

## Who's Afraid of the Precautionary Principle?

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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 states that a lack of scientific certainty should not preclude states from adopting cost-effective measures to control environmental risks.<sup>2</sup> The European Union has expressly endorsed the precautionary principle as part of its regulatory directives and some argue that the principle is so widely accepted that it should be recognized as customary international law.

Despite its growing popularity, the precautionary principle has come under fire in recent years. Its critics generally have been drawn from the ranks of those who are well known critics of environmental regulation. They argue that the precautionary principle is incoherent, potentially paralyzing, and that it will lead regulators to make bad choices.

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<sup>2</sup> "Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effect measures to prevent environmental degradation." Principle 15, United Nations Conference on Environment and Development, Declaration of Principles (1992), quoted in R. Percival, et al., *Environmental Regulation: Law, Science & Policy* 1039 (4<sup>th</sup> ed. 2003) ("Rio Declaration").

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 long has been an important element of much of U.S. environmental law, in practice, U.S. 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 -- 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. It 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.

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 still should 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.<sup>3</sup> Others trace it to a doctor's recommendation in 1854 to remove the handle of a water pump to stop a cholera epidemic<sup>4</sup> or to the 1874 amendment of the British Alkali Act that imposed technology-based limits on emissions of noxious gases by certain factories.<sup>5</sup>

Although many examples exist of precautionary measures being undertaken prior to the twentieth century,<sup>6</sup> 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 *vosorgeprinzip* developed in Germany during consideration of

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<sup>3</sup> Phillippe H. Martin, If you don't know how to fix it, please stop breaking it! 2 *Foundations of Science* 262 (1997), at 276.

<sup>4</sup> Paul Harremoes, et al., *The Precautionary Principle in the 20<sup>th</sup> Century: Late Lessons from Early Warnings* 5 (2002).

<sup>5</sup> Nigel Haigh, The Introduction of the Precautionary Principle into the UK, in *Interpreting the Precautionary Principle* (T.O'Riordan & J. Cameron 1994), at 241,

<sup>6</sup> See Daniel Bodansky, The Precautionary Principle in US Environmental Law, in *Interpreting the Precautionary Principle* (T.O'Riordan & J. Cameron 1994), at 204 (citing examples from the 1970 Clean Air Act in the United States).

legislation in the 1970s to prevent air pollution from damaging forests.<sup>7</sup> One translation of *vosorgeprinzip* into English is “principle of foresight planning,” though that does not adequately capture its true meaning.<sup>8</sup> *Vorsorge* is “a word that combines notions of foresight and taking care with those of good husbandry and best practice.”<sup>9</sup> It does not demand elimination of risk regardless of its likelihood or the costs entailed in doing so.<sup>10</sup> Rather, *vosorge* emphasizes the importance of developing mechanisms for detecting risks to human health and the environment so that measures can be taken to prevent harm. In 1984 the German Federal Interior Ministry explained the meaning of *vosorge* 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, synchronized (harmonized) research, in particular about cause and effect relationships. . . . [I]t also means acting when conclusively ascertained understanding by science is not yet available. Precaution means to develop, in all sectors of the economy,

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<sup>7</sup> Sonja Boehmer-Christiansen, *The Precautionary Principle in Germany – Enabling Government in Interpreting the Precautionary Principle* (T.O’Riordan & J. Cameron 1994), at 36.

<sup>8</sup> Timothy O’Riordan and James Cameron, *The History and Contemporary Significance of the Precautionary Principle* in *id.*, at 12.

<sup>9</sup> Noga Morag-Levine, *Chasing the Wind: Regulating Air Pollution in the Common Law State* 11 (2003).

<sup>10</sup> *Id.*

technological processes that significantly reduce environmental burdens, especially those brought about by the introduction of harmful substances.<sup>11</sup>

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. But during the 1980s these concepts came to be articulated more specifically as the precautionary principle, or precautionary approach,<sup>12</sup> which first was endorsed in a series of international agreements to protect the North Sea.<sup>13</sup>

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:

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<sup>11</sup> Federal Interior Ministry (BMI), *Dritter Immissionsschutzbericht 10/1345* (1984), at 53, quoted in Sonja Boehmer-Christiansen, *supra* note 5, at 37.

<sup>12</sup> 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* 92 (2002).

<sup>13</sup> See the 1984 Bremen Ministerial Declaration of the International Conference on the Protection of the North Sea (“Conscious that damage to the marine environment can be 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 . . .”) and the 1987 London Ministerial Declaration of the Second International Conference on the Protection of the North Sea (“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, *id.*, at 94 nn. 4 & 5.

“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.”<sup>14</sup>

While the English translation of Principle 15 refers to “the precautionary approach,” the official translation in several other languages refers to “the precautionary principle.”<sup>15</sup>

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<sup>16</sup> and in the Preamble to the Convention on Biological Diversity,<sup>17</sup> which were adopted at the Rio Earth Summit. The Maastricht Treaty of 1992 adopted the precautionary principle without explaining what it provides, as did the 1997 Treaty establishing the European Community (“EC Treaty”), which declared that EC environmental policy “shall be based on the

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<sup>14</sup> Rio Declaration, *supra* note 2.

<sup>15</sup> Per Sandin, *Better Safe than Sorry: Applying Philosophical Methods to the Debate on Risk and the Precautionary Principle in 5 Theses in Philosophy* from the Royal Institute of Technology 5 (2004) (noting, e.g., that the official Swedish translation uses the word “försiktighetsprincipen,” or precautionary principle).

<sup>16</sup> The United Nations Framework Convention on Climate Change commits its parties “to take precautionary measures to anticipate, prevent or minimize the cause of climate change and mitigate its adverse effects.” 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.” Article 3(3), United Nations Framework Convention on Climate Change, 31 I.L.N. 849 (1992).

<sup>17</sup> Preamble to the Convention on Biological Diversity (“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.”) (1992), quoted in De Sadeleer, *supra* note 7, at 97.

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.”<sup>18</sup> 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.<sup>19</sup>

The United States government has been reluctant to embrace the precautionary principle, even though it generally is 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 U.S. and the EU with the U.S. arguing that it should not be applied to justify banning the importation of genetically modified food products. In May 2003, the U.S., with the support of Canada, filed a complaint with the World Trade Organization (WTO), charging that the moratorium applied by the European Commission (EC) since October 1998 on the approval of biotech products has restricted imports of agricultural and food products from the US and Canada. The U.S. 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 for import and marketing in the EC.<sup>20</sup>

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<sup>18</sup> Article 174, Treaty of Amsterdam Amending the Treaty on European Union, the Treaties Establishing the European Communities and Related Acts (1997).

<sup>19</sup> Communication from the Commission on the Precautionary Principle (COM(2000) 1).

<sup>20</sup> In the “beef hormones dispute,” the WTO previously had endorsed the notion 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. It also

## 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 argued that “the precautionary principle is deeply perverse in its implications for the environment and human welfare.”<sup>21</sup> Complaining that the growing popularity of the precautionary principle threatened risk analysis, Gail Charnley complained that the principle was anti-science and its proponents were waging “the newest skirmish in the age-old battle between science and ideology.”<sup>22</sup> Aaron Wildavsky complained that the precautionary principle is “a marvelous piece of rhetoric”<sup>23</sup> and Bjørn Lomborg maintained that if it is used to strengthen environmental protections, “the precautionary principle is actually all about making *worse* decisions than we need to.”<sup>24</sup> More recently, Robert Hahn and Cass Sunstein argue that “taken seriously, the precautionary principle can be paralyzing, providing no direction at all,”<sup>25</sup> in contrast to

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has emphasized that the Agreement on the Application of Sanitary and Phytosanitary Measures has expressly recognized “the sovereign right of Members to provide the level of health protection they deem appropriate.”<sup>20</sup> 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.” WTO Director General Pascal Lamy, Speech, October 10-11, 2005, Geneva, Switzerland, at [http://www.wto.org/english/news\\_e/sppl\\_e/sppl07\\_e.htm](http://www.wto.org/english/news_e/sppl_e/sppl07_e.htm) (last visited, October 14, 2005).

<sup>21</sup> Frank B. Cross, Paradoxical Perils of the Precautionary Principle, 53 Wash. & Lee L. Rev. 851, 851-852 (1996).

<sup>22</sup> Gail Charnley, President’s Message, 19 RISK Newsletter 2 (1999); Gail Charnley, Annual Meeting: Past President’s Message, 20 RISK Newsletter 3 (2000).

<sup>23</sup> Aaron Wildavsky, But Is It True? 428 (1995).

