Margin of Safety as a Risk-Management Concept in Environmental Legislation

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I. INTRODUCTION

In 1970, Congress amended the Clean Air Act[1] to include the requirement that the Environmental Protection Agency Administrator set standards for air pollutants which would allow an "adequate margin of safety" to protect the public health.[2] Congress also mandated an "ample" margin of safety for pollutants deemed "hazardous."[3]

This Congressional directive to provide margins of safety in setting ambient air standards was a novel application of a concept, derived from the field of engineering, to a public health standard.[4] This approach to environmental standard setting was subsequently hailed as "imaginative and sound" by Professor William H. Rodgers, Jr.[5] In his assessment, Rodgers stressed the public health advantages of using margins of safety: "the Clean Air Act allows the administrative prohibition of certain activities without actual proof of health hazards to an identifiable group, *so long as the prohibition can be defended as a scientifically supportable margin of safety.*"[6]

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1. 42 U.S.C. §§ 7401-7642 (1976 & Supp. I 1977, Supp. II 1978) (originally at §§ 1857a-1858a).

2. 42 U.S.C. § 7409 (1976 & Supp. I 1977 Supp. II 1978).

3. 42 U.S.C. § 7412 (Supp. I 1977 & Supp. II 1978).

4. Thomas Jorling states: "A new concept, included for the first time in statutory language in the context of a public health standard, is the directive to the administrator that in establishing the primary standard he shall apply an 'adequate margin of safety.'" Jorling, *The Federal Law of Air Pollution Control*, in FEDERAL ENVIRONMENTAL LAW 1083 (E. Dolgin and T. Guilbert eds. 1974).

5. RODGERS, ENVIRONMENTAL LAW 266 (1977).

6. *Id.* (emphasis added).

This paper will critique the application of the margin of safety concept to environmental standard setting by examining the Congressional purpose behind its original enactment and then reviewing it in the context of subsequently developed administrative actions, court decisions, and scientific analyses. The author has concluded that, despite its initial promise, the margin of safety concept has proved to be inadequate for health-risk management because it is inherently vague and because it acts to conceal the fact that standard setting under the Clean Air Act actually includes economic and feasibility considerations. The margin of safety concept should therefore be replaced by a more explicit process of weighing risks and benefits to the public. Because this balancing process involves significant public policy choices it should be more closely controlled by Congress.

II. LEGISLATIVE BACKGROUND OF THE CONCEPT

The first step in this analysis is to examine the legislative history behind adoption of the margin of safety approach by Congress in 1970. This examination must begin outside the area of environmental legislation itself, for the direct evidence of legislative intent regarding the 1970 Amendments to the Clean Air Act is rather sparse.[7]

Research indicates that the margin of safety concept was first developed in the field of engineering.[8] The "Interim Mandatory Safety Standards for Underground Coal Mines" of the 1969 Mine Safety Act,[9] contains the earliest reference to the margin of safety

7. Only one page of SENATE COMM. ON PUBLIC WORKS, A LEGISLATIVE HISTORY OF THE CLEAN AIR AMENDMENTS OF 1970, S. REP. NO. 18, 93d Cong., 2d Sess. 410 (1974) [hereinafter SENATE REPORT ON CLEAN AIR AMENDMENTS], a 1596 page document, contains any general discussion of the margin of safety concept.

8. K. HALL, *The Control of Toxic Pollutants Under the Federal Water Pollution Control Act Amendments of 1972*, 63 IOWA L. REV. 609, 630 (1978).

How it has been used in that field is indicated by a discussion of the "factor of safety" at the introduction of a text in structural engineering, A. PIPPARD AND SIR J. BAKER, THE ANALYSES OF ENGINEERING STRUCTURES (1968). In a chapter on "Definitions and General Principles," the authors state:

> It is impossible to determine exactly either the external loads or the internal forces to which a structure is subjected. Moreover, the materials available are subject to certain variations in quality, and workmanship at times will fall below the average. It is therefore necessary in order to guard against these contingencies to allow a margin of safety over and above that which calculation indicates as being just right. This allowance is made by the introduction of either a factor of safety or a load factor.

9. 30 U.S.C. §§ 861-78 (1976, Supp. I 1977, Supp. II 1978 & Supp. III 1979).

concept in Federal legislation that is still in effect. This act provides that "every hoist . . . shall be equipped with . . . hoisting cable adequately strong to sustain the fully loaded platform, cage or other device; and have a proper margin of safety."[10] Regulations promulgated pursuant to this Section state: "Hoists shall have rated capacities consistent with the loads handled and the recommended safety factors of the ropes used."[11] In such a mining hoist context the margin of safety is not needed for the external loads or internal forces of the hoists since there is virtually no variation in these factors if the loads handled are kept within rated capacities. Instead it is unknown variation in the quality of the material and workmanship of the ropes that must be guarded against by providing for a margin of safety. Since the parameters of such variations are susceptible to experimental determination, setting a "proper margin of safety" in this context is relatively simple.[12]

Application of the margin of safety concept to environmental legislation was first publicly proposed by Dr. John T. Middleton, while he was Commissioner of the National Air Pollution Control Administration. When Dr. Middleton testified in support of the Clean Air Act Amendments of 1970[13] before the Senate Subcommittee on Air and Water Pollution, he was asked by Senator Muskie whether a national air quality standard could be set at a "no-effects" level.[14] Dr. Middleton replied that "to identify a no-known-effects level is something that would be . . . not only extremely difficult but very likely not possible."[15] Instead, he suggested, the Administrator could set the standard somewhere below the smallest known effects level:

> The criteria documents state the level at which effects begin. . . . The Clean Air Act provides that the standards shall be protective of health, which means they must be lesser than the

10. 30 U.S.C. § 874(a) (1976).

11. 30 C.F.R. 75.1401-1 (1977).

12. A similar set of factors is involved in the context of the second legislative reference to the margin of safety concept. Section 314(e) of the 1969 Mine Safety Act, 30 U.S.C. § 874(e) (1976), stipulates that mine locomotives and haulage cars shall have automatic brakes or other stopping devices "which are designed to stop the locomotives and haulage cars with the proper margin of safety." *Id.*

13. 42 U.S.C. §§ 7401-7642 (Supp. I 1977 & Supp. II 1978) (originally at §§ 1857a-58a).

14. SENATE REPORT ON CLEAN AIR AMENDMENTS, *supra* note 7, at 1182, 1183.

15. *Id.*

> level at which this thing was observed. In addition, we say that a margin of safety must be included.[16]

Later in his testimony, Dr. Middleton explained that a margin of safety was required in setting national air quality standards because of general ignorance concerning whether meteorological conditions mitigate or exacerbate the health effects of pollutants.[17]

The Senate Committee concurred with Dr. Middleton's view of the importance of providing a margin of safety to offset our lack of knowledge of health effects in setting national ambient air quality standards. The subcommittee's opinion on the mandatory nature of margins of safety is expressed in the Senate Report that accompanied the National Air Quality Standards Act of 1970, which states that in setting "National Air Quality Standards" the Administrator:

> . . . should consider and incorporate not only the research summarized in the air quality criteria documents, but also the need for margins of safety. *Margins of safety are essential to any health-related environmental standards if a reasonable degree of protection is to be provided against hazards which research has not yet identified.*[18]

The Senate Report also makes it clear that, in establishing national air quality standards, the Environmental Protection Agency ("EPA") must take into account the health needs of all segments of the population, no matter how sensitive:

> [T]he Committee emphasizes that included among those persons whose health should be protected by the ambient standard are particularly sensitive citizens such as bronchial asthmatics and emphysematics who in the normal course of daily activity are ex-

16. *Id.* at 1185.

