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The "Significance" of Toxic Health Risks: An Essay on Legal Decisionmaking Under Uncertainty

Howard A. Latin*

INTRODUCTION

When confronted by uncertainty in the course of a scientific investigation, the systemic response of a scientist is suspension of judgment pending the acquisition of more data and the development of testable hypotheses. In science, "no decision" can mean just that. In legal disputes, however, "no decision" perpetuates the status quo and ordinarily promotes some interests at the expense of others. Lacking a comparable option to suspend the flow of events, legal decisionmakers must often create public policy in spite of, or in light of, the absence of a reasonable scientific consensus. This essay addresses the question of how courts should respond to factual uncertainties1 that arise in the fields of environmental protection, public health and safety.2

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1. In legal contexts, uncertainty can be characterized as either factual or normative. Factual uncertainty stems from incomplete knowledge, while normative uncertainty arises from conflicts in values and priorities. This Article concerns factual uncertainty: those problems resulting from inadequate descriptions rather than incompatible prescriptions.


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Courts may employ either of two incompatible approaches to resolve problems of uncertainty. One treatment emphasizes judicial reliance on uniform procedural rules applied in different types of disputes. For example, the common law generally imposes the burden of proof, and hence the risk of uncertainty, on the "moving" party in a controversy. Of greater significance for judicial review of regulatory decisions, the Administrative Procedure Act (APA) assigns the burden of proof to "the proponent of a rule or order." The APA doctrine entails reductionism because only one consideration—the procedural posture of the parties—is material to allocation of the burden of proof. Important distinctions can be drawn between the legislative policies underlying different organic acts, between the various factual issues that arise in different regulatory contexts, and between the abilities of different parties to resolve particular factual uncertainties. Under the reductive rule of the APA, the burden of proof is assigned without consideration of these factors. This approach, like all reductive treatments, offers the advantages of ease of judicial application and apparent consistency of results. In many cases, however, a reductive treatment of uncertainty may impede achievement of the substantive policies of the organic legislation, a high price to pay for simplicity of judicial administration.

The principal thesis of this Article is that, because legislative choices vary with respect to different regulatory programs and different factual issues, the decisionmaking strategy employed to resolve uncertainty in any given program should correspond with the social policies underlying that particular program. Courts routinely construe statutory provisions and legislative history to determine the meaning of ambiguous terms and the scope of powers delegated to administrative agencies. This essay proposes that a comparable approach should be adopted for the legal resolution of factual uncertainty.

In Industrial Union Department, AFL-CIO v. American Petroleum Institute (the benzene case), the Supreme Court invalidated an Occu-

5. "Reductionism" is "any method or theory of reducing data, processes, or statements to seeming equivalents that are less complex or developed." The term is usually used in a disparaging manner. Webster's New World Dictionary of the American Language 1191 (2d ed. 1972).
pational Safety and Health Administration (OSHA) regulation aimed at reducing employee exposure to the toxic substance benzene. The critical uncertainty in that case pertained to the degree of risk posed by prevailing levels of benzene exposure. Because the health hazards at the existing exposure limit could not be determined, the plurality's opinion held that OSHA had failed to prove a stricter benzene standard was reasonably necessary. The court reached this conclusion only because it imposed the burden of proof on the Agency; yet that allocation was made with little reference to the purposes of the Occupational Safety and Health Act of 1970 (the OSH Act). The plurality instead relied on the reductive rule in the APA without adequately considering the degree to which its allocational doctrine would frustrate Congress' goal of strict toxic substance control. This Article contends that the plurality's approach to legal decisionmaking under uncertainty was conceptually unsound, and led to an incorrect result in the benzene case itself.

The immediate consequence of the Supreme Court's analysis is that many thousands of workers will be exposed to unnecessarily high levels of benzene. Other health standards will be invalidated as lower courts follow the reasoning in the benzene decision, and some standards will not even be proposed because OSHA cannot meet the mandated burden of proof. On a larger scale, the approach adopted in the benzene case may emasculate many regulatory programs designed to reduce environmental cancers, because for the great majority of carcinogens the health risk at low levels of exposure is likely to be uncertain. Nothing in the mode of analysis employed by the plurality

9. Id. at 611-62 (Stevens, J.); id. at 662-64 (Burger, C.J., concurring); id. at 664-71 (Powell, J., concurring in part and in the judgment); id. at 671-88 (Rehnquist, J., concurring in the judgment). Justices Brennan, White and Blackmun joined Justice Marshall in dissent. Id. at 688-724. All the Justices addressed the merits of OSHA's benzene standard except Justice Rehnquist, who felt that the statutory provision governing toxic substances was unacceptably ambiguous. Id. at 683. Justice Rehnquist concurred in the judgment on the grounds that the provision represented an invalid delegation of legislative power. Id. at 675; see Rothstein, OSHA After Ten Years: A Review and Some Proposed Reforms, 34 Vand. L. Rev. 71, 83 (1981).
11. Id. at 653; see infra text accompanying notes 61-68.
13. See 448 U.S. at 615-16 & n.6; id. at 701, 714 (Marshall, J., dissenting).
15. See infra Section II.B.
16. Serious factual uncertainties stem from inadequate scientific knowledge about causal processes for cancer. See infra text accompanying notes 244-66 and 325-31. These uncertainties will impede regulation of carcinogenic risks regardless of the particular regulatory context.
limits its application to control of benzene, or even to OSHA regulations. This Article examines the undesirable ramifications the benzene decision will have if its reductive approach is followed in other cases where factual uncertainty impedes effective regulation of toxic substances. Concurrently, a more flexible and particularized approach to legal decisionmaking under uncertainty is advocated.

Section I presents a synopsis of the plurality opinion and identifies some of its methodological deficiencies. The Section then criticizes the plurality’s failure to assess the individual circumstances of particular regulatory statutes, factual issues, and parties. The principal question addressed in Section II is whether the critical factual uncertainties in the benzene case could have been resolved by OSHA, or by any other party. The plurality cited several examples of how it thought OSHA could meet the burden of proof assigned in the benzene case. Section II demonstrates, however, that those examples were inapposite, and that the Agency will seldom be able to resolve scientific uncertainties surrounding the estimation of carcinogenic risks.

Section III evaluates the Supreme Court’s approach to the resolution of uncertainty in terms of the legislative policies embodied in the OSH Act. The major proposition is that the plurality misplaced the burden of proof on the determinative factual question in the benzene case. Moreover, given the range of issues pertinent to toxic substances regulation under the OSH Act, Section III contends that any reductive treatment of uncertainty is inefficient and in conflict with the statutory intent. This extended discussion of toxic substances regulation illustrates the weaknesses of a reductive approach to uncertainty, and is intended to serve as a model of how the approach recommended here could be implemented in a specific regulatory context.

I
OVERVIEW OF THE BENZENE DECISION

Toxic substances are subject to regulation under section 6(b)(5) of the OSH Act, which provides in part that:

The Secretary . . . shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by the standard for the period of his working life. 17

Despite the expansive statement that “no employee” should suffer material health impairment, the plurality opinion in the benzene case relied on definitional language in section 3(8) of the Act 18 to create a

18. 29 U.S.C. § 652(8) (1976) provides that a safety or health standard is one "which
threshold requirement that all OSHA standards, including those for toxic substances, be “reasonably necessary or appropriate to provide safe or healthful employment.” 19 That statutory phrase was then construed to confine the Secretary’s authority to the regulation of “significant” risks. 20 Justice Stevens emphasized that the OSH Act did not require perfect safety 21 and that OSHA was not empowered to regulate whenever “some employee somewhere in the country may confront some risk of cancer . . . .” 22 The plurality opinion concluded that section 6(b)(5) requires imposition of a highly protective standard, but only when some standard is necessary to avoid a significant risk of material health impairment. 23 As Chief Justice Burger observed in his concurring opinion:

> When the administrative record reveals only scant or minimal risk of material health impairment, responsible administration calls for avoidance of extravagant, comprehensive regulation. Perfect safety is a chimera: regulation must not strangle human activity in the search for the impossible. 24

There is, however, a crucial difference between regulating a substance that presents a risk known to be insignificant and regulating a carcinogen whose risk at a given level of exposure is uncertain. Contrary to Chief Justice Burger’s characterization, the benzene record revealed uncertain risk rather than “scant or minimal” risk. 25 In its analysis, the plurality effectively equated uncertain risk with insignificant risk. Despite the doubtful precedential value of the decision, 26 lower courts are following the plurality’s holding that only demonstrably significant risks are appropriate for regulation. 27 Recently, in *American Textile Manufacturers Institute v. Donovan* (the cotton dust case), 28 Justice Brennan and the other benzene case dissenters appeared to accept the threshold requirement of significance. 29 The following

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19. 448 U.S. at 615, 639.
20. Id. at 615, 639-46.
21. The plurality relied on Senator Dominick’s statement during the Senate debate that the Act did not envision perfect safety. Id. at 647-49.
22. Id. at 652.
23. Id. at 643 n.48.
24. Id. at 664.
25. See infra Section II.
26. No analysis received support from a majority of the Justices. Justice Rehnquist, *id* at 676-81, and Justice Marshall for the four dissenters, *id* at 708-13, rejected the proposition that section 3(8) was intended to limit the scope of section 6(b)(5). For their reasons, see *infra* text accompanying notes 428-34. Moreover, Justice Powell did not agree with several important aspects of the plurality’s reasoning. See *infra* notes 55, 223.
29. See *id.* at 505 n.25.
discussion examines and criticizes this requirement in light of the fundamental distinction between insignificant and uncertain risks.