<sup>24</sup> Bjørn Lomborg, The Skeptical Environmentalist: Measuring the Real State of the World 350 (2001).

<sup>25</sup> Robert W. Hahn and Cass R. Sustein, The Precautionary Principle as a Basis for Decisionmaking, 2 The Economists’ Voice 7 (2005).



cost-benefit analysis, which they favor as a decision rule. Sunstein devotes much of his book “The Laws of Fear: Beyond the Precautionary Principle” to attacking the principle as indefensible, though he ultimately concludes that it can be useful in some circumstances.<sup>26</sup>

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.”<sup>27</sup> In a recent lecture Cass Sunstein declares that “the precautionary principle is incoherent.”<sup>28</sup>

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. 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.”<sup>29</sup> 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

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<sup>26</sup> Cass R. Sunstein, *Laws of Fear: Beyond the Precautionary Principle* (2005).

<sup>27</sup> John Graham, *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,”

<sup>28</sup> Cass Sunstein, Eleventh Annual Lloyd Garrison Lecture, “Irreversible and Catastrophic: Global Warming, Terrorism, and Other Problems,” at the Pace University School of Law, April 25, 2005 (transcript on file with author).

<sup>29</sup> Principle 15, Rio Declaration, *supra* note 14. The words “cost-effective” in Principle 15 reportedly were added at the insistence of the U.S. delegation to the Rio Earth Summit.

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.<sup>30</sup> 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 private groups demanding unambiguous evidence of harm, which no rational society requires.”<sup>31</sup>

Rather than focusing their fire on the Rio Declaration, critics of the precautionary principle focus on what they describe as a “strong version” of it that would require stringent regulation of anything that cannot be shown *not* to pose a possible risk to health, safety, or the environment.<sup>32</sup> For example, Frank Cross argues:

Applied fully and logically, the precautionary principle could cannibalize itself and potentially obliterate all environmental regulation. Environmentalists would apply the principle to chemicals and industries, but why not apply it to the

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<sup>30</sup> See, e.g., Bjørn Lomborg, *supra* note 23, at 349; Frank B. Cross, *supra* note 20, at 920.

<sup>31</sup> Sunstein, *supra* note 25, at 23, 24.

<sup>32</sup> 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. 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.” They use the Wingspread Statement as a strawman 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.

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.<sup>33</sup>

Such an extreme version of the precautionary principle seems far-fetched, but its critics at times seem intent on creating a caricature of it in an effort to defuse its growing popularity.<sup>34</sup> Their 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 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.<sup>35</sup> This objection is similar to the now-familiar “risk-risk” tradeoff argument made by critics of environmental regulation.<sup>36</sup> 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

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<sup>33</sup> Frank B. Cross, Paradoxical Perils of the Precautionary Principle, 53 Wash. & Lee L. Rev. 851, 861 (1996).

<sup>34</sup> As John Applegate notes, “the precautionary principle is frequently caricatured as requiring the regulator to ban or forego an activity or technology altogether, and sometimes it has been used to justify such action (for example, bans on genetically modified organisms (GMOs)). 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. John S. Applegate, The Taming of the Precautionary Principle, 27 Wm. & Mary Envtl. L. & Pol. Rev. 12, 20-21 (2002).

<sup>35</sup> See Sunstein, *supra* note \_\_, at 26-32.

<sup>36</sup> See John D. Graham & Jonathan Weiner, Risk Versus Risk: Tradeoffs in Protecting Health and the Environment, Harv. Univ. Press (1995).

take their place and be even more significant. Since history teaches that the most common way society becomes aware of risk is from the actual manifestation of harm,<sup>37</sup> 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, risk-tradeoff analysis has been shown to be biased against environmental regulation because it focuses only on ancillary risks generated by regulation and not on regulation's ancillary benefits.<sup>38</sup> 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 ancillary benefits for public use and preservation of habitats. Medical interventions--most notably drug therapies--have been observed to have significant ancillary benefits.<sup>39</sup>

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<sup>37</sup> This phenomenon is referred to as “the dilemma of preventive regulation” in Robert Percival, Christopher Schroeder, Alan Miller & James Leape, *Environmental Regulation: Law, Science and Policy* 343-45 (4<sup>th</sup> ed. 2003).

<sup>38</sup> See Rascoff & Revesz, *The Biases of Risk Tradeoff Analysis: Toward Parity in Environmental and Health-and-Safety Regulation*, 69 *U. Chic. L. Rev.* 1763 (2002).

<sup>39</sup> *Id.* at 1766.

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.<sup>40</sup> 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.<sup>41</sup> David Dana has presented a strong counter-argument that the precautionary principle is justified as a mechanism to counteract the same cognitive biases on which Sunstein relies.<sup>42</sup> 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. Sunstein concedes that this criticism “is not implausible” and “undoubtedly leads to some good results.”<sup>43</sup> But he maintains that the same myopia that supports Dana’s argument also would apply to the public’s perceptions of the countervailing risks

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<sup>40</sup> Frank B. Cross, *Paradoxical Perils of the Precautionary Principle*, 53 *Wash. & Lee L. Rev.* 851, 898-899 (1996).

<sup>41</sup> See Sunstein, *supra* note 25, at 36-49.

<sup>42</sup> David A. Dana, *A Behavioral Economic Defense of the Precautionary Principle*, 97 *Nw. Univ. L. Rev.* 1315, 1320-1330 (2003).

<sup>43</sup> Sunstein, *supra* note 25, at 53.

that would be incurred by the taking of precautionary action.<sup>44</sup> Thus, Sunstein's argument appears to rest largely on the notion that precautionary action is more likely to be counter-productive than beneficial because the public is incapable of knowing what statistically is in its best interests. He concludes that only cost-benefit analysis offers a way out of this self-constructed conundrum, without analyzing how efforts to quantify the costs and benefits of regulation may distort decisionmakers' perceptions of the levels of uncertainty associated with them. Yet he ultimately concedes that for risks to 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.

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 European Union (EU). 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. 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."<sup>45</sup> Ironically, this criticism of the precautionary principle -- that it can be manipulated to promote arbitrary decisionmaking -- 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

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<sup>44</sup> *Id.*

<sup>45</sup> Gary E. Marchant & Kenneth L. Mossman, *Arbitrary and Capricious: The Precautionary Principle in the European Union Courts* 72 (2005).

regulatory constraints on industry.<sup>46</sup>

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 dimension.<sup>47</sup> The “threat dimension” refers to the potential dangers of the activity, product or substance that would trigger precautionary action. The “uncertainty dimension” refers to the limits of knowledge concerning whether the regulatory target poses the hazard. 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. 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?

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<sup>46</sup> See Robert V. Percival, Checks Without Balance: Executive Office Oversight of the Environmental Protection Agency, 54 Law & Cont. Problems 127, 184-89 (1991).

<sup>47</sup> Per Sandin, Dimensions of the Precautionary Principle, 5 Human and Ecol. Risk Assessment 889 (1999).

(4) With what force are these measures recommended (mandatory, merely permitted, etc.)?<sup>48</sup>

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 concerning 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.<sup>49</sup> One should not postpone 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.

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<sup>48</sup> Per Sandin, Martin Peterson, Sven Ove Hansson, Christina Ruden, and Andre Juthe, *Five Charges Against the Precautionary Principle*, 5 *Journal of Risk Research* 287, 290 (2002).

<sup>49</sup> 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. *Id.* at 289. As an example of a prescriptive version of the principle, Sandin cites the Wingspread Declaration.



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 they must be informed by the products of democratic political processes. 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 in decisionmaking processes in many of these countries.<sup>50</sup>

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. As John Applegate notes, this Communication seeks “to fit the precautionary principle into the risk paradigm” rather than serving as an alternative to it.<sup>51</sup> 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:

4. 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.

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<sup>50</sup> See, e.g., Adrian Devill & Ronnie Harding, *Applying the Precautionary Principle* (1997).

<sup>51</sup> Applegate, *supra* note 32, at 61.

5. 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 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.

6. 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.<sup>52</sup>

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, it endorses measures to require prior approval of potentially dangerous products and

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<sup>52</sup> Commission of the European Communities, Communication from the Commission on the Precautionary Principle, February 2, 2000, COM (2000) 1.

in certain cases shifting the burden of proof to the producer, manufacturer or importer.<sup>53</sup>

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 U.S.<sup>54</sup> 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, environmental tobacco smoke and terrorism. Although this has been deemed a surprise because the precautionary principle has been much more influential in Europe than in the U.S., 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 policy 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. 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 ROLE OF PRECAUTION IN U.S. ENVIRONMENTAL LAW

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<sup>53</sup> 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 (ii) an assessment of the risk-weighted consequences of various options.” Deville and Harding, *supra* note 43, at 13.