17. Dr. Middleton testified:

> We really do not know to what extent the very dry atmosphere of Arizona, as an example, really has some aggravating effect with respect to a given pollutant, so contrasted to another state, Maryland, where the atmosphere a good part of the year is rather humid.
>
> Whether the standard ought to be different because of environmental factors, physical factors, of the environment, I would like to give you an answer for it, but I can't.
>
> But that is one reason why we say that a margin of safety is necessary to be sure that the air quality number takes that into account.

Id. at 1192.

18. *Id.* at 410 (emphasis added). The provision referred to by the Committee is § 4(a) of the Clean Air Act Amendments of 1970, 42 U.S.C. § 7409 (Supp. I 1977 & Supp. II 1978).

> posed to the ambient environment. In establishing an ambient standard necessary to protect the health of these persons, reference should be made to a representative sample of persons comprising the sensitive group. . . .[19]

Finally, the Committee makes no reference to considerations of economic or technological feasibility in the establishment of ambient air quality standards. Indeed, Senator Muskie, in introducing the "key provisions" of the bill to the Senate, emphasized that the standards for hazardous air pollutants "must be set to provide an ample margin of safety to protect the public health. This could mean, effectively, that a plant would be required to close because of the absence of control technique. It could include emission standards which allowed for no measurable emissions."[20]

In 1972 Congress again used the margin of safety concept as a risk management approach when it amended the Federal Water Pollution Control Act.[21] As in the Clean Air Act of 1970, the margin of safety concept appears to have been viewed as a precaution against currently unknown health hazards. The statute specifies the permissible load of pollutants in certain of the nation's waters as follows: "[s]uch load shall be established at a level necessary to implement the applicable water quality standards with seasonal variations and a margin of safety which takes into account any lack of knowledge concerning the relationship between effluent limitations and water quality."[22]

Congress' treatment of toxic water-borne pollutants[23] indicates that the specification of an "ample," rather than an "adequate," margin of safety requires the Administrator to exercise particular caution in setting standards for hazardous pollutants. Section 1317(a)(4), like its parallel provision in the Clean Air Act, Section 112, states: "Any effluent standard promulgated under this section shall be at that level which the Administrator determines provides an ample margin of safety."[24]

A third use of the margin of safety concept in Federal environmental legislation soon followed. Only nine days after passage of

19. SENATE REPORT ON CLEAN AIR AMENDMENTS, *supra* note 7, at 410.
20. *Id.* at 133.
21. 33 U.S.C. §§ 1251-1376 (1976, Supp. I 1977, Supp. II 1978 & Supp. III 1979).
22. 33 U.S.C. § 1313(d)(1)(C) (1976).
23. 33 U.S.C. § 1317(a)(4) (1976).
24. *Id.*

the Water Pollution Control Act Amendments, Congress passed the Noise Control Act,[25] which required the Administrator to "publish information on the levels of environmental noise the attainment and maintenance of which in defined areas under various conditions are requisite to protect the public health and welfare with an adequate margin of safety."[26]

The most recent use of the concept by Congress in environmental legislation followed two years later, with the passage of the Safe Drinking Water Act.[27] This statute requires the Administrator to set a level for each contaminant "at which, in the Administrator's judgment . . . no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety."[28]

The 1970's, however, have not seen Congress relying exclusively on the margin of safety concept in its formulations of risk management approaches to public health and safety standards. In the Motor Vehicle Safety Standards Act,[29] for example, Congress defines "safety" in terms of whether a given risk is reasonable.[30] Similarly, the Toxic Substances Control Act of 1976[31] calls upon EPA's Administrator to determine that substances "will not present an unreasonable risk of injury to health or the environment."[32]

In other statutory contexts, Congress has avoided both the "margin of safety" and "reasonable risk" language and has used terms which seem designed to provide the administrative agency involved with an additional degree of discretion. Examples of such language may be found in the Radiation Control for Health and

25. 42 U.S.C. §§ 4901-4918 (1976, Supp. I 1977 & Supp. II 1978).

26. 42 U.S.C. § 4904(a)(2) (1976).

27. 42 U.S.C. §§ 201, 300f-300j-9 (1976, Supp. I 1977 & Supp. II 1979), 21 U.S.C. § 349 (1976).

28. *Id.*

29. 15 U.S.C. §§ 1381-1431 (1976, Supp. I 1977, Supp. II 1978 & Supp. III 1979).

30. The language used is as follows:

> 'Motor Vehicle Safety' means the performance of motor vehicles or motor vehicle equipment in such a manner that the public is protected against unreasonable risk of accidents occuring as a result of the design, construction or performance of motor vehicles and is also protected against unreasonable risk of death or injury to persons in the event accidents do occur, and includes nonoperational safety of such vehicles.

Id. § 1391 (1976).

31. 15 U.S.C. §§ 2601-2629 (1976, Supp. I 1977, Supp. II 1978 & Supp. III 1979).

32. *Id.* § 2605(e)(2)(B) (1976).

Safety Act[33] and in the Atomic Energy Act.[34]

In sum, Congress has employed the margin of safety concept in two distinct contexts. In its original, engineering context, the margin of safety is used to set standards at levels beyond those which calculation or experimental results indicate are generally necessary. This allowance compensates for unknown factors in specific instances, such as defects in workmanship and materials. Since the parameters of such variation can be experimentally determined, an adequate margin of safety can be determined with a high level of confidence.

However, in the more recent context of determining pollutant standards, where establishing "no-effects" levels is extremely difficult, if not impossible, and the magnitude of the hazards not yet identified by research are unknown, the usefulness of the margin of safety concept is much more problematic and cannot be assumed merely because of its utility in the original engineering context.

III. Case Development of the Concept

Litigation involving the margin of safety requirement would normally be expected to clarify its meaning. However, both the amount of environmental litigation and the extent of judicial examination of the margin of safety concept has been limited.[35]

33. 42 U.S.C. §§ 263b-263n (1976, Supp. I 1977 & Supp. II 1978). This statute merely provides that the Secretary of Health, Education and Welfare shall:

> (1) . . . develop and administer performance standards for electronic products; (2) plan . . . activities to minimize the emissions of and the exposure of people to unnecessary electronic production radiation.

Id. § 263d(a) (1976).

34. *Id.* §§ 2011-2296 (1976). This statute authorizes the Atomic Energy Commission to:

> establish . . . such standards and instructions to govern the possession and use of special nuclear material . . . as the Commission *may deem necessary or desirable* to promote the common defense and security or to protect health or to minimize danger to life or property. . . .

Id. § 2201(b) (1976) (emphasis added).

A similar standard is used with regard to commercial nuclear licenses, for the Act states that the Commission shall issue licenses to applicants "who are equipped to observe and who agree to observe such safety standards to protect health and to minimize danger to life or property as the Commission may by rule establish. . . ." *Id.* § 2133(b)(2).

