IMPLICATIONS OF THE PRECAUTIONARY PRINCIPLE FOR ENVIRONMENTAL REGULATION IN THE UNITED STATES: EXAMPLES FROM THE CONTROL OF HAZARDOUS AIR POLLUTANTS IN THE 1990 CLEAN AIR ACT AMENDMENTS

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I

INTRODUCTION

In this Article we take a cautionary approach to the Precautionary Principle. We argue that the hazardous air pollutant provisions of the 1990 Clean Air Act Amendments provide an example of the Precautionary Principle incorporated into U.S. environmental legislation. Evaluating the outcome thus far leads us to the conclusion that utilizing the Precautionary Principle as a basis for legislation can be problematic to public-health goals. Our reasons for this conclusion include the potential inhibition of the development of more effective air pollution control technology once the regulations have been written, the inhibitory effect on further research and the demonstration of health benefit, and the loss of focus on those hazardous air pollutant compounds and sources that provide the greatest likelihood for toxicity and misplaced focus on individual rather than population exposure—a loss of focus that undermines the public-health basis of the Clean Air Act. A clear understanding of its potential negative aspects is needed to maximize the many potential benefits of the Precautionary Principle to public-health and environmental laws and regulations.

Many advocates of more expansive environmental and public-health control measures urge prolific use of the Precautionary Principle as a rationale for regulatory intervention. One of the earliest and substantial formulations of the Precautionary Principle was adopted in the 1992 Rio Declaration: "Nations shall use the precautionary approach to protect the environment. Where there are threats of serious or irreversible damage, scientific uncertainty shall not be

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used to postpone cost-effective measures to prevent environmental degradation."[1]

Yet, the Precautionary Principle is a broad statement of principle, subject to varying interpretations. More recent formulations, such as the Wingspread Statement,[2] have moved away from Rio's emphasis both on cost effectiveness and how serious a threat must be to invoke the Precautionary Principle, and have extended the Precautionary Principle to address protection of public health as well as the environment.

Such broad statements can be very valuable, even if vaguely defined. Precaution is a universal value similar to "sustainable development," which serves as a rather amorphous rallying cry for many divergent interests that support economic development in a manner that does not harm the environment.[3] It is hard to imagine that anyone is against sustainable development. The Precautionary Principle also is supportable as a primary preventive approach that is as old as the Hippocratic Oath's adjuration: "Above all do no harm."

Thus, the Precautionary Principle is increasingly advocated and grounded in legally enforceable contexts such as international treaties. For instance, as urged by the European Community in the hormone-treated beef case, the World Trade Organization was forced to consider whether the Precautionary Principle is an established principle of law applicable to adjudication of international trade disputes,[4] and the WTO will undoubtedly face the issue again in future disputes over genetically modified organisms and biodiversity. In such contexts, the exact definition of the Precautionary Principle and the legal implications of its use are of critical importance.

A major motivation for advocacy and action under the Precautionary Principle is a sense of frustration with the slow pace of science and risk-based regulation. This is understandable. An all-too-familiar ploy of industry is to obstruct or delay risk-based regulation by requesting more scientific study[5] or

1. *Rio Declaration on Environment and Development*, U.N. Conference on Environment and Development, Principle 15, U.N. Doc. A/CONF.151/5/Rev.1 (1992), *reprinted in* 31 I.L.M. 874 (1992).

2. The Wingspread Statement is as follows: "When an activity raises threat of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically." PROTECTING PUBLIC HEALTH AND THE ENVIRONMENT: IMPLEMENTING THE PRECAUTIONARY PRINCIPLE 8 (Carolyn Raffensperger & Joel Tickner eds., 1999).

3. An example of the ability of both industry and environmental groups to support sustainable development was Clinton's Presidential Council on Sustainable Development, which was co-chaired by Jonathon Lash, head of the World Resources Institute, a leading environmental group, and David Buzzelli, a vice-president of Dow Chemical. *See Forum; Sustainable Development Council*, 101 ENVTL. HEALTH PERSP. (Oct. 1993), *available at* http://ehpnet1.niehs.nih.gov/docs/1993/101-5/forum.html. Also, industry has developed the World Business Council on Sustainable Development, which has 160 multinational members and is headquartered in Geneva. *See* The World Business Council for Sustainable Development, *at* www.wbcsd.ch (last visited Mar. 28, 2003).

4. *See* EC Measures Concerning Meat and Meat Products (Hormones), Jan. 16, 1998, WT/DS26/AB/R (1998), *available at* http://docsonline.wto.org/DDFDocuments/t/WT/DS/26-12.wpf.

5. For a recent critique of industry delaying tactics that links its thesis specifically to the Precautionary Principle, see SHELDON RAMPTON & JOHN STAUBER, TRUST US WE'RE EXPERTS: HOW INDUSTRY MANIPULATES SCIENCE AND GAMBLES WITH YOUR FUTURE 120-51 (2002).

challenging its scientific validity in the courts.[6] Even when ultimately unsuccessful, such challenges often delay regulation by years. Inevitably, in any situation in which a chemical has been regulated after the slow accretion of proof of harm, there is a time period during which advocates of control have been forced to wait until new information developed or was accepted.[7] When the scientific information does become sufficiently preponderant to warrant regulatory action, it is then obvious that it would have been beneficial to public health or the environment to heed the voice of advocates much earlier. The European Community, in its current push for general acceptance of the Precautionary Principle, has recently published a scholarly review of situations in which earlier regulatory action based upon as yet inconclusive science would have been beneficial.[8]

However, to some advocates of the Precautionary Principle this is not simply an issue of when there is sufficient information to make a decision. Rather, the Precautionary Principle involves concepts of deconstructionism and postmodern science and democracy, the need to replace a non-democratic technocracy with a more humanistic and community-oriented approach to decision-making.[9] To these supporters of the Precautionary Principle, risk assessment and its practitioners are a threat to the future of our planet and the Precautionary Principle is seen as an effective means to firmly shift the burden of proof onto the would-be polluter.[10]