<sup>54</sup> Jonathan B. Weiner, *Whose Precaution After All? A Comment on the Comparison and Evolution of Risk Regulatory Systems*, 13 *Duke J. Comp. & Intl. L.* 207 (2003).

Review of the history of U.S. environmental law can shed light on why Congress took a decidedly precautionary turn when it adopted comprehensive regulatory legislation to protect human health from environmental risks during the 1970s. 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.<sup>55</sup> Yet despite the regulatory statutes' commitment to preventative regulation, chemicals still rarely are regulated until after they have been released into the environment and damage to public health has become apparent.<sup>56</sup> This "dilemma of preventative regulation" reflects the facts that it always is 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 regulatory policy will make bad choices if it responds to what they view as excessive public fear of certain risks. Yet the

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<sup>55</sup> See, e.g., Mary Douglas & Aaron Wildavsky, *Risk and Culture* (1982); Peter W. Huber, *Safety and the Second Best: The Hazards of Public Risk Management in the Courts*, 85 *Colum. L. Rev.* 277 (1985); Kenneth R. Foster, David E. Bernstein and Peter W. Huber, *Phantom Risk: Scientific Inference and the Law* (1993); Philip H. Abelson, *Toxic Terror; Phantom Risks*, 261 *Science* 407 (1993).

<sup>56</sup> 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. 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.

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 with 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.

#### *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 its chemical properties make it easy to use in a variety of products, lead performs no useful function in the human body. Exposures from anthropogenic sources have caused lead to be present in the bodies of all humans as a result of the use of lead in products, paint, plumbing, emissions from gasoline combustion and smelters, and lead in waste streams. 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). The Industrial Revolution and a massive increase in combustion of leaded gasoline have increased lead

levels in icecap strata today to a level (0.2100 mg/kg) more than 400 times natural background levels.<sup>57</sup>

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. At lower levels of exposure, lead can cause anemia, kidney damage, neurological injury, reproductive and developmental dysfunction. Lead also interferes with blood biochemistry and is associated with high blood pressure.<sup>58</sup> At some level of exposure to lead "virtually all body systems will be injured or have a high risk of injury."<sup>59</sup> But lead also is particularly dangerous because of the apparently irreversible neurologic and reproductive damage that it can cause even at relatively low levels of exposure that still are not uncommon today. Because many of the health effects caused by exposure to lead do not have easily identifiable symptoms, lead poisoning is often difficult to diagnose, 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. 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

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<sup>57</sup> National Research Council, *Lead in the Human Environment* (1980); Thomas D. Matte, Philip J. Landrigan & Edward L. Baker, "Occupational Lead Exposure" in *Human Lead Exposure* 155 (Needleman, ed. 1992).

<sup>58</sup> 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* (July 1988).

<sup>59</sup> *Id.* at IV-3.

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.<sup>60</sup> 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. 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.<sup>61</sup> While in Paris in 1767, Franklin visited a hospital that had become famous for treating "what he called Dry Bellyach, or Colica Pictonum." After obtaining a list of the occupations of the patients, Franklin noted that:

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

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<sup>60</sup> An Act for Preventing Abuses in Distilling of Rum and other Strong Liquors, with Leaden Heads or Pipes, enacted Sept. 3, 1723, quoted in Carey P. McCord, *Lead and Lead Poisoning in Early America*, 22 *Ind. Medicine & Surg.* 393, 397 (1953). The Act declared that "the strong liquors and spirits that are distilled through leaden heads or pipes are judged on good grounds to be unwholesome and hurtful." It specified a fine of one hundred pounds for each violation and directs municipalities to appoint inspectors to enforce the prohibition. 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.*

<sup>61</sup> Marjorie Smith, *supra*, at 20-21; Carey P. McCord, *Lead and Lead Poisoning in Early America: Benjamin Franklin and Lead Poisoning*, 22 *Ind. Medicine & Surg.* 393-394 (1953).

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 molten 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.<sup>62</sup>

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 practic'd on."<sup>63</sup>

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,<sup>64</sup> but health and safety regulation otherwise was 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.<sup>65</sup> In 1907 Illinois created a Commission on Occupational Diseases whose report helped win enactment in 1911 of an Occupational Diseases Act. This legislation required employers to "adopt and provide reasonable and appropriate devices, means or methods for the prevention of such

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<sup>62</sup> Benjamin Franklin, Letter to Benjamin Vaughan, July 31, 1786, reprinted in McCord, *supra*, at 398.

<sup>63</sup> *Id.*

<sup>64</sup> Robert L. Rabin, Federal Regulation in Historical Perspective, 38 *Stan. L. Rev.* 1189, 1196 (1986). Congress initially adopted legislation regulating steamships boilers in 1838 and then strengthened the law in 1852.

<sup>65</sup> David Rosner & Gerald Markowitz, *Dying for Work* 65 (1987).



industrial or occupational diseases as are incident to such work or process.”<sup>66</sup> However, the preventative provisions in the law were largely unenforced until the 1930s when they were struck down by the Illinois Supreme Court as “an unwarranted and void delegation of legislative power.”<sup>67</sup>

In 1906, Congress responded to public concern about the safety of the food supply by enacting federal meat inspection legislation<sup>68</sup> and the Pure Food and Drugs Act.<sup>69</sup> 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.<sup>70</sup> 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.<sup>71</sup>

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<sup>72</sup> and that environmental, in addition to occupational, sources of lead could be significant. A link between use of lead-based paint and childhood lead

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<sup>66</sup> Claudia Clark, *Radium Girls: Women and Industrial Health Reform, 1910-1935* 188 (1997).

<sup>67</sup> *Vallat v. The Radium Dial Company*, 360 Ill. 407, 412-13 (1935).

<sup>68</sup> Meat Inspection Act, 34 Stat. 669 (1906).

<sup>69</sup> Pure Food and Drugs Act, 34 Stat. 768 (1906).

<sup>70</sup> Robert L. Rabin, *Federal Regulation in Historical Perspective*, 38 *Stan. L. Rev.* 1189, 1228-1229 (1986).

<sup>71</sup> Chris Schroeder, *The Evolution of Federal Toxics Policy* 31 (Wilson Center Working Paper, June 1984).

<sup>72</sup> T. Oliver, *Lead Poisoning* (1914).

poisoning had been established in Australia by Lockhart Gibson in 1899. Earlier, it had been shown that the children of workers in the Staffordshire potteries were intoxicated by the lead brought into the home by their parents, whose working conditions were appallingly contaminated.<sup>73</sup> 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*

By the early 1920s, lead poisoning was well recognized as a major public health problem. A German publication in 1922 listed more than three thousand references to lead poisoning in scientific literature.<sup>74</sup> A medical monograph published in the U.S. 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.<sup>75</sup>

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, 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

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<sup>73</sup> Id.

<sup>74</sup> E. Blansdorf, *Bleiliteratur Schriften aus dem Gesamtgebiet der Gewerbehygiene* (1922).

<sup>75</sup> Joseph C. Aub, Lawrence T. Fairhall, A.S. Minot & Paul Reznikoff, *Lead Poisoning* ix (1926).

increased industrial use of lead. The discovery of tetraethyl lead ensured that every street and highway in the nation would be dusted with substantial lead deposits.

To facilitate the manufacture of cars with larger engines, General Motors sought to develop a new fuel additive that would enhance gasoline combustion and avoid engine knock. After testing 33,000 chemical compounds during years of trial and error experimentation, GM researcher Thomas Midgley, Jr., discovered in December 1921 that tetraethyl lead had the properties it desired.<sup>76</sup> General Motors joined with Standard Oil of New Jersey to form the Ethyl Corporation to market the new lead additive. 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.

On December 22, 1922, Hugh Cumming, the U.S. Surgeon General, sent a letter to Pierre Du Pont that reflected an awareness of the severity of the lead poisoning problem. 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 tetraethyl in engines."<sup>77</sup> DuPont referred the letter to Midgley. Although Midgley had become severely lead poisoned as a result of his research, he was convinced that the effects of his own illness were reversible and that tetraethyl lead (TEL) posed no

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<sup>76</sup> Seth Cagin & Philip Dray, *Between Earth and Sky* 34 (1993). In addition to Cagin & Dray, the other comprehensive description of the history of the controversy over introduction of tetraethyl lead into gasoline is Rosner & Markowitz, "A Gift of God?: The Public Health Controversy over Leaded Gasoline During the 1920s," 75 *Amer. J. Public Health* 344 (1985).