A. Allocation of the Burden of Proof

Judge Clark in the Fifth Circuit Court of Appeals opinion\textsuperscript{30} and Justice Stevens writing for the Supreme Court plurality\textsuperscript{31} agreed the evidence warranted OSHA's finding that benzene is a toxic substance appropriate for regulation under section 6(b)(5). Abundant evidence had been presented in OSHA's proceeding that benzene causes cancer\textsuperscript{32} and other serious health problems\textsuperscript{33} at high levels of exposure. While there was some disagreement about the actual extent of exposure, it was clear that OSHA's existing regulations covered several hundred thousand workers exposed to benzene vapors.\textsuperscript{34}

The major conflict in the case centered on the degree of risk at particular levels of exposure and the benefits that might result from lowering the permissible exposure limit (PEL). After accumulating evidence on the toxicity of benzene,\textsuperscript{35} OSHA promulgated a stringent regulation reducing the existing 10 parts per million (ppm) PEL\textsuperscript{36} to 1 ppm.\textsuperscript{37} The Agency settled on the 1 ppm limit as the safest standard that could feasibly be imposed on employers\textsuperscript{38} and administered by responsible officials.\textsuperscript{39} Industry experts contended a threshold level exists below which most people would experience no risk most of the time,\textsuperscript{40} but even advocates of this position conceded that especially vulnerable individuals in the population could not be identified with certainty.\textsuperscript{41} Thus, industry witnesses agreed that absolute safety could be achieved only with a zero exposure limit.\textsuperscript{42} It follows that some risk is present at the existing 10 ppm PEL. The Court of Appeals specifically held this conclusion was supported by substantial evidence.\textsuperscript{43} Judge Clark also noted "general agreement in the scientific community" that lower expo-

\textsuperscript{30} American Petroleum Inst. v. OSHA, 581 F.2d 493, 498-99 (5th Cir. 1978).
\textsuperscript{31} 448 U.S. at 616.
\textsuperscript{32} Id. at 618-22.
\textsuperscript{33} Id. at 616-17, 631.
\textsuperscript{34} Compare id. at 628-29 & n.28, with id. at 701-02 & n.22 (Marshall, J., dissenting).
\textsuperscript{35} See id. at 618-22 & nn.9, 12 & 15.
\textsuperscript{36} Id. at 617.
\textsuperscript{37} Id. at 623-28. The standard not only reduced average permissible exposures from 10 ppm to 1 ppm, but decreased the maximum allowable exposure for short periods from 50 ppm to 5 ppm. Occupational Exposure to Benzene, 43 Fed. Reg. 5918-19 (1978).
\textsuperscript{38} 43 Fed. Reg. 5918, 5932 (1978); see 448 U.S. at 637; id. at 671 (Rehnquist, J., concurring in the judgment).
\textsuperscript{39} See 448 U.S. at 621 n.14, 650-51.
\textsuperscript{40} See 43 Fed. Reg. 5918, 5931, 5946 (1978).
\textsuperscript{41} See 448 U.S. at 636-37 n.41.
\textsuperscript{42} Id.
\textsuperscript{43} American Petroleum Inst., Inc. v. OSHA, 581 F.2d 493, 503 (5th Cir. 1978).
sure ordinarily entails less risk than higher exposure. He therefore approved the Agency's determination that some benefit would result from reducing the permissible limit to 1 ppm.

Justice Stevens did not set aside these qualitative findings, but he ruled they were insufficient to meet OSHA's burden of proof. The Supreme Court plurality required that "the risk from a toxic substance be quantified sufficiently to enable the Secretary to characterize it as significant in an understandable way . . . ." Although the "exact probability of harm" need not be calculated, OSHA must find "that a certain level of risk exists . . . ." These formulations call for considerable specificity on the part of the Agency. Citing the clause in section 6(b)(5) that allows regulation on the basis of the "best available evidence," the plurality conceded that OSHA should be granted "some leeway where its findings must be made on the frontiers of scientific knowledge." Yet this deference apparently extends only to cases where quantification of risks is approximate, not where it is absent. Justice Stevens acknowledged that the definition of a "significant" risk is a policy question within the Agency's discretion, but he held that this latitude does not authorize OSHA to regulate toxic exposures without a supportable estimate of the risks to be avoided. Chief Justice Burger, in his brief concurring opinion, agreed that OSHA must determine "whether a specific risk of health impairment is significant in terms of the policy objectives of the statute."

Although the Court insisted on quantitative estimates of toxic risk levels, it failed to understand that quantitative evidence may be avail-

44. Id.
46. See 448 U.S. at 635-36; id. at 689 (Marshall, J., dissenting).
47. Id. at 652-55, 659.
48. Id. at 646 (emphasis added). After quoting this passage, the Chief Justice wrote that "[p]recisely what this means is difficult to say." Id. at 663 (Burger, C.J., concurring). A central thesis of this Article is that OSHA cannot quantify most carcinogenic risks in a scientifically meaningful way. See infra Sections II B & III B.
49. Id. at 655.
50. Id. at 655 n.62 (emphasis added).
51. Id. at 656.
52. Id.
53. In the passage immediately preceding the concession of "some leeway," Justice Stevens characterized a chance of one in a billion as an insignificant risk but odds of one in a thousand as potentially significant. He followed these quantitative examples with the statement that the "exact probability" of harm need not be determined. Id. at 655.
54. Id. at 655-56 n.62. Justice Stevens stated that:

While the Agency must support its finding that a certain level of risk exists by substantial evidence, we recognize that its determination that a particular level of risk is 'significant' will be based largely on policy considerations. At this point we have no need to reach the issue of what level of scrutiny a reviewing court should apply to the latter type of determination.
55. Id. (emphasis added).
able for some purposes but not for others. Epidemiological information like that submitted in the benzene proceeding is often sufficient to identify aggregate health effects, the cumulative effects from all levels of past exposure to a given substance. OSHA relied on quantitative evidence of aggregate health effects to demonstrate that benzene is "toxic" despite uncertainty about what specific levels of exposure had prevailed in the past. However, the plurality's analysis requires quantitative estimates of disaggregated health effects, the risks associated with particular levels of exposure—the existing 10 ppm PEL and the proposed 1 ppm limit. The plurality opinion repeatedly confused the essential distinction between quantitative proof of aggregate health effects and quantitative estimates of disaggregated risks. For example, in attempting to show Congress intended OSHA to regulate only "significant" risks, Justice Stevens cited legislative history that indicated 20,000 insulation workers were likely to die from inhalation of asbestos fibers. This is a quantitative figure, but it describes aggregate health effects and provides no insight on the relative safety of particular levels of exposure. If the present PEL for asbestos is lower than it was in the past, evidence that 20,000 workers will die from past contact with asbestos could not prove the risk is significant at current exposure levels.

After requiring quantitative estimates of disaggregated risks, the plurality acknowledged that the critical legal issue was how to allocate the burden of proof when scientific knowledge is imperfect. The opinion characterized OSHA's position as requiring industry to prove a given exposure level is safe. The Court then rejected that position and allocated the burden of proof to the Agency:

As we read the statute, the burden was on the Agency to show, on the basis of substantial evidence, that it is at least more likely than not that long-term exposure to 10 ppm of benzene presents a significant risk of

57. See infra text accompanying notes 171-73 & 180-84.
58. See infra text accompanying notes 289-98 & 383-85.
59. See id. at 646, citing S. Rep. No. 1282, 91st Cong., 2d Sess. 3 (1970), reprinted in LEGISLATIVE HISTORY OF THE OCCUPATIONAL SAFETY AND HEALTH ACT OF 1970 143 (1971) [hereinafter cited as LEG. HIST.]. Justice Stevens also cited legislative belief that 100,000 workers suffered from byssinosis as a result of exposure to cotton dust. 448 U.S. at 646. This is another aggregate figure, which reveals nothing about the hazards of particular exposure levels.
60. The evidence on asbestos health risks is briefly discussed below to demonstrate that the current occupational standard for asbestos would not be approved under the plurality's significance test. See infra text accompanying notes 393-411.
61. 448 U.S. at 652.
62. Id. Industry had submitted evidence to show the risk at the existing 10 ppm limit for benzene was very small. Id. at 653-54. For a detailed critique of that evidence, see infra Section II-A.
Despite the introductory phrase in this passage, the plurality did not assign legal responsibility for uncertainty through reference to the OSH Act. Rather, the opinion relied on the APA, which imposes the burden of proof on "the proponent of a rule or order." It is true that the OSH Act does not explicitly allocate the burden of proof, but the question remains whether the statute does so implicitly. Justice Stevens disposed of that possibility in a perfunctory manner by citing another health-oriented statute in which Congress had expressly assigned the burden to industry on the safety issue. He then asserted that the absence of a comparable provision in the OSH Act meant Congress "intended the Agency to bear the normal burden of establishing the need for a proposed standard." Because OSHA conceded the risk of harm from exposure to 10 ppm of benzene was unknown, Justice Stevens held the Agency "did not even attempt" to meet its burden of showing that a stricter standard more likely than not is reasonably necessary.

The plurality in the benzene case did not discriminate between controversies where OSHA simply fails to quantify the risk and those where it demonstrates that the risk cannot be quantified. Justice Powell, in his concurring opinion, refused to accept this facet of the plurality's analysis. He read the "best available evidence" provision in section 6(b)(5) to mean that OSHA can rely on qualitative judgments derived from expert opinion once it shows quantitative evidence is inconclusive. He further indicated that nothing in the Act "suggests that OSHA's hands are tied when reasonable quantification cannot be accomplished by any known methods." On that basis, Justice Powell decided OSHA had attempted to prove the risk at 10 ppm was significant. He articulated a two-part test to measure the sufficiency of the Agency's findings on that question: did OSHA show by substantial evidence that a numerical estimate of risks was unavailable, and if so, did it show by substantial qualitative evidence that a significant risk

63. 448 U.S. at 653.
64. Id.
66. 448 U.S. at 653.
68. 448 U.S. at 653. Section III, infra, discusses the validity of the Court's statutory interpretation.
69. Justice Powell specifically refused to join in Part III-D of the plurality opinion, the section that allocated the burden of proof. Id. at 664 (Powell, J., concurring in part and in the judgment).
70. Id. at 666.
71. Id.
72. Id. at 667.
exists? Justice Powell concluded that OSHA did not succeed in meeting its burden of proof, without indicating which part or parts of his test the Agency had failed. Evidently, a showing of some risk and some benefit from reduction of that risk was not sufficient. Yet the discussion below suggests the Agency will rarely be able to make a more definitive determination.