The Precautionary Principle can be considered generally under two headings:[11]

1. Precautionary actions that supplant standard risk-based approaches through actions based upon the threat of a problem without sufficient information to assign risk, or through shifting the burden of proof to the

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6. For examples of industry challenging the scientific validity of regulation in the courts, see, David Rosner & Gerald Markowitz, *Industry Challenges to the Principle of Prevention in Public Health: the Precautionary Principle in Historical Perspective,* 117 PUB. HEALTH REP. 501-12 (2002), and EUROPEAN ENVTL. AGENCY, LATE LESSONS FROM EARLY WARNINGS: THE PRECAUTIONARY PRINCIPLE 1896–2000 (2001), *available at* http://reports.eea.eu.int/environmental_issue_report_2001_22/en/Issue_Report_No_22.pdf (last visited Apr. 11, 2003).

7. *See, e.g.*, EUROPEAN ENVTL. AGENCY, *supra* note 6.

8. *Id.* Notably, the document does not explore situations in which early warnings about a beneficial chemical turned out to have been mistaken.

9. *See, e.g.*, MARY O'BRIEN, MAKING BETTER ENVIRONMENTAL DECISIONS (2000). For a more generalized discussion of postmodern thought and environmentalism, see Paul Wapner, *Leftist Criticism of "Nature:" Environmental Protection in a Postmodern Age,* DISSENT MAG., Winter 2003, at 71-75, *available at* http://www.dissentmagazine.org/menutest/articles/wi03/wapner.htm (last visited Apr. 11, 2003).

10. *Cf.* O'BRIEN, *supra* note 9, at 15, 39 ("Risk assessment is an extremely flexible and powerful tool for dispelling calls for change" and "is primarily used to defend unnecessary activities that harm the environment or human health.").

11. We recognize that for the purposes of this Article we are creating a simplified operational dichotomy of the many possible approaches that fall at least arguably under the heading of the Precautionary Principle. John Applegate has introduced a useful term—Precautionary Preference—in his discussion of how American environmental law reflects the Precautionary Principle. *See* John S. Applegate, *The Precautionary Preference: An American Perspective on the Precautionary Principle*, 6 HUM. & ECOLOGICAL RISK ASSESSMENT 413, 413-43 (2000).

presumption of harm. We will call these "pre-emptive precautionary approaches."

2. Precautionary actions that take more prudent approaches to risk assessment and increase risk management activity, for example, by establishing more conservative default assumptions to risk assessment, or through choosing a more stringent risk level on which to base regulatory controls, or by adding additional safety factors. We will call these "risk-based precautionary approaches."[12]

While many risk professionals view the Precautionary Principle not as something new, but merely as another call to build further prudent assumptions and safety factors into risk assessment and risk management,[13] the regulation of hazardous air pollutants ("HAPs") in the 1990 Clean Air Act Amendments[14] ("CAAA") embodies pre-emptive precautionary actions that supercede risk assessment and establish a new principle for regulatory intervention.

We have evaluated the 1990 CAAA concerning HAPs as it is our belief that in such legislation Congress radically altered the United States' approach to regulating HAPs by a classic imposition of the Precautionary Principle.[15] The CAAA are, therefore, an appropriate means to evaluate the implications of the use of the Precautionary Principle in environmental regulation in the United States.

II

REGULATION OF HAZARDOUS AIR POLLUTANTS: BACKGROUND[16]

Before the 1990 CAAA, HAPs had been regulated through a science-based process that called for EPA to identify unregulated air pollutants that were likely to cause serious adverse health effects at ambient air concentrations.[17] To

12. Risk-based approaches include the many safety factors and prudent default assumptions built into contemporary risk assessment. An example is the additional factor of ten for the protection of children in the Food Quality Protection Act. *See* Pub. L. No. 104-170, 110 Stat. 1489 (1996). Other examples are the many conservative default assumptions built into risk assessment, such as assuming an individual stays stationary in a high-risk location around the clock for seventy years, or that any single molecule of a carcinogen can cause cancer.

13. The use of a "maximally exposed individual" as the target for the residual risk determination in the Clean Air Act Amendments' hazardous air pollutant provisions might be considered an example of a risk-based precautionary approach. *See* 42 U.S.C. § 7412(f)(2)(A) (2000).

14. Clean Air Act Amendments of 1990, Pub. L. No. 101-549, 104 Stat. 2399 (1990) (codified as amended in scattered sections of 42 U.S.C.).

15. We have found no indication that HAPs were discussed by Congress explicitly in terms of the Precautionary Principle. Nor did we find the term "Precautionary Principle" in the published legislative history. Nonetheless, we believe, as discussed *infra*, that the amended HAPs Program clearly embodies the Precautionary Principle.

16. For an overview of HAP control, see, for example, Arnold W. Reitze, Jr. & Randy Lowell, *Control of Hazardous Air Pollution*, 28 B.C. ENVTL. AFF. L. REV. 229 (2001).

