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REGULATORY STUDIES PROGRAM

Public Interest Comment on the OMB's Draft 2003 Report to Congress on the Costs and Benefits of Federal Regulations[1]

The Regulatory Studies Program (RSP) of the Mercatus Center at George Mason University is dedicated to advancing knowledge of the impact of regulation on society. As part of its mission, RSP conducts careful and independent analyses employing contemporary economic and legal scholarship to assess rulemaking proposals from the perspective of the public interest. Thus, this comment on the OMB's Draft 2003 Report to Congress on the Costs and Benefits of Federal Regulations does not represent the views of any particular affected party or special interest group, but is designed to evaluate the effect of the Agency's proposals on overall consumer welfare.

Introduction

In OMB's Draft Report to Congress on the Costs and Benefits of Federal Regulations, the Administration explains that it has formed an "Interagency Work Group on Risk Management."[2] To assist in the Work Group's efforts, the Draft Report requests information on "current risk assessment and management practices in federal agencies, with an emphasis on the role of precaution in risk policy and regulation."[3]

The essence of OMB's request is: How should regulators act when uncertainty exists about the likelihood or magnitude of potential harm associated with human action? In response to this question, some advocate reliance on the precautionary principle. While precaution has a place in federal policy, reliance on the precautionary principle would not improve federal risk management efforts. To the contrary, reliance on the precautionary principle as it is typically formulated would, in all likelihood, produce unintended consequences that undermine government efforts to enhance social welfare.

Precaution as a Guiding Principle for Regulatory Policy

While there is no widely endorsed definition of the precautionary principle a widely cited formulation is the "Wingspread Consensus Statement," a document drafted by several dozen

[1] Prepared by Jonathan H. Adler, Assistant Professor at Case Western Reserve University School of Law and Daniel Simmons, Research Fellow, Regulatory Studies Program. This comment is one in a series of Public Interest Comments from Mercatus Center's Regulatory Studies Program and does not represent an official position of George Mason University.

[2] Draft 2003 Report to Congress on the Costs and Benefits of Federal Regulations, 68 Fed. Reg. 5492, 5499 (2003).

[3] *Id.*

environmental activists in January 1998.[4] Under the Wingspread formulation: "When an activity raises threats of harm to human health or environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically."[5] The precautionary principle appeals to the common sense idea that "it is better to be safe than sorry." At its core, the precautionary principle embodies "the belief that society should seek to avoid environmental damage by careful forward planning, blocking the flow of potentially harmful activities."[6]

Simple safety measures, such as wearing a seatbelt or motorcycle helmet, can greatly reduce the risk of substantial harm at relatively modest cost. In many instances preventing harm can be easier and less costly than repairing damage after the fact. While the precautionary principle appeals to conventional notions of "safety" and "taking care," as typically formulated, it calls for more drastic measures than the adoption of cost-effective safety measures.

Rather, the precautionary principle calls for a presumption that government action is necessary to address every potential risk that could arise from technological advance or productive economic activity. The principle is premised on the idea that all technologies and chemical substances are dangerous until proven safe. Drastic changes in regulatory policy are therefore required. In the words of its proponents, "new principles for conducting human affairs are necessary" as it is time to "adopt a precautionary approach to *all human endeavors*."[7]

As applied in the environmental context, this means that it is better to err on the side of regulating or controlling new technologies than to risk new or unforeseen problems; "decision makers should act in advance of scientific certainty to protect the environment (and with it, the well-being of future generations) from incurring harm."[8] In this sense, the precautionary principle establishes a default rule for regulating new innovations, irrespective of the relative risk that they actually pose to human health or the environment. At its extreme, the principle calls for the elimination of substances that are not proven safe: "the precautionary principle calls for the prohibition of the release of substances which might cause harm to the environment *even if insufficient or inadequate proof exists regarding the causal link*."[9]

On the one hand, this aspect of the precautionary principle does not call for much. Scientific certainty is rare, and few environmental regulations would exist if absolute scientific certainty were required before their imposition. Rather, policy makers traditionally consider the weight of the evidence for or against a given causal relationship, and the costs involved with

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[4] Signatories of the statement included representatives of Greenpeace, Physicians for Social Responsibility, the W. Alton Jones Foundation, the Silicon Valley Toxics Coalition, and the Indigenous Environmental Network, among others.

[5] The Wingspread Statement is reprinted in Appendix A, *Protecting Public Health & The Environment*, pp. 353–55.

[6] Joel Tickner, Carolyn Raffensperger, and Nancy Myers, *The Precautionary Principle in Action: A Handbook* (Science and Environmental Health Network, 1999), p. 3.

[7] The Wingspread Statement on the Precautionary Principle, reprinted in Appendix A, *Protecting Public Health & The Environment*, Carolyn Raffensperger and Joel Tickner, eds. (Washington, DC: Island Press, 1999), pp. 353-55.

[8] Andrew Jordan and Timothy O'Riordan, "The Precautionary Principle in Contemporary Environmental Policy and Politics," in *Protecting Public Health and the Environment*, p. 23.

[9] P. Horsman of Greenpeace quoted in Jordan and O'Riordan, p. 25.

implementing a particular policy. In some cases, such as the link between cigarettes and lung cancer, the causal connection is easy to identify. In other cases, such as a postulated connection between water chlorination and the incidence of bladder cancer, the connection is more suspect, and the costs of reducing the risk are substantial. Most environmental laws nonetheless authorize regulation of potentially dangerous substances or activities with less-than absolute proof or quantification of environmental risk.

On the other hand, by emphasizing the need to act in the face of scientific uncertainty, before there is clear evidence of scientific harm, the precautionary principle lowers the threshold for what is considered reliable evidence of a potential effect. "Better safe than sorry" can be used to call for regulatory measures when there is little, if any, evidence of an actual health or environmental impact. After all, it is impossible to disprove the existence of risk. There is no evidence that even a single individual has suffered a negative reaction from the consumption of genetically engineered food.[10] Yet proponents of the precautionary principle call for moratoria on the development and marketing of such products because such risks are "possible" and have yet to be *un*proven.

