of the initial industry consensus standards that it adopted, and it has not been able to implement most of the recommendations of its research arm, the National Institute for Occupational Safety and Health (NIOSH)).

284. PERCIVAL ET AL., *supra* note 1, at 379.

285. *Id.* at 378-79.

286. Morriss & Dudley, *supra* note 187, at 48-50.

287. *See id.* at 9.

288. In 1929, a total of 500 out of 2000 workers tunneling through a vein of nearly pure quartz in Gauley Bridge, West Virginia died from acute silicosis. *Id.* at 30.

ter the Reagan Administration took office in 1981. President Reagan created a Task Force for Regulatory Relief, chaired by then-Vice President George H.W. Bush, which invited business executives to nominate regulations that they thought should be repealed.[289] The lead phasedown program was near the top of the industry "hit list." The Task Force directed EPA to relax or abolish the lead standard.[290]

In response to this directive, EPA in February 1982 proposed relaxing or rescinding the lead standard for large refiners and suspending indefinitely the October 1, 1982 date for small refiners to comply with the 0.5gpg standard.[291] EPA based this proposal entirely on a desire to reduce the costs incurred by petroleum refineries. In developing the proposal EPA gave no consideration to the health effects of increased lead usage other than to state that eventually the use of leaded gasoline would cease after cars without catalytic converters disappeared from the highways.[292] Although President Reagan had decreed that all significant new regulatory proposals had to be subjected to rigorous cost-benefit analysis,[293] his administration did not interpret this decree to apply to proposals to relax regulations because they would save industry money. Thus, no attempt was made to determine whether relaxation of the lead standard would result in net benefits to society.[294]

The Reagan Administration's effort to relax the lead standard ultimately was unsuccessful, in part due to data that became available while EPA's rulemaking was underway. The scientific equivalent of a "smoking gun" linking leaded gasoline with lead poisoning was contained in the results of the second National Health and Nutrition Examination Study (NHANES II).[295] This study was conducted between 1976 and 1980, a period during which a substantial reduction occurred in the use of leaded gasoline as the result of turnover of the vehicle fleet to new cars using unleaded gasoline. The study showed that as gasoline lead use

---

289. Robert V. Percival, *supra* note 62, at 148.

290. *Id.* at 187-88.

291. Regulation of Fuel and Fuel Additives, 47 Fed. Reg. 7812 (proposed Feb. 22, 1982) (to be codified at 40 C.F.R. pt. 80).

292. *See id.* at 7813.

293. Exec. Order No. 12,291, 46 Fed. Reg. 13,193 (Feb. 19, 1981).

294. Robert V. Percival, *supra* note 62, at 187-88.

295. *See generally* J.L. ANNEST & K. MAHAFFEY, NATIONAL CENTER FOR HEALTH STATISTICS, SERIES 111 NO. 233, BLOOD LEAD LEVELS FOR PERSONS AGES 6 MONTHS – 74 YEARS: UNITED STATES, 1976-80 (1984).

declined between 1976 and 1980, mean blood levels declined in closely parallel fashion from 14.6 to 9.2 μg/dl.[296]

During the period from 1976 to 1980, use of lead additives in gasoline declined.[297] Over these same four years, median blood lead levels in the U.S. population aged six months to seventy years also declined by about 37 percent.[298] This decrease was observed in *all ages* sampled.[299] Thus it could not be related to sources such as paint, which present particular problems of exposure to young children. Of greater epidemiological significance, there was a similar decrease in the *prevalence* of children with blood-lead levels in excess of 30 μg/dl (formerly the definition of clinical lead toxicity).[300]

The NHANES II study represented the most significant demonstration of the link between lead additives in gasoline and human lead exposure. Because the study covered thousands of persons and gathered meticulous demographic information on them, it was possible to examine other variables to assess their contribution to the downward trend in levels of lead in human blood. The NHANES II data showed the extraordinary strength of the link between lead usage in gasoline and blood-lead levels, which persisted after controlling for age, sex, race, geographic regions, income levels, and other factors.[301] Other studies demonstrated that even as leaded gasoline usage fluctuated seasonally, blood-lead levels fluctuated in parallel fashion.[302]

In the face of overwhelming evidence that relaxation of the lead standard would dramatically increase the incidence of lead poisoning among children, the EPA abandoned its efforts to abolish the lead standard.[303] In October 1982, the agency adopted

296. *See id.* at 13.