35. The first reported case mentioning the ideas was Kennecott Copper Corp. v. EPA, 262 F.2d 846 (D.C. Cir. 1972), which raised, but did not attempt to resolve the question of whether and to what extent EPA was permitted a "margin of error" un-

The margin of safety concept first received judicial scrutiny, although briefly, in *Ethyl Corporation v. EPA*.[36] Here, the court was faced with the issue of determining the meaning of Section 211 of the Clean Air Act, which authorizes the EPA to regulate gasoline additives that "will endanger" public health. Ruling that the Act authorized the EPA to prevent harm the agency judged likely to occur, the court noted that the margin of safety concept plays a precautionary role:

> Congress did provide a precautionary element in standard-setting under Sections 108-110. Section 109 expressly requires that the ambient air standards ultimately issued provide for "an adequate margin of safety." 42 U.S.C. Sect. 1857c-4(b)(1). Thus, while the threshold decision to regulate under Sections 108-110 is not precautionary but rather requires proof of demonstrable harm caused by the suspect pollutant, *once the decision is made the standards promulgated must be preventive in nature*.[37]

A much more elastic view of the margin of safety concept was developed in *National Association of Demolition Contractors, Inc. v. Costle*,[38] where air quality standards requiring even the strict "ample" margin of safety were permitted by the court to be less than absolutely preventive of harm to human health.

A health problem arose because the demolition of older buildings constructed with asbestos between the walls and floors releases asbestos fibers into the ambient air. Since asbestos is a carcinogen. EPA scientists had come to the conclusion that "for asbestos . . . it is impossible to prescribe and enforce allowable numerical concentrations or mass emission limitations known to provide an ample margin of safety to protect public health, since *no safe level has been identified*."[39]

The EPA subsequently promulgated regulations requiring demolition contractors to wet down buildings as they demolish them in order to lessen the probability of asbestos particles entering the ambient air. Unfortunately, during sub-freezing temperature periods, the wetting-down process proved to make footing hazardous for workmen engaged in the demolition. Despite its finding that no

der the Clean Air Act in setting secondary standards at levels below documented effects. *Id.* at 849 n.13.

36. 541 F.2d 1 (D.C. Cir. 1976), *cert. denied*, 426 U.S. 941 (1976).
37. *Id.* at 14-15 (emphasis added).
38. 565 F.2d 748 (D.C. Cir. 1977).
39. EPA Document 450/2-74-009a (October 1974) (emphasis added).

level of asbestos emissions could provide the "ample" margin of safety statutorily required to protect the public health, the EPA decided to suspend the wetting requirements during sub-freezing temperatures. The agency decision was accompanied by a facile, unsubstantiated assertion that: "it is the Administrator's judgment that . . . the suspension of the wetting requirements during periods of freezing weather will continue to protect human health with an ample margin of safety."[40]

The demolition contractors argued that since the rate of emission of asbestos into the air during demolition does not vary with the temperature, then wetting was not required to provide an "ample margin of safety" in above freezing temperatures if it was not required to meet that standard in sub-freezing temperatures. The EPA, on the other hand, took the position that while strict health considerations did not change with weather conditions, the methods available for controlling asbestos emissions in above freezing and below freezing conditions differed significantly.

The Circuit Court of Appeals agreed with the EPA, ruling that "[p]rotection of the public with 'an ample margin of safety' may necessitate use of different control measures, including use of the 'best available control methods,' in different conditions."[41] The court focused its inquiry on whether wetting was required in above freezing conditions, not on whether waiving the wetting requirement in subfreezing conditions continued to provide an ample margin of safety. In addition, the court was careful to emphasize that its ruling was based on narrow grounds, stating specifically that: "[*t*]*he record and argument before us* provide no basis for concluding that the Administrator, in providing a limited exception to the wetting requirement to protect worker safety, acted in anything other than a reasonable fashion consistent with law."[42]

Nonetheless, the court's treatment of the margin of safety concept in *Demolition Contractors* tends to weaken it. First, the concept is no longer identified with an objective, measurable "margin" between a pollutant standard and an effect level, but is instead equated with a control technique. Second, the court's emphasis is not on whether the control technique which is to provide an "am-

40. 30 Fed. Reg. 38,066 (1975).

41. National Association of Demolition Contractors, Inc. v. Costle, 565 F.2d 748, 753 (D.C. Cir. 1977).

42. *Id.* (emphasis added).

ple" margin of safety does in fact protect the public health, but on whether it is the "best available" means of doing so. Thus, the *Demolition Contractors* court opens the door to agency consideration of cost and technological feasibility in applying a statutory standard in which these factors have no part. In contrast, the court in *Ethyl Corporation*[43] had earlier ruled that these provisions of the Clean Air Act were "technology forcing" and that "the attainment of the primary, health-based standards takes precedence over the cost and present technological feasibility of achieving the requisite control."[44]

Finally, in *Demolition Contractors* the court was construing a provision which required not only an "adequate" margin of safety, but an "ample" one. By deferring to the agency's contention that it had met the more protective form of the statutory standard, in a situation where the EPA's action effectively increased the level in the ambient air of a known carcinogen, the court seriously undermined other uses of the margin of safety concept as a legally-enforceable standard.

A similarly deferential attitude toward assumed agency expertise is also found in two other cases dealing with the margin of safety concept, *Environmental Defense Fund v. EPA*[45] and *Hercules, Inc. v. EPA*.[46] In these companion cases, the court reviewed toxic pollutant effluent regulations adopted pursuant to Section 307(a) of the Federal Water Pollution Control Act.

In a comment discussing these regulations at the proposal stage,[47] the EPA indicated that the determination of an "ample" margin of safety would involve the consideration of fiscal and technological factors:

> [T]he statutory "ample margin" concept is an elastic one which . . . allows for considerable exercise of judgment by the Administrator in setting the standards. In any case where a discharge is allowed, on the spectrum ranging from certain safety (a prohibition) to that uncertain point where harmful effects are caused and safety ends, a logical break point is struck where the very best that control technology can do is required. Setting a standard at this point . . . achieves the purpose of the Act with-

43. 541 F.2d 1 (D.C. Cir. 1976).
44. *Id.* at 14.
45. 598 F.2d 62 (D.C. Cir. 1978).
46. 598 F.2d 91 (D.C. Cir. 1978).
47. 41 Fed. Reg. 23,576 (1976).

> out inflicting unreasonable and unjustifiable economic and social costs.[48]

Industry then challenged the proposed standards on the ground that they were promulgated without consideration of whether less stringent standards could provide an ample margin of safety. In response, the EPA failed to provide a fully-developed rationale for the margin of safety it had selected, and merely cited the Administrator's previously published conclusion that "discharge of relatively modest amounts of a pollutant into the water at 200 to 300 times the ambient water criterion may be allowed . . . without necessarily failing to provide an ample margin of safety for affected organisms."[49]

In *Environmental Defense Fund v. EPA*[50] the D.C. Circuit initially noted the similarity of Section 307(a) of the Water Act to Section 112 of the Clean Air Act, including the fact that "both provide that standards shall be set at a level which provides 'an ample margin of safety.' "[51] Indeed, the court terms this phrase "the section's polestar—its guiding principle in protecting against incompletely understood dangers."[52]

The court's use of this metaphor is somewhat misleading, for the D.C. Circuit actually appears to view this "polestar" less as a fixed point of reference than as a license for the exercise of broad administrative discretion. The court stated:

> [S]ection 307(a)(4) directs [the] EPA to set discharge standards at a level providing an "ample margin of safety." The parties dispute the significance of this important subsection. [The] EPA argues that this subsection gives it latitude to protect against risks that are incompletely understood, in essence to 'err' on the side of 'overprotection' with respect to known risks in order to provide safety from unknown dangers. Industry petitioners disagree.
>
> [W]e find ourselves in agreement with [the] EPA, whose interpretation of the complex statutes it administers is, of course, entitled to some deference.[53]

48. *Id.* at 23,580.
49. *Id.* at 23,579.
50. 598 F.2d 62 (D.C. Cir. 1978).
51. *Id.* at 71 n.28.
52. *Id.* at 73.
53. *Id.* at 80.