A related, corollary to the precautionary principle is a shift in the burden of proof for new technologies and inventions. Government agencies would not be required to demonstrate that a technology poses a likely risk. Rather, "the proponent of an activity, rather than the public, should bear the burden of proof" of demonstrating that it is risk free.[11] Greenpeace's Jeremy Leggett explains: "the modus operandi we would like to see is: 'Do not admit a substance unless you have proof that it will do no harm to the environment.'"[12] The World Charter for Nature incorporates this position, holding that "where potential adverse effects are not fully understood, the activities should not proceed."[13]

Applied in even a mild formulation, the reverse onus idea will dramatically retard the development of new technologies. As precautionary principle advocate Joel Tickner acknowledges, the principle "establishes a type of 'speed bump,' which creates bottlenecks in the development process" to slow down the introduction of new technologies.[14] If this reverse onus were applied in a more rigorous fashion, it could stop the flow of new innovations altogether. "The truth of the matter is that whoever has the burden of proof loses," contends Boston University bioethicist George Annas.[15]

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[10] *See* C.S. Prakash, Feeding a World of Six Billion, AGBIOFORUM, Summer/Fall 1999 (quoting David Aaron of the U.S Commerce Department); see also COMMITTEE ON GENETICALLY MODIFIED PEST-PROTECTED PLANTS, BOARD ON AGRICULTURAL AND NATURAL RESOURCES, NATIONAL RESEARCH COUNCIL, GENETICALLY MODIFIED PEST- PROTECTED PLANTS (2000) (finding that genetically engineered crops are safe and that they do not pose any greater health or environmental risk than plants produced through traditional breeding practices); Paarlberg, supra note 20, at 21 ("There is no credible evidence of a food safety risk linked to any GM food currently on the market in Europe."); Tim Beardsley, Rules of the Game, SCI. AMER., Apr. 2000, at 42 (noting that "no harm from a GMO crop has ever been demonstrated").

[11] Jordan and O'Riordan, *supra* note 7, p. 354.

[12] Quoted in Julian Morris, "Defining the Precautionary Principle," in *Rethinking Risk and the Precautionary Principle*, Julian Morris ed. (Oxford, UK: Butterworth Heinemann, 2000), p. 4.

[13] United Nations General Assembly, *1982 World Charter for Nature*.

[14] Joel A. Tickner, "A Map Toward Precautionary Decision Making," in *Protecting Public Health*.

[15] Quoted in Ronald Bailey, "Precautionary Tale," *Reason*, April 1999.

Application of the principle to existing technologies, such as various industrial chemicals, would require eliminating thousands of substances from economic use. Proving that a new technology or product will cause no harm requires proving a negative, something that science cannot do. "It is not possible to prove something is harmless, any more than it is possible to prove that there are no fairies at the bottom of one's garden."[16] The scientific process can test the robustness of a given hypothesis—substance X will cause cancer in mice or substance Y disrupts amphibian reproduction—but it cannot *prove* that a given substance is risk-free. Substance X might not cause rodent tumors, but it could always cause something else. For this reason, scientists fear that the precautionary principle could "block the development of any technology if there is the slightest theoretical possibility of harm."[17] Indeed, "taken literally, the directive would be: 'Don't do anything.'"[18]

"Not doing anything," however, may also be contrary to the precautionary principle. When the precautionary principle counsels regulators to take precautionary measures with respect to new harms, that counsel only considers one half of the equation. New technologies create not only new risks, but also new benefits.[19] By doing nothing, society is deprived of the benefits of new technologies, including harms and deaths that society could otherwise avoid. This begs the question, what is more precautionary, keeping the status quo, or forgoing preventable deaths. As Cass Sunstein argues, the problem is not that the precautionary principle "provides no guidance . . . but that it forbids all courses of action, including inaction."[20]

Another corollary to the precautionary principle that is equally problematic is that the consideration of a given technology or environmental decision must "involve an examination of the full range of alternatives, including no action."[21] Taken literally, this corollary calls for paralysis by analysis. It is simply impossible to consider the "full range" of alternatives.[22] Some advocates of the precautionary principle suggest that this corollary would merely require a consideration of likely or possible alternatives as a part of the decision-making process, much like federal agencies in the United States must consider alternatives to proposed actions when undergoing Environmental Impact Statements under the National Environmental Policy Act. Thus, before a company could introduce a new pesticide, a regulatory agency would need to consider alternative means of controlling the target pest and whether the pest needs to be controlled at all. Even in this more mild form, the additional burden placed upon new technologies could be substantial, while doing little to improve public health or environmental

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[16] Morris, *supra* note 10, p. 10.

[17] Soren Holm & John Harris, "Precautionary Principle Stifles Discovery," *Nature*, vol. 400 (1999), p. 398.

[18] Christopher D. Stone, "Is There a Precautionary Principle?" *Environmental Law Reporter*, vol. 31, (July 2001), p. 10790.

[19] AARON WILDAVSKY, SEARCHING FOR SAFETY 39–58 (1988) (arguing that accepting risks may increase safety and that the guiding criterion should be "net benefits" not "no harm").

[20] Cass R. Sunstein, *The Paralyzing Principle*, REGULATION, Winter 2002–2003, at 33.

[21] The Wingspread Statement, quoted in Appendix A, p. 354.

[22] Even under NEPA agencies do not need to consider every possible alternative, thus the onus of the precautionary principle would be would than under NEPA and even NEPA's analysis are already very burdensome. The Administration is considering reducing the analysis requirements to combat the problem of Forest Health. *See* Healthy Forests: An Initiative for Wildfire Prevention and Stronger Communities (2002).

protection. If existing alternatives were adequate, it is unlikely that a new product would be purchased in the marketplace. Substituting government regulators' tastes and preferences for market forces will create monopolies and hinder innovation, both of which harm individuals.

Precautionary Principle in Practice

In this section we respond to three questions posed in the Draft Report:

1. Ways is in which "precaution" is embedded in current risk assessment procedures

2. Examples of unbalanced approaches in human and ecological risk assessment and management methods by U.S. regulatory agencies

3. How the U.S. balances precautionary approaches to health and safety and environmental risks with other interest such as economic growth and technological innovation

Though the precautionary principle has not been explicitly embraced as U.S. policy, many regulatory and other policy actions reflect a precautionary approach to potential risks. We discuss five such policies. The first three—new drug approval, pesticide regulation, and environmental risk assessment—have been recognized elsewhere as embodying precautionary approaches. The latter two—water flow and forest planning—are less obvious examples of the influence of precaution in policy making.[23]