297. Small Refiner Lead Phase-down Task Force v. EPA, 705 F.2d 506, 527 (D.C. Cir. 1983).

298. ANNEST & MAHAFFEY, *supra* note 295, at 13.

299. *See id.* at 3.

300. *See id.* at 7, 8 tbl.A.

301. *See generally id.*

302. *Small Refiner Lead Phase-down*, 705 F.2d at 528.

303. An unexpected, and influential, opponent of relaxing the lead standard was columnist George Will, who had befriended President Reagan. He wrote a powerful column praising the administration's proposal to strengthen limits on levels of lead in gasoline. George F. Will, *The Poison Poor Children Breathe*, WASH. POST, Sept. 16, 1982, at A23. Despite the NHANES data, Will stood virtually alone among the conservative establishment in opposing administration efforts to relax the lead standard. When EPA abandoned the proposal, the editors of the *Wall Street Journal* attacked the agency for giving into scare tactics by environmentalists. Editorial, *Lead Balloon*, WALL ST. J., Aug. 27, 1982, at A16. Louis Rukeyser, host of the popular television

new regulations that actually strengthened the existing standard by modifying it to restrict the total number of grams of lead that could be used per *leaded* gallon of gasoline produced, and by applying the same lead limits to all refiners, large and small.[304]

In a subsequent court challenge to the new standard brought by small refiners, the U.S. Court of Appeals for the District of Columbia Circuit was so impressed by the strength of the scientific evidence linking leaded gasoline with levels of lead in children's blood that it questioned why EPA had not decided to ban lead additives entirely.[305] The court concluded that,

> In sum, the demonstrated connection between gasoline lead and blood lead, the demonstrated health effects of blood lead levels of 30 μg/dl or above, and the significant risk of adverse health effects from blood lead levels as low as 10-15 μ g/dl would justify EPA in banning lead from gasoline entirely.[306]

Although scientific evidence was mounting that lead emissions posed an even greater danger to public health than previously believed, the EPA did not consider strengthening the lead standard again until it was confronted by an entirely separate problem. Emissions of conventional pollutants (e.g., hydrocarbons, nitrogen oxides, and carbon monoxide) from motor vehicles were increasing because many new cars that were supposed to use only unleaded gasoline were mis-fueled with leaded gasoline because it was slightly cheaper.[307] The use of leaded gasoline in new vehicles equipped with catalytic converters had rendered many of these emissions-control devices ineffective.[308] Environmentalists urged EPA to solve the mis-fueling problem by phasing out the use of gasoline lead additives.[309] Curiously, the decision to consider slashing the lead content of gasoline was initiated almost by accident. Prior to his death, former EPA Deputy Administrator Al Alm wrote that this action, which he believed to be the most significant EPA initiative during his five and one-half years at the agency, came about in the following manner:

---

program "Wall Street Week," called limits on lead in gasoline "economically damaging restrictions" that produced no "health gains." Louis Rukeyser, *The Lead War: Reagan Caves in on Deregulation*, RICH. TIMES-DISPATCH, Sept. 5, 1982, at G6.

304. *Small Refiner Lead Phase-down*, 705 F.2d at 513.

305. *See id.* at 530-31.

306. *Id.* at 531.

307. *See* Robert V. Percival, *supra* note 62, at 188.

308. *See id.*

309. *See id.*

> [T]he overwhelming environmental agenda facing EPA did not include further removal of lead from gasoline as a serious priority. Then by chance, in a meeting in my office, someone asked me, 'Why are you allowing *any* lead in gasoline? There don't appear to be any benefits from it, and there are any number of health risks.' On the basis of this statement, I commissioned a group of people in EPA's policy office to look into the problem. They came up with an absolutely superb document concluding that the risks of continuing to use lead in gasoline were high, and that the benefits of its continued use were negative. The argument for eliminating lead in gasoline clearly emerged as compelling, and it would have been irresponsible to pursue any other course.[310]

EPA staff then prepared a study of the costs and benefits of strengthening the lead standard as a means not only of protecting health, but also of reducing mis-fueling.