<sup>77</sup> Cagin & Dray at 36.

danger to the public because it would be sold in diluted form.<sup>78</sup> 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.”<sup>79</sup>

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. 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. Several dozen other workers also had been hospitalized.<sup>80</sup> Dubbed "loony gas" in the popular press, TEL subsequently was found to be responsible for four other deaths of workers in a DuPont plant, two deaths in a GM facility, and many other hospitalizations.<sup>81</sup> 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 tetraethyl lead.<sup>82</sup>

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<sup>78</sup> Id. at 35-36.

<sup>79</sup> Id. at 36-37.

<sup>80</sup> R. Wedeen, *The Politics of Lead*, in *Toxic Circles* 168-200 (Sheehan & Wedeen, eds. 1993).

<sup>81</sup> Id. at 49-50.

<sup>82</sup> There were at least thirteen deaths from exposure to TEL in the various plants. Willard F. Machle, *Tetra Ethyl Lead Intoxication and Poisoning by Related Compounds of Lead*, 105 *J. Amer. Med. Ass.* 578 (1935). In the best traditions of tabloid journalism, the *New York World* issued the following forecast of what would happen if TEL was widely used in gasoline: ". . . then when you go out in front of your house or shop when the dust is stirred up, as New York dust always is, and snuff and snuff until you have inhaled from two to three milligrams, and do this every day for a week, then you will be a goner." *Mines Bureau Hit by Health Service for Partial O.K. of Ethyl Gasoline*, *N.Y. World*, May 3, 1925.

In March 1925, the Bureau of Mines released its study of the health effects of TEL. The study was based on research exposing rabbits, dogs, sheep, ducks and rats to exhaust from autos burning leaded gasoline for several hours a day over a period of months. It found no health risks from exposure to the exhaust fumes. Public health officials criticized the study because the Bureau of Mines had little expertise on health issues and the study had been funded by GM and Standard Oil. At the urging of Harvard public health professor Alice Hamilton and others, the Surgeon General convened a conference in May 1925 to consider the health risks of TEL. 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. The manufacturers of such additives agreed not to sell them until the panel convened by the Surgeon General completed its studies.

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. In January 1926, the PHS released its study, which detected no difference in the health of the different groups of subjects. 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.<sup>83</sup> The study concluded that workers in tetraethyl lead plants could be adequately protected by installing devices to prevent worker exposure to fumes. Dangers to gas station attendants were deemed slight and dangers to the general public were thought to be virtually nonexistent unless they used

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<sup>83</sup> Id. at 54.

gasoline to clean textiles. To control the latter risk, it was agreed that lead gasoline should be dyed and clearly labeled as such.

The study provided little basis for evaluating the long-term health effects of emissions from leaded gasoline and it was criticized by Alice Hamilton and other members of the public health community who wanted a safe substitute for TEL to be developed. 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.<sup>84</sup> 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.<sup>85</sup>

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.”<sup>86</sup> However, she noted that “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.”<sup>87</sup> Hamilton thought the Tetraethyl Lead Conference had

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<sup>84</sup> See generally Clark, *supra* note 59.

<sup>85</sup> *Id.* at 154.

<sup>86</sup> Alice Hamilton, *Nineteen Years in the Poisonous Trades*, *Harper's*, Oct. 1929, at 587.

<sup>87</sup> *Id.*

at least helped protect workers in tetraethyl lead 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.<sup>88</sup>

The Surgeon General actually had recognized that the Public Health Service study was inadequate for assessing the long-term effect of lead additives on human health. His report, issued in 1926, warned that:

"It remains possible that, if the use of leaded gasolines 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 lead poisoning 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.... With the experience obtained and the exact methods now available, it should be possible to follow closely the outcome of a more extended use of this fuel and to determine whether

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<sup>88</sup> Alice Hamilton, *Exploring the Dangerous Trades* 416-417 (1943). This statement has puzzled historians in light of the fact that the conference disregarded Hamilton's plea that a substitute for tetraethyl lead be developed to protect public health. William Graebner states that "its overly sanguine character might be explained as the product of the nearly two-decade lapse between the event and its recollection" and Hamilton's "ardent belief in cooperation and persuasion as problem-solving devices." William Graebner, *Private Power, Private Knowledge, and Public Health: Science, Engineering, and Lead Poisoning, 1900-1970*, in *The Health and Safety of Workers* 38 (R. Bayer, ed. 1988).

or not it may constitute a menace to the health of the general public after prolonged use or under 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."<sup>89</sup>

However, in the decades to follow, the lead industry continued to control virtually all research and the close monitoring recommended by the Surgeon General was not undertaken. It was not until the 1970s that regulatory attention focused on the chronic effects of exposure to lead on children's health. The U.S. refused to sign the 1921 International Labor 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.

The lead industry worked hard to convey the impression that extensive scientific investigation had resolved all concerns about the health effects of lead emissions from gasoline combustion. Promoting the notion that most human lead exposure was part of a natural process, Dr. Robert Kehoe, medical director for the Ethyl Corporation, argued that the human body excreted as much lead as it absorbed.<sup>90</sup> Thus, according to the industry, there was little cause for concern about the rapidly increasing use of lead in industrial products. However, there was evidence that levels of lead in street dust had increased by 50 percent in the first decade after the introduction of tetraethyl lead in

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<sup>89</sup> Rosner and Markowitz, *supra* at .

<sup>90</sup> See Robert A. Kehoe, Frederick Thamann & Jacob Cholak, On the Normal Absorption and Excretion of Lead, 15 *J. Ind. Hygiene* 257 (1933).



gasoline.<sup>91</sup> Reports of widespread lead poisoning in children continued to mount during the 1950s. Julian Chisholm reported that Baltimore children were excreting six times more lead than workers exposed to lead in occupational settings.<sup>92</sup> Physicians in Philadelphia reported that 41 children had died from lead poisoning between 1956 and 1960 and that the annual death toll was increasing.<sup>93</sup>

In 1959 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. Without making any effort to evaluate the extent to which prior use of tetraethyl lead had contributed to air emissions of lead, an advisory committee formed by the U.S. Public Health Service decided that this would not pose a hazard to public health. Efforts to monitor levels of lead in ambient air were launched in the early 1960s. In 1961, the U.S. Public Health Service 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.<sup>94</sup> The Public Health Service later conducted a “seven-city study”<sup>95</sup> in cooperation with representatives of the lead industry. As with previous studies involving the lead industry, the Public Health Service continued to permit the lead-industry representatives

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<sup>91</sup> S. Kaye and P. Reznikoff, A Comparative Study of the Lead Content of Street Dirts in New York City in 1924 and 1934, 29 *J. Indus. Hygiene* 178 (1947). This report was virtually ignored.

<sup>92</sup> J.J. Chisholm & H.E. Harrison, The Exposure of Children to Lead, 18 *Pediatrics* 943 (1956).

<sup>93</sup> Ingalls, Tiboni & Werrin, Lead Poisoning in Philadelphia, 1955-1960, 3 *Archives of Env'tl Health* 575, 576 (1961).

<sup>94</sup> J.R. Goldsmith, J.R. and C.A. Hexter, Respiratory exposure to lead: Epidemiological and experimental dose-response relationships, 158 *Science* 132-134 (1967).

<sup>95</sup> L.B. Tepper and R. Levine, R., A survey of air and populations lead levels in selected American communities, in *Lead* 152-195 ( T.R. Griffin and J. H. Knelson, eds., 1975).

to control the dissemination of information about the studies' results.<sup>96</sup> Based on these studies, the Public Health Service declared in 1965 that existing levels of lead in the ambient air did not pose a significant threat to public health.

In Senate hearings held in 1966, 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.”<sup>97</sup> 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.”<sup>98</sup>

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.<sup>99</sup> 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.<sup>100</sup> Kehoe maintained that this should not be of concern because studies “have demonstrated clearly that the quantity of lead which is being

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<sup>96</sup> The Public Health Service had agreed that the results of the studies could not be made public without the permission of the lead industry. G.S. Wetstone & J. Goldman, *Chronology of Events Surrounding the Ethyl Decision*, in *Judicial Review of Scientific Uncertainty* (Davis, et al., eds. 1981).