Drug Lag

Perhaps the most prominent example of the harm caused by an unbalanced approach to human risk assessment is "drug lag"—the delay in approval of potentially life-saving medicines and treatments. The Food and Drug Administration (FDA) must approve new pharmaceuticals and medical devices before they may be used or prescribed. The purpose of FDA approval is to ensure that only "safe and effective" drugs approved. In a precautionary fashion, the FDA seeks to prevent the release of an unsafe drug. Delaying the availability of potentially life-saving treatment, however, poses risks of its own. In the simplest terms, if a new drug or medical treatment will start saving lives once it is approved, then the longer it takes for the government to approve the drug, the more likely it is that people will die awaiting treatment.[24]

This is not merely a theoretical concern. Consider the example of Misoprostol, a drug that prevents gastric ulcers.[25] Misoprostol was developed in the early 1980s, and was first approved in some nations in 1985. The FDA, however, did not approve use of Misoprostol until 1988. Even though the drug was already available in several dozen foreign countries, the FDA

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[23] For other examples of the problems with the precautionary principles in an international setting, *see* Jonathan H. Alder, *More Sorry Than Safe: Assessing the Precautionary Principle and the Proposed International Biosafety Protocol*, 35 TEXAS INT'L L.J. 173 (2000); Jonathan H. Adler, *The Cartagena Protocol And Biological Diversity; Biosafe Or Bio-Sorry*, 12 GEO. INT'L ENVTL. L. REV. 761 (2000).

[24] Sam Kazman, "Deadly Overcaution: FDA's Drug Approval Process," *Journal of Regulation and Social Costs*, September 1990, p. 35.

[25] *See id*. at 47-48.

subjected Misoprostol to a nine-and-one-half month review. At the time, between 10,000 and 20,000 people died from gastric ulcers per year. Therefore, had Misoprostol been approved more rapidly, it could have saved as many as 8,000 to 15,000 lives. In other words, FDA's delay cost lives, just as surely as does the approval and use of unsafe treatments. Thus, precautionary regulation by the FDA does not always enhance protection of public health.

Pesticides

Another example of an unbalanced approach to risk assessment is pesticide regulation. As with the drug lag, it is not clear that more government regulation of chemical pesticides always makes people safer. In some cases, restrictions on the use of a pesticide can expose people to other risks, such as disease, or result in the use of more harmful substitutes. Ethylene dibromide (EDB), for example, was a powerful fungicide used to prevent the growth of molds on grain and other foods. Molds produce some of the most potent carcinogens found in nature, such as aflatoxin.[26] Yet EDB was also deemed a potential carcinogen, and was banned by the U.S. Environmental Protection Agency (EPA). The ban was a precautionary measure, yet the EPA did not consider whether the risk of EDB was greater or less than that posed by aflatoxin. Moreover, EDB was replaced with fungicides that had to be applied in greater quantities, increasing the risk for exposed workers.[27] Thus, the EDB ban may have, on net, *increased* risks to human health.

Among the chemicals targeted for elimination by advocates of the precautionary principle is DDT. Once widely used for mosquito control, DDT was banned in most developed nations due to concerns that its widespread use interfered with the reproduction of several bird species, including the bald eagle. In the years after World War II, DDT became the ultimate weapon in the battle against malaria. In Ceylon (now Sri Lanka), DDT spraying reduced the number of malaria cases from approximately three million in 1946 to approximately 7,300 in only a decade. By 1964, there were only 29 recorded malaria cases on the island nation.[28] In India, malaria cases dropped from an estimated 75 million in 1951 to approximately 50,000 by 1961.[29] In industrialized nations, DDT helped eliminate malaria completely.[30]

Evidence that DDT contributed to egg-shell thinning in some bird species, and fears that it could harm people as well, led to a ban on DDT in the United States in 1972. Other developed countries followed soon thereafter, and many developing countries restricted its use.[31] At the time, there was concern—though little evidence—that DDT might pose a risk to public health.

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[26] George M. Gray and John D. Graham, "Regulating Pesticides," in *Risk versus Risk: Tradeoffs in Protecting Health and the Environment*, John D. Graham and Jonathan Baert Weiner eds. (Cambridge: Harvard University Press, 1995), pp. 186-87.

[27] Cross, "Paradoxical Perils," pp. 875-76.

[28] Richard Tren and Roger Bate, *Malaria and the DDT Story* (London: Institute of Economic Affairs, 2001), pp. 36-37.

[29] *Id.*, p. 37.

[30] *See* Indur M. Goklany, *The Precautionary Principle* 18–27 (2001).

[31] Some argue that the development of resistance to DDT by mosquitoes led to a reduction in DDT use in developing nations. DDT, however, remained effective at mosquito control even after some resistance was developed. *See id.* at 46-47.

Rachel Carson's *Silent Spring* and media alarmism contributed to fears that DDT use was poisoning America's children. Foreshadowing later precautionary appeals for chemical phase-outs, then-EPA administrator William Ruckleshaus argued that DDT was "a warning that man may be exposing himself to a substance that may ultimately have a serious effect on his health."[32] Solid evidence of DDT's health risks never materialized, however. A few animal studies suggest some risk, but epidemiological and other research have been inconclusive, producing no more than "weak evidence of harm to human health."[33] Indeed, Harvard University's Amir Attaran notes that "The scientific literature does not contain even one peer-reviewed, independently replicated study linking DDT exposures to any adverse health outcome" in humans.[34]

Continuing concerns about potential human health effects of DDT led to the pesticide's inclusion on a proposed list of "persistent organic pollutants" to be completely phased out under an international agreement sponsored by the United Nations Environment Program. During the negotiations, however, the complete elimination of DDT was reconsidered. Although DDT is virtually synonymous with industrial pollution in western nations, it is known as a life-saving compound in much of the developing world. DDT is still used in nearly two dozen countries for malaria control, and for good reason.

> DDT remains one of the few affordable, effective tools against the mosquitoes that transmit malaria, a plague that sickens at least 300 million and kills over one million, mainly children, in economically underdeveloped areas of the tropics each year. Such a toll is scarcely comprehensible. To visualize it, imagine filling seven Boeing 747s with children, and then crashing them, every day.[35]

The phaseout of DDT before the development of a suitable, cost-effective alternative would condemn millions of people in the developing world to malaria infection and potential death. Application of the precautionary principle to DDT, and eliminating it on the basis of speculative concerns that it *might* harm human health, would leave much of the world far less safe than it is today. The use of DDT may yet be shown to cause health problems in humans; in many developing countries, doing without DDT will definitely cause health problems for millions. As two malaria researchers observe, "DDT has saved countless millions of lives, while Greenpeace struggles to find some evidence that it harms mankind."[36]

Consumer Product Safety Commission and Arsenic

Another example of an unbalanced approach to human and ecological risk assessment is the recent briefing package assembled by the staff of the Consumer Product Safety Commission

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[32] Quoted in ibid., p. 46.