In March 1984, EPA released the results of this cost-benefit analysis, which showed that a 90-percent reduction in the lead content of gasoline would generate net benefits of several billion dollars.[311] While the cost of making gasoline would increase by less than 1 percent, EPA estimated that such a reduction in lead usage would reduce the number of children with blood-lead levels above 30 µg/dl by more than 50,000 in 1986; further, it would substantially reduce emissions of conventional pollutants by reducing mis-fueling while saving nearly a billion dollars annually in vehicle maintenance expenses.[312]

In August 1984, the EPA proposed to reduce the lead content of leaded gasoline by more than 90 percent (to 0.10 gpg), effective January 1, 1986.[313] EPA adopted this proposal in March 1985, along with an interim phasedown to 0.50 gpg, which became effective on July 1, 1985.[314] During the EPA rulemaking, new studies linking elevated lead levels in adult males with high blood pressure provided further evidence that the deleterious health effects

310. Al Alm, *The Multimedia Approach to Pollution Control: An Impossible Dream?, in* MULTIMEDIA APPROACHES TO POLLUTION CONTROL: A SYMPOSIUM PROCEEDINGS 114, 115 (1987).

311. *See* JOEL SCHWARTZ ET AL., COSTS AND BENEFITS OF REDUCING LEAD IN GASOLINE summary tbl.1 (1984).

312. *See id.* at I.7, III.2, IV.1, V.3.

313. Regulation of Fuels and Fuel Additives: Lead Phase Down, 49 Fed. Reg. 31,032, 31,032 (proposed Aug. 2, 1984).

314. Regulation of Fuels and Fuel Additives: Gasoline Lead Content, 50 Fed. Reg. 9386, 9386 (Mar. 7, 1985).

of lead emissions are not confined to young children.[315] Although EPA did not rely on the blood-pressure studies in making its decision to strengthen the lead standard, the studies did provide further impetus for banning lead from gasoline entirely.[316] In the 1990 Amendments to the Clean Air Act, Congress banned the sale of leaded gasoline after December 31, 1995.[317]

I. EPA's Asbestos Phaseout Rule and the *Corrosion Proof Fittings* Decision

Enacted in 1976, the TSCA was designed to provide EPA with an integrative approach to regulating substances whose uses, from cradle to grave, posed significant risks to human health and the environment.[318] After the legislation was signed into law by President Ford in October 1976, then-EPA Administrator Russell Train hailed it as "one of the most important pieces of 'preventive medicine' legislation ever passed by Congress."[319] However, TSCA has largely failed to achieve its promise of comprehensive, preventive regulation on a multi-media basis.

This is well illustrated by the Fifth Circuit's decision in *Corrosion Proof Fittings v. EPA*,[320] which invalidated one of EPA's most significant initiatives during the administrations of Presidents Reagan and George H.W. Bush: EPA's effort to phase out remaining uses of asbestos. EPA understood well the human health risks of asbestos, which had led it to ban some of the most dangerous uses of asbestos, including friable insulation products.[321] After an

---

315. *See* James L. Pirkle et al., *The Relationship Between Blood Lead Levels and Blood Pressure and Its Cardiovascular Risk Implications*, 121 AM. J. EPIDEMIOLOGY, No. 2, at 246 (1985).

316. *See* Albert L. Nichols, *Lead in Gasoline*, *in* ECONOMIC ANALYSES AT EPA: ASSESSING REGULATORY IMPACT 49, 71-75 (Richard D. Morgenstern ed., 1997).

317. Clean Air Act Amendments of 1990, Pub. L. No. 101-549, § 220, 104 Stat. 2399, 2500 (codified at 42 U.S.C. § 7545(n)). David Schoenbrod, a critic of congressional delegation of authority to agencies, argues that by authorizing EPA to deal with the lead-in-gasoline problem, Congress prolonged the continuation of this massive health hazard. *See* DAVID SCHOENBROD, SAVING OUR ENVIRONMENT FROM WASHINGTON: HOW CONGRESS GRABS POWER, SHIRKS RESPONSIBILITY, AND SHORTCHANGES THE PEOPLE 35-38 (2005). However, he fails to acknowledge that the final, total ban on tetraethyl additives was indeed mandated by Congress, albeit quite belatedly.

318. *See* Toxic Substances Control Act, Pub. L. No. 94-469, 90 Stat. 2003 (1976) (codified as amended at 15 U.S.C. §§ 2601-2692).

319. Press Release, EPA, Train Sees New Toxic Substances Law as "Preventive Medicine" (Oct. 21, 1976), http://www.epa.gov/history/topics/tsca/03.htm (internal quotation marks omitted).

320. 947 F.2d 1201, 1229-30 (5th Cir. 1991).