After holding that OSHA had not made the threshold finding of significance, the plurality opinion did not explicitly address the remaining legal issues. However, as a logical corollary of its analysis, the plurality would surely impose on OSHA the burden of demonstrating that appreciable benefits would result from implementation of a proposed standard. It is difficult to see how a regulatory standard could be “reasonably necessary” if it did not significantly reduce the existing risk. Lower courts have ruled that OSHA must show why a new standard will be better than the current one. To accomplish that under the benzene decision’s reasoning, the estimated risk at the proposed PEL must be compared to the risk at the prior limit. Thus “significance” is relevant in two distinct respects: the initial level of risk must be significant and the benefits derived from regulating that risk must also be significant. Whether OSHA can develop scientifically meaningful

73. Id.
74. See id. Although Justice Powell regarded the sufficiency of OSHA’s proof as a “close” question, id., he did not indicate just where substantial evidence was lacking. In any event, he went on to conclude that the OSH Act required a balancing of benefits against costs, which the Agency did not even attempt. Id. at 667-70.
75. See infra Section II.
76. In its preliminary statement of the benzene case holding, the plurality noted OSHA must find that the “toxic substance in question poses a significant health risk in the workplace and that a new, lower standard is therefore ‘reasonably necessary.’” 448 U.S. at 615. Later, the plurality indicated an OSHA finding that benefits were “likely” to be “appreciable” would not be sufficient. Id. at 653. The inference is that OSHA must quantify both risks and anticipated benefits, and show significant benefits are more likely than not to accrue from a new standard. Even if the initial risk was clearly significant, no benefits would result if the new standard did not reduce the risk. See, e.g., AFL-CIO v. Brennan, 530 F.2d 109 (3d Cir. 1975) (substitution of new safety rules for the former “no hands in dies” rule for factory workers would not necessarily be beneficial).
78. In the cotton dust case, where quantitative evidence on disaggregated risks was available, Justice Brennan found OSHA had proved that a significant risk of material impairment was present at existing exposure levels and that byssinosis “should be significantly reduced” by the proposed standard. American Textile Mfrs. Inst., Inc. v. Donovan, 452 U.S. 490, 505 n.25 (1981). In the most important aspect of the opinion, Justice Brennan concluded that OSHA was not required, or apparently even permitted, to conduct a cost-benefit analysis in conjunction with each separate toxic standard. See id. at 511-12.
Congress itself defined the basic relationship between costs and benefits, by placing the “benefit” of worker health above all other considerations save those making attainment of this “benefit” unachievable. Any standard based on a balancing of costs and benefits by the Secretary that strikes a different balance than that struck by Congress would be inconsistent with the command set forth in Sec. 6(b)(5).
judgments on the significance of carcinogenic risks and thereby meet the burden imposed by the benzene decision is the central question of Section II. The discussion below first considers the broader implications of a reductive approach to legal resolution of factual uncertainties.

B. Reductive Treatment of Uncertainty

The plurality in the benzene case treated the allocation of the burden of proof strictly as a procedural question, and relied on the Administrative Procedure Act to justify imposition of the burden in a reductive manner.79 As a gap-filling device intended for widespread application, the APA could not be sensitive to the thousands of disparate factual issues that arise in different regulatory contexts nor to the varying legislative policies reflected in different organic acts. A reductive approach to legal decisionmaking under uncertainty ignores four important variables discussed in this Section: (1) the hierarchy of interests established in particular regulatory statutes; (2) the particular factual issues about which the uncertainty arises; (3) the respective abilities of the parties to resolve particular uncertainties; and (4) the question of what legal outcome is desirable when no party can resolve the uncertainty.

1. Differing Legislative Priorities

Regulatory statutes reflect a wide range of legislative purposes and priorities. In one program the legislature may prefer health and safety to economic considerations;80 in a second, the primary objective may be environmental protection;81 the predominant goal of a third act may be economic development;82 and a fourth statute may require a balancing of competing objectives, with no interest clearly favored.83 Uncertainties that arise in these dissimilar contexts could be resolved through

Thus, cost-benefit analysis by OSHA is not required by the statute because feasibility analysis is.

79. 448 U.S. at 653.
the adoption of generalized procedural rules, but they should not be. When the legislature has expressed a preference for one interest over another, uncertainty should be resolved in a manner that promotes the underlying hierarchy of legislative purposes.

Even statutes whose primary objective is the protection of health and safety may differ in congressional intent. Three statutes intended to regulate toxic substances illustrate varying legislative balances of competing interests. The Delaney clause of the Food, Drug and Cosmetic Act\(^84\) bans any food additive that has been shown in any amount to cause cancer in humans or animals.\(^85\) Under this statutory mandate, uncertainty about disaggregated risks may be legally irrelevant. The OSH Act requires that toxic risks be eliminated to the greatest extent "feasible."\(^86\) In contrast, the Consumer Product Safety Act authorizes regulation of toxic substances only if they present an "unreasonable" risk of injury.\(^87\) In the cotton dust case, Justice Brennan suggested this language reflects a congressional determination that potential benefits from regulation must be balanced against the regulation's costs.\(^88\) These statutory prescriptions indicate that Congress established different balances between competing interests in different "health and safety" programs that often apply to the same toxic substances. Because legislative objectives vary in different regulatory programs, the treatment of uncertainty should be tailored wherever possible to the policies embodied in particular organic acts.

2. Differing Factual Issues

A reductive treatment of uncertainty does not distinguish between different factual issues that arise in regulatory contexts. For example, regulation under the Endangered Species Act (ESA)\(^89\) presents three distinct issues: is a particular species "endangered" within the meaning of the ESA,\(^90\) will a particular activity affect the species or its critical natural habitat,\(^91\) and will the challenged activity harm the endangered

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90. The Act requires the Secretary of the Interior to designate endangered and threatened species. Id. § 1533. The U.S. Fish and Wildlife Service and the National Marine Fisheries Service "bear the responsibility for gathering sufficient information on which to base such actions." 45 Fed. Reg. 13016 (1980).
91. Those who challenge activities must demonstrate that the activities directly or indirectly affect the endangered species. See, e.g., National Wildlife Fed'n v. Coleman, 529 F.2d
species?\textsuperscript{92} Millions of plant and animal species exist, and innumerable human actions may affect ecological conditions. If government did not bear the burden of proof on the first two issues, the ESA would provide it with virtually unlimited authority to regulate developmental activities. Neither the ESA nor its judicial interpretations\textsuperscript{93} indicate that Congress intended to confer such unbounded regulatory discretion. However, once government demonstrates a particular activity affects an endangered species, the purposes of the ESA might best be served by shifting the burden of proof to the defendant to show that his actions will not further threaten the species.\textsuperscript{94} A definitive analysis is not necessary here; the point is that legislative objectives might best be served by discriminating between the treatments of uncertainty on different factual issues.

Recent judicial decisions\textsuperscript{95} have identified six discrete issues with respect to regulation of toxic substances under the OSH Act: (1) Is the substance under consideration sufficiently dangerous to be classified as toxic? (2) Is occupational exposure present? (3) Does the existing permissible exposure limit pose a significant risk of material health impairment? (4) Will the stricter PEL in OSHA's proposed standard significantly reduce the risk? (5) Is the new PEL technologically feasi-


\textsuperscript{93} That allocation of the burden of proof would foster conservation of endangered species, the preeminent purpose of the ESA. See 16 U.S.C. 1531(b), (c); Tennessee Valley Authority v. Hill, 437 U.S. 153 (1978). Congress recognized that the dangers to threatened species would often be uncertain, and specifically provided that the Secretary may proceed "on the basis of the best scientific and commercial data available to him . . . ." 16 U.S.C. § 1533(b)(1) (Supp. IV 1980). This provision is equivalent to the "best available evidence" clause in section 6(b)(5) of the OSH Act. See infra text accompanying notes 355-60. The Secretary has interpreted the "best evidence" provision to allow the listing of endangered species despite some deficiencies in the "supporting data base." 45 Fed. Reg. 13013 (1980). Once the Secretary has shown that a species is endangered, that it will be affected by an agency or private action, and that there is some basis to believe that the species may be harmed by the action, it would conflict with the protective purpose of the ESA to require that the Secretary demonstrate the action "more likely than not" will be harmful.
The burden of proof in the benzene case, however, was imposed on a party, the "proponent of a rule or order," not on an issue-by-issue basis. In other words, the plurality relied on the APA to assign the burden of proof to OSHA for all factual questions.

In Section III, this Article concludes that OSHA should indeed bear the burden on the preliminary issues of toxicity and occupational exposure. Yet a judicially-imposed allocational doctrine that prevents OSHA from effectively regulating the majority of recognized toxic substances because of uncertainty about the degree of toxicity at particular exposure levels is incompatible with the substantive mandate in the OSH Act. The legislative policies underlying the OSH Act would be promoted if the burden of proof were allocated to OSHA for the first two legal issues but not for the issues requiring disaggregated risk estimation. No reductive rule can achieve this degree of discrimination.

3. Differing Capacities of the Parties to Resolve Uncertainties

Another important variable is the comparative abilities of the parties to resolve particular factual uncertainties. In the cotton dust case the majority opinion's analysis of economic feasibility illustrates the importance of this variable. In its cotton dust proceedings, OSHA had not attempted to determine actual compliance costs of the proposed PEL, and the Agency admitted it relied on cost projections that were very imprecise. Moreover, OSHA never contended it could not acquire better information, but simply that it could not make a more reliable estimate based on data then available. The cotton dust majority acknowledged that a cost estimate based on the promul-
gated PEL "surely would be preferable," but refused to hold as a matter of law that one was required. Justice Brennan concluded instead that the Agency had "acted reasonably" in light of the information before it. He identified several factors supporting the reasonableness of OSHA's action: (1) the "pre-eminent value" placed on employee protection in the OSH Act, (2) the inclusion in section 6(b)(5) of the "best available evidence" clause, (3) the typical imprecision in estimates of compliance costs, and (4) industry's refusal to provide more descriptive data. Information needed to assess the economic costs of proposed standards ordinarily is more readily available to industry than to OSHA. An allocational doctrine that requires the Agency to use reasonable efforts to collect information and then allows regulatory judgments to be based on available data would not foreclose industry from challenging determinations of economic feasibility. Industry could do so, however, only by providing sufficient economic information to rebut OSHA's initial finding. For courts to rule otherwise would permit industry to frustrate strict control of toxic substances by concealing data, and would make OSHA's task extremely difficult in situations where industry had not even attempted to institute effective protection for employees and there were no data concerning compliance costs.