[33] Amir Attaran, et al., "Balancing Risks on the Backs of the Poor," *Nature Medicine*, Vol. 6, no. 7 (July 2000), pp. 729–31.

[34] Quoted in Ronald Bailey, "Green's vs. the World's Poor," *Reason Online*, November 29, 2000, available at http://www.reason.com/hod/rb112900.html.

[35] Attaran., "Balancing Risks," p. 729.

[36] Tren and Bate, *supra* note 25, p. 60.

(CPSC) to analyze a petition to ban wood treated with chromated copper arsenate (CCA).[37] CCA is the most commonly used preservative in the pressure treatment of wood.[38] In 2001, CCA was used in 98 percent of the pressure-treated wood produced for residential uses.[39] On May 22, 2001, two environmental groups, arguing that new studies indicate that arsenic was more dangerous than previously thought, filed a petition with the CPSC to ban CCA-treated wood for used in playgrounds.

In response, CPSC staff assembled briefing materials for the Commission to evaluate the petition. These briefing materials estimate that a child who plays on playground structures made of CCA-treated wood has an increased risk of 2 to 100 per million of developing lung or bladder cancer.[40] The briefing package relies on a number of unrealistic assumptions to estimate that children exposed to CCA-treated playground equipment face an increased risk of cancer. First of all, the briefing package does not provide evidence that arsenic is actually carcinogenic at low doses.

In drawing their conclusion that arsenic is carcinogenic at high doses, CPSC staff cites studies from Taiwan, Chile, and Argentina that show what high doses of arsenic in water could contribute to increased risks of cancer. There are a number of reasons these studies are not conclusive. For example, the Taiwanese studies treated everyone within the same city as being exposed to the same amount of arsenic.[41] However, arsenic concentrations varied greatly from well to well. It is possible that the people who drank from the wells with chronic levels of arsenic are the only ones who developed cancer and people who drank from other wells within the same study did not develop cancer. By lumping people with very different exposure rates, the studies probably overestimated the risks of cancer. Another reason that the studies may not be comparable to the United States, and especially to children, is because the members of the Taiwanese cohorts had higher incidents of smoking and poorer nutrition.[42]

Even assuming that arsenic is carcinogenic at the levels found in drinking water in Taiwan, that does not necessarily mean that arsenic is carcinogenic at the levels children come in contact with by playing on structures made of CCA-treated wood. To calculate the risks of small doses of arsenic exposure, CPSC staff chose a linear dose-response curve. Instead of relying on any studies that indicate a linear dose-response curve was appropriate, they explained they chose a linear dose-response curve, in the "absence of data that the shape of the dose-response at low

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[37] Petition HP 01-3 Requesting a Ban of Chromated Copper Arsenate (CCA)-Treated Wood in Playground Equipment, 68 Fed. Reg. 7,510 (Feb. 14, 2003). The petition is available at http://www.healthybuilding.net/pdf/petition.pdf (last visited Mar. 24, 2003). A more complete analysis of the CPSC's Briefing Materials is Daniel R. Simmons, *Public Interest Comment on the Consumer Product Safety Commission's Briefing Package Prepared to Evaluate a Request to Ban Chromated Copper Arsenate in Playground Equipment*, available at http://www.mercatus.org/article.php/224.html (last visited Apr. 25, 2003).

[38] CPSC BRIEFING PACKAGE at 5.

[39] *Id.*

[40] *Id.* at 1.

[41] KENNETH G. BROWN, COMMENTS ON CPSC'S ANALYSIS OF CANCER RISK TO CHILDREN FROM CONTACT WITH CCA-TREATED WOOD PRODUCTS 4 (2003).

[42] ROBERT RAUCHER, PUBLIC INTEREST COMMENT ON EPA'S NATIONAL PRIMARY DRINKING WATER REGULATIONS; ARSENIC RULE, REGULATORY STUDIES PROGRAM, MERCATUS CENTER, GEORGE MASON UNIVERSITY (2000).

doses is not linear.[43] However, the National Research Council expert panel believes, based on the evidence on the mode of action for arsenic-associated cancers, that the dose-response function is more likely to be sublinear—meaning that the linear extrapolation used by the CPSC significantly overstates the expected risk at low doses.[44]

While CPSC staff relied on questionable studies from other countries and chose a dose-response curve that likely overstates the expected risks of low doses of arsenic exposure, they also discounted some of the most applicable studies on arsenic exposure. The only studies on arsenic in drinking water in the United States do not show a link between arsenic in drinking water and increased cancer rates. To justify excluding one of these studies conducted in Utah, CPSC staff argues "this cohort differed from the larger population in important ways."[45] Specifically, the "cohort was rural and belong to a religion with strict lifestyles rules."[46]

The members of the cohort studied were mostly members of the Church of Jesus Christ of Latter-day Saints, and as a result, most did not drink alcohol, coffee, tea, and most did not smoke. CPSC staff points out this fact as if this were a confounding factor. However, it is likely the dietary habits of the members of the cohort actually reduced the confounding influence of other possible causes of cancer, making it easier to discern any influence elevated levels of arsenic could have in incidents of cancer.

Thus, CPSC staff first approving cites studies that are of questionable application to the situation of children in the United States. Second, they discount any studies that tend to prove them wrong (and which happen to be the only studies conducted in the United States, and also happen to be on people who have a diet similar to children since children don't often smoke or drink). Third, after discounting any contrary evidence, CPSC staff argues, "[t]hus, there is no convincing evidence that arsenic does not cause cancer at relatively low exposures."[47] Given the evidence presented by CPSC staff, it is easier to draw the conclusion that "there is no convincing evidence that arsenic causes cancer at relatively low exposures."

In the CPSC staff's risk assessment it seems that they erred on the side of caution whenever faced with a choice. As a result, they arrive at a result for which there is no scientific support.

Klamath Basin

In 2001, a drought coupled with over-committed water resources lead to a confrontation between irrigators in the Klamath Basin and the federal government. The Bureau of Reclamation (BOR) manages the Klamath Basin Project in Oregon and California. The operation of the project affects a number of endangered species, including the Lost River sucker, the shortnose sucker, and the coho salmon. The suckers are managed by the Fish and Wildlife

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[43] CPSC BRIEFING PACKAGE AT 315. They further argue that "data do not exist that elucidate the mechanism of arsenic-induced carcinogenicity or define a non-linear effect, and that linear extrapolation at low doses is appropriate in this case." *Id.*

[44] *See* National Research Council, Arsenic in Drinking Water (1999).