321. Proposed Amendments to Asbestos & Mercury Emission Standards, 39 Fed. Reg. 38,064, 38,064 (Oct. 25, 1974).

extensive investigation, which extended for more than a decade and included the promulgation of a rule requiring companies using asbestos to report data to EPA, the agency proposed its phaseout rule.[322] The agency issued the final rule based on its conclusion that only a staged-ban "will adequately control" the life cycle of asbestos exposure risks that occur whenever the substance is mined, used in manufacturing, released into the environment through deteriorating asbestos-containing products, or is disposed.[323] A panel of Fifth Circuit judges struck down this regulation, concluding that the agency had failed to perform sufficiently detailed cost-benefit analyses of banning not only each particular use of asbestos, but also of all intermediate alternatives short of a ban.[324]

Three aspects of the *Corrosion Proof Fittings* decision are particularly relevant to consideration of the precautionary principle: (1) the court's discussion of unquantified benefits, (2) its conclusion that EPA failed to perform sufficient analysis of the risks of substitutes for asbestos, and (3) its endorsement of EPA's decision to ban future uses of asbestos.[325] Section 6 of TSCA requires EPA to balance costs and benefits in determining if "there is a reasonable basis to conclude" that any chemical substance "presents or will present an unreasonable risk of injury to health or the environment."[326] The legislative history of TSCA indicates that Congress did not intend to require EPA to base its judgment concerning the reasonableness of risk on the results of detailed cost-benefit analyses. The House committee report on the legislation states that the balancing required by section 6 does not require "factual certainty" because "factual certainty respecting the existence of an unreasonable risk of a particular harm may not be possible."[327] The Senate committee report emphasized that "it is not feasible to reach a decision just on the basis of quantitative comparisons" because "one is weighing noncommensurates," and

322. Asbestos Restrictions, 51 Fed. Reg. 3738, 3738 (proposed Jan. 29, 1986).

323. Asbestos: Manufacture, Importation, Processing, and Distribution in Commerce Prohibitions, 54 Fed. Reg. 29,460, 29,468 (July 12, 1989).

324. *Corrosion Proof Fittings,* 947 F.2d at 1216-17.

325. *See id.* at 1216, 1218-21, 1229-30.

326. Toxic Substances Control Act, Pub. L. No. 94-469, § 6, 90 Stat. 2003 (1976) (codified as amended at 15 U.S.C. § 2605(a), (c)).

327. H.R. REP. No. 94-1341, at 32 (1976).

that EPA must give "full consideration" to the "burdens of human suffering and premature death."[328]

Despite this legislative history, the Fifth Circuit interpreted the statute not only to require detailed, product-by-product cost-benefit analyses, but also to require detailed analyses of the costs and benefits of every intermediate step short of a ban for controlling asbestos risks.[329] It also rejected EPA's conclusion that its "unreasonable risk determination" was justified because the benefits it could not quantify (given the lack of data on actual ambient air levels of asbestos attributable to particular asbestos products) were an order of magnitude greater than the quantified benefits.[330] Rather than employing conservative default assumptions when data were lacking, EPA analysts working on the asbestos phaseout rule instead assumed that where exposure data were lacking there was no exposure to asbestos.[331] This "led to easy agreements between EPA and OMB regarding the costs and benefits of the rule, and avoided charges that the agency might be overstating risk or understating costs"; but it ultimately resulted in a gross underestimation of the true risks posed by asbestos.[332] The reviewing court then rejected the agency's efforts to justify the phaseout rule on the basis of unquantified benefits.[333] The court's decision erected an impossibly high analytical burden that barred EPA from phasing out nearly all remaining uses of a substance that the agency believed posed an unreasonable risk to human health. In doing so, the court applied a kind of reverse precautionary principle. Its decision essentially declares that for a substance known to cause serious and irreversible damage to health, lack of certainty concerning the costs and benefits of all regulatory alternatives *shall be used* as a reason for not regulating it.

328. S. REP. NO. 94-698, at 13 (1976), *as reprinted in* 1976 U.S.C.C.A.N. 4491, 4503.

329. *See Corrosion Proof Fittings*, 947 F.2d at 1216-17, 1223.

330. *See id.* at 1218-19 ("Unquantified benefits can, at times, permissibly tip the balance in close cases. They cannot, however, be used to effect a wholesale shift on the balance beam.").

331. *See* Christine M. Augustyniak, *Asbestos*, *in* ECONOMIC ANALYSES AT EPA: ASSESSING REGULATORY IMPACT, *supra* note 316, at 171, 191-92.