The court went on to find support for such broad administrative discretion in the distinction between an "adequate" and an "ample" margin of safety:

> If administrative responsibility to protect against unknown dangers presents a difficult task, indeed, a veritable paradox—calling as it does for knowledge of that which is unknown—the term "margin of safety" is Congress' directive that means be found to carry out the task and to reconcile the paradox. Addition of a generous measure —"ample"—is Congress' recognition that the EPA would need great latitude in meeting its responsibility.[54]

After finding that the "ample" margin of safety concept is a legislative grant of administrative latitude, the Court further dimmed this "polestar's" guiding light by articulating several grounds for deferring to whatever margin of safety has been selected by the Administrator.

First, the EPA's determination of a standard incorporating a particular margin of safety was reviewed under the traditional substantial evidence test.[55] Accordingly, the court, when reviewing a specific standard level or corresponding margin of safety, does not attempt to determine whether that figure is the most desirable, but accepts it if it is within a "zone of reasonableness."

Secondly, since the agency must resolve issues "on the frontiers of scientific knowledge,"[56] the court stated it would uphold agency conclusions based only upon policy judgments (as opposed to factual determinations). Standard setting was deemed to involve inherently legislative decisions requiring basic policy determinations rather than requiring the resolution of factual controversies.[57] Finally, the court deferred to the EPA's judgment not merely regarding specific environmental hazards, but also regarding the general acceptability of risks. It stated: "[the] EPA, not the court, has the technical expertise . . . to formulate policy with respect to what risks are acceptable."[58]

Thus, judicial review of the EPA standard setting based on the use of margins of safety has not resulted in a sharply focused delin-

54. *Id.* at 81.

55. This test holds that "[t]he evidence supporting the agency's conclusion must be such, in light of all of the evidence on the record as a whole, that 'a reasonable mind might accept it as adequate to support the conclusion.'" *Id.* at 85 (quoting Consolidated Edison Co. v. NLRB, 305 U.S. 197, 229 (1938)).

56. Environmental Defense Fund v. EPA, 598 F.2d 62, 82-83 (D.C. Cir. 1978).

57. *Id.* at 82.

58. *Id.* at 83-84.

eation of the concept. There are two discernable reasons for this. First, the challenges to agency determinations have come from the regulated industries. In response to an industry plea that a given environmental standard is more restrictive than necessary, the courts have been inclined to support the EPA's position in light of the uncertainties surrounding the effect of pollutants on public health. The problem of the adequacy of the EPA's margins of safety would be articulated much more clearly, however, if challenges to the EPA standards had come from environmental public interest groups. Such litigation would focus on the crucial question of whether a particular margin of safety was "ample" or "adequate" enough to protect the public health, rather than whether the EPA mandated standard was too restrictive.

Secondly, even if such a legal challenge came from such public interest groups, it is unlikely that the courts would directly confront the issues implicit in the requirement to provide a margin of safety adequate to protect the public health. The question of how many individuals in the general public can be subjected to a given level of risk of a particular type of adverse effect before the "public health" is endangered is likely to be sidestepped by judicial deference to assumed agency expertise or the invocation of a "zone of reasonableness."

IV. Administrative Interpretations of the Concept

Additional perspectives on the margin of safety concept can be gained by examining two alternative approaches developed by different departments of the EPA.

The first approach rejects the more traditional procedure of specifying a safe level by subtracting a stated margin of safety from a determined harmful effects level. Instead it seeks to determine a level protective of public health through the adoption of a series of most conservative or "worst case" assumptions throughout the process of standard setting. This is the approach adopted by the EPA's Office of Noise Abatement and Control in setting standards regarding noise control:

> Section 5(a)(2) . . . requires an adequate margin of safety. The level identified to protect against hearing loss, is based on three margins of safety considerations:
>
> 1. The level protects at the frequency where the ear is most sensitive (4,000 Hz.).
> 2. It protects virtually the whole population from exceeding

> 5 dB NIPTS.
> 3. It rounds off in the direction of hearing conservation (downward) to provide in part for uncertainties in analyzing the data.[59]

The actual amplitude of the margin of safety which results from the use of such conservative assumptions is effectively masked. This can result in complaints from the regulated industries that the "worst case" assumptions tend to produce a much wider margin of safety than is necessary to protect the public health. The EPA, on the other hand, may find that the obfuscation that results is an advantage, for this approach makes industry challenges to what may be arbitrary decisions all the more difficult to sustain.

The EPA Office of Air Quality Planning and Standards has been experimenting with a different approach, which involves the use of panels of experts to assess the risks associated with varying levels of pollutants to determine whether a given margin of safety is adequate. This tack is premised on the notion that a "threshold risk" can be determined for each pollutant:

> In order to make a meaningful judgment on whether a possible standard provides an adequate margin of safety a conception is needed of *the threshold risk associated with the possible standard*. [Emphasis in original] The threshold risk associated with a possible standard is the risk that ambient concentrations of the pollutant will exceed the health effects threshold concentration for the most sensitive group in the general population when air quality just achieves that standard. If the threshold risk associated with the possible standard is deemed to be *acceptable in view of the circumstances* then that standard is judged in a meaningful way to allow an adequate margin of safety.[60]

While serving to make explicit some of the often tacit assumptions behind determinations of margins of safety, this approach creates policy difficulties by the very degree of clarity it produces. For example, since each pollutant level has associated with it *some* degree of risk, the Administrator is really given no guidance in determining what is "acceptable in view of the circumstances." Indeed, since his choice must necessarily be made from what will

59. "Information on Levels of Environmental Noise Requisite to Protect Health and Welfare with an Adequate Margin of Safety," EPA Document 550/9-74-004, at 20 (March, 1974).

60. Environmental Protection Agency, Method for Assessing the Health Risks Associated with Alternative Air Quality Standards for Photochemical Oxidants (undated external review draft) 2-3, (emphasis added).

clearly be a continuum of values, any such selection is likely to appear arbitrary.

On the other hand, using mathematical or statistical techniques to conceal such problems is inappropriate. Since experts often differ markedly on their assessments of risks, the use of the arithmetical mean of the quantified guesses of health experts to indicate the risk associated with each pollutant level can imply a higher degree of certainty associated with the standard setting than does in fact exist. Actual uncertainty would thus be cloaked in mathematical precision.

This difficulty is illustrated by three EPA health experts' appraisals of the probability that ozone will result in reduced resistance to bacterial infection.[61] At an ozone level of .12 ppm, the level to which the EPA Administrator allowed the pollutant standard to rise in January, 1979, the average estimated probability of harm through reduced resistance to bacterial infection is presented as .26, or roughly one in four.[62] This average masks sharp disagreement, however, among the experts. Expert A feels the probability of harm to even the most sensitive group at this level is slight, less than one-half of one percent, while expert B rates the probability at better than fifty percent, and expert C thinks the probabilities are better than eight out of ten that ozone at a .12 ppm level harms human health through reduced resistance to bacterial infection.[63]

Although these two approaches provide information for setting margins of safety, neither directly confronts the question of how to determine whether a given margin of safety is in fact adequate.