17. 42 U.S.C § 7412(b)(1)(A) (1988) (amended 1990). A "hazardous air pollutant" was defined as an air pollutant to which no ambient air quality standard is applicable and that, in the judgment of the EPA administrator, causes or contributes to air pollution that may reasonably be anticipated to result in an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness. § 7412(a)(1) (amended 1990).

a large extent, this was aimed at regulating known human carcinogens.[18] During this period, risk-based regulation of HAPs was an arduous and time-consuming process, subject to lengthy hearing procedures and court challenges.[19] In the eighteen years before the 1990 amendments, EPA listed only eight substances as HAPs and promulgated emission limitations for only seven substances.[20]

The regulation of benzene as a HAP provides a marked demonstration of the cumbersome nature of the regulatory process. In 1977, after decades of scientific debate, it was clearly established that benzene is a human carcinogen.[21] Accordingly, the Occupational Safety and Health Administration ("OSHA") went through a number of procedural approaches to set a new workplace standard that, after challenge by industry, was struck down by the Supreme Court in

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18. These compounds, such as benzene, could not readily be regulated under the "national ambient air quality standards" ("NAAQS") provisions of the Clean Air Act for two major reasons. First, in contrast to the NAAQS pollutants, such as ozone and particulates, there was no direct evidence of adverse effects on humans at ambient concentrations in the general environment. When standards for the NAAQS pollutants, the so-called "primary air quality pollutants," were set, these pollutants were known to cause adverse effects in humans at actual outdoor levels based upon epidemiological studies or observations of humans experimentally exposed to these pollutant levels. In contrast, as an example, benzene had only been shown to cause leukemia in humans at concentrations encountered in the workplace that were approximately a thousand-fold higher than the worst anticipated outdoor levels, and there were no epidemiological studies demonstrating that ambient levels of benzene were capable of increasing leukemia risk. *See, e.g.,* Bernard D. Goldstein & Gisela Witz, *Benzene, in* ENVIRONMENTAL TOXICANTS: HUMAN EXPOSURES AND THEIR HEALTH EFFECTS 121-50 (Morton Lippman ed., 2d ed. 1999). Instead, benzene and other such HAP compounds, particularly the carcinogens, were assumed to be harmful based upon risk analysis, including extrapolation from animals to humans, or from high dose in the workplace to much lower doses in the general environment. Second, setting an ambient standard in the NAAQS process required the EPA administrator to determine the level of a compound that, with an adequate margin of safety, would not produce an adverse effect in a sensitive population. *See* 42 U.S.C. § 7409(b)(1) (2000). On the requirement to protect sensitive populations, see, for example, *American Lung Ass'n v. EPA*, 134 F.3d 388 (D.C. Cir. 1998). This requirement implies that there is some harmless level of a compound. In contrast, standard prudent risk assessment for carcinogens uses a model that in essence assumes that every molecule poses a risk, however small, so that there is no level that is without any risk. It has been impossible for Congress, or for any administration, to suggest that there is an acceptable level of an environmental carcinogen. *See* Bernard D. Goldstein, *Toxic Substances in The Atmospheric Environment*: *A Critical Review*, 33 J. AIR POLLUTION CONTROL ASS'N 454, 454-67 (1983); Bernard D. Goldstein, *Critical Review of Toxic Air Pollutants—Revisited*, 36 J. AIR POLLUTION CONTROL ASS'N 367, 367-70 (1986).

19. Congressional frustration with EPA's lack of progress is reflected by the courts. *See, e.g.*, Natural Res. Def. Council v. Thomas, 689 F. Supp. 246, 260 (S.D.N.Y. 1988) (commenting on the plaintiff's assertion of unreasonable delay by EPA):

> It is a question of substance because of the leaden pace of EPA's progress in this area. Indeed, . . . in 1983 a congressional oversight subcommittee took then-EPA Administrator Ruckelshaus to task for delays in implementing Section 112. The subcommittee received from Mr. Ruckelshaus assurances which the Agency has not redeemed. In reviewing the chronology, replete with endless reviews, open-ended studies, proclaimed needs for further analysis, consultations and testings, but with minimal results, one is reminded of Gilbert's lyric in *Iolanthe*, Act 2:
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> > 'The House of Peers,
> > throughout the war,
> > Did nothing in particular,
> > And did it very well.'

Id. at 260.

20. Nat'l Mine Ass'n v. EPA, 59 F.3d 1351, 1353 n.1 (D.C. Cir. 1995).

21. Bernard D. Goldstein, *Benzene Hematotoxicity in Humans*. 2 J. TOXICOLOGY & ENVTL. HEALTH 69, 69-105 (Supp. 1977).

the 1980 decision *Industry Union Department, AFL-CIO v. American Petroleum Institute*, which emphasized the importance of risk assessment as a regulatory tool.[22] Meanwhile, EPA was moving through its own HAPs regulatory process with respect to benzene. Following the initial OSHA emergency action in 1977, EPA Administrator Douglas Costle began the first step of the Section 112 process by listing benzene as a hazardous air pollutant. An EPA press release of May 31, 1977 quotes Costle as saying: "EPA will begin a thorough review of current scientific data to determine the health risks from benzene in the ambient (outside) air. After this health risks assessment is completed, EPA will decide which sources of benzene emissions must be controlled, and the extent of control needed." [23]

Yet, six years later EPA had not yet regulated benzene. Congressional frustration with the slow pace of this process was evident in hearings for the new EPA administrator, William D. Ruckelshaus, during which Congress extracted a promise from Ruckelshaus of rapid agency action on benzene and other HAPs.[24] Pursuant to that promise, EPA in 1984 moved forward with emission standards for benzene.[25] The benzene regulation contained a table listing all of the major industrial sources of benzene, the tonnage of benzene released, the leukemia risk to the maximally exposed individual, the leukemia risk to the total population, the extent to which these risks would be reduced by the proposed control technology, the capital costs of these controls, and the yearly maintenance costs of the controls.[26] Based upon this information, EPA regulated some but not all of the sources of benzene.[27] Administrator Ruckelshaus carefully pointed out that the decision as to which benzene source to regulate and which not to regulate was based upon all of the information, rather than on any single risk or cost factor.[28] While this left the EPA administrator with maximum flexibility for future regulatory decisions on HAPs, it also left industry and public groups with further frustration concerning the selective and unpredictable nature of the process.

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22. 448 U.S. 607, 659 (1980).

23. Press Release, U.S. Envtl. Protection Agency, EPA to Regulate Benzene, a Suspected Cause of Leukemia (May 31, 1977), *available at* http://www.epa.gov/history/topics/benzene/01.htm (last visited Apr. 11, 2003).