332. *Id.* at 198.

333. *Corrosion Proof Fittings*, 947 F.2d at 1218-19. The court also rejected EPA's belated effort to rely on analogous exposure data (instead of assuming that the absence of exposure data meant the absence of risk), because the agency had not subjected the analogous exposure methodology to notice and comment procedures. *See id.* at 1212.

Critics of the precautionary principle argue that it is potentially paralyzing because any regulatory action may create risks of its own that could leave society worse off than before.[334] They frequently cite *Corrosion Proof Fittings* in support of this proposition because the court chastised EPA for failing to perform detailed analyses of the risks of substitutes for asbestos.[335] But the issue of the risks of substitutes arose during the asbestos rulemaking only because producers of asbestos, who maintained that their products did not pose significant risks, disingenuously argued that other products that might appear as substitutes for them would.[336] This was classic strategic behavior by the purveyors of one of the most thoroughly studied toxic substances (the legislative history of TSCA indicates that asbestos was one of the substances Congress considered to be a prime candidate for a phaseout),[337] and it was designed simply to erect yet another impossible analytic burden on an agency seeking to regulate a known risk. By requiring EPA to conduct an analysis of the toxicity of substitutes whenever a regulatory target "brings forth credible evidence" suggesting its toxicity, the Fifth Circuit applied a reverse precautionary principle that could prevent known unreasonable risks from being phased out if there is uncertainty concerning the risks of what may replace them.

Despite the decision's obvious faults, lurking in one aspect of *Corrosion Proof Fittings* is a surprisingly powerful endorsement of the precautionary principle. Almost unnoticed in the wake of the court's invalidation of the asbestos phaseout is the court's surprising holding affirming EPA's decision to ban all past asbestos products that no longer were being produced in the United States, as well as all unknown, future uses of asbestos.[338] The court noted that although products no longer being sold in the United States currently pose zero risk, "[t]his would soon change if the product returned, which is precisely what the EPA is trying to avoid."[339] For future products, the court conceded that "EPA cannot possibly evaluate the costs and benefits of banning unknown, uninvented

334. *See* sources cited *supra* notes 43, 45-46.

335. *See, e.g.*, SUNSTEIN, *supra* note 35, at 32.

336. The author represented Environmental Defense Fund during these and subsequent rulemakings. His description of the arguments that the lead and asbestos industry made is based upon his personal knowledge.

337. *See, e.g.,* 94 CONG. SENATE DEBATES 8281-8300 (1976).

338. *Corrosion Proof Fittings*, 947 F.2d at 1229.

339. *Id.*

products."[340] However, it held "that the nebulousness of these future products, combined with TSCA's language authorizing the EPA to ban products that 'will' create a public risk, allows the EPA to ban future uses of asbestos even in products not yet on the market."[341] For these products, the court requires neither cost-benefit analysis, nor analysis of the risks of possible substitutes. It recognizes that because the uncertainties surrounding future products make it impossible to perform such analyses, EPA's precautionary approach is proper to avoid the appearance (or re-appearance) of potentially deadly products.

While the Fifth Circuit's decision effectively precludes EPA from banning existing uses of asbestos, many other countries have done so, and even the World Trade Organization (WTO) has ruled in favor of such bans. As of January 2005, thirty-eight countries, including most EU member states, have banned asbestos.[342] In September 2000, a WTO dispute-resolution panel upheld France's ban on imports of chrysotile asbestos, rejecting arguments by Canada that it was an unjustified restriction on trade, an argument representatives of the Canadian asbestos industry had made during the EPA rulemaking.[343] The panel concluded that the risks of asbestos had been so thoroughly researched that the ban, which normally would violate WTO rules promoting free trade, was justified as necessary to protect human health.[344]

IV. CONCLUSION: REGULATORY POLICY & THE PRECAUTIONARY PRINCIPLE

The foregoing, rather extensive review of aspects of the history of U.S. regulatory policy offers some useful lessons concerning how society has responded to environmental risk and the value of a precautionary approach to regulation.

A. Lessons from the History of Lead Poisoning

The history of lead poisoning demonstrates that regulatory policy sometimes errs, and errs badly, by underestimating or over-

340. *Id.* at 1219.

341. *Id.*

342. Canadian Association of University Teachers, Current Asbestos Bans and Restrictions (Jan. 4, 2005), http://www.caut.ca/en/issues/asbestos/current_bans.pdf.