Although the cotton dust opinion did not expressly repudiate any part of the benzene decision, there is a great difference between a showing that an agency did as much as it reasonably could and a showing that it produced substantial evidence on a contested issue. Under the benzene plurality's analysis, OSHA could not prevail when its reasonable efforts still leave important uncertainties unresolved, because the Agency cannot show a proposed standard is "more likely than not"

104. Id. at 528-29.
105. Id. at 529.
106. Id. at 527-30; see id. at 525-30 n.55.
107. Id. at 540.
108. Id. at 528.
109. Id. at 528-29 nn.52, 54.
110. Id. at 527-30 & n.51, 53.
111. When the means of technological compliance are known, economic feasibility depends on the costs of compliance and the ability of regulated industries to bear those costs. Compliance costs are largely determined by the types and quantities of equipment in industrial facilities and by the prevailing levels of toxic exposure. This information is more likely to be available to industry than to OSHA. See id. at 525-30 & nn.43, 45, 47 & 51.
The result in the cotton dust case points in the opposite direction. Moreover, Justice Brennan reached that result through a particularized interpretation of the OSH Act itself. He held Congress intended that OSHA act even under conditions of continuing uncertainty, that considerations of safety should generally prevail over considerations of cost, and that expenses associated with injury prevention should be internalized by industry as necessary costs of doing business. It remains unclear whether Justice Brennan would construe the OSH Act to impose the burden of undertaking only “reasonable” efforts on the Agency for every relevant factual issue, or if his analysis was limited to economic feasibility. Nothing in the cotton dust opinion indicates that its treatment of uncertainty about economic feasibility would be suitable if applied to the threshold issue of toxicity or even to the companion issue of technological feasibility. If judges are to assign the burden of proof for different factual issues partly on the basis of the parties’ abilities to resolve uncertainties in each specific area, as the cotton dust opinion implies, the courts must reject the reductive approach of the benzene case.

116. The plurality’s reductive analysis treats all issues in the same manner. Because the plurality held that OSHA must prove a significant health risk “more likely than not” exists before it may regulate risks, see supra text accompanying note 63, there is no reason to doubt the Court would require OSHA to demonstrate every relevant factual determination, including feasibility, is “more likely than not.” 448 U.S. at 653; see Texas Indep. Ginners Ass’n v. Marshall, 630 F.2d 398, 413-14 (5th Cir. 1980).


119. Id. at 541, 521.

120. The issues of toxic risk estimation, technological feasibility, and economic feasibility present different factual questions and require different kinds of data and expertise. Although industry may generally have better access to information on the costs of compliance than OSHA has, AFL-CIO v. Marshall, 617 F.2d 636, 656-58 (D.C. Cir. 1979), industry is not necessarily in a better position to identify long-term toxicological effects or to develop effective techniques for toxic substances control. The OSH Act authorized creation of the National Institute of Occupational Safety and Health to serve as a repository of expertise, and authorized OSHA to undertake appropriate research projects. See infra text accompanying notes 385-89. No reviewing court has doubted that OSHA has the initial responsibility to determine whether substances are toxic. See, e.g., 448 U.S. at 543 n.48.

The Circuit Courts of Appeals are in sharp disagreement about the extent to which OSHA can require industry to conduct basic research aimed at developing more effective toxic substances control technologies. On the issue of “technology-forcing,” compare United Steelworkers v. Marshall, 647 F.2d 1189, 1264-73, 1265 n.105 (D.C. Cir. 1980), cert. denied, 453 U.S. 913 (1981), and Society of Plastics Indus., Inc. v. OSHA, 509 F.2d 1301, 1309 (2d Cir.), cert. denied, 421 U.S. 992 (1975), with Texas Indep. Ginners Ass’n v. Marshall, 630 F.2d 398, 413 & n.49 (5th Cir. 1980), and American Iron & Steel Inst. v. OSHA, 577 F.2d 825, 838 (3d Cir. 1978), cert. dismissed, 448 U.S. 917 (1980). Where adequate control technologies have not been developed, neither industry nor OSHA may be able to predict compliance costs with any degree of reliability. See United Steelworkers v. Marshall, 647 F.2d 1189, 1277 (D.C. Cir. 1980).
4. When Uncertainty Cannot Be Resolved

Reductive analysis does not distinguish between cases where factual uncertainties can be resolved and cases where no party can answer the critical factual questions. In *Reserve Mining Co. v. United States*,\(^{121}\) for example, a panel of the Eighth Circuit Court of Appeals stayed an injunction against discharges of an asbestos-like substance into Lake Superior.\(^ {122}\) The Court recognized that *inhalation* of high levels of asbestos creates a serious health hazard,\(^ {123}\) but found the risk associated with *ingestion* of relatively low levels "unquantifiable" and "unknown."\(^ {124}\) The Court then used a simple procedural analysis to determine the legal consequence of this uncertainty.

Although Reserve's discharges represent a possible medical danger, they have not in this case been proven to amount to a health hazard. The discharges may or may not result in detrimental health effects, but, for the present, that is simply unknown. The relevant legal question is thus, what manner of judicial cognizance may be taken of the unknown.

We do not think that a bare risk of the unknown can amount to proof in this case. Plaintiffs have failed to prove that a demonstrable health hazard exists. This failure, we hasten to add, is not reflective of any weakness which is within their power to cure, but rather, given the current state of medical and scientific knowledge, plaintiffs' case is based only on medical hypothesis and is simply beyond proof. . . . Although we are sympathetic to the uncertainties facing the residents of the North Shore, we are a court of law, governed by rules of proof, and unknowns may not be substituted for proof of a demonstrable hazard to the public health.\(^ {125}\)

The court's analysis was very similar to the reductive treatment in the benzene case. Judge Bright assigned the burden of proof without referring to the policies of applicable regulatory statute, the Federal Water Pollution Control Act.\(^ {126}\) He assigned the burden of proof for all factual issues to the government plaintiffs simply because they were the moving parties.\(^ {127}\) The only difference between Judge Bright's rea-

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122. The substance was taconite mill tailings, an asbestiform by-product of low-grade iron ore processing. *Id. at* 1074.

123. *See id. at* 1078.

124. *Id. at* 1082. The court also relied on a study that showed the tissues of persons who drank lake water were virtually free of asbestos. *Id. at* 1078-79.

125. *Id. at* 1083-84.

126. In staying the District Court's injunction closing Reserve's plant, the Court of Appeals relied on its own attempt to balance environmental dangers against economic dislocation rather than on any balance of interests in the statute. *Compare id. at* 1077 with *Reserve Mining Co. v. EPA*, 514 F.2d 492, 527-29 (8th Cir. 1975) (en banc).

127. While the Court recognized the danger from asbestos inhalation, its allocation of the burden of proof on the danger from ingestion was in no way influenced by the known
soning and Justice Stevens’ approach in the benzene case is that the former derived his allocational doctrine from the “rules of proof” applied in “a court of law”\textsuperscript{128} rather than from the reductive rule in the APA.

When the Eighth Circuit, sitting \textit{en banc}, reviewed \textit{Reserve Mining} on the merits, the Court of Appeals adopted an entirely different mode of analysis. In that opinion, Judge Bright again found the plaintiffs had not demonstrated significant harm was “more likely than not” to occur.\textsuperscript{129} Nevertheless he held “an acceptable but unproved medical theory”\textsuperscript{130} that Reserve’s discharges were carcinogenic was sufficient to support “a reasonable medical concern for the public health.”\textsuperscript{131} He then construed the FWPCA itself, and determined that prevention of harm was the major objective of the statute.\textsuperscript{132} In light of this congressional priority, Judge Bright concluded even a “threat” of harm\textsuperscript{133} justified reasonable abatement measures.\textsuperscript{134} He clearly recognized the inability of parties to resolve the uncertainties in the case,\textsuperscript{135} but was unwilling to defer regulation indefinitely until the uncertainty could be resolved. Instead he approved reasonable regulation on the grounds that inaction in the face of uncertainty would be inconsistent with the preventive purpose of the FWPCA.\textsuperscript{136} This mode of analysis is clearly incompatible with the procedural treatment of uncertainty in Judge Bright’s earlier opinion and with the reductive approach in the benzene case.

In \textit{Reserve Mining}, the Court of Appeals found the risk from ingestion of asbestos could not be reliably quantified. In the benzene case OSHA similarly argued that its inability to estimate carcinogenic risks resulted not from lack of diligence, but from inadequate scientific knowledge.\textsuperscript{137} These examples of unresolvable uncertainty suggest a distinction between \textit{information uncertainty} and \textit{knowledge uncertainty} that will be developed below. As the term is employed here, informa-

\begin{itemize}
  \item \textsuperscript{128} See \textit{Reserve Mining Co. v. United States}, 498 F.2d 1073, 1078-79 (8th Cir. 1974).
  \item \textsuperscript{129} \textit{Id.} at 1084.
  \item \textsuperscript{129} \textit{Reserve Mining Co. v. EPA}, 514 F.2d 492, 520 (8th Cir. 1975) (\textit{en banc}).
  \item \textsuperscript{130} \textit{Id.} at 529.
  \item \textsuperscript{131} \textit{Id.}
  \item \textsuperscript{132} \textit{Id.} at 527-29.
  \item \textsuperscript{133} \textit{Id.} at 529.
  \item \textsuperscript{134} The district court had ordered immediate closing of Reserve’s operations. The Court of Appeals rejected this and held that a judicial remedy for the potentially dangerous discharges must “strike a proper balance between the benefits conferred and the hazards created by Reserve’s facility.” \textit{Id.} at 535. The Court applied a balancing test and determined that the company should be given a reasonable time to abate its discharges. \textit{Id.} at 536-39.
  \item \textsuperscript{135} \textit{See id.} at 519-20, 536.
  \item \textsuperscript{136} \textit{Id.} at 528-29, 536, 538.
  \item \textsuperscript{137} 448 U.S. at 631-32 & n.33.
\end{itemize}
tion uncertainty arises when relevant data is not collected, although it could be, or when existing information is not made available to the decisionmaker who needs it. Knowledge uncertainty, in comparison, stems from a lack of adequate scientific understanding, or from situations where the collection of necessary information is infeasible.

There is no clear demarcation between information uncertainty and knowledge uncertainty; the marginal point at which information becomes so difficult or expensive to collect that it is effectively unobtainable will often be indistinct. Nevertheless, the dichotomy is significant from a legal perspective because the consequences of allocating the burdens of production and proof may vary greatly depending on the nature of the uncertainty presented. Information uncertainty can be eliminated if the value of the missing data makes collection worthwhile. A doctrine designating one party responsible for resolution of information uncertainty presents that party with a realistic choice: either provide the information or surrender the point. Which alternative is selected depends on how the designated party perceives the relative costs and benefits of production. The picture is quite different when knowledge uncertainty is involved. Research may be directed toward a critical problem, but there is rarely any assurance that the desired knowledge can be acquired, especially within the time frame associated with a specific legal controversy. Thus, a rule assigning legal responsibility for knowledge uncertainty also determines the eventual result in most cases: whoever bears that burden generally loses.