<sup>97</sup> *Air Pollution - 1966, Hearings before a Subcomm. on Air and Water Pollution of the Senate Comm. on Public Works, 89th Cong., 2d Sess, 204 (1966)* (statement of Robert Kehoe, Medical Director, Ethyl Corporation).

<sup>98</sup> *Id.*

<sup>99</sup> “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.

<sup>100</sup> *Id.* at 209.

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.”<sup>101</sup>

Yet even Kehoe conceded that “Lead poisoning in industry is still one of the most frequent occupational diseases . . . despite the fact that we know how to prevent it.”<sup>102</sup> 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. Wormser blamed “misdiagnosis” for “unduly increased public concern about lead.” 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.”<sup>103</sup> 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.”<sup>104</sup> Wormser concluded that “more is known about the biological effects of lead than about almost any other air-borne substance.” 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.”<sup>105</sup>

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

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<sup>101</sup> Id. at 206, 220.

<sup>102</sup> Id. at 205.

<sup>103</sup> Id. at 235.

<sup>104</sup> Id.

<sup>105</sup> Id. at 239.

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."<sup>106</sup>

Kehoe's claims were challenged by Clair Patterson, a scientist with the California Institute of Technology. At the same Senate hearings in 1966, he criticized public health officials and the academic community for defending and promoting "ideas that may be dangerous to the health of all Americans." Based on his own 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.<sup>107</sup> 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.<sup>108</sup>

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.<sup>109</sup> This legislation amended the 1965 Motor Vehicle Air Pollution Control

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<sup>106</sup> Id. at 207.

<sup>107</sup> Air Pollution - 1966, Hearings before a Subcomm. on Air & Water Pollution, Senate Comm. on Public Works, 89th Cong., 2d Sess. 314 (1966).

<sup>108</sup> Id. at 314-315. 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 (on the order of 200-500 fold) due to centuries of human use. D.M. Settle and C.C. Patterson, Lead in Albacore: Guide to Lead Pollution in Americans, 207 Science 1167 (1980).

<sup>109</sup> Pub. L. No. 90-148, 81 Stat. 485 (1967).

Act,<sup>110</sup> which had initiated the process of establishing federal emissions standards for new motor vehicles. Ironically, the first regulatory action that reduced levels of lead in ambient air was a mandate to slash levels of photochemical oxidants and hydrocarbon emissions from mobile sources. As the deadline for complying with this mandate approached, the only available technology to achieve it was the catalytic converter, a platinum-based device that increased the overall efficiency of combustion of gasoline fuels. Fortunately for the health of children, the platinum-based converter was “poisoned” by lead. In 1970, President Nixon asked Congress to promote the development of lead-free gasoline by imposing a federal tax on lead additives.<sup>111</sup>

### *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 asbestos 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. In 1924 the first case of a death clearly attributed to asbestosis appeared in the medical literature. In the late 1920s, studies of elevated mortality rates among asbestos workers were published. These studies inspired the British Parliament in 1931 to enact legislation requiring improved ventilation and dust suppression in the asbestos-textile industry.<sup>112</sup>

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<sup>110</sup> Pub. L. No. 89-272, 79 Stat. 992 (1965).

<sup>111</sup> President to Propose Congress Adopt Tax on Lead Additives in Motor Fuels, 1 Env. Rep. 71 (1970).

<sup>112</sup> Paul Brodeur, *Outrageous Misconduct* 11 (1985).

The U.S. asbestos industry succeeded in suppressing evidence of elevated mortality among its workers during the 1930s, even as its insurers quietly moved to restrict coverage of workers exposed to asbestos. Workers in other industries whose lungs were scarred through inhalation of silica filed tort suits in massive numbers during this decade.<sup>113</sup> 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.<sup>114</sup> While many attributed the escalation of silicosis claims to the onset of the Great Depression, they 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.

During World War II, four and one-half million Americans working in shipyards were exposed to dangerous levels of asbestos, which was widely used as a form of insulation.<sup>115</sup> 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 seven times the expected rate.<sup>116</sup> The evidence associating friable asbestos insulation with alarming rates of asbestosis, mesothelioma, and lung cancer was so compelling that EPA banned the use of such products shortly after it was given the authority to do so in the 1970s. By the year 2000, an avalanche of tort litigation had been filed against manufacturers of asbestos

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<sup>113</sup> Andrew P. Morriss & Susan E. Dudley, *Defining What to Regulate: Silica & the Problem of Regulatory Categorization 27* (SSRN Draft Paper 2005).

<sup>114</sup> *Id.*

<sup>115</sup> Brodeur, *supra* note 105 at 120.

<sup>116</sup> *Id.* at 30-31.

products, including more than 600,000 lawsuits against more than 6,000 defendants, resulting in \$54 billion in damages and litigation costs.<sup>117</sup> 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.<sup>118</sup> 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 phase out remaining uses of asbestos, as discussed in Part I 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 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.<sup>119</sup> Following a 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

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<sup>117</sup> Stephen J. Carroll, et al., *Asbestos Litigation Costs and Compensation: An Interim Report* (Rand Institute for Justice 2002), at 40, 49, and vii, quoted in Morris and Dudley, *supra* note 106, at 61.

<sup>118</sup> Environmental Working Group, *Governmental Data on Asbestos Mortality*, at [http://www.ewg.org/reports/asbestos/maps/government\\_data.php#moreinfo](http://www.ewg.org/reports/asbestos/maps/government_data.php#moreinfo) (last visited October 18, 2005).

<sup>119</sup> 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).

federal and state common law and for violations of the Refuse Act,<sup>120</sup> the Clean Water Act (CWA),<sup>121</sup> and state air and water pollution regulations.

After an EPA chemist discovered that the taconite tailings released fibers structurally similar to asbestos in a source of drinking water serving Duluth, a town with a population of 200,000, the case focused on whether ingestion of the fibers posed cancer risks similar to those associated with inhalation of asbestos. 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. 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.<sup>122</sup>

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.<sup>123</sup> 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:

“ . . . [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

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<sup>120</sup> Rivers and Harbors Appropriation Act of 1899 §13, 33 U.S.C. §407.

<sup>121</sup> 33 U.S.C. §§1251-1387.

<sup>122</sup> *United States v. Reserve Mining Co.*, 380 F.Supp. 11 (D.C. Minn. 1974), *modified and remanded by* 514 F.2d 492 (8th Cir. 1975).

<sup>123</sup> *United States v. Reserve Mining Co.*, 498 F.2d 1073 (8<sup>th</sup> Cir. 1974).



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.<sup>124</sup>

By rejecting a precautionary approach to regulation, the panel's decision alarmed federal and state environmental officials. In response to it, a bill was introduced in

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<sup>124</sup> Reserve Mining Co. v. United States, 498 F.2d 1073, 1083-1084 (8<sup>th</sup> Cir. 1974).

Congress to shift the burden of proof to polluters to prove the safety of their discharges once it was shown that they present “a reasonable risk of being a threat to public health.” 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 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.<sup>125</sup>

While this proposed legislation was not enacted by Congress, Reserve ultimately was forced to end its discharges into Lake Superior. Although the Eighth Circuit panel refused to endorse the district court’s precautionary approach to respond to a potential health hazard, it concluded that the company was likely to lose on the claims that its discharges violated the terms of its permit. 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.”<sup>126</sup> 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,

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<sup>125</sup> Letter from Russell Peterson to Hon. Wallace H. Johnson, reprinted in *Burdens of Proof in Environmental Litigation*, Hearing Before the Subcommittee on Environment of the Senate Commerce Committee, 93d Cong., 2d Sess. 8 (1974).

<sup>126</sup> 498 F.2d at 1085.

it gave Reserve “reasonable time” to abate them “on reasonable terms.”<sup>127</sup> 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.” 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.” But it justified its decision to require abatement of the hazard on the ground that “[t]he evidence calls for preventive and precautionary steps.” 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.” 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.”

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. Thus, the Eighth Circuit

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<sup>127</sup> Reserve Mining Co. v. EPA, 514 F.2d 492 (8th Cir. 1975).

upheld the trial court's order directing Reserve to phaseout disposal of taconite tailings in Lake Superior.

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.<sup>128</sup> In 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.<sup>129</sup> These decisions later were upheld in full by the Eighth Circuit.<sup>130</sup>

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

During the 1970s, Congress adopted far-reaching legislation establishing comprehensive programs to protect the environment.<sup>131</sup> These laws – the National Environmental Policy Act, the Clean Air Act, the Clean Water Act, the Toxic Substances Control Act -- represent a sharp departure from the common law approach to environmental protecting 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 (NEPA)<sup>132</sup> – directs federal agencies before undertaking any major actions to prepare and consider detailed assessments of their environmental impacts and of alternatives to them. This environmental assessment requirement has been widely emulated throughout the world and it has become a central

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<sup>128</sup> Reserve Mining Co. v. Lord, 529 F.2d 181 (8th Cir. 1976).