[45] CPSC BRIEFING PACKAGE AT 90.

[46] *Id. at* 90.

[47] *Id. at* 89.

Service (FWS), while the salmon (because it is an anadromous fish) is managed by the National Marine Fisheries Service (NMFS). Under section 7 of the Endangered Species Act, all federal agencies must consult the FWS or the NMFS to ensure that the agency's actions are "not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification" of the species critical habitat.[48]

Under the requirements of section 7, the BOR submitted a biological assessment of its proposed operation of the Klamath Basin Project and its likely effects on the suckers. On April 6, 2001, the FWS released its report on the biological assessment that found that the BOR's proposed operation of the Klamath Basin project would jeopardize the continued existence of the endangered suckers.[49] To avoid jeopardizing the continued existence of the suckers, the FWS proposed "reasonable and prudent alternatives" (RPA) for the operation of the Klamath Project.[50] Among other things the RPAs called for the BOR to maintain higher lake levels than the BOR called for in its assessment.

Because the operation of the Klamath Project would also affect the coho salmon in the Klamath River, the NMFS also reviewed the BOR's biological assessment. Like the FWS, the NMFS's biological opinion found that the BOR's proposed plan would jeopardize the continued existence of the coho salmon.[51] The NMFS proposed RPAs which called for higher water flows in the Klamath River to protect the coho salmon.

During 2001, as the drought progressed, it became impossible for the BOR to fulfill the requirements of the FWS's and NMFS's RPAs as well as provide water to the farmers who used the Klamath Project water to irrigate their crops. As a result, on April 6, the BOR stopped water deliveries to the irrigators. With no irrigation water, the farmers' crops withered and died. Some estimate the economic lost was over $150 million.[52]

Because of the severe economic consequences, coupled with allegations the FWS and NMFS used poor science in their decision-making, the National Research Council (NRC) of the National Academy of Sciences reviewed the scientific validity of the FWS's and NMFS's biological opinions. The NRC found that there was "no sound scientific basis" for maintaining lake levels as high as the FWS's RPAs called for.[53] The NRC also "did not find clear scientific

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[48] ESA §7.

[49] Fish and Wildlife Service, Biological/Conference Opinion Regarding the Effects of Operation of the Bureau of Reclamation's Klamath Project on the Endangered Lost Ricer Sucker (*Deltistes luxatus*), Endangered Shortnose Sucker (*Chasmistes brevirostris*), Threatened Bald Eagle (*Haliaeetus leucocepahalus*), ad Proposed Critical Habitat for the Lost River/Shortnose Suckers i (Apr. 2001) (available at http://www.mp.usbr.gov/kbao/esa/34_final_sucker_bo_4_06_01.pdf).

[50] *Id.* at 144.

[51] National Marine Fisheries Service, Biological Opinion: Ongoing Klamath Project Operations (Apr. 2001) (available at http://www.mp.usbr.gov/kbao/esa/38_cohobo_4_6-01.pdf).

[52] Ron Hathaway, Klamath Water Allocation Background. In "Water Allocation in the Klamath Basin: An Assessment of Natural Resource, Economic, Social, and Institutional Issues" 14 (Dec. 2001)

[53] NATIONAL ACADEMY OF SCIENCES, COMMITTEE ON ENDANGERED AND THREATENED FISHES IN THE KLAMATH RIVER BASIN, INTERIM REPORT ON ENDANGERED AND THREATENED FISHES IN THE KLAMATH RIVER BASIN 4 (2002).

or technical support for increased minimum flows in the Klamath River."[54] Worse the NRC found that the increased flows that the NMFS called for could actually be lethal for the coho because the water would be too hot.[55] In other words, the two reasonable and prudent alternatives, which cost the irrigators the irrigation waters during 2001, were found not to be supported by sound scientific evidence.

One reason why the both the FWS and NMFS would write biological opinions not supported by the scientific evidence is that scientists' were following the precautionary principle. The Endangered Species Act is a good example of a statute that, while it does not mention the precautionary principle by name, nevertheless follows much of the spirit of the precautionary principle. For example, the *TVA v. Hill*,[56] the Supreme Court held that "it was the intent of Congress in enacting this statute to halt and reverse the trend toward species extinction, whatever the cost."[57] Furthermore, the Supreme Court found that Congress had made it "abundantly clear that the balance has been struck in favor of affording endangered species the highest of priorities, thereby adopting a policy that it described as 'institutionalized caution.'"[58]

Because the scientists were operating under the "whatever the cost" mandate of the Endangered Species Act, they took actions they thought would be best for the species, at literally, whatever the cost. While there was "no sound scientific basis for recommending" keeping the lake levels high,[59] the FWS biologist must have assumed that they would err on the side of caution and recommend high lake levels. Because, as the NRC pointed out, there was no conclusive evidence between sucker mortality and lake levels,[60] the FWS biologists must have reasoned that because of the lack of certainty, they would take the course of action that makes the most intuitive sense—suckers needs water to survive, if there isn't enough water the suckers will die, therefore, more water should give the fish a better chance to survive. The NRC's review of the data explained that there is no scientific evidence to support a position of higher or lower lake levels. Because the Endangered Species Act does not weigh the costs of these decisions, the biologists, when faced with uncertainty, try to be cautious, whether or not there is any scientific evidence for that decision.

One of the problems with the precautionary principle is laid bare by the NMFS's decision to keep higher minimum flows in the Klamath River. Like the FWS biologists, the NMFS's biologists had to make a decision when there was a lack of scientific information. Also like the FWS biologists, they also made the decision which made the most intuitive sense—since salmon need water to survive, more water in the river will help the salmon live. As the NRC found, however, "there were no scientific or technical support for increased minimum flows in the

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[54] *Id.* at 5.

[55] *Id.*

[56] 437 U.S. 153 (1978).

[57] *Id.* at 184.

[58] *Id.* at 194.

[59] NATIONAL ACADEMY OF SCIENCES, COMMITTEE ON ENDANGERED AND THREATENED FISHES IN THE KLAMATH RIVER BASIN, INTERIM REPORT ON ENDANGERED AND THREATENED FISHES IN THE KLAMATH RIVER BASIN 4 (2002).