24. Goldstein, *Benzene Hematotoxicity*, *supra* note 21.

25. National Emission Standards for Hazardous Air Pollutants; Benzene Emissions from Maleic Anhydride Plants, Ethylbenzene/Styrene Plants, and Benzene Storage Vessels; Proposed Withdrawal of Proposed Standards, 49 Fed. Reg. 8386 (proposed Mar. 6, 1984). These regulations actually were a revision of a proposal made by the outgoing Carter Administration on which no action had been taken. *See* 46 Fed. Reg. 1165 (proposed Jan. 5, 1981). The resultant regulatory maneuvering led *to Federal Register* documents through which EPA withdrew some of the earlier proposed actions and promulgated others. *See* National Environmental Standards for Hazardous Air Pollutants—Benzene Equipment Leaks (Fugitive Emission Sources), 49 Fed. Reg. 23,498 (June 6, 1984); Proposed National Environmental Standards for Hazardous Air Pollutants—Benzene Emissions, Coke By-Product Recovery Plants, 49 Fed. Reg. 23,522 (June 6, 1984).

26. *Id.*

27. *Id.*

28. This was specifically stated by Ruckelshaus to his staff at this time and also can be inferred from the lack of specificity in the federal regulations. *Id.*

Congressional and public impatience about the protracted pace of regulating the many chemicals emitted by industrial sources was further fueled by the Emergency Planning and Community Right-to-Know Act.[29] As a result of that Act, a Toxic Release Inventory provided readily accessible information that accounted for the pounds of specific HAP compounds released into a given community.[30] In part recognizing that TRI-fed public outrage would lead to a demand for control measures regardless of the degree of actual harm, industry offered relatively little opposition to the forthcoming legislation, and as a result,[31] in the 1990 CAAA, Congress embraced the Precautionary Principle by creating a HAPs program that imposed control measures regardless of the degree of risk.

III

HAPS PROGRAM UNDER THE 1990 CLEAN AIR ACT AMENDMENTS

The central elements of the amended HAPs program mandate precautionary action that is not based on, and in fact supplants, risk analysis and thus constitutes what we have called pre-emptive precautionary action. The amendments were a radical departure from the original HAPs program.

One major departure was Congress's enumeration of 189 chemicals it decreed as EPA-regulated HAPs.[32] Prior to the amendment, a substance could be regulated as a HAP only after EPA made a science-based determination following a rigorous risk analysis that determined the substance posed a substantial risk to human health at ambient air levels.[33] Thus, the amendment substituted legislative fiat for risk assessment in determining what substances are HAPs. The main role for science was left to be an exculpatory one: if an industry wants to remove a substance from the HAPs list, it must affirmatively demonstrate, by adequate scientific data, that the substance may not reasonably be anticipated to cause adverse effects to human health or the environment.[34]

"EPA will not remove a substance from the list of HAP based merely on the inability to conclude that emissions of the substance will cause adverse effects

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29. Pub. L. No. 99-499, 300-330, 100 Stat. 1613, 1728-58 (1986) (codified as amended at 42 U.S.C. §§ 11001-50).

30. *See* 42 U.S.C. § 11023 (2000); *see also* The Toxics Release Inventory Explorer, *at* http:www.epa.gov/triexplorer/chemical.htm (last visited Mar. 28, 2003).

31. The potential counter-argument—that the major public concern about HAPs was cancer, and that the HAP chemicals responsible for the overwhelming majority of cancer risk caused by air pollution were already regulated—was considered unlikely to be publicly or politically acceptable.

32. 42 U.S.C. § 7412(b), (d) (2000).

33. *See* Pub. L. No. 91-604, 84 Stat. 1685 (1970) (amending § 4(a) of the Clean Air Act).

34. 42 U.S.C. § 7412(b)(3).

> The Administrator shall delete a substance from the list upon a showing by the petitioner or on the Administrator's own determination that there is adequate data on the health and environmental effects of the substance to determine that emissions, ambient concentrations, bioaccumulation or deposition of the substance may not reasonably be anticipated to cause any adverse effects to the human health or adverse environmental effects.

§ 7412(b)(3)(C).

on human health or the environment."[35] This shift in the burden of proof is central to many of the explications of the Precautionary Principle.[36] It assumes that the harmfulness of chemicals, or at least synthetic chemicals, is implicit and that the only appropriate way to protect human health and the environment is to avoid their use unless rigorously shown to be safe.[37]

Another departure from the previous HAPs program in keeping with the Precautionary Principle is that the amendment mandates that EPA regulate all industrial sources of all HAPs based on a "maximum available control technology" ("MACT") standard[38] that essentially requires that the most stringent technologically-achievable emission standards are applied to all industrial sources emitting any listed HAP, regardless of the degree of risk to human health. All listed HAP sources are regulated using the same MACT standard.[39] Whether a source sits in the middle of a desert or the edge of the ocean with no one downwind for many miles, or in the midst of a densely populated city, makes no difference in setting emission limits. Nor is there any consideration of

35. 66 Fed. Reg. 21,930 (May 2, 2001). This interpretation was upheld *in American Forest and Paper Ass'n v. EPA*, 294 F.3d 113 (D.C. Cir. 2002), as accurately reflecting the unambiguous language of the statute. *See id*. at 119. Thus, the burden of proof has shifted. To put it simplistically, a substance listed by Congress is deemed guilty until proven harmless rather than innocent until proven harmful.

36. Sheldon Krimsky, *The Precautionary Approach*, 13 F. FOR APPLIED RES. & PUB. POL'Y 34, 34-37 (Fall 1998). *But see* J. Martin Wagner, *The Precautionary Principle and Chemical Regulation in the United States*, 6 HUM. & ECOLOGICAL RISK ASSESSMENT 459, 459-77 (2000) (pointing out that U.S. rules for regulating chemicals are schizophrenic in this regard, putting a higher burden of proof on new chemicals that may be safer than existing chemicals).