Particular regulatory statutes may expressly allocate to different parties the burdens of resolving information and knowledge uncertainty. For example, in some regulatory programs the legislature could assign responsibility for information collection and record-keeping to the entrepreneur. Industry could not then prevail unless it provided the designated information to the agency or court. It does not follow, however, that the burden of resolving knowledge uncertainty would also be imposed on the entrepreneur. A rational social policy might treat responsibility for information collection as a legitimate cost of do-

138. The distinction is less meaningful from a scientific perspective because uncertainty from any source frustrates the development of accurate hypotheses. In science, the choice is "to explain" or "to reserve judgment." In law, the choice is ultimately which disputant should prevail.


ing business, and yet the legislature may choose not to inhibit developmental activities when harm is currently indeterminable. In contrast, assigning both the burden of production and the burden of proof to industry might be appropriate when a variance is sought from a regulatory standard.¹⁴¹ The OSH Act arguably embodies another pattern, one which requires a bifurcated allocational doctrine. It assigns the burden of reasonable information collection to OSHA but, at least for the estimation of disaggregated risk, allocates to industry the burden of resolving knowledge uncertainty. These combinatorial possibilities illustrate the inefficiency of imposing a uniform allocational rule without regard for legislative policies underlying regulatory programs.

The great majority of environmental statutes, such as the Clean Air Act,¹⁴² the Clean Water Act,¹⁴³ and the Resource Conservation and Recovery Act,¹⁴⁴ do not explicitly address the placement of the burden of proof. Neither does the Food, Drug and Cosmetic Act¹⁴⁵ or the Consumer Product Safety Act.¹⁴⁶ These statutes contemplate strict control of toxic substances,¹⁴⁷ which means that the same types of factual uncertainties will arise as were presented in the benzene case.¹⁴⁸ If the plurality's exclusively procedural treatment of the burden of proof prevails in future cases, it will have serious ramifications for a wide range of regulatory programs.

The analytical process advocated in this Article requires judges to resolve factual uncertainties by referring to the legislative policies of specific regulatory statutes. Courts should determine whether the legislative intent would best be promoted if the burdens of production and proof were assigned to particular parties for particular factual issues. In effect, one form of legal consistency would be subordinated to another. Consistency between the goals of a specific act and the rules developed to allocate the burdens of production and proof in that regulatory context should be considered much more important than proce-

¹⁴⁸. Many of the most intractable uncertainties result from inadequate scientific knowledge about causal mechanisms. See infra text accompanying notes 244-66. Because the problems in regulation of carcinogens cut across jurisdictional boundaries, OSHA, EPA, FDA and CPSA formed a liaison group to coordinate their research and regulatory efforts. See INTERAGENCY REGULATORY LIAISON GROUP, SCIENTIFIC BASES FOR IDENTIFICATION OF POTENTIAL CARCINOGENS AND ESTIMATION OF RISKS, 44 Fed. Reg. 39858 (1979) [hereinafter cited as IPLG REPORT].
dural consistency in disparate regulatory settings. The allocational process described here lacks the administrative simplicity of a reductive rule, but it is less likely to hamper regulatory programs than the purely procedural treatment of uncertainty adopted in the benzene case. It is true Congress did not intend to define a clear hierarchy of interests in some statutes, and that the legislative policy in other statutes may be too ambiguous to offer useful guidance. In these cases, the judiciary has little choice but to employ a reductive allocational rule such as the one in the APA. Yet, contrary to the approach of the plurality in the benzene case, a reductive legal response to uncertainty should be adopted only as a last resort, after careful analysis of the relevant organic legislation.

II

VALIDITY OF "SIGNIFICANCE" DETERMINATIONS

OSHA's asserted inability to estimate the risk at low levels of benzene exposure, and hence its inability to meet the plurality's significance test, may be characterized in terms of knowledge uncertainty: the Agency contended that it was beyond current scientific capability to quantify disaggregated carcinogenic risks in a meaningful way. Yet the Supreme Court repeatedly emphasized the need to estimate the risks posed by low-level exposure to benzene. In view of this conflict it is necessary to determine 1) whether there was adequate support for OSHA's conclusion that it could not formulate a reliable correlation between benzene exposure levels and disaggregated health risks, and 2) whether, in the future, OSHA will be able to assess the significance of carcinogenic risks in a way that would meet the Court-imposed standards.

A. Uncertain Correlation Between Exposure Levels and Risks

OSHA attempted to reduce the PEL for benzene to 1 ppm in response to three types of health effects: potentially fatal nonmalignant blood disorders, 149 "excess" leukemia deaths150 and chromosomal

149. 43 Fed. Reg. 5918, 5921-25 (1978). Leukemia itself is a blood disorder. Other blood disorders are characterized as "nonmalignant" not because their effects are relatively harmless, but rather because their causal mechanisms differ from those of cancers.

150. Id. at 5925-32. Because leukemia and other cancers occur naturally among the population at large, the risk posed by occupational exposures to carcinogens must be measured in terms of "excess deaths." The natural incidence of cancer complicates the problem of correlating occupational exposures with observable health effects in many contexts.

Some forms of cancer, however, are so rare among the populace as a whole that for all practicable purposes they can be directly correlated with exposure in an industrial setting. See Society of Plastics Indus., Inc. v. OSHA, 509 F.2d 1301, 1306 (2d Cir.), cert. denied, 421 U.S. 992 (1975) (angiosarcoma of the liver caused by exposure to vinyl chloride).
Although the danger of leukemia was "of greatest concern to OSHA," the proposed standard was justified in terms of the combined risks associated with the three types of harm. The Agency first demonstrated a causal link between benzene and the manifestation of some harm, although OSHA and industry agreed there was very little direct evidence of harm at the 10 ppm PEL. OSHA drew inferences from the empirical evidence associated with high or unknown levels of exposure, but decided those inferences would not support a quantitative estimate of the risk at low exposure levels. Thus, the Agency concluded that a valid dose-response relationship could not be determined at either the 10 ppm or 1 ppm exposure limits. OSHA further concluded that a reliable estimate of the benefits from imposing the stricter standard could not be made in the absence of a valid dose-response curve. The Agency relied instead on qualitative judgments that some risk exists at low exposure levels and that the risk would be reduced by some degree if exposure limits were lowered to the extent feasible.

Industry generally conceded that benzene could cause nonmalignant blood diseases, leukemia and chromosomal damage at high exposure levels, but actively contested the Agency's other findings. Industry submitted animal test results that purported to show very little or no risk of nonmalignant blood disorders at the existing 10 ppm exposure limit. Industry experts also contended that blood disorders can be detected through medical monitoring before they become harmful and that endangered workers would recover after their expo-

152. 448 U.S. at 624 n.18, citing the testimony of Grover Wrenn, OSHA's Deputy Director of Health Standards.
153. Justice Stevens interpreted OSHA's acknowledgement that leukemia was "of greatest concern" to mean that the 1 ppm PEL was based exclusively on the risk of cancer. See id. However, the Agency's explanation for the benzene standard specifically stated that protection against nonmalignant blood disorders provided an independent rationale for the 1 ppm limit. 43 Fed. Reg. 5918, 5925 (1978). OSHA indicated that nonmalignant health effects had been observed at the 25-40 ppm range and that it was "customary" to use a safety factor of 10-100 or greater. Id.: see 448 U.S. at 698 (Marshall, J., dissenting).
157. Id. at 5932, 5940-41.
158. The quantitative correlation between levels of exposure and disaggregated health effects is expressed in terms of a dose-response curve. See 448 U.S. at 632 n.33.
160. Id. at 5925, 5940.
161. See id. at 5925, 5940.
162. See id. at 5924-25, 5940-41, 5946.
163. Id. at 5924, 5931, 5933, 5946.
164. Id. at 5924. Animal test results were introduced only on the issue of nonmalignant blood effects. Benzene has not been shown to cause leukemia in reliable animal studies. Id. at 5930-31; see 448 U.S. at 657 n.64.
Industry asserted that the only documented cases of leukemia resulting from benzene had occurred after high exposures, and introduced several epidemiological studies to prove the absence of excess deaths at low exposure levels. Based on this evidence, industry experts posited the existence of a threshold exposure level below which there is virtually no risk of leukemia. They further asserted that nonmalignant blood disorders are always a precursor or prerequisite for benzene-induced leukemia, and consequently that the measures available to prevent serious blood diseases would virtually eliminate the risk of leukemia. Finally, industry experts claimed that no clear correlation had been demonstrated between chromosomal damage and leukemia or other harmful health effects. OSHA made two distinct types of counterarguments to these industry contentions: that the available epidemiological data were insufficient to develop reliable dose-response relationships, and that the state of scientific knowledge was inadequate to interpret available data in a valid manner.

1. Unreliability of Epidemiological Data

OSHA identified at least nine types of deficiencies in the epidemiological data on benzene:

(1) **Failure to define the cohort of workers under study.** Industry's negative studies failed to document that all workers included in the sample were actually exposed to benzene. Inclusion of those who were not in fact exposed would cause "dilution" of the incidence of observed harm.

(2) **Inadequate followup of workers who leave the cohort.** One of the central problems with epidemiological studies of carcinogens is that harmful effects generally entail a long latency period. The latency period for benzene-induced leukemia extends from two to more than twenty years. Before leukemia symptoms become evident, exposed workers may retire or leave the cohort for other reasons.

165. See id: at 5923.
168. See id. at 5931, 5946.
169. See id. at 5929.
170. See id. at 5933.
173. Id. at 5931.
177. 43 Fed. Reg. 5918, 5928 (1978). This problem may be compounded if one assumes
Failure to monitor these workers after their departure may cause serious understatement of the long-term health effects of exposure to benzene.  

(3) **Lack of data on individual workers' exposures.** Identification of disaggregated health risks requires not merely knowledge of which workers were exposed, but information on actual levels of exposure. By definition, a dose-response curve cannot be developed if dosages are unknown. Most epidemiological studies did not contain information on specific levels of exposure. The studies that purported to have exposure data obtained the data by areawide monitoring rather than by individual examinations.  

Given that leukemia may have a long latency period, that exposures in an industrial setting vary widely over time, and that high levels of exposure were generally prevalent in the past, OSHA concluded there was little reliable epidemiological data on the health effects of low exposure levels.