[60] *Id.* at 4–5.

Klamath River."[61] Worse, the NMFS apparent attempt to take the cautious approach to protecting the coho salmon could have resulted in more salmon dying. According to the NRC report, the additional water to maintain minimum flows in the river would come from reservoirs and "this water could equal or exceed the lethal temperatures for coho salmon during the warmest months."[62] Thus, in an attempt to be cautions in evaluating the risks of lower versus higher water flows, the NMFS in taking a cautious approach, likely made it more difficult for the coho to survive.

This example demonstrates the problems of making decisions when there is a lack of scientific information. Taking apparently precautionary measures turned out not to be precautionary at all. The seemingly precautionary measures provided no benefits for the suckers, it likely harmed the coho salmon, and it cost the area about Klamath Falls, Oregon well over $100 million.

Forest Planning

As noted above, a corollary to the precautionary principle is that the consideration of an environmental decision must "involve an examination of the full range of alternatives, including no action."[63] Taken literally, this corollary calls for paralysis by analysis. That is the current situation in our nation's national forests.

A precautionary approach to forest management does not improve forest management. To the contrary, it can undermine forest management goals. According to the Administration, 190 million acres of public lands are at increased risk of catastrophic wildfire;[64] tens of millions of acres of forestlands are threatened by insects and diseases;[65] and invasive species are rapidly spreading, endangering forest, rangelands, and riparian areas.[66] These costs must be weighed against the potential environmental consequences of policies designed to reduce fuel loads in national forests.

Fires are an important and necessary part of many forest ecosystems, but when forests become too dense, forest fires that would otherwise be beneficial or benign become destructive and damaging. Because of fire suppression[67] and a lack of anthropogenic fire ignition,[68] many of our forests are denser than in the past. In some places, such as some ponderosa pine forests, the "forests are 15 times more dense than they were a century ago."[69] Coupling dense, unhealthy forests with drought conditions in much of the West means that when fires start they frequently

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[61] *Id.* at 5.

[62] *Id.*at

[63] The Wingspread Statement on the Precautionary Principle.

[64] Healthy Forests: An Initiative for Wildfire Prevention and Stronger Communities 1 (2002).

[65] Forest Service, *The Process Predicament* 5 (2002).

[66] *Id.*

[67] *Id.*

[68] *See* STEPHEN PYNE, FIRE IN AMERICA: A CULTURAL HISTORY OF WILDLAND AND RURAL FIRE (1997).

[69] Healthy Forests: An Initiative for Wildfire Prevention and Stronger Communities 4 (2002).

become holocaust fires killing large stands of trees, damaging fisheries, destroying endangered species habitat, and sterilizing the soil.[70]

While almost everyone agrees that the forest health is a problem and thinning should occur on much of the national forest, very little work is getting done on the ground. A major stumbling block is that the forest planning and environmental review process requires so much analysis. Some of the important function of forest planning is to look at alternatives and to analyze risks. The National Forest Management Act (NFMA) arose out of concerns the Forest Service was too focused on cutting trees, and was blind to the environmental consequences of its actions.[71] In other words, the Forest Service seemed only concerned with the benefits of cutting trees without considering the ecological risks of those decisions. As a result, NFMA increases the public participation requirements in forest planning to make sure that risks of decision made in the forest were properly assessed.[72] However, the problem is that the identification and planning for the management of the risks has grown so cumbersome, very little work on the ground occurs. According to the Administration:

- It can take six months to prepare environmental planning documents for even routine prescribed fire treatments. More complicated projects can take two years or longer.
- Timber sales to achieve fuels reduction and forest health objectives, consistent with forest health management plans, can take two to four years to prepare and complete.
- A study commissioned by the Forest Service in 2001 found that project decisions by the agency involve as many as 800 individual requirements and over 100 points where various laws and required processes interact. The study concluded that "the process interaction between laws is extremely complex" making the project planning process "highly susceptible to recursion/interruption and even non-completion."
- Forest Service officials have estimated that planning and assessment activities consume 40 percent of total work at national forests—at a cost of more than $250 million per year.[73]
- Between January 2001 and July 2002, 48 percent of all Forest Service mechanical fuels reduction projects were appealed. In north Idaho and Montana, 100 percent of the mechanical fuel reductions projects were appealed.[74]

How does the Forest Service manage ecological risks in the forest? The answer far too often is that the Forest Service plans to manage risks, but does not take any on-the-ground actions. They are experiencing analysis paralysis because of the incredibly complex planning requirements, coupled with litigation over forest plans. Frequently it seems that more thought is put into managing the risks of litigation than in managing the ecological risks of actions in forest.

While some forest planning is necessary, forest plans require such extensive consideration of alternatives—including alternatives that will not be implemented—that the complexity creates analysis paralysis. By requiring forest plans to have a full range of

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[70] *Id.* at 4–6.

[71] *See* George C. Coggin et al., FEDERAL PUBLIC LAND AND RESOURCES LAW 713–16 (2001).

[72] *See* NFMA §6.

[73] Healthy Forests: An Initiative for Wildfire Prevention and Stronger Communities 13 (2002).

[74] *Id.* at 14.

alternatives, very little work can be achieved on the ground. The problem in the forest is that waiting to take action means that more forest burn in catastrophic forest fire instead of being restored to more natural conditions. In the name of planning and protecting the forest through plans, millions of acres of forest are sacrificed to catastrophic forest fires every year.[75] This example illustrates that even the more mild form of the precautionary principle, that which primarily calls for consideration of the full range of potential alternative actions, can frustrate efforts to enhance environmental protection.

In fact, in some of the efforts to improve forest health, such as the Administration's "Healthy Forest Initiative"[76] as well as in legislation currently before Congress,[77] one of the ways that they are trying to get more work done on the ground is by limiting the amount of alternatives that need to be considered by agencies.