<sup>129</sup> United States v. Reserve Mining Co., 417 F. Supp. 789 (D. Minn. 1976).

<sup>130</sup> United States v. Reserve Mining Co., 543 F.2d 1210 (8th Cir. 1976).

<sup>131</sup> A superb history of these developments is presented in Richard J. Lazarus, *The Making of Environmental Law* (2004).

<sup>132</sup> 42 U.S.C. §§4321 to 4347.

element of the environmental protection infrastructure in many countries. By requiring agencies to carefully examine the prospective consequences of their actions, NEPA enhances the ability of decisionmakers to take precautionary action.

The first major federal regulatory statute Congress adopted was the Clean Air Act Amendments of 1970.<sup>133</sup> This legislation endorsed precautionary regulation by requiring the newly-created Environmental Protection Agency to set national ambient air quality standards to protect public health with a margin of safety built into the standards.<sup>134</sup> This legislation also directed EPA to set standards that would require at least a 90 percent reduction in exhaust emissions from new motor vehicles. Congress also authorized the EPA to control or to prohibit the use of any fuel additive whose emission products "will endanger the public health or welfare . . ."<sup>135</sup> To meet the required 90 percent reduction in conventional pollutants, new automobiles had to be equipped with catalytic converters. 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.

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.<sup>136</sup> In February 1972, the EPA proposed regulations to ban the use of leaded gasoline in cars with catalytic converters and to require a phased reduction in the lead content of leaded

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<sup>133</sup> Pub. L. 91-604, 84 Stat. 1676.

<sup>134</sup> 42 U.S.C. §7409 ("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.").

<sup>135</sup> 42 U.S.C. §7545(c)(1)(A) (1976).

<sup>136</sup> 36 Fed. Reg. 1486 (1971).

gasoline to 1.25 grams per gallon (gpg) by 1977.<sup>137</sup> 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<sup>3</sup> were associated with a sufficient risk of adverse physiological effects to endanger public health.<sup>138</sup> 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.<sup>139</sup>

The EPA Administrator determined that it was difficult, if not impossible, to identify the precise level of airborne lead that would "endanger" health. However, he repropoed the 1.25 gpg limit based on a new health assessment document that considered the cumulative effect of airborne lead exposure on total human exposure to lead. The Administrator emphasized that there 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. The EPA's new proposal required phased reductions in the lead content of gasoline beginning in 1975 and culminating in 1978 with the 1.25 gpg limit.<sup>140</sup>

In response to a lawsuit by environmentalists, the EPA was ordered in October 1973 to decide within 30 days whether or not lead additives in gasoline should be regulated for health reasons.<sup>141</sup> In November 1973, the EPA issued a revised health

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<sup>137</sup> 37 Fed. Reg. 11786 (1972).

<sup>138</sup> EPA, Health Hazards of Lead (1972).

<sup>139</sup> 38 Fed. Reg. 1254 (1973).

<sup>140</sup> 38 Fed. Reg. 1258 (1973).

assessment document that determined that lead emissions from gasoline presented "a significant risk of harm" because they significantly increase total human exposure to lead.<sup>142</sup> In December 1973, it 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.<sup>143</sup> 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. 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. By January 1, 1979, all refineries were required to comply with a standard of 0.5 gpg for all gasoline produced, 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 2-1 vote, with Judge J. Skelly Wright dissenting. 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 Air Act. The court stated that "the case against auto lead emissions is a speculative and inconclusive one at best."

The EPA appealed this decision to the full court, which agreed to rehear the case. In March 1976, the court by a 5-4 vote reversed the three-judge panel's decision and

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<sup>141</sup> Natural Resources Defense Council v. Environmental Protection Agency, No. 72-2233 (D.C. Cir. 1973).

<sup>142</sup> EPA, EPA's Position on the Health Effects of Airborne Lead (1973).

<sup>143</sup> 38 Fed. Reg. 33734 (1973).

upheld the lead standard.<sup>144</sup> 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. 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."<sup>145</sup>

The tetraethyl lead manufacturers argued that there was no definitive proof that emissions of lead from gasoline caused harm. They maintained that EPA was required to present some "dispositive study" to demonstrate that lead additives in gasoline had caused lead poisoning in individuals. 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. "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."<sup>146</sup>

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/dl are indicative of a danger to health, elevated blood levels exist to a small but significant extent in the general adult

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<sup>144</sup> Ethyl Corp. v. Environmental Protection Agency, 541 F.2d 1 (D.C. Cir. 1976).

<sup>145</sup> 541 F.2d at 13.

<sup>146</sup> 541 F.2d at 24-25.



population and to a very great extent among children; (2) that airborne lead is directly absorbed into 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. The court observed that while no specific blood-lead level could be identified as the threshold for danger, the 40- $\mu\text{g}/\text{dl}$  level was a conservative standard, and that studies 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. 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.

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." 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. 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 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."<sup>147</sup>

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 decision 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.<sup>148</sup> 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." 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 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."<sup>149</sup> Under his view, the fact that lead has been

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<sup>147</sup> 541 F.2d at 28.

<sup>148</sup> 541 F.2d at 38.

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%) of adults had elevated blood 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. While Judge Wilkey asserted that EPA was simply "picking and choosing" data to support its conclusion, the majority supported EPA's approach. As discussed in Section H below, subsequent events have decisively confirmed the wisdom of EPA's precautionary approach.

*F. Action to Phase Out 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 chlorofluorocarbons (CFCs) could damage the earth's ozone layer. In 1974 two scientists from the University of California -- Sherwood 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. Chlorofluorocarbons (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

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<sup>149</sup> 541 F.2d at 95 (Wilkey, J., dissenting).

Midgely, the same chemist who invented tetraethyl lead. At the time of his 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. 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. The chlorine would then act as a catalyst, converting ozone (O<sub>3</sub>) to oxygen, destroying the Earth's protective ozone shield.

Rowland and Molina's study sparked considerable research that confirmed that their hypothesis was theoretically sound, though at the time it was not possible then 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 less than two years the market for products with such sprays dropped by two-thirds without any government regulation. 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, that federal regulation would be preferable to potentially conflicting state standards. In March 1978 regulations were jointly issued by EPA (under TSCA), the FDA, and the CPSC to limit the use of CFCs in "nonessential" aerosol propellants (military and medical uses were exempted).

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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. 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.<sup>150</sup>

#### *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. The Clean Water Act requires EPA to set technology-based effluent limits on discharges of water pollutants on an industry-wide basis. The Occupational Health and Safety Act requires OSHA to promulgate an occupational health standards that "most adequately assures, to the extent feasible, on the basis of the best available evidence," that "no worker suffers material impairment of health or functional capacity" even if exposed to the hazard throughout his working life.<sup>151</sup> Because technology-based standards are not based on

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<sup>150</sup> R. Benedick, *Ozone Diplomacy: New Directions in Safeguarding the Planet* 31 (1991) (hereinafter *Ozone Diplomacy*); L. Dotto and H. Schiff, *The Ozone War 195-197* (1978).

<sup>151</sup> 29 U.S.C. §655(b)(5).

assessment of the extent of likely harm caused by regulated pollutants, they often are viewed as an example of precautionary regulation.<sup>152</sup>

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 worker suffers material impairment of health or functional capacity” even if exposed to the hazard throughout his working life,<sup>153</sup> did not automatically require reducing exposure to carcinogens to the lowest feasible level. Instead it held that the Occupational Safety and Health Administration (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.<sup>154</sup> 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

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<sup>152</sup> See generally Noga Morag-Levine, *Chasing the Wind: Regulating Air Pollution in the Common Law State* (2003) (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 U.S.).

<sup>153</sup> 29 U.S.C. §655(b)(5).

<sup>154</sup> *Industrial Union Department, AFL-CIO v. American Petroleum Institute*, 448 U.S. 607 (1980).

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 specified that risk assessment need not be quantitative in circumstances where such analysis was not possible given the extent of uncertainty.<sup>155</sup>

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.<sup>156</sup> 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. 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.<sup>157</sup>

OSHA currently is considering a new permissible exposure limit for silica to replace the national consensus standard it initially adopted, which is now woefully outdated. Despite periodic assertions that the problem of worker exposure to silica has

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<sup>155</sup> These aspects of the Court’s decision have been criticized by opponents of the precautionary principle. See, e.g., *supra* note \_\_\_, at \_\_\_.