(4) **Inadequate data on causes of death.** Workers die from many causes. Uncertainty about actual causes of death is common in retrospective studies, but only fatalities clearly attributable to the subject disease would be included in a study's results.  

(5) **Ambiguity from multiple causative agents.** When multiple causative agents are possible, observable health effects cannot fairly be correlated with exposure to any given toxic substance. For example, a review of 594 Dow Chemical workers exposed to low levels of benzene revealed 2 deaths from nonmalignant blood disorders as against 0.2 expected fatalities and 3 leukemia deaths as against an expected total of 0.8. Workers who had been exposed to more than one carcinogen, however, were excluded from the data used to construct Dow's projected dose-response curve. This practice may understate the real but indeterminate health effects of benzene.

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178. OSHA noted that the difficulty of identifying benzene-related health effects over extended periods of time is exacerbated by "the high mobility of our society." *Id.* at 5931.
179. *Id.* at 5931-32.
180. See *id.* at 5925-29.
181. *Id.* at 5925. The problem with areawide sampling is that personal exposure levels vary within areas and within areas over time. OSHA concluded "[i]t is difficult to determine individual worker exposure based on area sampling." *Id.*
182. *Id.* at 5925, 5945.
183. See *id.* at 5946.
184. *Id.* at 5929, 5946.
185. See *id.* at 5927-28; 448 U.S. at 699 n.16 (Marshall, J., dissenting); see generally Generic Cancer Policy, 45 Fed. Reg. 5002, 5040 (1980).
187. *Id.* at 5928.
188. *Id.*
189. *Id.* at 5928-29, 5931.
(6) *Varying individual susceptibilities.* OSHA found that individual susceptibilities to both nonmalignant blood disorders and leukemia varied greatly within the population as a whole.\(^{190}\) However, the Agency determined the available epidemiological data were inadequate to identify the characteristics of especially susceptible subgroups or individuals.\(^{191}\) OSHA promulgated the strict 1 ppm PEL in part to protect sensitive workers as well as those with average resistance.\(^{192}\)

(7) *Small cohort size.* The size of most extant epidemiological studies did not ensure that a sufficient number of sensitive persons were included as subjects.\(^{193}\) Thus the results of those studies might understate the true risk of benzene exposure.

(8) *Lack of pre-exposure data on blood characteristics.* OSHA noted a general absence of pre-exposure data on workers' hematological conditions.\(^{194}\) Because levels of blood constituents vary widely among individuals, a given employee's initial blood condition may be appreciably changed by benzene exposure and yet may still remain within the "normal" range for the population as a whole.\(^{195}\) Industry contended that workers would recover from non-malignant blood disorders if these were detected in time. However, without personalized information on pre-exposure blood characteristics, it is impossible to determine if full recovery occurs after exposure ends.\(^{196}\)

(9) *Inadequate follow-up of "recovered" workers.* In the benzene proceedings experts disagreed on the question of whether nonmalignant blood disorders always precede the onset of leukemia.\(^{197}\) The epidemiological studies of benzene-induced nonmalignant blood diseases had not provided for long-term monitoring of exposed workers, and consequently did not indicate whether "recovered" workers were subject to an increased risk of leukemia.\(^{198}\) The Agency concluded not that industry's contentions were wrong, but rather that they were open to serious doubt\(^{199}\) and that the empirical evidence did not enable a reliable resolution of the outstanding uncertainties.\(^{200}\)

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190. Id. at 5925, 5930; see generally Generic Cancer Policy, 45 Fed. Reg. 5002, 5121-24, 5137-38 (1980).


192. See id. at 5918, 5930 (1978).

193. See id. at 5925; see generally Generic Cancer Policy, 45 Fed. Reg. 5002, 5040, 5049-52 (1980).


195. See id. at 5925, 5929.

196. See id.

197. See id. at 5929, 5946.

198. Id. at 5929.

199. OSHA observed that nonmalignant blood disorders may occur shortly after exposure. Leukemia often has a long latency period, which suggests that different etiological processes may be involved. See id. Moreover, there was some evidence that leukemia may occur as a direct result of changes in blood cells. Id.

200. Id. at 5929, 5932, 5946.
Because many of the deficiencies in the benzene data cannot be remedied in the near future, they must be characterized primarily as knowledge uncertainty. It is impossible to reconstruct the preexisting blood conditions and actual exposure levels of workers who came into contact with benzene in past decades. In many cases it would be very difficult to monitor the health of workers who have left the cohorts under study. Because occupational exposure levels fluctuate over time and in different locations, it will often prove impossible to track personal exposures reliably over the long period needed to document the health effects of benzene and similar carcinogens. Only rigorous, controlled studies, which would take decades to complete, could resolve these problems.

2. Inadequate Scientific Understanding

Administrative agencies are expected to develop expertise on subjects within their jurisdiction and to draw upon that expertise in rulemaking contexts. OSHA had already confronted the difficulties associated with carcinogenic risk assessment in several controversies, and had uniformly found the level of scientific understanding was inadequate to estimated disaggregated risks. At the time of the benzene decision, OSHA was in the process of developing a uniform policy to govern the regulation of carcinogenic hazards. The proposed generic cancer policy presumed that no risk-free exposure level can be demonstrated for carcinogens, and required imposition of the safest feasible standards. Justice Stevens deduced on two grounds that OSHA had impermissibly relied on the generic policy in reaching its decision on benzene. First, he observed that the identical results in OSHA's benzene decision and generic cancer policy suggested the Agency had not considered in good faith industry's evidence. The parallel results,

201. Knowledge uncertainty was defined as uncertainty derived from inadequate scientific understanding or from effectively unavailable information. See supra text accompanying notes 137-39.
204. This is especially true because average latency periods are often longer at lower levels of exposure. See Generic Cancer Policy, 45 Fed. Reg. 5002, 5040-41 (1980).
207. See 448 U.S. at 645 n.31.
208. 448 U.S. at 635 n.39.
209. Id.
however, may not show reliance on the general policy, but may instead stem from manifestation of the same types of factual uncertainties and methodological constraints in both proceedings. Problems documented in OSHA's lengthy explanation of its generic cancer policy included the long latency period of many cancers, uncertainty about actual levels of exposure, inadequate followup of workers after exposure, and the typically large margin of error in negative studies. As discussed above, OSHA found exactly these types of deficiencies when it reviewed the epidemiological data in the benzene record.

With the generic cancer policy, OSHA attempted to foreclose submission of evidence on the safety of known carcinogens at particular levels of exposure. Justice Stevens' second criticism of the benzene proceeding was that OSHA, in its notice of proposed rulemaking, did not ask for public input on the significance of the health risk at the existing benzene PEL. Because the Agency did receive voluminous information on that issue and reviewed it in detail, the omission in the notice of proposed rulemaking might well be characterized as harmless error. It is, however, by no means certain that this Agency decision was even nominally erroneous. The benzene record makes clear the Agency's view that the current state of scientific understanding was inadequate to derive reliable conclusions on disaggregated risks. If OSHA determines that a reasonable consensus does not exist on the meaning of scientific information, why should it be required to invite submission of that information?

Administrative agencies are not bound by the exclusionary rule that forbids submission of scientific evidence in court unless it has achieved "general acceptance in the scientific community." Yet, the latitude given an agency to consider debatable scientific claims does not mean it should be compelled to do so in contexts where similar

211. Id. at 54151-52.
212. Id. at 54146.
213. Id. at 54155-56.
214. Id.
215. See 43 Fed. Reg. 5918, 5925-29 (1978). OSHA thought it had to respond to this information because its generic cancer policy had not yet been adopted. See 448 U.S. at 635-36 n.39.
217. 448 U.S. at 625.
contentions have been addressed in previous proceedings.\footnote{221} If the procedures mandated by the OSH Act\footnote{222} permit the Agency to exclude unreliable or inconclusive evidence by means of a generic policy,\footnote{223} there is no apparent reason why it would not be entitled to do so in conjunction with rulemaking on a particular toxic substance.\footnote{224} The critical question in both contexts should be whether the excluded information is likely to prove material. In the benzene proceeding, there was no claim by industry witnesses that their interpretations were supported by a reasonable scientific consensus. In light of "divided opinion in the scientific community,"\footnote{225} OSHA adopted a conservative regulatory strategy that rejected industry's hypotheses as unproven.\footnote{226} Until the time a general scientific consensus at least arguably prevails, OSHA should be allowed discretion to exclude evidence intended to support theories it has already considered and rejected.\footnote{227} However,

\footnote{221} OSHA stated that:

The issue of the levels at which cancer is induced by chemical agents and whether or not there is a "threshold" has been a major issue in every OSHA rulemaking concerning the regulation of occupational carcinogens. See preambles to Carcinogen standard (39 FR 3758); Vinyl Chloride (39 FR 35892); Coke Oven emissions (41 FR 46742). The benzene hearing was no exception.

\footnote{43 Fed. Reg. 5918, 5946 (1978).}

\footnote{222} OSHA is authorized to employ informal rulemaking procedures and yet its determinations must be supported by "substantial evidence" in the "record." \textit{See} Industrial Union Dep't, AFL-CIO v. Hodgson, 499 F.2d 467, 472-76 (D.C. Cir. 1974).

\footnote{223} \textit{See} 448 U.S. at 665 (Powell, J., concurring in part and in the judgment). To the extent the plurality's significance test requires estimates of the disaggregated risks presented by individual toxic substances, a generic policy could not exclude submission of industry evidence or the purported safety of each potential carcinogen. In response to the benzene decision, OSHA amended its generic cancer policy to indicate that it was required to consider industry evidence on this issue. \textit{See} 46 Fed. Reg. 4889 (1981). But the thesis of this Section is that the benzene decision was wrong in demanding disaggregated risk estimates because they usually cannot be determined in a scientifically valid manner. If that premise is correct, it would serve no purpose for OSHA to attempt quantification of risk levels in each separate proceeding. For a discussion of the advantages of a generic treatment of questions on which scientific knowledge is inadequate, \textit{see} McGarity, \textit{supra} note 2, at 754-59.

\footnote{224} For decisions that must be made on the record, the APA provides: "Any oral or documentary evidence may be received, but the agency as a matter of policy shall provide for the exclusion of irrelevant, immaterial, or unduly repetitious evidence." § 556(d) (1976). Prior to the benzene proceeding, OSHA had frequently considered and rejected claims that carcinogenic risks at low exposure levels could be reliably quantified. \textit{See} the sources cited in note 187 \textit{supra}.