V. The Logic of the Margin of Safety Approach to Standard Setting

We have thus far examined the origin of the margin of safety concept and its treatment by the courts and by the EPA. An analysis of the logical premises and implications of the margin of safety concept is necessary in order to further assess its utility and weaknesses.

The basic conceptualization of the margin of safety standard setting approach is that the Administrator determines the lowest level

61. *Id.* at 29-69.
62. *Id.* at 65.
63. *Id.* at 57.

at which harm has been shown to occur (the "threshold" level), then sets a standard of acceptability for that hazard far enough below the threshold level to protect against unknown threats. The margin of safety is the gap between the threshold or "effects" level and the standard. These gaps, in the words of the Senate Committee reporting on the 1970 Clean Air Act Amendments, "are *essential* to any health-related environmental standards if a reasonable degree of protection is to be provided against hazards which research has not yet identified."[64]

Hazards "which research has not yet identified" exist in the field of public health for a number of reasons. First, the wide variation in human susceptibility to harmful environmental conditions means a truly representative sample of the entire population would be needed before the EPA could speak confidently about setting a standard at a level below that which would adversely affect the health of everyone in the population.[65] Of course, even with a massive sample, probability theory indicates that some rare individuals with extreme sensitivities would escape sampling. Yet most clinical pollutant studies make no pretense of selecting a nationally-representative sample of subjects. In one widely-cited study, for example, the health effect of ozone was analyzed on the basis of the clinical exposure of only four "healthy male subjects."[66] However, the susceptibility of pregnant women, young children, the handicapped, and the elderly is likely to differ quite markedly from the "healthy male subjects" of such a clinical study.

Another problem faced by research scientists is that clinical studies can only measure the short-range effects of exposure to harmful pollutants. Thus, for example, no adequate method exists to assess the effect on children of life-time exposure to low levels of pollutants. This inability to "compress time" in a laboratory setting

64. S. REP. ON THE CLEAN AIR AMENDMENTS, *supra* note 7, at 410 (emphasis added).

65. Typically, nationally representative samples of the American population are only considered adequate for analysis of political characteristics if they contain a sampling of between 1000 and 2000 subjects. N. LIN, FOUNDATIONS OF SOCIAL RESEARCH 162 (1976).

66. J.R. Goldsmith and J.A. Nadel, *Experimental Exposure of Human Subjects to Ozone*, 19 AIR POLLUTION CONTROL ASSOCIATION JOURNAL 329 (1969). The authors summarized their findings by stating in part: "Four presumably healthy male subjects were exposed for one hour to ozone at 0.1, 0.4, 0.6 and 1.0 ppm. Airway resistance increased slightly but significantly after exposure in two subjects at the lowest concentration, in one each at the two intermediate concentrations, and all four at 1.0 ppm." *Id.* at 329.

makes such long-term exposure a "hazard which research has not yet identified" and *cannot* identify with certainty until after the experience of a generation can be analyzed.

In addition, scientific analysis of the causes and effects of diseases is inherently subject to the limitation that a study failing to show that a pollutant has a hazardous effect cannot conclusively demonstrate that it does not. A finding of "no effect" may be due to shortcomings in the research methodology, rather than the absence or impotence of the causal variable. For example, the effect of the independent variable may not be seen in the experimental situation because the testing intrument is not sensitive enough to exhibit effects that are in fact present, since the consequences might not be apparent for many years, or because the conditions of the experiment may mask effects. Additionally, experimental ethics may bar research that might reveal potential hazards in humans, because of possible irreversible harm to the subjects.

Given the limitations of studies involving small, unrepresentative samples exposed to harmful pollutants for brief time periods, with effects measured by inadequate testing equipment and inadequate testing procedures, an assertion that such clinical studies have conclusively "demonstrated" the limits of health risk, for example, to children raised in a pollution ridden environment is without scientific basis.[67]

VI. Problems with the Margin of Safety Concept

A recent legal analysis of the Federal Water Pollution Control Act of 1972 acknowledged that the margin of safety concept is "inherently imprecise" and neither the Act nor its legislative history contain "explicit guidance as to what Congress intended by the

67. Ignoring the "non-provability-of-negative findings" scientific maxim is a source of error for some who deal with the "margin of safety" concept. This is a clear weakness of a recent petition to the EPA Administrator, for example. This petition states:

> Since *new information on health effects has demonstrated that the threshold for adverse human health effects is substantially higher than estimated by EPA in 1971*, the standard should be revised accordingly while maintaining an adequate margin of safety comparable to that originally intended by EPA.

Petition of American Petroleum Institute for Review 61 (1976) (Emphasis added). Of course the fact is that the studies cited by Kirkland, Ellis and Rowe in this petition (including the study with the four person sample referred to in note 65, *supra*) could not possibly have "*demonstrated* that the threshold for adverse human health effects is substantially higher."

term." However, the author maintained that the concept has "substantive meaning: . . . [b]y using the term 'margin of safety,' Congress intended that the EPA's regulation of toxic substances err on the side of protection of health, rather than on the side of economic savings."[68]

While few would argue with the view that Congress intended to bias the EPA regulations in the direction of public health protection, the intrinsic vagueness of the concept precludes it from being an effective means for achieving this purpose. Indeed, the fact that no objective criteria exist for determining a proper amplitude of the margin casts into doubt the degree to which the concept actually has "substantive meaning." In his testimony first suggesting the use of a margin of safety in environmental legislation before the Senate Subcommittee on Air and Water Pollution in May 1970, Dr. John Middleton touched on this difficulty: "[W]e say that a margin of safety must be included in setting national ambient air quality standards. What the margin of safety is to be is always debatable. Some people say it ought to be 10 times less than the minimum observed effect level; others have different views."[69]

The Panel of Nitrogen Oxides of the National Academy of Sciences and National Academy of Engineering Coordinating Committee on Air Quality Studies suggested establishing a margin of safety based on precedent in its report to the Senate Committee on Public Works in 1974:

> A reasonable margin of safety would be an air quality standard at least 50% below exposure concentrations at which illness has occurred. In instances in which a threshold concentration has not or cannot be established, there is precedent in the Atomic Energy Commission's decision to establish permissible concentrations of 1/100th of that which clearly produces radiation injury in the most susceptible cohort of the population.[70]

But analysis of the use of margins of safety in the field of radiation reveals that the precedents here are themselves based on arbitrary choices. In his text, *Of Acceptable Risk*, Lowrance identifies the essentially arbitrary nature of the margin of safety selected by experts for the general public to protect it from radiation hazards, saying:

68. K. Hall, *supra* note 8, at 630.

69. S. REP. ON CLEAN AIR AMENDMENTS, *supra* note 7, at 1185.

70. SENATE COMM. ON PUBLIC WORKS, AIR QUALITY AND AUTOMOBILE EMISSION CONTROL, S. REP. NO. 24, 93d Congress, 2d Sess. 42 (1974).