343. Panel Report, *European Communities—Measures Affecting Asbestos and Asbestos-Containing Products*, ¶¶ 8.231-8.241, WT/DS135/R (Sept. 18, 2000).

344. *Id.* ¶¶ 8.169-8.223.

looking truly significant risks.[345] While availability of scientific knowledge has a critical impact on regulatory priority-setting, public awareness of risk seems to be an even more important influence in focusing regulatory attention on suspected problems. Despite widespread awareness of the risks of exposure to lead, regulatory attention is far less likely to be devoted to similar chronic low-level environmental hazards than to acute highly visible incidents that command public attention.[346]

The deaths of workers producing TEL in the 1920s only briefly focused the attention of public health and regulatory authorities on the potential long-term health effects of lead in gasoline. Public alarm gave regulatory authorities an opportunity to consider whether to permit a new technology that ultimately would disperse massive quantities of a known toxic substance into the environment, causing enormous damage to public health. An appropriate precautionary step was taken when leaded gasoline temporarily was removed from the market pending the results of further research. Unfortunately, the study designed to assess the risks of leaded gasoline focused only on short-term exposures. Children, who we now know are the most susceptible to damage from lead emissions, were not included in the study, even though there already was some knowledge about what groups were likely to be most susceptible to damage from lead emissions.[347]

Perhaps the crucial shortcoming of regulatory policy was its failure to follow up on the initial studies of the health effects of TEL, despite the recommendations from the blue-ribbon panel that further long-term research was needed. As a result, for more than four decades virtually no research, independent of that per-

345. *See, e.g.*, Graham, *supra* note 36, stating that,

> Americans have experienced the pain and suffering that can result from insufficient precaution in risk management. The health risks of smoking, the neurotoxic effects of low doses of lead, once used as an additive to gasoline, and the respiratory diseases from exposure to asbestos in the workplace: each became major public health problems in the USA. Public health historians teach us that these problems could have been reduced or even prevented altogether if early signals of danger had stimulated precautionary measures by risk managers.

Id. See also Harremoës et al., *supra* note 8.

346. This also appears to apply to the enactment of environmental legislation. For example, CERCLA was enacted in response to Love Canal and other incidents involving widespread public concern over uncontrolled hazardous waste sites; the origins of the Emergency Planning and Community Right-to-Know Act can be traced to the Bhopal tragedy. PERCIVAL ET AL., *supra* note 1, at 224, 483.

347. *See* GERALD MARKOWITZ & DAVID ROSNER, DECEIT AND DENIAL: THE DEADLY POLITICS OF INDUSTRIAL POLLUTION 33-35 (2002).

formed by the lead industry, focused on the health effects of lead emissions from gasoline. In part, this may have been the product of an unwarranted perception that the question had been settled once and for all, at least for purposes of regulatory decision-making. Such myopia unfortunately is too frequently a feature of the regulatory process. A preliminary decision that a substance does not warrant regulatory attention may have an important influence on the future direction of scientific research.

While it is now known that public health would be far better off if regulators had never permitted the use of leaded gasoline, it was almost by coincidence that regulatory attention eventually focused on the health effects of lead additives. The initial EPA restrictions on the use of leaded gasoline were a response to the need to protect catalytic converters, rather than humans, from the effects of lead.[348] Similarly, the eventual decision to drastically reduce lead levels in gasoline was set in motion as much by frustration with the mis-fueling problem as by concern over the health effects of lead emissions. Yet once policymakers eventually focused on the appropriate questions, a compelling case was made for regulatory action.

While the elimination of lead additives from gasoline has been a major success story for environmental regulation, it is only one important element of the total problem of human lead exposure, which also includes a massive residue of lead paint in the urban housing stock and lead in plumbing and piping fixtures that carry drinking water. In 1980, a report by the National Academy of Sciences stressed the need for a coordinated approach to control all sources of human exposure to lead.[349] The report noted that "six federal agencies, acting under authority of at least eight separate laws, have developed regulations or administer programs intended to protect the public health from lead hazards."[350] Although TSCA was designed to provide EPA with such comprehensive regulatory authority, the *Corrosion Proof Fittings* decision effectively crippled the agency's ability to conduct multi-source, multi-media regulation by imposing seemingly impossible analytical preconditions on regulation.