37. One could argue that there is an inexorable global move toward regulating the environment and health in keeping with the Precautionary Principle, that the Precautionary Principle is no more than another ratcheting up of the demand for health and for a clean environment occurring as part of economic development. Yet, there is also at least one example, dietary supplements, where the opposite appears to have occurred. Federal legislation, the 1994 Dietary Supplement Health and Education Act, severely limits the FDA from regulating the safety and efficacy of supplements sold to the public. *See* 21 U.S.C. § 342(f) (2000). There, the burden of proof was shifted away from the industry, which formerly had to demonstrate safety, and onto the FDA, which must now prove harm, the reverse of what happened to EPA with hazardous air pollutants. *Id.* It would be interesting to determine whether those who support the precautionary shift in the burden of proof in relation to hazardous air pollutants also support the retrogressive shift in the burden of proof in the case of dietary supplements. Is what we are observing a worldview related to nature and natural products rather than a belief in the Precautionary Principle?

38. Emission standards must require the "maximum degree of reduction" in HAP emissions that EPA determines is achievable (including a complete prohibition, where achievable), taking into consideration cost and any non-air-quality health and environmental impacts and energy requirements. 42 U.S.C. § 7412(d)(2). The "maximum degree of reduction in emissions" deemed achievable for existing sources may not be less stringent than the average emission limitation achieved by the best-performing twelve percent of sources in the category or subcategory. § 7412(d)(3). For new sources, it may not be less stringent than the emission control achieved in practice by the single best-controlled similar source. *Id.*

39. 42 U.S.C. § 7412(d). EPA is directed to establish emission standards for each subcategory and subcategory of HAPs sources. *Id.* EPA may make distinctions based on class, type, and size of source within a category or subcategory, but nothing in the statute permits the agency to make distinctions based on such risk factors as how potentially dangerous the substance is or how many people live nearby. *Id.* Also, MACT is not really the "maximum" available control technology. Wisely, section 112 contains language in which "maximum" is defined as the upper twelve percent of existing control technology, and there are other provisions that make it somewhat less daunting to define MACT. 42 U.S.C. § 7412(d)(3)(A).

how harmful the emitted chemical is known to be at ambient levels. This across-the-board, one-size-fits-all approach, without regard to the extent of population exposure or risk, contrasts markedly with EPA's risk and cost based selection of sources to regulate in the 1984 benzene NESHAPs.[40] In sum, the 1990 amendments ignore science and risk in determining which substances to designate as HAPs, which industrial sources of those substances to regulate, and how stringently to regulate them. Moreover, they shift the burden of proof from those advocating regulation to those opposing regulation, at least with respect to the 189 HAPs listed by Congress. They are therefore a regulatory action falling squarely within the category of primary precautionary action.

The amended program does, however, retain elements that can be viewed as risk-based precaution in its residual risk provisions, for example, the one-in-a-million target for the residual risk determination or the choice of the MEI as a target for the regulation of residual risk.[41] Nevertheless, these elements are secondary to the true thrust of the amendments. They are provisions that only serve to bolster the inclusiveness of the primary precautionary provisions.

IV

IMPLICATIONS OF THE 1990 CAAA FOR UNDERSTANDING THE IMPACT OF THE PRECAUTIONARY PRINCIPLE

The question arises, then, have these precautionary approaches worked? The 1990 advocacy position was that the new approach would be faster, better, and cheaper. It is at least arguable that it has not been faster or cheaper, given how long it has taken to write the regulations and their high cost of development and administration, not to mention the toll that uncertainty has on the marketplace. EPA has missed each one of its statutory deadlines for providing the regulations (although not by that much) and this has led to much grumbling from states and industry.[42] However, the key issue is whether this new approach has been better in achieving the public-health goals that are both explicit and implicit in the 1990 CAAA.

Achieving MACT inherently means that many tons of HAPs will be removed from the air, but we do not know how much of a health difference this will make, at least directly (it presumably has helped with ozone control). Almost all of the HAPs for which there was at least presumptive evidence that ambient levels provided a risk of adverse effects had been regulated before the 1990 CAAA, and those few for which there is new information, for example,

40. *See* National Emission Standards for Hazardous Air Pollutants; Benzene Emissions from Maleic Anhydride Plants, Ethylbenzene/Styrene Plants, and Benzene Storage Vessels; Proposed Withdrawal of Proposed Standards, 49 Fed. Reg. 8386 (proposed Mar. 6, 1984).

41. 42 U.S.C. § 7412(f)(2)(A).

42. U.S. GENERAL ACCOUNTING OFFICE, STATUS OF IMPLEMENTATION AND ISSUES OF THE CLEAN AIR ACT AMENDMENTS OF 1990 (Apr. 2000), *available at* http://www.gao.gov/newitems/rc0072.pdf (last visited Apr. 11, 2003).

butadiene, could have been regulated under the pre-1990 approach.[43] By requiring MACT, these amendments have led to more stringent control of at least some harmful pollutants, an impact that could be quantified (for example, reduction of outdoor benzene levels and the corresponding decrease in exposure and leukemia risk). However, for almost all of these newly regulated pollutants, which include the overwhelming majority of the 189 on the original list, there is inadequate data on which to base any firm presumption of health or environmental benefit.[44]

Of course, the reason there is so much uncertainty about health benefit is implicit in the Precautionary Principle. If you regulate pollutants without some degree of proof they are harmful, how can you quantify what harm has been averted? The congressional requirement that EPA perform a cost-benefit analysis, which can be done for NAAQS pollutants, cannot be achieved for those HAPs for which there is no evidence of benefit.[45] EPA is attempting to deal with the cost-benefit issues of HAPs and is caught in the very difficult situation of having to tell Congress that a legislative provision based on a precautionary approach that requires an agency to take actions without direct evidence of adverse effect is not readily compatible with another provision of the same law requiring cost-benefit analysis.[46] But, EPA has avoided making this statement, instead focusing on methodological issues and case studies of compounds that were previously regulated.[47]

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43. The developing toxicological and epidemiological information on butadiene led to two formal reviews of this compound by the U.S. National Toxicology Program since 1990. The outcomes were that butadiene was listed first as a "reasonably anticipated human carcinogen," the second highest hazard classification, and then additionally listed as a "known human carcinogen," the highest classification. *See* U.S. DEP'T OF HEALTH & HUM. SERVS., 10TH REPORT ON CARCINOGENS: 1-3, BUTADIENE (2002), *available at* http://ehp.niehs.nih.gov/roc/tenth/profiles/s025buta.pdf (last visited Apr. 11, 2003). As all commonly emitted air toxics that are "known human carcinogens" had been regulated before 1990, it is fair to assume that butadiene would have been regulated under the old rules.