\footnote{226} \textit{See} 43 Fed. Reg. 5918, 5920, 5932, 5941, 5946 (1978). In the benzene transcript, a high OSHA official stated that the Agency would be very reluctant to accept "speculation or elaborate theories" on the safety of low exposure levels. 448 U.S. at 625 n.20, quoting Grover Wrenn, OSHA's Deputy Director of Health Standards.

\footnote{227} Although an adversary proceeding, whether before an Agency or a Court, is generally a poor setting in which to determine basic scientific truths, scientific evidence may be useful in proceedings:

What further distinguishes scientific evidence from other kinds of potentially unre-
OSHA did not exclude industry's risk estimates in the benzene case—it merely failed to solicit those data.

OSHA has had great difficulty in assessing carcinogenic risks because science currently lacks a comprehensive theoretical understanding of cancer causation. In its benzene findings, OSHA acknowledged that the mechanism by which benzene produces toxic effects is still unknown. The Agency stressed the documented correlation between benzene exposure and excess leukemia deaths, but that determination pertains only to aggregate health effects. The identification of disaggregated risks associated with specific exposure levels requires more knowledge than is available on the nature of the causal relationship. Even if the extent of direct carcinogenicity can be established through controlled experiments, the severity of the risk posed by the substance may be compounded through indirect causal mechanisms. A substance that is relatively harmless by itself may greatly increase the risk of cancer when present with other substances or stimuli. An accurate risk assessment must therefore consider the substance's possible role in a variety of causal processes. In the case of

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liable submissions is that a responsible extrajudicial mechanism exists to assess the reliability of a scientific process. Inherent in the scientific method is the publication or other dissemination of hypotheses and the results of experimentation. Judges may, therefore, have recourse to assessments of innovative techniques by scientists working in an environment presumably more dispassionate and objective than that which exists during litigation.

Latin, Tannehill and White, supra note 220, at 1380-81.

The thesis here is not that a party should be barred unconditionally from submitting evidence on the risks posed by known carcinogens, but rather that it should be permitted to do so only when that evidence supports scientific hypotheses that have achieved a reasonable scientific consensus. Thus, industry would have to establish that scientific knowledge is adequate to interpret data in a reasonably reliable manner before the data themselves would be admissible. One commentator has characterized the distinction between hypotheses and data in terms of "scientific inferences" as opposed to "scientific interpretations." McGarity, supra note 2, at 757-58.

230. Id. at 5931, 5941, 5946.
231. See id. at 5941.
232. There are four paths by which a toxic substance may contribute to the incidence of cancer: as a primary carcinogen, a secondary carcinogen, a procarcinogen, or a cocarcinogen. A primary carcinogen causes neoplastic alteration directly, without host-activated mediation. A secondary carcinogen increases the susceptibility of a cell to a primary carcinogen. A cocarcinogen requires the presence and interaction of another chemical to induce a neoplastic response. And a procarcinogen requires prior neoplastic alteration before it acts as a carcinogen. A given substance may contribute to cancer causation through more than one mechanism. For example, it may be both a weak procarcinogen and a strong cocarcinogen. See id. at 5929. Because benzene has not been shown to cause leukemia in animal experiments, id., while a clear correlation has been established between benzene exposure and excess leukemia deaths, id. at 5929, 5932, it is likely that an indirect causal mechanism is involved.
benzene, as is frequently true for carcinogens, OSHA was unable to determine which causal path or paths were responsible for the onset of cancer.

A factual issue contested in every OSHA rulemaking on carcinogens is whether a threshold level exists below which exposure is safe. The answer depends on a theory of causation at low dosages, but competing theories have been introduced in OSHA proceedings and none has yet achieved general scientific acceptance. In its benzene findings OSHA made clear that it selected the most conservative tenable causal theory as a policy determination in light of continuing uncertainty, not because that theory had been conclusively demonstrated to apply.

Identification of a threshold level or other dose-response relationship is complicated by variations in individual sensitivities to carcinogens. Within the exposed population, responses can fluctuate a hundredfold because of genetic differences. OSHA found that individual susceptibilities to benzene were dependent on physiological factors such as genetic constitution, age, sex, nutritional state, ability to metabolize benzene, and exposure to other agents that also affect bone marrow. As noted above, the Agency could not identify especially sensitive workers in advance and promulgated its strict standard in part to protect such persons.

Even if a threshold level does exist for most persons, it may be

236. Id. at 5946.
238. See id. at 5137; McGarity, supra note 2, at 733-35.
241. See id. at 5930; see generally Generic Cancer Policy, 45 Fed. Reg. 5002, 5199 (1980).
244. See supra text accompanying notes 190-193.
246. See 448 U.S. at 636-37 n.41, where Justice Stevens noted that "[i]n light of the improbability of a person contracting cancer as a result of a single hit, a number of scientists on both sides of the issue agreed that every individual probably does have a threshold exposure limit below which he or she will not contract cancer." The problem with this observation, aside from the fact that other scientists dispute its validity, is that a given individual may be more susceptible at some times than others, depending on age, nutrition, physical condition and exposure to other toxic substances. Certainly, most people do not contract cancer from most exposures to carcinogens, but the "improbability" proves nothing when viewed from the perspective of millions of people who are each subjected to many discrete
below the strictest exposure limit that could feasibly be imposed on industry.247 The issue then becomes how to extrapolate from arguably safe doses to an estimate of the risk at higher levels of exposure. Essentially the same problem is posed by extrapolation from documented health effects at a high exposure level to an estimate of the risk at lower doses. Again, there are several competing theories: the risk may vary in a linear manner as a function of dosage, or it may vary as a log function, or it may change in a series of discrete stages.248 A valid theory of extrapolation must be developed before exposure levels and health risks can be correlated, but no theory has achieved a reasonable scientific consensus.249

Justice Stevens placed considerable emphasis on industry’s submission of dose-response curves that attempted to quantify the incidence of harm at low exposure levels.250 One industry witness testified that only two cancer deaths every six years would result from exposure to 10 ppm of benzene.251 Justice Stevens identified “three possible interpretations” for the Agency’s rejection of this testimony: OSHA believed the risk was greater than industry stated, or the stated risk was large enough to be deemed significant, or the Agency thought it was obligated to regulate all toxic risks whether significant or not.252 Justice Stevens concluded that the Agency had relied at least in part on the third theory, which he held was a mistaken construction of the OSH Act.253 Surprisingly, a fourth plausible interpretation was not considered: that the industry evidence was regarded as unreliable because OSHA believed the risk from low levels of benzene exposure could not be determined in a scientifically valid manner.254

exposures over a period of years. This comment is not intended to argue that threshold levels do or do not exist, for that issue is under active debate among scientists, but rather to indicate that Justice Stevens was in no position to resolve this disputed question of scientific fact. See generally McGarity, supra note 2, at 33-36.

247. At the hearings on OSHA’s generic cancer policy, several witnesses posited that exposure to a minimum of 10,000 molecules of a carcinogenic substance may be necessary for cancer induction. The Agency found this theoretical threshold level was irrelevant because 10,000 molecules is a much smaller dose than the strictest exposure limit that industry could feasibly implement. See Generic Cancer Policy, 45 Fed. Reg. 5002, 5131 (1980).


250. 448 U.S. at 635, 654.

251. Id.

252. Id. at 654-55.

253. Id. at 655. There is, however, a vital distinction between a theory that indicates all risks, no matter how insignificant, must be regulated to the greatest extent feasible, and a theory that requires risks associated with a known carcinogen to be limited as much as possible when the harm at particular levels of exposure is uncertain and currently indeterminable.

There is no doubt that OSHA carefully reviewed the industry claim of only two cancer deaths every six years and that this testimony was rejected on the grounds of unreliability. Other studies, including some evidence introduced by industry experts, indicated that the risk might be considerably higher. In dissent, Justice Marshall described specific OSHA criticisms of the testimony on this asserted dose-response relationship. In light of the clear evidence of aggregate health effects from benzene and uncertainty surrounding disaggregated risk estimation, OSHA adopted the "protective" strategy of limiting the risk from benzene exposure to the greatest extent feasible.

...
Differing assumptions about threshold levels and extrapolative theories may produce great disparity among carcinogenic risk assessments. Recent estimates on the harm from ingestion of saccharine illustrate this problem. Reliance on the "one-hit" theory, which posits no risk-free threshold level, and a linear extrapolation hypothesis led to a prediction of 1,200 cancers per million lifetime exposures; the log (probit) model predicted 450; and the multistage theory predicted 5. A risk assessment sponsored by industry estimated one cancer per billion exposures. The millionfold variance between the highest and lowest risk estimates for saccharine, where more experimental data were available than for benzene, may put in proper perspective the claim of the industry witness that only two cancer deaths every six years would result from exposure to 10 ppm of benzene. OSHA did not conclude that the witness was necessarily wrong; rather, the Agency determined only that uncertainties in the available data and in the theory of extrapolation precluded development of a reliable dose-response curve. Because of this scientific uncertainty, experts often may be able to characterize a carcinogenic risk as "significant" or "insignificant" by varying the assumptions used in the risk assessment. In the absence of an adequate data base and reasonable scientific agreement on the proper method for extrapolation, OSHA's acknowledgement of continuing uncertainty is preferable to the generation of quantitative dose-response estimates based on an arbitrary selection of questionable extrapolative hypotheses.

B. Invalid Proof of "Significance"

The preceding discussion demonstrates (1) there was ample support in the record for OSHA's finding that reliable correlations between benzene exposure levels and health risks cannot be developed and (2) the same types of knowledge uncertainties are very likely to arise whenever regulatory agencies are required to identify disaggregated carcinogenic risks. The question then becomes whether OSHA and other agencies can regulate toxic substances in a scientifically meaningful way within the legal parameters established by the Supreme Court's benzene decision. If not, the courts must change their approach to legal decisionmaking under uncertainty, or society must forego protection.

259. See supra note 239.
264. See 448 U.S. at 716 (Marshall, J., dissenting).
against carcinogenic risks until scientific knowledge is adequate to meet the judicially-imposed burden of proof.