<sup>156</sup> Thomas O. McGarity & Sidney A. Shapiro, *Workers at Risk: The Failed Promise of the Occupational Safety and Health Administration* (1992) (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)).

<sup>157</sup> See Percival, et al., *supra* note \_\_\_, at 376-77.

been solved, today between 200 and 300 workers die annually of silicosis. Thus, a problem that commanded national attention seventy years when the Gauley Bridge disaster was publicized, remains an example of regulatory policies that have been insufficiently precautionary.<sup>158</sup>

#### *H. The Phaseout of Tetraethyl Lead from Gasoline*

Despite the *Ethyl* decision endorsing precautionary regulation, a serious attempt to repeal lead phasedown came shortly after 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. The lead-phasedown program was near the top of the industry “hit list.” The Task Force directed the Environmental Protection Agency (EPA) to relax or abolish the lead standard in order to save refiners the two cents per gallon claimed to be the extra cost of producing unleaded gasoline.

In response to this directive, EPA in February 1982 proposed to relax or rescind the lead standard for large refiners and to suspend indefinitely the October 1, 1982 date for small refiners to comply with the 0.5 gpg standard.<sup>159</sup> 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. Although President Reagan

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<sup>158</sup> In the early 1930s, a total of 500 out of 2,000 workers tunneling through a vein of nearly pure quartz in Gauley Bridge, West Virginia died from acute silicosis. Morriss and Dudley, *supra* note \_\_, at 30.

<sup>159</sup> 47 Fed. Reg. 7812 (1982).



had decreed that all significant, new regulatory proposals had to be subjected to rigorous cost-benefit analysis,<sup>160</sup> his administration did not interpret this decree to apply to proposals to relax regulations because it was assumed that they would save industry money. Thus no attempt was made to determine if relaxation of the lead standard would result in net benefits to society.<sup>161</sup>

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). 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 declined between 1976 and 1980, mean blood levels declined in closely parallel fashion from 16 to 10  $\mu\text{g}/\text{dl}$ .<sup>162</sup>

Over the period from 1976 to 1980, use of lead additives in gasoline declined approximately 40 percent, from 105,000 to 50,000 tons per year. Over these same four years, median blood lead levels in the U.S. population aged 6 months to 70 years also

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<sup>160</sup> Executive Order 12,291, 3 C.F.R. 127 (1982).

<sup>161</sup> Robert V. Percival, Checks Without Balance: Executive Office Oversight of the Environmental Protection Agency, 54 Law & Cont. Problems 127, 187-88 (1991).

<sup>162</sup> Annest, J. L., Pirkle, J. L., Makug, D., Neese, J. W. Bayse, D.D., and Kovar, M.G. (1983). Chronological trend in blood lead levels between 1976 and 1980. *NEJM*, 308, 1373-1377.

declined by about 35 percent.<sup>163</sup> This decrease was observed in *all ages* sampled. 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 to toxicity).

The NHANES 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. Other studies demonstrated that even as leaded gasoline usage fluctuated seasonally, blood-lead levels fluctuated in parallel fashion.

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.<sup>164</sup> In November 1982 the agency

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<sup>163</sup> Mahaffey, K. R., Annett, J. L., Roberts, J., and Murphy, R.S. National estimates of blood lead levels: US 1976-1980, association with selected demographic and socioeconomic factors. 307 *New England J. Medicine* 575-579 (1982).

<sup>164</sup> An unexpected, and influential, opponent of relaxing the lead standard was columnist George Will, who had befriended President Reagan. He wrote a powerful column attacking the administration's proposal to relax limits on levels of lead in gasoline. George Will, *The Poison Poor Children Breathe*, Washington Post, Sept. 16, 1982, p. A23.

adopted 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.

In a subsequent court challenge to the new standard brought by small refiners, the U.S. Court of Appeals 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. 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 µg/dl would justify EPA in banning lead from gasoline entirely."<sup>165</sup>

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 until it was confronted by an entirely separate problem. Emissions of conventional pollutants (e.g., hydrocarbons, nitrogen oxides, carbon monoxide) from motor vehicles were increasing because many new cars that were supposed to use only unleaded gasoline had been misfueled with leaded gas because it was slightly cheaper. The use of leaded gasoline in new vehicles equipped with catalytic converters had rendered many of these emissions-control devices ineffective. Environmentalists urged EPA to solve the misfueling problem by phasing out the use of gasoline lead additives. Curiously, the decision to consider slashing the lead content of

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<sup>165</sup> *Small Refiner Lead Phasedown Task Force v. Environmental Protection Agency*, 705 F.2d 506 (D.C.Cir. 1983).

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:

“[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.”<sup>166</sup>

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 misfueling.

In March 1984, the EPA released the results of this cost-benefit analysis, which showed that a 90% reduction in the lead content of gasoline would generate net benefits of several billion dollars. While the cost of making gasoline would increase by less than 1%, EPA estimated that such a reduction in lead usage would reduce the number of

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<sup>166</sup> Alm, "The Multimedia Approach to Pollution Control: An Impossible Dream?" in National Research Council, *Multimedia Approaches to Pollution Control: Symposium Proceedings* 114-115 (1987) (emphasis in original).

children with blood-lead levels above 30 µg/dl by more than 50,000 in 1986 and would substantially reduce emissions of conventional pollutants by reducing misfueling while saving nearly a billion dollars annually in vehicle maintenance expenses.

In August 1984, the EPA proposed to reduce the lead content of leaded gasoline by more than 90% (to 0.10 gpg), effective January 1, 1986. This proposal was adopted by EPA in March 1985, along with an interim phasedown to 0.50 gpg, which became effective on July 1, 1985. 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 of lead emissions are not confined to young children.<sup>167</sup> Although the EPA did not rely on the blood-pressure studies in making its decision to strengthen the lead standard, they provided further impetus for banning lead from gasoline entirely. In the 1990 Amendments to the Clean Air Act, Congress banned the sale of leaded gasoline after December 31, 1995.<sup>168</sup>

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

Enacted in 1976, the Toxic Substances Control Act (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. After the legislation was signed into law by President Ford in October 1976, then EPA

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<sup>167</sup> Pirkle, J. L., Schwartz, J., Landis, J. R., and Harlan, W. R. The relationship between blood lead levels and blood pressure and its cardiovascular risk implications. *Am. J. Epidemiology.*, 121, 246-258 (1985).

<sup>168</sup> 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. David Schoenbrod, *Saving Our Environment from Washington* 35-38 (2005). However, he fails to acknowledge that the final, total ban on tetraethyl additives was indeed mandated by Congress, albeit quite belatedly.

Administrator Russell Train hailed it as "one of the most important pieces of 'preventive medicine' legislation" ever passed by Congress.<sup>169</sup> 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*,<sup>170</sup> which invalidated one of EPA's most significant initiatives during the administrations of President Reagan and George H.W. Bush – EPA's effort to phase out remaining uses of asbestos. EPA well understood the human health risks of asbestos, which had led it to ban some of the most dangerous uses of asbestos, including friable insulation products. After an extensive investigation that extended for more than a decade and that included the promulgation of a rule requiring companies using asbestos to report data to EPA, the agency proposed its phaseout rule. The agency did so 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. This regulation was struck down by a panel of Fifth Circuit judges who concluded that the agency had failed to perform sufficiently detailed cost-benefit analyses of banning not only of each particular use of asbestos, but also of all intermediate alternatives short of a ban.<sup>171</sup>

Three aspects of the *Corrosion Proof Fittings* decision are particularly relevant to consideration of the precautionary principle: (1) the court's discussion of unquantified

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<sup>169</sup> EPA Press Release, "Train Sees New Toxic Substances Law as 'Preventive Medicine'," October 21, 1976, at <http://www.epa.gov/history/topics/tasca/03.htm> (last visited October 17, 2005).

<sup>170</sup> 947 F.2d 1201 (5th Cir. 1991)

<sup>171</sup> 947 F.2d at 1217.

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. 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."<sup>172</sup> 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 a formal benefit-cost analysis" because "such an analysis would not be very useful" given the uncertainties associated with efforts to quantify benefits and costs of chemical regulation.<sup>173</sup> 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 that EPA must all give "full consideration" to the "burdens of human suffering and premature death."<sup>174</sup>

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. It also rejected EPA's conclusion that its "unreasonable risk determination" was justified because the benefits it could not quantify (given the lack of

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<sup>172</sup> 15 U.S.C. §2605(c).