> In 1956 both the National Council on Radiation Protection and the International Commission on Radiation Protection recommended that for the general public, exposure should be limited to no more than one-tenth the occupational levels. *In this case, as in many others, the esthetically neat factor one-tenth is apparently an arbitrary selection; the factor one-eleventh is never chosen.*[71]

The lack of an objective basis for choosing safety factors is also shown in the following exchange during cross-examination of Dr. Nisbet, an expert in the toxicity of PCBs ("polychlorinated biphenyls"), by Dr. Highland of the Environmental Defense Fund during administrative hearings on the use of PCBs:

> Highland: So the conventional safety factor that you are aware of and that you have used is to apply a 1 to 100 value to the dose rate in terms of milligrams per kilogram per day to a no-effect level in an appropriate animal species to determine the acceptable exposure level for human beings, is that correct?
>
> Nisbet: Yes. It is usually called the acceptable daily intake.
>
> Highland: Okay. Could you explain briefly the rationale for the use of a safety factor such as 1 to 100?
>
> Nisbet: *This conventional safety factor* of 100 consists of a product of two independent factors, a factor 10—*these are both conventional safety factors. . . .*
>
> Highland: Am I correct in understanding, then . . . *you would consider the conventional 1 to 100 safety factor to be inadequate when applied to PCBs*?
>
> Nisbet: Yes, *although I used it in 1972, I would now consider it inadequate. . . .*
>
> Highland: In light of that response, what would you consider now to be an adequate safety factor for PCBs?
>
> Nisbet: I would think it ought to be at least 20. The second factor of 10, I know of no reason to suspect that PCBs . . . that one should use a larger or smaller factor than the conventional one there. . . . *I think one should set additional safety factors, but I do not know how large they should be.*[72]

71. W. LOWRANCE, OF ACCEPTABLE RISK: SCIENCE AND THE DETERMINATION OF SAFETY 85 (1978) (emphasis added).

72. Hearings in the Matter of Polychlorinated Biphenyls, EPA Doc. 4, Washington, D.C., October 20, 1976, at 1647-50 (EPA stenographic transcript) (emphasis added).

Even in the field of engineering, with its relatively straightforward and easily tested variables, margins of safety are based on subjective considerations. For example, in *Fatigue Design*, Osgood states: "Present safety factors are based upon past experience and engineering judgment, and are inevitably affected by the subjectivity of the designer."[73] Authors in other engineering contexts have emphasized also the absence of objective criteria in determining margins of safety.[74]

In *The Acceptability of Risk*, the British Council for Science and Society concludes that, since there is no objective basis for assessing risks, and hence for setting margins of safety, the personality and experiential differences of individuals will lead them to disagree over the margin of safety required for any given hazard:

> In every hazard the various interests naturally and legitimately bring their own valuations and perceptions to it. Even the scientists do not always reach an unambiguous, conclusive assessment of the severity of the risks. To suppose that people can or should have the same perception of the risk is naive, and not useful for understanding or improving the way society actually copes with risks.[75]

In addition to the vagueness inherent in the margin of safety concept itself, the addition of the words "adequate" and "ample" to the legislative mandate compounds the ambiguities because they are merely relative terms. A standard reference dictionary, for ex-

73. C. OSGOOD, FATIGUE DESIGN 39 (1970).

74. A. H-S. Ang and Y.K. Wen also emphasize the absence of objective criteria for determining levels of safety:

> Resolving the question of "how safe is safe enough?" is central to proper engineering. In this regard, it is important to recognize that safety, specially for protection against natural hazards, cannot be assured with absoluteness. Realistically, safety may be assured only within the context of some acceptable risk.

A. H-S. Ang and Y.K. Wen, *Risks and Safety Analysis in Design for Natural Hazards Protection*, in PROCEEDINGS OF THE U.S.-SOUTHEAST ASIA SYMPOSIUM ON ENGINEERING FOR NATURAL HAZARDS PROTECTION (A. H-S. Ang ed., 1978).

Alfred Freudenthal, in a report to the International Conference on Structural Safety and Reliability, echoes this perspective, stating: "There is no intrinsic significance to a particular failure probability since no a priori rationalization can be given for the adoption of a specific quantitiative probability level in preference to any other, so that the selection of this level remains an arbitrary decision." A. FREUDENTHAL, INTERNATIONAL CONFERENCE ON STRUCTURAL SAFETY AND RELIABILITY 6 (1972). Freudenthal concludes that for the engineer, it is only when other criteria such as expected financial gain, return on investment, etc., are provided that the arbitrariness of safety factors can be resolved.

75. *Id.* at 33.

ample, defines "adequate" as "equal to the requirement or occasion; commensurate; fully sufficient, suitable, or fit" and "ample" is defined as "fully sufficient for the purpose or for needs; enough and to spare."[76] Although an "ample" margin of safety might well be, to some unspecified degree, larger than an "adequate" one, these definitions show that an attempt to give absolute content to these terms must fail. Thus, at best, the terms "adequate" and "ample" to modify the phrase "margin of safety" are merely precatory verbiage expressing Congressional hopes and add nothing of substance to guide the Administrator.

Thus, because of the uncertainties which surround the "margin of safety" concept, it is impossible for an administrator charged with setting public health standards to know whether a given margin of safety is either "adequate" or "ample." Our lack of knowledge regarding the threats posed by hazardous substances precludes our knowing precisely how to guard against these threats. Only after the passage of time and further development of scientific knowledge might we be able to assess whether the margins of safety which had formerly been established will have been adequate to protect against hazards which had yet to be identified when these margins of safety were set. And even then, it is likely that still more risks may be identified by future research. The tragic example of the drug thalidomide is a poignant reminder that what is an "adequate" or "ample" margin of safety can never be known at the time standards are set when dealing with unknown hazards.[77]

A further major difficulty with the margin of safety concept is that recent scientific developments suggest that a discrete, quantifiable effects threshold regarding a particular pollutant can rarely be determined.

In 1970, when the use of the margin of safety concept in environmental legislation was first contemplated, the Manufacturing Chemists Association could confidently argue that: "With respect to chemical toxicants, the 'threshold' concept enjoys general acceptance. There is no consensus that dosages below the threshold

76. AMERICAN COLLEGE DICTIONARY 15, 43 (1963).

77. The "acceptable" level for thalidomide in human use was set at one hundredth of an effect level shown on test animals, a standard which scientific convention at that time would provide an adequate margin of safety and which is conventionally followed even to this date. Yet, tragically, what was clearly thought to provide an "ample" margin of safety for humans proved to be inadequate for human fetuses.

level have any deleterious effect upon those so exposed."[78]

By 1974, however, scientific experts from the National Academy of Sciences and National Academy of Engineering, reporting to the Senate Committee on Public Works, attacked the threshold concept, upon which the margin of safety concept depends:

> [I]n no case is there evidence that the threshold levels have a clear physiological meaning, in the sense that there are genuine adverse health effects at or above some level of pollution, but no effect at or below that level. On the contrary, evidence indicates that the amount of health damage varies with the upward and downward variations in the concentration of the pollutant, and with no sharp lower limit.[79]

By 1977, the validity of the safe threshold concept had eroded to the point that the Committee Report by the House Interstate and Foreign Commerce Committee on the Clean Air Act Amendments of 1977 flatly states: "From the fact that the 'safe threshold' concept is, at best, a necessary myth to permit the setting of some standards, it necessarily follows that the margin of safety concept is also an illusion."[80]

With regard to carcinogens, health effects are found to be proportional to the dose, no matter how small. Thus the idea of a safe threshold or use of a margin of safety is particularly inappropriate for cancer-causing pollutants. As with the carcinogen asbestos, "it is impossible to prescribe . . . limitations known to provide an ample margin of safety to protect public health, since no safe level has been identified."[81]

Another difficulty with the margin of safety concept is that its use implies that public health will be absolutely protected. But even when it includes what is hoped to be an "ample" margin of safety, a standard cannot guarantee that the public will be risk free, for safety itself is a relative term. As William Lowrance has said:

> Nothing can be absolutely free of risk. One can't think of anything that isn't, under some circumstances, able to cause harm.