Biased Toward a Precaution

In any decision involving uncertainty, there is the possibility of what statisticians call Type I or Type II errors. In regulatory terms, a Type I error occurs when a good outcome (e.g., life-saving drug) is incorrectly rejected, and a Type II error occurs when a bad outcome (e.g., a new drug that has negative effects) is allowed. Predictably, precautionary agencies are much more reluctant to make Type II errors, because victims of new products with unexpected negative side effects (like the diet drug Phen-Fen) are identifiable. Regulators become the subjects of hearings before Congress and appear in news stories.[78] As former FDA Commissioner Schmidt describes:

> [I]n all of FDA's history, I am unable to find a single instance where a congressional committee investigated the failure of the FDA to approve a new drug. But the times when hearings have been held to criticize our approval of new drugs have been so frequent that we aren't able to count them…. The message to the FDA staff could not be clearer. Whenever a controversy over a new drug is resolved by its approval, the agency and the individuals involved likely will be investigated. Whenever such a drug is disapproved, no inquiry will be made. The congressional pressure for our negative action on new drug applications is, therefore, intense.[79]

Type I errors are not identifiable, in part because the dead do not speak. We cannot identify with certainty which people died solely because they were not able to get drugs like Misoprostol. The victims of Type I errors are the silent victims of malaria who die because DDT

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[75] According to the National Interagency Fire Center 6.9 million acres burned in wildland fires in 2002. http://www.nifc.gov/stats/wildlandfirestats.html While not all of the fires were catastrophic, many were.

[76] *See* The Healthy Forest Initiative, at http://www.whitehouse.gov/infocus/healthyforests/ (last visited May 5, 2003).

[77] *See* H.R. 1904 (108th Congress).

[78] Peter Huber describes this precautionary approach in what he called "gatekeeper" activities. (1983) "Exorcists vs. gatekeepers in risk regulation." *Regulation* 7: 23-32

[79] A. Schmidt, "The FDA Today: Critics, Congress, and Consumerism," speech to National Press Club, (Washington, D.C., Oct. 29, 1974), cited in Aaron Wildavsky, *Searching for Safety* p. 224 (1988).

isn't readily available. These victims are not readily represented in the policy-making process—they do not appear at Congressional hearings, participate in notice-and-comment rulemakings, or appear on the evening news. But such victims are no less real than those who may be harmed by a dangerous new technology.

Agencies have substantial incentive to take actions for which they can claim credit. This is because agencies try to increase their budgets by convincing legislators and the public that their services are absolutely essential.[80] One good way for an agency to prove its worth is to protect the public from new and deadly risks or from new, and unproven drugs.

Thus, to avoid committing Type II errors and thereby allowing harmful activities to occur, agencies are understandably cautious in their decision-making. This precautionary bias is embedded in agency risk assessments, regardless of any agency procedures or statutory requirements.

Wealthier Is Healthier – Richer Is Cleaner

A particular problem with a precautionary bias is that it retards economic growth and technological progress. Economic growth and technological progress have been a tremendous boon to both human health and environmental protection. Efforts to limit such progress are likely to be counterproductive. Regulatory measures that stifle innovation and suppress economic growth will deprive individuals of the resources necessary to improve their quality of life, and deny societies the ability to make investments that protect people and their environs.

The rise of industrial society has coincided with a massive explosion of wealth and health that is unprecedented in the history of human civilization. For centuries average life expectancy hovered in the twenties and thirties. U.S. life expectancy in 1900 was only 47. Today, in developed nations life expectancy is nearly 80.[83] Infant and maternal mortality plummeted over this same period, as have the incidence and mortality of typhoid, diptheria, tuberculosis, and other lethal diseases. [84] These positive trends are largely the result of increased wealth, and the benefits such wealth brings. Higher economic growth and aggregate wealth strongly correlate with reduced mortality and morbidity.[85] This should be no surprise as the accumulation of wealth is necessary to fund medical research, support markets for advanced life-saving

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[80] William C. Mitchell & Randy T. Simmons, *Beyond Politics* p. 61 (1994).

[83] See, e.g., Nicholas Eberstadt, Population, Food and Income, in The True State of the Planet (Ronald Bailey ed., 1995).

[84] *Id.*

[85] See, for example, Susan L. Ettner, "New Evidence on the Relationship Between Income and Health," 15 *Journal of Health Economics*, vol 15 (1996), p. 67; John D. Graham, et al., "Poorer is Riskier," *Risk Analysis*, vol. 12, no. 3 (1992), p. 333-37; Ralph L. Keeney, "Mortality Risks Induced by Economic Expenditures," *Risk Analysis*, vol. 10, no. 1 (1990), pp. 147-59.

technologies, and build infrastructure necessary for better food distribution, and so on. In a phrase, "richer is safer and poorer is sicker."[86]

Cancer rates are often blamed on environmental exposures to chemicals and other synthetic substances. Were this so, one would expect cancer rates to increase with the proliferation of synthetic chemicals in our food supply and environs. This has not been the case. The most recent report of the National Cancer Institute shows that overall incidence and death rates for cancer are also declining.[87] Even lung cancer incidence, largely the result of smoking, has begun to decline.[88] Simply put, "[t]he common belief that there is an epidemic of death from cancer in developed countries is a myth, except for the effects of tobacco. . . . For most non-smokers, the health benefits of modern society outweigh the new hazards."[89] In short, "the Western world is a remarkably healthy place to live."[90]

Economic progress is no less essential for environmental protection than for protection of public health. Environmental protection is a good and, like all goods, it must be purchased. Wealth is required to finance environmental improvements, from the purification of drinking water to invention and installation of low-emission technologies. Not only are wealthier communities healthier than poorer communities, on average, they tend to be more concerned about protecting environmental values as well. Wealthier societies have both the means and the desire to address a wider array of environmental concerns.[91]

Pollution, while still a serious environmental problem in much of the world, is not the mortal threat to human survival it once was. At the dawn of the 20th century, soot and smoke permeated cities, sometimes to lethal effect. In 1948, a four-day weather inversion in Donora, Pennsylvania, blanketed the town with pollution from local factories, killing eighteen people.[92] Over the past several decades, pollution levels in wealthy, industrialized societies have declined, particularly in the case of those emissions for which the health impacts are most severe.[93] "Countries undergo an environmental transition as they become wealthier and reach a point at which they start getting cleaner."[94] This occurs first with particularly acute environmental concerns, such as access to safe drinking water and sanitation services. As affluence increases,

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[86] Aaron Wildavsky, *Searching for Safety* 58 (1988).

[87] Holly L. Howe, et al., "Annual Report to the Nation on the Status of Cancer (1973 Through 1998), Featuring Cancers With Recent Increasing Trends, *Journal of the National Cancer Institute*, Vol. 93, No. 11, June 6, 2001.

[88] *Id.*

[89] Richard Peto, et al., *Mortality from Smoking in Developed Countries, 1950-2000*, (Oxford: Oxford University Press, 1994).