---

348. *See* Warren T. Piver, *Potential Dilemma: The Methods of Meeting Automotive Exhaust Emission Standards of the Clean Air Act of 1970*, 8 ENVTL. HEALTH PERSPECTIVES 165, 165, 166, 178 (1974).

349. LEAD IN THE HUMAN ENVIRONMENT, *supra* note 81.

350. *Id.* at 4.

B. The Elusive Search for a Regulatory Decision Rule

Proponents of cost-benefit analysis as a regulatory decision rule are highly critical of the precautionary principle. Yet when they are asked to respond to potentially catastrophic risks that are so uncertain that one cannot with a straight face assign numerical values to the costs and benefits of controlling them, they end up suggesting something like a precautionary approach.[351] This is essentially what the *Corrosion Proof Fittings* court did in upholding EPA's ban on future uses for asbestos, and this is what society generally does in opting to protect endangered species.

While a cost-benefit analysis ultimately helped grease the wheels for EPA's decision to virtually eliminate lead additives from gasoline,[352] it ultimately was the undoing of the agency's initiative to phaseout most remaining uses of asbestos. The difference is not because the latter was a poor decision, but rather that it was more vulnerable to challenge because the agency deliberately had not employed its usual precautionary approach in estimating all of the benefits it anticipated from the rule.[353] That, combined with a reviewing court's imposition of impossibly detailed analytic requirements not contemplated by Congress when it enacted TSCA, led to invalidation of the rule and paralysis in using TSCA as a vehicle for addressing multi-media risks in a comprehensive fashion.

The *Ethyl* decision leaves little doubt that had EPA been required to base its initial decision to limit the amount of lead additives in gasoline on the results of a cost-benefit analysis, it would have been impossible to promulgate this crucial regulation.[354] The agency's initial rule was upheld by a five-four vote of the U.S. Court of Appeals for the D.C. Circuit, sitting *en banc*, in a decision expressly endorsing the precautionary principle.[355] Had this decision gone the other way, the lead limits would have been invalidated and the initial reductions in levels of lead in children's blood would not have occurred. Thus, a precautionary approach was crucial to the initial development of a regulation that was later

351. *See* Lisa Heinzerling, *The Accidental Environmentalist: Judge Posner on Catastrophic Thinking* 18-25 (Georgetown Univ. Law Ctr., Working Paper No. 770326, 2005) (reviewing RICHARD A. POSNER, CATASTROPHE: RISK AND RESPONSE (2004)), *available at* http://ssrn.com/abstract=770326; SUNSTEIN, *supra* note 35, at 109-128.

352. Nichols, *supra* note 316, at 49.

353. *See* Augustyniak, *supra* note 331, at 198-99.

354. *See* Frank Ackerman et al., *Applying Cost-Benefit to Past Decisions: Was Environmental Protection Ever a Good Idea?*, 57 ADMIN. L. REV. 155, 159-61 (2005).

355. Ethyl Corp. v. EPA, 541 F.2d 1, 28, 55 (D.C. Cir. 1976).

broadened to produce one of the most dramatic success stories for environmental regulation.

C. Fear Not the Precautionary Principle

The precautionary principle does not answer the question of how precautionary regulatory policy should be, but it can serve as an important reminder that regulatory policy should seek to prevent harm before it occurs, and that it should reject the insistence of regulatory targets that a never-ending quest for improved information should indefinitely postpone sensible regulatory measures. Despite the popularity of the precautionary principle, in practice U.S. regulatory policy generally has been reactive, rather than precautionary. Yet it has the capability of responding in a precautionary manner when a serious threat of potential harm, such as destruction of the Earth's protective ozone layer, captures public imagination and stimulates regulatory action.

The German concept of *Vorsorge*, from which the precautionary principle has evolved, emphasizes the importance of early detection of dangers to health and the environment through comprehensive research. The absence of pre-market testing requirements for new chemicals in the United States, and the lack of toxicity information for a large percentage of chemicals currently on the market,[356] may help explain the generally reactive nature of U.S. regulatory policy. This is why the environmental and public health communities have been pressing to require testing of high production volume chemicals and to close serious data gaps in EPA's Integrated Risk Information System.[357]

Critics of the precautionary principle have focused largely on a caricature of it that does not reflect the realities of global efforts to refine procedures for detecting and responding to environmental risks.[358] They argue that regulation creates its own hazards without making a persuasive case that control of known risks will lead to substitute hazards that are systematically likely to be worse, and less amenable to control, than those that have triggered precautionary regulation. A strong case can be made that

356. *See generally* EPA's Office of Pollution Prevention & Toxics, *Analysis of Test Data Availability for HPV Chemicals*, 22 CHEM. REG. REP. 261 (1998).