44. A demonstration of the relative lack of information for many of the chemicals on Congress's list can be obtained by considering how many of the 189 chemicals were chosen for additional study under the new "high production volume" (HPV) agreement between EPA and the chemical industry. *See, e.g.*, U.S. ENVTL. PROTECTION AGENCY, 1990 HPV CHEMICAL LIST (1990), *available at* http://www.epa.gov/chemrtk/hpv_1990.pdf (last visited Apr. 11, 2003); U.S. ENVTL. PROTECTION AGENCY, 1994 HPV CHALLENGE PROGRAM CHEMICAL LIST (1994), *available at* http://www.epa.gov/chemrtk/hpv_1994.pdf (last visited Apr. 11, 2003); U.S. ENVTL. PROTECTION AGENCY, ORIGINAL LIST OF HAZARDOUS AIR POLLUTANTS, *available at* http://www.epa.gov/ttn/atw/orig189.html (last visited Mar. 28, 2003). We count 108 of the 189 toxic air pollutants to also be in the HPV list.

45. As discussed *infra*, evidence of benefit could be obtained if there is a willingness to invest in research to determine if the precautionary decrease in pollutant levels has had a positive impact on public health or the environment. EPA apparently recognizes the problem, as it reportedly has asked for FY 2004 budgetary funds to assess air toxics, among other programs, as the "agency has failed to generate data demonstrating health or environmental improvements." *See EPA Seeks Funds to Launch Effort Showing Program Effectiveness*, 10 RISK POL'Y REP. No. 2, at 17-18 (2003).

46. *See* 42 U.S.C. § 7612 (2000).

47. U.S. ENVTL. PROTECTION AGENCY, WORKSHOP ON THE BENEFITS OF REDUCTIONS IN EXPOSURE TO HAZARDOUS AIR POLLUTANTS: DEVELOPING BEST ESTIMATES OF DOSE-RESPONSE FUNCTIONS, SAB Report No. EPA-SAB-EC-WKSHP-02-001 (2002). This lack of being able to estimate benefit is a common problem in primary prevention. We often wave our hands and say that there is a 16:1 cost-benefit ratio based on the notion that an ounce of prevention is worth a pound of cure.

V

IMPLICATIONS OF THE PRECAUTIONARY PRINCIPLE FOR SCIENTIFIC RESEARCH

Using the Precautionary Principle as a weapon against pollutants holds important implications for scientific research. A central issue is the development of benefit indicators that go beyond tons of pollutants. Using pollutant weight rather than pollutant effect as a marker for achievement can be problematic, particularly where there is a clear differential in the potential for toxicity. Removing a ton of toluene from air emissions is probably meaningless in terms of public health, while removing a ton of benzene is probably of value. The current approach under the Clean Air Act initially focuses the same attention on both, which necessitates the residual risk provision,[48] the requirement of additional action if pollution risk persists, to distinguish between them, if at all.[49] Better indicators of the potential for adverse health effects are needed to develop cost-effective approaches to reducing the presence of HAPs. For example, much of the outdoor pollutant exposures regulated by the Clean Air Act are relatively trivial compared to indoor exposures.[50]

Nevertheless, actions under the Precautionary Principle are based more upon information than on understanding—there must be sufficient information to raise the possibility of harm, but not sufficient understanding to know whether the harm will in fact occur. As demonstrated by the HAPs situation, in a precaution-driven world there should be a premium on developing and using the appropriate metrics to effectively drive the precautionary action. While the driving force for the precautionary approach to regulating HAPs was information about the tons of pollutants released, derived in large part from the Toxic Release Inventory, it would be far better and far more precautionary if we were able to act on information related to the likelihood that the emitted pollutant would produce harm at the level to which the public is being exposed. The justification for invoking the Precautionary Principle under almost any circumstance is that we cannot wait for the slow process of accumulating all of the scientific evidence before acting to protect public health and the environment.[51]

But public health also requires efficient use of resources to achieve benefit, something that is difficult to demonstrate in the present approach.

48. *See* 42 U.S.C. § 7412(f).

49. We note that as of this writing it is thirteen years since the passage of the 1990 CAAA and the residual risk regulations have yet to be rolled out, let alone tested in the courts. A recent attempt by EPA to include a low-risk exemption in its air toxics rules has been highly controversial and is yet unresolved. *See EPA Delays Inclusion of Low-risk Exemptions in Air Toxic Rules*, 10 RISK POL'Y REP. No. 3, at 22-23 (2003).

50. Lance Wallace, *Comparison of Risks from Outdoor and Indoor Exposure to Toxic Chemicals*, 95 ENVTL. HEALTH PERSP. 7, 7-13 (1991).

51. Invoking the Precautionary Principle requires at least two conditions to be met:

(1) There is uncertainty about whether there is an effect—if there was certainty there would be no need to invoke the Precautionary Principle;

(2) There are substantial economic or social costs involved in the precautionary action—if the action could be done cheaply there would be no need to argue about it.