<sup>173</sup> Toxic Substances Control Act, Report by the Committee on Interstate and Foreign Commerce, U.S. House of Representatives, H.R. Rep. 94-1341, 94<sup>th</sup> Cong., 2d Sess. 14 (1976).

<sup>174</sup> Toxic Substances Control Act, Report of the Senate Committee on Commerce, S.Rep. 94-698, 94<sup>th</sup> Cong., 2d Sess. 12 (1976).

data on actual ambient air levels of asbestos attributable to particular asbestos products) were an order of magnitude greater than the quantified benefits.<sup>175</sup> 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. This “led to easy agreements between EPA and OMB regarding the costs and benefits of the rule, an 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.<sup>176</sup> The reviewing court then rejected the agency’s efforts to justify the phaseout rule on the basis of unquantified benefits.<sup>177</sup> The court’s decision erects 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 essentially applied a 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.

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. They frequently cite *Corrosion Proof Fittings* in support of this

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<sup>175</sup> 947 F.2d at 1219 (“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.”).

<sup>176</sup> Christine M. Augustyniak, Asbestos, in *Economic Analyses at EPA: Assessing Regulatory Impact* 198 (Richard D. Morgenstern, ed. 1997).

<sup>177</sup> See note 168, *supra*. The court also rejected EPA’s belated effort to generate analogous exposure data instead of assuming that the absence of exposure data meant the absence of risk because the agency had not subjected the data to notice and comment procedures.



proposition because the court chastised EPA for failing to perform detailed analyses of the risks of substitutes for asbestos.<sup>178</sup> 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. 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 substances Congress considered to be a prime candidate for a phaseout) 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 again 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 U.S. as well as all unknown, future uses of asbestos. The court noted that although products no longer being sold in the U.S. currently pose zero risk, “[t]his would soon change if the product returned, which is precisely what the EPA is trying to avoid.”<sup>179</sup> For future products, the court conceded that “EPA cannot

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<sup>178</sup> See, e.g., Sunstein, *Laws of Fear*, supra note \_\_\_, at 32.

<sup>179</sup> 947 F.2d at 1229.

possibly evaluate the costs and benefits of banning unknown, uninvented products.”

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.”<sup>180</sup> 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 court’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, 38 countries, including most EU members, have banned asbestos.<sup>181</sup> 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.<sup>182</sup> 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.

#### IV. CONCLUSION: REGULATORY POLICY & THE PRECAUTIONARY PRINCIPLE

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<sup>180</sup> Id.

<sup>181</sup> [http://www.caut.ca/en/issues/asbestos/current\\_bans.pdf](http://www.caut.ca/en/issues/asbestos/current_bans.pdf) (visited Sept. 13, 2005).

<sup>182</sup> World Trade Organization, European Communities – Measures Affecting Asbestos and Asbestos-Containing Products, WT/DS135/R, Sept. 18, 2000.

The foregoing, rather extended, 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 overlooking truly significant risks.<sup>183</sup> 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 chronic, low level environmental hazards than it is to acute, highly visible incidents that command public attention.<sup>184</sup>

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

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<sup>183</sup> See also Graham, *supra* note 26 (“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.”). See also *Late Lessons from Early Warnings: The Precautionary Principle 1896-2000* (European Environmental Agency, ed. 2001).

<sup>184</sup> This also appears to apply to the enactment of environmental legislation, e.g., 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.

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.<sup>185</sup>

Perhaps the crucial shortcoming of regulatory policy was its failure to follow up on the initial studies of the health effects of tetraethyl lead 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 performed 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 decisionmaking. 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.

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<sup>185</sup> David Rosner and Gerald Markowitz, *A gift of God?: The public health controversy over leaded gasoline during the 1920s*. 75 *Am. J. Public Health* 344-352 (1985). See also Gerald Markowitz and David Rosner, *Deceit and Denial: The Deadly Politics of Industrial Pollution* 12-35 (2002).

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.<sup>186</sup> Similarly, the eventual decision to drastically reduce lead levels in gasoline was set in motion by frustration with the misfueling problem, as much 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. It 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.”<sup>187</sup> Although the Toxic Substances Control Act was designed to provide EPA with such comprehensive regulatory authority, the *Corrosion Proof Fittings* decision

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<sup>186</sup> W.P. Piver, Potential dilemma: The methods of meeting automotive exhaust emission standards of the Clean Air Act of 1970, 8 *Environ. Health Perspectives* 165-190 (1974).

<sup>187</sup> National Research Council, *Lead in the Human Environment* 4 (1980).

effectively crippled the agency's ability to conduct multi-source, multi-media regulation by imposing seemingly impossible analytical preconditions on regulation.

*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.<sup>188</sup> 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 greased the wheels for EPA's decision to virtually eliminate lead additives from gasoline,<sup>189</sup> it ultimately was the undoing of the agency's initiative to phase out 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 the benefits it anticipated from the rule.<sup>190</sup> 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

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<sup>188</sup> Lisa Heinzerling, *The Accidental Environmentalist: Judge Posner on Catastrophic Thinking*, 94 *Georgetown Law J.* \_\_\_\_ (2006) (review of Richard A. Posner, *Catastrophe: Risk and Response* (2004)); Sunstein, *supra* note 25, at 109-128.

<sup>189</sup> Albert L. Nichols, *Lead in Gasoline*, in *Economic Analysis at EPA: Assessment Regulatory Impact* 49 (R. Mogenstern, ed. 1997).

<sup>190</sup> Christine M. Augustyniak, *Asbestos*, in *Economic Analysis at EPA: Assessing Regulatory Impact 198-99* (R. Mogenstern, ed. 1997).

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.<sup>191</sup> The agency's initial rule was upheld by a 5-4 vote of the U.S. Court of Appeals for the D.C. Circuit, sitting *en banc*, in a decision expressly endorsing the precautionary principle. 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 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

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<sup>191</sup> See Frank Ackerman, Lisa Heinzerling, Rachel Massey, Applying Cost-Benefit to Past Decisions: Was Environmental Protection Ever a Good Idea? 57 Admin. L. Rev. 155, 160 (2005).

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 U.S. and the lack of toxicity information for a large percentage of chemicals currently on the market,<sup>192</sup> 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.<sup>193</sup>

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.<sup>194</sup> 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 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

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<sup>192</sup> EPA, Analysis of Test Data Availability for HPV Chemicals, 22 Chem. Reg. Rep. 261 (1998).

<sup>193</sup> See Rena I. Steinzor, Katherine Baer & Matt Shudtz, Overcoming "Environmental Data Gaps": Why What EPA Doesn't Know about Toxic Chemicals Can Hurt, CPR White Paper #510 (July 2005).

<sup>194</sup> See Applegate, *supra* note 32, which traces the "taming" of the precautionary principle as efforts have been made to integrate it into a risk assessment framework.



(erroneously deeming a safe chemical to be hazardous),<sup>195</sup> 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.<sup>196</sup>

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.<sup>197</sup> As former EPA Administrator Christie 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.<sup>198</sup>

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<sup>195</sup> See Talbot Page, A Generic View of Toxic Chemicals and Similar Risks, 7 *Ecol. L. Q.* 207 (1978).

<sup>196</sup> See Rascoff & Revesz, *supra* note 34.

<sup>197</sup> 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.

<sup>198</sup> Christine Todd Whitman, *It's My Party Too* 163-64 (2005).

Fears that the precautionary approach inexorably will lead to massive overregulation greatly underestimate the ability of regulatory targets to fend off regulation.<sup>199</sup> This is reflected in the fact 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.<sup>200</sup>

Critics of the precautionary principle have picked on a strawman by arguing that it will produce overregulation when it in fact 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 to sensibly remind us of the reasons why environmental policy has shifted away from the common law's approach that required individualized proof of causal injury before environmental harm could be redressed. While it undoubtedly is 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

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<sup>199</sup> See generally Thomas O. McGarity et al., *Sophisticated Sabotage: The Intellectual Games Used to Subvert Responsible Regulation* 17-18 (Environmental Law Institute 2004); Lisa Heinzerling & Frank Ackerman, *The Humbugs of the Anti-Regulatory Movement*, 87 *Cornell L. Rev.* 648 (2002).

<sup>200</sup> Lisa Heinzerling, *Regulatory Costs of Mythic Proportions*, 107 *Yale L.J.* 1981 (1998). □

repetition of tragedies like those caused by tetraethyl lead and asbestos than it is to cause them. Fear not the precautionary principle.