78. *Air Pollution: Hearings on S. 3229, S. 3466, and S. 3546 Before the Subcomm. on Air and Water Pollution of the Senate Public Works Comm.*, 91st Cong. 2d Sess. 1630 (1970) (Part 5, Appendix).

79. SENATE COMM. ON PUBLIC WORKS, AIR QUALITY AND AUTOMOBILE EMISSION CONTROL, S. REP. NO. 24, 93d Cong., 2d Sess. 17 (1974).

80. H.R. REP. NO. 24294, 95th Cong. 2d Sess. 111 (1977).

81. EPA Document 450/2-74-009a (Oct. 1974).

> Because nothing can be absolutely free of risk, nothing can be said to be absolutely safe. There are degrees of risk, and consequently there are degrees of safety. . . . [T]wo very different activities are required for determining how safe things are: *measuring risk*, an objective but probabilistic pursuit; and *judging the acceptability of that risk (judging safety)*, a matter of personal and social value judgment.[82]

Thus it is clear that no matter how great the margin of safety selected regarding any given hazard, some degree of risk must be associated with it. Moreover, even if the standard is set at zero, the very act of so setting the standard is likely to trigger other accommodative changes in society causing other levels of risk to rise.

Finally, the hope that the margin of safety concept, with its emphasis on protection of public health, would provide a bulwark against the tendency to compromise public safety because of economic considerations has been disappointed. An examination of how the concept was used in two recent cases of standard setting illustrates its impotence in this regard.

Vinyl chloride is a carcinogen which has a no-effects threshold, and thus no safe level can be prescribed. Consequently, the only level which provides an ample margin of safety for the public health is a zero emission standard. Despite this, in EPA's "Proposed Standard for Vinyl Chloride,"[83] the Agency interpreted section 112 of the Clean Air Act[84] as authorizing it to establish standards at the "lowest level achievable by use of the best available control technology . . . where complete emission prohibition would result in widespread industry closure and EPA has determined that the cost of such closure would be grossly disproportionate to the benefits of removing the risk that would remain after imposition of the best available control technology."[85]

The Environmental Defense Fund petitioned the U.S. Court of Appeals for the District of Columbia Circuit to review the standard. Eventually, the EPA and the EDF reached a settlement by compromising on a new proposed standard. Though the EPA acknowledged that "the only level of vinyl chloride which would appear to be absolutely protective of health is zero, which may be

82. LOWRANCE, *supra* note 70, at 8 (emphasis added).
83. 40 Fed. Reg. 59,532 (1975). *See also* 40 C.F.R. Part 61 (1978).
84. *See* text accompanying notes 13-20 *supra*.
85. 40 Fed. Reg. 59,532, 59,534 (1975).

achievable only by banning vinyl chloride emissions completely,"[86] the agency compromised by protecting the public health as much as it felt possible, without shutting down the industry:

> In order to insure that the standard continues to approach the only level of emissions which is known to be absolutely protective of health, namely zero emissions, EPA is proposing amendments which require more efficient use of existing control technology at existing plants and more effective controls at new plants, and which encourage technology to reach this goal without banning vinyl chloride.[87]

Thus economic and technological considerations taken into account in the decision not to prohibit the production of vinyl chloride in apparent contradiction to the requirement of section 112 of the Clean Air Act that only public health factors be considered in such decisions. Strict observance of the margin of safety standard was ignored.

The recent relaxation of the ozone ambient air quality standards provides an illustration of the impotence of the margin of safety concept in protecting the public health from noncarcinogenic air pollutants.

The EPA's Preamble and Proposed Revision to the National Ambient Air Quality Standard for Ozone[88] stated that costs should not be considered in setting ambient air quality standards, since only health considerations are relevant:

> The Clean Air Act specifies that National Ambient Air Quality Standards are to be based solely on scientific criteria relating to the level that should be attained to adequately protect public health and welfare. Considerations of cost of achieving those standards or the existence of technology to bring about needed reductions of emissions are not germane to such a determination, as the words of the Act and its legislative history clearly indicate.[89]

On June 13, 1978, the EPA announced that it would allow the permissible ozone level to rise from .08 ppm to .10 ppm. The Administrator claimed that "[this] increase would leave a margin for safety between dangerously polluted and acceptable air quality."[90]

86. 42 Fed. Reg. 28,154 (1977). *See also* 40 C.F.R. Part 61 (1978).
87. 42 Fed. Reg. 28,154 (1977).
88. Unnumbered EPA document dated May, 1978.
89. *Id.* at 7.
90. Washington Post, June 14, 1978, at 3, col. 3.

However, only six months earlier a *Summary Statement from the EPA Advisory Panel on Health Effects of Photochemical Oxidants* prepared for the EPA under the supervision of the Institute for Environmental Studies of the University of North Carolina at Chapel Hill had come to a much different conclusion. The panel felt there was little reason to alter the current standard of .08 ppm, since it left hardly any margin of safety:

> In reviewing the body of evidence on health effects, the Health Panel concluded that *there is no compelling reason to suggest a change from the concentration defined by the existing primary air quality standard, namely 0.08 ppm.* This conclusion was based upon the previously cited Panel consensus that a variety of adverse effects are likely to occur in some segments of the population from short-term ozone exposures of 0.15 to 0.25 ppm, and upon other evidence that suggests, though less conclusively, the possibility of effects at concentrations as low as 0.10 ppm. The Panel recognized that *this standard provides very little margin of safety* for the reasons cited immediately above.[91]

However, when he took final action on the ozone standard in early 1979, the Administrator even further relaxed the permissible ozone level, allowing it to rise to .12 ppm. Despite acknowledging White House pressures on EPA to set an even more lax standard, and an EPA estimate that setting the standard at .12 ppm would cost industry $4.5 billion a year by 1987, the Administrator, repeating the wording of the Preamble and Proposed Revision to the Ozone Standard, claimed that "[c]onsideration of cost is not germane," since the Clean Air Act stipulated that standards be based on public health considerations alone.[92]

But economic considerations clearly affected the Administrator's decision, since the raising of the ozone level from .08 ppm can hardly be justified on public health grounds alone. Data from the EPA's own health experts indicate that ozone will cause increases either in reduced pulmonary functioning, chest, nose, and throat irritation, reduced resistance to infection, or aggravation of asthma, emphysema, and bronchitis in the American population. The chances of such effects rise from an estimated probability of .27 at the .08

91. ENVIRONMENTAL PROTECTION AGENCY, SUMMARY STATEMENT FROM THE EPA ADVISORY PANEL ON HEALTH EFFECTS OF PHOTOCHEMICAL OXIDANTS, at 18-19 (Jan. 1978) (emphasis added).

92. Washington Post, Jan. 27, 1979, at 1, col. 1.

ppm ozone level to .76 at the .12 ppm ozone level.[93] In other words, the chances that some people will suffer adverse health effects rises from approximately one in four to a highly probable three out of four as a result of the EPA action. Once again, a margin of safety requirement served as no barrier to the weakening of a public health standard.