Yet acting under the Precautionary Principle should not be an excuse to avoid obtaining the necessary information. And because the Precautionary Principle inevitably carries with it the possibility that a costly precautionary action will be taken erroneously, it is a tautology that the more precautionary a society, the more likely it is that its regulatory decisions have been erroneous and costly.[52] Thus, the Precautionary Principle places a higher premium on research to determine whether the precautionary action has been justified.

Accordingly, those invoking the Precautionary Principle should, at the least, discuss a research program that would, after the precautionary action, let us know whether the action was appropriate and beneficial. However, research after regulation would be unusual for a regulatory agency. After the major stress of promulgating new regulations, it is only human nature to avoid discovering that one was wrong. In addition, the limited research budget available to regulatory agencies inevitably focuses their research on the next issue in the pipeline. Yet, given the magnitude and probability of error in employing the Precautionary Principle in regulations, there ought to be a higher priority for research to find out if the precautionary action is beneficial.[53] Unfortunately, since the 1990 CAAA, EPA has shown little interest in research on HAPs.[54] This does not bode well for correcting the costly mistakes that, while justified at the time, are built inevitably into actions taken under the Precautionary Principle.

VI

RESIDUAL RISK AND THE PRECAUTIONARY PRINCIPLE

The CAAA HAPs provisions also contain language concerning residual risk that calls for additional action if a prescribed level of risk persisted after instal-

Bernard D. Goldstein, *The Precautionary Principle and Scientific Research Are Not Antithetical*, 107 ENVTL. HEALTH PERSP. 594, 594-95 (1999).

52. The costs of unnecessary regulation of HAPs can be expressed in dollars. For certain other precautionary actions—for example, regulating endocrine disruptors to protect amphibians—if there is another cause that is responsible, it is likely to be missed because of the misplaced focus on the erroneous precautionary action.

53. Performing the study at the time of regulation has the added benefit of providing a greater likelihood of determining a cause-and-effect relationship. About the only time that real-world studies of humans or the environment can approach the tight control measures of a laboratory study is when we can anticipate a change in exposure. Studying the impact of the change in the level of a pollutant that results from a regulatory action is about the best we can do.

54. For example, EPA's STAR program has shown little interest in toxic air pollutants. The STAR program is an approximately $100 million-per-year extramural research program that sends out a list of specific topics of interest to EPA to the nation's research community. *See* NAT'L CENTER FOR ENVTL. RESEARCH, U.S. ENVTL. PROTECTION AGENCY, STAR GRANTS AND COOPERATIVE AGREEMENTS, *at* http://es.epa.gov/ncer/grants (last visited Mar. 23, 2003). Of the 136 topics for which grants were awarded from 1995, the year the program began, until 2002, only the two years of funding in Urban Air Toxics (1998-1999) qualifies as a HAP research topic—and this topic is really concerned with environmental justice issues. In addition, in 1995, one of the six grants in the general air pollution category dealt with the health effects of a hazardous air pollutant. *Id.* The recent announcement of research opportunities for 2003 lists twenty-one topics, again none that are directly related to HAPs. *Id. at* http://es.epa.gov/ncer/rfa/#star (last visited Mar. 23, 2003).

lation of MACT. There are two measures of risk for this requirement that could be considered to be risk-based precautionary actions. The first is the risk management decision to set the target at a risk of one in one million. This test is far more stringent than has been used in past NESHAP rules and, particularly for certain compounds like benzene, will be difficult to achieve.[55] The amendment specifies that the guiding risk be that of the maximally exposed individual ("MEI") rather than the population.[56] The problem with using the MEI rather than the entire exposed population is that its focus on the individual is the antithesis of public-health laws for which the concern should be the population.[57] Furthermore, it is much more likely to be erroneous than population-based approaches and is not well-tailored to achieve precautionary goals.

VII

LOSS OF PUBLIC-HEALTH FOCUS

From a public-health point of view, the major criticisms of the Clean Air Act go well beyond its misplaced emphasis on the MEI as a target for residual risk determinations. The precautionary approach embodied in the 1990 CAAA intended to decrease exposure to air pollutants that could conceivably cause harm on one level is consistent with public-health principles but on another level is contradictory. The basic principles of public-health practice include a respect for efficient approaches to decrease the potential for harm. In environmental health, this occurs primarily through reducing emissions, interdicting

55. The current EPA cancer risk potency figure for benzene is that a one-in-a-million leukemia risk occurs with exposure to 0.13 to 0.45 ug/m^3 for seventy years. S*ee* U.S. EPA Integrated Risk Information System, Benzene: Reference Concentration for Chronic Inhalation Exposure, *at* http://www.epa.gov/iris/ subst/0276.htm#refinhal (last visited Apr. 11, 2003). Compare this to outdoor urban levels in Los Angeles in 1987 of 7.1 ug/m^3 in February and 3.7 ug/m^3 in July. *See* Lance Wallace et al., *The Los Angeles Team Study: Personal Exposures, Indoor-Outdoor Air Concentrations, and Breath Concentrations of 25 Volatile Organic Compounds*, 1 J. EXPOSURE ANALYSIS & ENVTL. EPIDEMIOLOGY 157, 157-92 (1991).

56. Just as with maximum control technology, "maximum" does not really mean maximum, but rather has been defined operationally by EPA to be toward the upper end of the expected exposure distribution. *See supra* note 39.