357. *See, e.g.*, Rena I. Steinzor et al., *Overcoming 'Environmental Data Gaps': Why What EPA Doesn't Know About Toxic Chemicals Can Hurt* (Ctr. Progessive Reform, White Paper #510, 2005).

358. See Applegate, *supra* note 44, which traces the "taming" of the precautionary principle as efforts have been made to integrate it into a risk assessment framework.

the consequences for society of false negatives (erroneously deeming a hazardous chemical to pose no hazard) generally are far worse than the consequences of false positives (erroneously deeming a safe chemical to be hazardous),[359] as illustrated by the history of regulation of lead and asbestos. Moreover, those who insist that the precautionary principle is undermined by potential secondary and tertiary *risks* spawned by regulatory action ignore the often-substantial secondary and tertiary *benefits* of regulation.[360]

Regulatory targets invariably seek to deflect attention from the risks their activities generate by pointing the finger elsewhere, as well illustrated by the regulatory history of both lead and asbestos.[361] As former EPA Administrator Christine Todd Whitman observed in her remarkably candid memoirs:

> Numerous businesses and trade associations, often represented by powerful Republicans, spend millions of dollars each year lobbying against virtually any new environmental regulation, invariably claiming it will hamstring their ability to stay in business, even though a great many American companies have figured out that good environmental practices are also good business practices. Many others, however, almost reflexively oppose any mandate to improve their environmental performance, no matter how much it needs improving. I sometimes wonder whether those companies spend more money trying to defeat new regulations than they would by simply complying with them.[362]

Fears that the precautionary approach inexorably will lead to massive overregulation greatly underestimate the ability of regulatory targets to fend off regulation.[363] This is reflected in the fact

359. For a discussion of these approaches, see Talbot Page, *A Generic View of Toxic Chemicals and Similar Risks*, 7 ECOLOGY L.Q. 207, 230-37 (1978).

360. *See generally* Rascoff & Revesz, *supra* note 49.

361. The Ethyl Corporation resisted regulation of tetraethyl lead by arguing that lead paint was the primary cause of childhood lead poisoning. During EPA's asbestos phaseout rulemaking, the asbestos industry told EPA that OSHA's ongoing rulemaking to tighten the standard for occupational exposure to asbestos made EPA's proposal unnecessary, while simultaneously arguing before OSHA that its proposed rule was infeasible. Again, this information is based on the author's personal knowledge. *See supra* note 336.

362. CHRISTINE TODD WHITMAN, IT'S MY PARTY TOO: THE BATTLE FOR THE HEART OF THE GOP AND THE FUTURE OF AMERICA 163-64 (2005).

363. *See generally* THOMAS O. MCGARITY ET AL., SOPHISTICATED SABOTAGE: THE INTELLECTUAL GAMES USED TO SUBVERT RESPONSIBLE REGULATION 17-18 (2004); Lisa Heinzerling & Frank Ackerman, *The Humbugs of the Anti-Regulatory Movement*, 87 CORNELL L. REV. 648, 670 (2002).

that the vast majority of the regulatory initiatives that have become the focus of critics of environmental regulation because they were projected to be overly costly were never actually implemented, as Lisa Heinzerling has demonstrated.[364]

Critics of the precautionary principle have picked on a straw man by arguing that it will produce overregulation when in fact, it does not specify how precautionary regulatory policy should be. Each sovereign country must decide for itself how precautionary regulatory policy should be, and such decisions ideally should be the product of democratic processes. Countries legitimately may opt to establish levels of environmental protection that are higher than those required by existing international standards. What the precautionary principle does is sensibly remind us of the reasons why environmental policy has shifted away from the common law's approach, which required individualized proof of causal injury before environmental harm could be redressed. While it is undoubtedly possible to be overly precautionary and to take actions in the name of precaution that end up backfiring, the history of regulatory policy suggests that adherence to the precautionary principle is more likely to contribute to avoiding a repetition of tragedies like those caused by tetraethyl lead and asbestos than it is to cause them. Fear not the precautionary principle.

364. Lisa Heinzerling, *Regulatory Costs of Mythic Proportions*, 107 YALE L.J. 1981, 1984 (1998).