[90] *Id.*

[91] *See* Seth W. Norton, "Property Rights, the Environment and Economic Well-Being", in *Who Owns the Environment?* Peter J. Hill & Roger E. Meiners eds. (Lanham, MD: Rowman & Littlefield, 1998), pp. 37, 45.

[92] Cited in Indur Goklany, "Richer Is Cleaner," in *The True State of the Planet*, R. Bailey, ed. (New York: The Free Press, 1995), p. 347.

[93] See, generally, *id.* See also, Indur Goklany, *Clearing the Air: The Real Story of the War On Air Pollution* (Washington, D.C.: Cato Institute, 1999).

[94] Goklany, "Richer Is Cleaner," pp. 339, 341.

so does the attention paid to conventional pollution concerns, such as fecal coliform bacteria and urban air quality.[95]

There is no doubt that chemicals pose risks. Indeed, some of the chemicals and other technologies targeted by advocates of the precautionary principle can cause problems if misused. Yet it is notable that the proliferation of these technologies has coincided with the greatest explosion of prosperity and longevity in human history. If modern society were as risky as precautionary principle advocates suggest, this should not be the case.

Conclusions and Recommendations

In evaluating the role of precaution, the Work Group should review the 1983 National Academy of Sciences report that spelled out the process by which regulators should quantitatively evaluate risks and make policies to reduce those risks.[96] It suggested separating the process into two parts: risk assessment and risk management. *Risk assessment* is a purely scientific process that measures the risk of an activity. For example, risk assessment could estimate the risk of contracting cancer from exposure to a certain chemical over a certain length of time. Risk assessment does not evaluate whether a risk is too high, or what should be done about it. That decision is made in the risk management phase. *Risk management* takes scientific risk assessment information and combines it with other information, such as the cost and feasibility of reducing risks, to determine what action to take.[97]

Risk assessments should focus on developing the most accurate possible assessment of potential risks. To achieve this, the most probable assumptions should be used, not those that are the most conservative. Reliance on the most probable assumptions does not mean that risk assessments should avoid uncertainty. To the contrary, risk assessments typically involve an element of uncertainty. Rather than addressing this uncertainty by systematically biasing the risk assessments in a particular direction, it would be preferable to make the level of uncertainty explicit in the risk assessment. Therefore, where risks are uncertain, risk assessments should characterize the extent of the uncertainty and provide bounded estimates. Uncertainty in risk assessment does not justify the incorporation of precautionary standards in risk assessments.

There are many problems with precautionary risk assessments. First, an overly cautious risk assessment systematically overstates risks. The overstatement of risk is frequently cited as

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[95] Goklany observes that while the "environmental transition" for drinking water and sanitation occurs "almost immediately as the level of affluence increases above subsistence," the transition appears to occur at approximately $1,375 per capita for fecal coliform and $3,280 and $3670 per capita for urban particulate matter and sulfur dioxide concentrations respectively. *Id.* at 342. For a fuller treatment of the correlation between affluence and air quality, see Goklany, *Clearing the Air*.

[96] National Academy of Sciences. *Risk Assessment in the Federal Government: Managing the Process.* Washington, DC: National Academy Press. 1983.

[97] *See* Mercatus Center Public Interest Comment on OMB's 2003 Benefit Cost Report, RSP 2003-11 (available at www.mercatus.org).

the expected value of the risk, and not for what it really is—the upper bound of a risk assessment. Thus, when an agency engages in risk management based on overstated risk assessments, they tend to focus their regulatory efforts on new risks, while ignoring older, but more significant risks.

Second, overestimating risks leads regulators to over-regulate new activities, thus forcing society to forgo the new benefits of a new activity or technology. The risks of change must be weighed against the risk of stagnation. In every case, "[t]he empirical question is whether the health [and environmental] gains from the regulation of the substances involved are greater or lesser than the health [and environmental] costs of the regulation."[98] As human history shows, economic growth and technological progress makes the world safer. Economic growth and technological progress are only possible through accepting new risk. Retarding these engines of change only retards societies' ability to make the world safer.

Third, another problem with a precautionary risk assessment occurs because eventual risk management decisions often involve trade-offs between different risks. Biasing risk assessments in one direction will produce risk management policies that are consistently biased in the same direction. This is unlikely to maximize social welfare or provide for the greatest protection of human health.

Overestimating risk in a risk assessment can predetermine the outcome of risk management. As a result, those who conduct the risk assessment can effectively dictate policy choices for agencies by producing risk assessments that only allows for certain limited forms of risk management.

Finally, when assessing the risks of new technologies or regulated activities, it is important to also assess the benefits of such activities, particularly the potential benefits to human health and environmental protection. Here again, uncertainty is not an excuse for excluding the consideration of certain potential impacts, nor is it an excuse for systematically biasing the assessments in one particular direction.

Agencies have strong incentives to be very cautious in their risk management. Coupling precaution in risk assessment with cautious risk management leads agencies to over-regulate and deny society of the safety improvements that come from new activities and technologies. Overregulation led to the FDA's delay in the approval of Misoprostol, causing needless suffering for ulcer sufferers. Malaria kills three thousand children a day,[99] but DDT, the most effective pesticide in fighting the spread of malaria, is banned in many countries because of regulatory over-cautiousness. In the Klamath Basin, over-cautiousness cost the region over a $150 million without aiding either suckers or the salmon (and may have harmed the salmon). As the example of the national forests show, being overly cautious in the management of forests can lead to the very conditions agencies seek to avoid.

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[98] Aaron Wildavsky, *But Is It True?* (1995), p. 428.

[99] World Health Organization, *Malaria is alive and well and killing more than 3000 African children every day* (Press Release) available at http://www.who.int/mediacentre/releases/2003/pr33/en/ (last visited May 3, 2003).

In sum, regulators need to be aware that even the most well-intentioned precautionary measures can have terrible results.[100] The precautionary principle's threat to technological progress is itself a threat to public health and environmental protection. In the name of precaution, agencies should avoid the precautionary principle.

[100] *See, e.g.*, Frank B. Cross, Paradoxical Perils of the Precautionary Principle, 53 WASH. & LEE L. REV. 851 (1996). STEPHEN BREYER, BREAKING THE VICIOUS CIRCLE: TOWARD EFFECTIVE RISK REGULATION 22 (1993); Edward W. Warren & Gary E. Merchant, "More Good Than Harm": A First Principle for Environmental Agencies and Reviewing Courts, 20 ECOLOGY L.Q. 379, 390 (1993).