57. Bernard D. Goldstein, *The Maximally Exposed Individual: An Inappropriate Basis for Public Health Decision-Making*, 6 ENVTL. F. 13, 13-16 (1989). Consider two examples. A plant at the edge of the Hudson River in northern New Jersey has no one living downwind for at least a mile, leading the MEI across the river in Manhattan to be exposed to only a 5–in–10-million lifetime risk of cancer. But there will be only a gradual drop off in risk beyond that one mile so that the average risk to perhaps 10 million people in the New York area could be 1–in–10-million lifetime risk; we would anticipate one cancer case every seventy years from that exposure. Now consider a plant at the edge of the Mojave Desert for which there is one family of four living immediately downwind subjected to a 1–in–1-million lifetime risk, and assume that there is no one else for a hundred miles. Standard risk assessment assumptions require that family of four to live there seventy years before being replaced by another family of four, ad infinitum. In that case, there would be one cancer case every 17.5 million years, a time about ten-fold longer than humans have been on this planet. But the MEI approach would force us to regulate the latter, not the former.

exposure pathways, or substituting harmful products for ones that are less harmful.[58]

Effective interdiction of exposure pathways logically should start with an understanding of the sources and pathways resulting in the greatest likelihood for exposure. In the case of HAPs, for the general public the likelihood of exposure is overwhelmingly indoors for well-studied HAP compounds that are known to be harmful, such as benzene.[59] If the goal of the law is to decrease exposure to HAPs, it has taken an approach that will have little impact as compared to focusing the same level of resources on indoor sources of the same compounds.

Another public-health deficiency in the precautionary approach of the 1990 CAAA is the treatment of all chemicals on the list as if they presented the same hazard at expected ambient concentrations. For the purposes of MACT, it does not matter whether the chemical is benzene or toluene (methyl benzene, the simplest alkyl benzene). And while there is no question that benzene is a cause of human leukemia, toluene, though chemically closely related to benzene, does not cause the bone marrow damage and leukemia observed with benzene, and has no demonstrated human toxicity except at concentrations at least a thousand-fold greater than that observed in ambient air.[60] The same holds true for other related alkyl benzenes also present in petroleum and used extensively in industry. In fact, one major effort to decrease workers' and the public's exposure to benzene has been encouraging substitution for benzene of well-studied alkyl benzenes that are far less risky, particularly at low concentrations. However, a consequence of the MACT approach to a list of 189 compounds of markedly different potentials for toxicity is that all compounds are treated the same in terms of required controls.

The driver in the 1990 CAAA for an industry to adopt the standard environmental health approach of substituting lesser toxic compounds comes from its residual risk provisions.[61] Though there is another item within the 1990 CAAA HAPs provisions leading to chemical substitution, the HAP amendments push industry to find relatively unstudied compounds that are not on the EPA list. This is not necessarily a public benefit, as there is the potential for unexpected risk in using relatively unstudied chemical compounds. It is hoped that the requirement that EPA add these newly used compounds to the HAP

58. A discussion of the Precautionary Principle in terms of being more "upstream" than pollution prevention or pollution control can be found in Brian Mayer et al., *Moving Further Upstream: From Toxics Reduction to the Precautionary Principle*, 117 PUB. HEALTH REP. 574, 574-612 (2002).

59. *See* Wallace, *supra* note 50, at 7-13.

60. Benzene is the only known carcinogen among all of the alkyl benzenes. It is thus treated as if every molecule had some finite risk of causing cancer, while, in contrast, the alkyl benzenes are considered to have a threshold below which they are assumed to be harmless. *See* Goldstein, *Benzene Hematotoxicity*, *supra* note 21, at 69.

61. *See* 42 U.S.C. § 7412(f)(2)(A).

list[62] will counteract the benefit industry receives by choosing those relatively unstudied compounds not already on the list.

VIII

JUDICIAL REVIEW OF THE PRIMARY PRECAUTIONARY ASPECTS OF THE 1990 CAAA HAP PROVISIONS

Despite the troublesome effects of legislating by the Precautionary Principle, there has been virtually no judicial review of the primary precautionary aspects of the HAPs amendments.[63] This is perhaps not surprising. It is difficult to conceive of any grounds for constitutional challenge to those provisions. While we have expressed some concerns about the effectiveness of those provisions to accomplish Congress's goal of reducing adverse health or environmental effects of air pollution, mere ineffectiveness does not render legislation vulnerable to judicial review.[64]

We found only four judicial opinions in the universe of reported judicial decisions that contain the term "Precautionary Principle" in the context of environmental and public-health regulation.[65] Of those, none dealt with HAPs. Nevertheless, we believe that the number of judicial opinions addressing the Precautionary Principle will rise dramatically as the concept becomes more frequently employed in legislation and as it becomes familiar to tort and environmental litigators. Distinguishing between pre-emptive precautionary and risk-based approaches may be helpful in sorting out the implications of actions embracing the uncertainty for which the Precautionary Principle stands.

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62. *See* 42 U.S.C. § 7412(b)(2), (b)(3)(B). Section (b)(2) requires the EPA administrator to periodically review and, where appropriate, revise the list, adding pollutants that present, or may present, a threat of adverse human health or environmental effects. Section (b)(3)(B) requires that when petitions to modify the list are made, the administrator shall add a substance upon a showing by the petitioner or on the administrator's own determination that emissions are known to cause or may reasonably be anticipated to cause adverse effects.

63. *But see* Am. Forest & Paper Ass'n v. EPA, 294 F.3d 113, 122 (D.C. Cir. 2002). In *American Forest and Paper*, the industry plaintiff unsuccessfully challenged EPA's denial of a petition to de-list methanol as a HAP. The court rejected the plaintiff's argument that EPA was improperly relying on mere speculation about adverse effects. *Id.* at 119-22. The court made it clear that the burden of proof—and therefore the burden of scientific uncertainty—rests on the petitioner. *Id.* at 119.

64. In the words of the Supreme Court:

> Our individual appraisal of the wisdom or unwisdom of a particular course selected by the Congress is to be put aside in the process of interpreting a statute. Once the meaning of an enactment is discerned and its constitutionality determined, the judicial process comes to an end. We do not sit as a committee of review, nor are we vested with the power of veto.

Tenn. Valley Auth. v. Hill, 437 U.S. 153, 194-95 (1978).

65. Westlaw search term, "Precautionary Principle," All State & Federal Cases Database (Feb. 2003); Lexis search term, "Precautionary Principle," Federal & State Cases Directory (Feb. 2003).