VII. CONCLUSION

Beyond the Margin of Safety Concept

This analysis has shown that the margin of safety concept suffers from inherent vagueness and, in practice, does not serve to protect public health interests against the corrosive influence of economic and technological considerations. Thus, despite the Congressionally-mandated requirement that the EPA Administrator set pollutant standards on public health grounds alone by using the margin of safety concept, he cannot escape making a subjective cost/benefit judgment as to whether the need to protect the public health outweighs the costs of pollution control. In the words of the Coordinating Committee on Air Quality Studies: "There is no escape from a reasoned judgment, containing an unavoidable subjective element, as to the level at which the possible benefits from reducing pollution further no longer justify the high probable costs of bringing about such further reduction."[94]

Accordingly, the public welfare would be best served if the process of balancing benefits to public health against economic costs were made explicit, rather than being hidden behind the illusory assurance that the Administrator is providing a margin of safety for the public health without considering economic factors. As a National Academy of Sciences Committee on Principles of Decision Making for Regulating Chemicals in the Environment concluded: "[P]racticality dictates that economic factors be considered in the decision-making process, because even if they are not considered

93. ENVIRONMENTAL PROTECTION AGENCY, A METHOD FOR ASSESSING THE HEALTH RISKS ASSOCIATED WITH ALTERNATIVE AIR QUALITY STANDARDS FOR PHOTOCHEMICAL OXIDANTS (External Review Draft), at 65.

94. SENATE COMM. ON PUBLIC WORKS, AIR QUALITY AND AUTOMOBILE EMISSION CONTROL, S. REP. NO. 24, 93d Cong., 2d Sess. 18 (1974).

explicitly, they will almost inevitably have an influence on the final decision."[95]

There are indications that explicit risk/benefit analyses of health problems are becoming politically acceptable. Amitai Etzioni, Director of the Center for Policy Research, recently suggested that the American public would actually welcome more of this type of analysis:

> A strong case can be made for shaping public policy in health and safety areas openly rather than implicitly. First there is precious little evidence that explicit policymaking has the feared dehumanizing impact. . . . Second, implicit decisionmaking is *hidden* decisionmaking. Hidden decisions tend to bow to prejudices and power; open decisions, while they cannot solve this problem, can help counter it. Finally, estimates of the comparative costs and benefits of various quality-of-life policies can help us make much more sensible use of whatever resources we do seek to set aside for improving safety.[96]

That the EPA administrators are not adverse to making decisions on an explicit risk/benefit analysis basis is indicated by the comments of Steven Jellinek, Assistant Administrator for Toxic Substances, before a Risk Assessment Workshop. After warning against the unreasoned use of quantification, Jellinek urged that:

> [W]e must make the numbers as good as we can—for risks as well as benefits—without sacrificing our main objective to the pursuit of the perfect analysis. [W]e should use the numbers as an aid to a decisionmaking process that is primarily concerned with understanding the nature of risk and benefit, identifying who benefits and who is made worse off, and protecting the society as a whole when the risks outweigh the benefits.[97]

For pollutants that exhibit any tendency to demonstrate a threshold effect, the weighing of public health benefits against other societal costs must be done within the range of values *below* any measurable health effect level in order to protect the public. But for carcinogens, which have a potentially greater public health impact, but paradoxically are less susceptible to regulation based upon the margin of risk paradigm, no such "natural" arena of delib-

95. NATIONAL ACADEMY OF SCIENCES, DECISION MAKING FOR REGULATING CHEMICALS IN THE ENVIRONMENT 20 (1975).

96. Washington Post, Jan. 28, 1979, § C, at 5, col. 3.

97. S. Jellinek, Speech before Risk Assessment Workshop, February 5, 1979.

erations suggests itself. Confounding the attempts at reasoned judgment of such risks is the fact that no such assessment can ignore the likely impact of exposure on the genetic makeup of indeterminate future generations of our children. Thus the concept of "public health" as affected by carcinogens carries with it an extreme temporal as well as demographic complexity.

Even more fundamental than *how* such determinations should be made is the question of *who* should be weighing the risks to the public health. Despite the courts' tendency to defer to agency expertise regarding acceptability of risk, this analysis has indicated that assessment of risk is primarily a matter of judgment, not of technical knowledge. Thus, acceptability of public risk should not be left for determination by an administrative elite, particularly since all citizens share, in varying degrees, in exposure to that risk.

In addition, democratic principles shared widely in our society suggest that more open determination of public health decisions should and would lead to greater equality. At present, when public health risk decisions are made without objective criteria and hidden from broad scrutiny, the disparities between those individuals and groups with high levels of resources and those without tend to be exaggerated. In the words of an advocate of risk/benefit analysis:

> [I]n practice, setting priorities subjectively means setting them politically, in response to either institutional or elective political pressures. Any group that lacks money, organization, or other forms of power will lose out over and over, allocation after allocation. As a practical matter we value lives at very different levels in our society already. Risk-benefit can treat everyone equally; it is blind to group identities in a way that intuition is not.[98]

It has been noted previously here that the court in the recent *Environmental Defense Fund v. EPA* decision acknowledged that "the formulation of standards involves choices that by their nature require basic policy determinations" and are "inherently legislative decisions."[99] If the setting of standards are "legislative decisions," the check on administrative arbitrariness is less to be found in judicial review of agency action than in political accountability. The Honorable Howard T. Markey, Chief Judge, U.S. Court of Customs of Patent Appeals, has taken this position in arguing against

98. Hapgood, *Risk-Benefit Analysis, Putting a Price on Life*, THE ATLANTIC MONTHLY, Jan., 1979, at 33-38.

99. Environmental Defense Fund v. EPA, 598 F.2d 62, 83-84 (D.C. Cir. 1978).

judicial review of cases involving risks and benefits since they contain political, nonjusticiable questions. In a speech before the Joint American Association for the Advancement of Science and House Science Committee Conference on Risk Analysis and the Legislative Process, July 24, 1979, Judge Markey stated that risk/benefit cases "involve broad public policy, future direction of large segments of society, level of acceptable risk, group preferment type questions, the very thing legislatures were designed to decide."[100] Judge Markey concluded:

> If our republican form of democracy means anything, it means that the people, through their representatives, shall make the basic decisions controlling their lives. The type and extent of the risks acceptable in their lives is perhaps the most basic of all those decisions. The power to make those final decisions should not be even indirectly vested in a few unelected bureaucrats, who have virtual life tenure in their jobs, under review by a few unelected judges who have a constitutional life tenure.[101]

The institution which has been devised and honed over the past two centuries to deal with just such basic policy determinations is the U.S. Congress. Despite the accelerating tendency toward wholesale delegation of regulatory power to the agencies which has been particularly evident in this century, Congress will fail in its political obligation in our society unless it counters this trend and accepts its responsibility to make the basic policy determinations on public health risks and costs for the American people both now living and yet to come. Only our public representatives can properly specify what are, in their collective judgment, "adequate" margins of safety for the public health, for this assessment is quintessentially political.

100. HOUSE COMMITTEE ON SCIENCE AND TECHNOLOGY, RISK/BENEFIT ANALYSIS IN THE LEGISLATIVE PROCESS, H. REP. NO. 71, 96th Cong., 1st Sess. 99 (1979).

101. *Id.*