The Fifth Circuit Court of Appeals, in its benzene decision, unequivocally placed the burden of knowledge uncertainty on the Agency. The same result is implicit in the Supreme Court’s benzene decision, which required development by the Agency of at least approximate estimates of the risks at particular exposure limits. Justice Stevens professed no view on the “difficult question of what factual determinations would warrant a conclusion that significant risks are present . . . .” Nonetheless he noted that a risk of one cancer in a billion exposures surely would not be significant but a reasonable person might well consider odds of one in a thousand a significant risk. OSHA cannot estimate the “odds” in this quantitative manner without a valid dose-response curve, and the Agency has consistently maintained it cannot derive reliable dose-response relationships for low-level carcinogenic exposures.

The plurality’s approval of the current 10 ppm benzene limit illustrates its analytical confusion. Justice Stevens noted that the benzene record contained voluminous evidence of adverse effects at exposure levels “well above 10 ppm.” He then concluded that regulation of benzene was justified and that the existing PEL was “reasonable” in light of the demonstrated harm. Yet elsewhere in the opinion the Justice observed that there was very little empirical evidence of any health effects at the 10 ppm exposure level, and that OSHA did not find exposures at or below the existing PEL “had ever in fact caused


OSHA must have some factual basis for an estimate of expected benefits before it can determine that a one-half billion dollar standard is reasonably necessary. For example, when studies of the effects of human exposure to benzene at higher concentration levels in the past are sufficient to enable a dose-response curve to be charted that can reasonably be projected to the lower exposure levels, or when studies of the effects of animal exposure to benzene are sufficient to make projections of the risks involved with exposure at low levels, then OSHA will be able to make rough but educated estimates of the benefits expected from reducing the permissible exposure level from 10 ppm to 1 ppm. Until such estimates are possible, OSHA does not have sufficient information to determine that a standard such as the one under review which it can only say might protect some worker from a leukemia risk is reasonably necessary.

266. See supra text accompanying notes 48-55.

267. 448 U.S. at 659.

268. Id. at 655.


270. 448 U.S. at 631.

271. Id.

272. See id. at 625, 631, 633, 652-53 n.60.
leukemia." The Agency did not construct a dose-response curve to describe health effects at the current PEL or higher levels. Neither animal experiments nor epidemiological data were dispositive on the risk at 10 ppm; indeed, OSHA concluded that the risk at low dosages could not be quantified. No estimate was made of the benefits derived from reducing higher exposures to the 10 ppm level. Under these conditions, how could the Agency demonstrate that the 10 ppm PEL is "reasonably necessary" to avoid a significant risk? All OSHA could say is that the aggregate effects of benzene exposure have been severe and that lowering the permissible limit to 10 ppm would reduce the carcinogenic risk by some indeterminate amount. That is, of course, exactly the argument the plurality rejected in connection with the proposed 1 ppm standard. In the absence of reliable disaggregated risk estimates, it is a complete mystery how the plurality determined that the 10 ppm PEL was "reasonable." Here, as elsewhere, the plurality opinion provided OSHA with no real insight on how it can demonstrate significance in future cases.

Justice Stevens asserted "there are a number of ways in which the Agency can make a rational judgment about the relative significance of the risks associated with exposure to a particular carcinogen." He then presented three examples he thought supported his contention: regulation of coke oven emissions, vinyl chloride, and fourteen other carcinogenic substances.

1. Coke Oven Emissions

Workers exposed to coke oven emissions are subject to an increased risk of lung and urinary tract cancers. OSHA's 1976 coke oven emissions standard reduced the PEL from 0.2 mg per cubic meter of air to 0.15 mg, the strictest limit that could feasibly be imposed on industry. The Third Circuit Court of Appeals found substantial evidence to support the only three qualitative determinations it thought

273. Id. at 634.
275. See id. at 5940-41, 5946.
276. The 10 ppm limit had been adopted as a national consensus standard in response to concerns over nonmalignant blood disorders. See 448 U.S. at 619. The Agency maintained that it could not estimate benefits in the absence of a dose-response curve, see 43 Fed. Reg. 5918, 5940 (1978), and it had no dose-response curve for low-level benzene exposures.
277. See supra text accompanying notes 35-68.
278. 448 U.S. at 656-57.
necessary on the issue of risk: that coke oven emissions are carcino-
getic, that serious aggregate health effects have been demonstrated,
and that no safe level of exposure exists for carcinogens.\textsuperscript{282} This was
the same line of reasoning adopted by OSHA in its benzene proceeding
and later rejected by the Supreme Court plurality. The Agency did not
conclude in the coke oven emissions proceeding that a specified level of
risk was present at the prior PEL or that significant benefits would ac-
crue from the proposed reduction.\textsuperscript{283} However, Justice Stevens appar-
etly believed the presence of two quantified risk estimates in the
record meant the Agency could and should have been made such
determinations:

OSHA had calculated that 21,000 exposed coke oven workers had an
annual excess mortality of over 200 and that the proposed standard
might well eliminate the risk entirely. In hearings on the coke oven
emissions standard the Council on Wage and Price Stability estimated
that 8 to 35 lives would be saved each year, out of an estimated popula-
tion of 14,000 workers, as a result of the proposed standard. Although
noting that the range of benefits would vary depending on the assump-
tions used, OSHA did not make a finding as to whether its own staff
estimate or CWPS's was correct, on the ground that it was not required
to quantify the expected benefits of the standard or to weigh those ben-
efits against the projected costs.\textsuperscript{[citations omitted].}\textsuperscript{284}

After adjusting for the difference in worker populations in the two
studies,\textsuperscript{285} one estimate was still as much as twenty times lower than the

\textsuperscript{282} \textit{Id.} at 831-32.

\textsuperscript{283} \textit{See} Exposure to Coke Emissions, 41 Fed. Reg. 46742, 46751 (1976): “We do not
believe we can forecast accurately the amounts of annual reductions in mortality and mor-
bidity that will result from the regulation . . . .”

\textsuperscript{284} 448 U.S. at 657 n.64.

\textsuperscript{285} The two estimates were evidently based on different extrapolations from the same
epidemiological data, although the precise basis for the estimates was not fully explained in
the Agency's statement of reasons for its coke oven standard. \textit{See} Exposure to Coke Oven
Emissions, 41 Fed. Reg. 46742, 46745-47 (1976), describing the data analyzed by Dr. Red-
mond and her associates. It was clear in the record that the CWPS estimate was derived
from Dr. Redmond's data. \textit{See id.} at 46750. The CWPS risk assessment was premised on
technical assumptions that OSHA believed were inaccurate. \textit{See id.} The OSHA “estimate”
was included in an Inflationary Impact Statement (IIS) that relied heavily on the analysis of
an outside consultant. \textit{See id.} at 46748-50, describing the participation of DB Associates.
The CWPS prediction was based only on coke oven workers, whereas the IIS estimate in-
cluded all workers in coke oven plants. \textit{Id.} Which of these population groups would be
more appropriate depends on the extent to which other workers in the plants are exposed to
coke oven emissions.

The IIS projected 240 excess deaths at the prevailing exposure level, \textit{id.} at 46750, but
the Agency reduced the expected risk to 211 deaths because it decided one of the IIS esti-
mate's underlying assumptions was clearly erroneous. \textit{See id.} The original IIS estimate
assumed a stable worker population exposed for a 45-year working life, but OSHA thought
the estimate should be reduced to account for deaths of some workers through other causes
before they were exposed for the full period. The record's treatment of the IIS prediction
indicates that it was regarded as one estimate, not as OSHA's official estimate. OSHA's
reduction of the IIS estimate to 211 excess deaths was, in turn, questionable because de-
Justice Stevens observed that OSHA "did not make a finding" on which estimate was correct, but nothing in the record suggests the Agency could have made such a finding in a scientifically valid manner. Because risk estimates vary depending on the assumptions used, as the Agency specifically noted, it is entirely possible that neither risk estimate was even approximately correct. In the coke oven record itself, OSHA concluded that meaningful estimates of excess deaths and illnesses could not be made, although some mortality and morbidity was clearly attributable to coke oven emissions. In short, OSHA based its final determination on a qualitative, not quantitative, analysis. OSHA's principal expert witness employed two alternative extrapolative theories and four possible latency periods to derive an array of potential health risks. He concluded that some risk of excess cancer deaths was present under every combination of the factors evaluated. There was no intimation that the actual level of risk could be identified in a scientifically reliable manner; indeed, that is precisely why the expert adopted a range of possibly applicable assumptions. Industry experts relied on different epidemiological data and different theories of extrapolation to argue that the existing PEL and even higher exposures were substantially safe. But again, industry made no claim that a scientific consensus existed on the proper extrapolative methodology.

Justice Stevens' assertion that the proposed coke oven emissions standard "might well eliminate the risk entirely" was completely unfounded. There was no prediction in the record of how much risk ceased workers will be replaced by new ones, for whom exposure will commence at that time.

286. The CWPS study group was only 60 percent of the population included in the IIS estimate. Id. Adjusting for this discrepancy in a linear fashion would produce a low CWPS estimate of 13 excess deaths (instead of 8) against the IIS estimate of 240 or OSHA's revised projection of 211. Of course, linear extrapolation is based on an arbitrary selection of assumptions and is intended only to illustrate the divergence in risk estimates produced by the adoption of one debatable set of extrapolative hypotheses or another.

287. 448 U.S. at 657 n.64.
289. Id. at 46750-51.
290. See id. at 46753.
291. See id.
292. See id. at 46755-56.
293. Id. at 46755.
294. See id. at 46746, 46754-55.
295. 448 U.S. at 657 n.64.
296. For coke oven emissions, for benzene, and for other carcinogens, OSHA maintains that no level of exposure is risk-free other than zero exposure. See 448 U.S. at 635-36; American Iron & Steel Inst. v. OSHA, 577 F.2d 825, 831-32 (3d Cir. 1978), cert. dismissed, 448 U.S. 917 (1980); 43 Fed. Reg. 5918, 5941, 5946 (1978); Generic Cancer Policy, 45 Fed. Reg. 5002, 5023-24 (1980). Yet the coke oven standard only reduced the PEL from 0.2 mg to 0.15 mg per cubic meter. Given their initial risk estimates, both the IIS and the CWPS studies assumed all risk would be eliminated solely for the purpose of calculating the maxi-
would actually remain at the 0.15 PEL, and no indication that the actual benefits from regulation could be quantified in a meaningful way.\footnote{ To the contrary, OSHA explicitly stated that it was not possible to estimate the reduction in mortality and morbidity, and consequently the benefits, from imposition of the proposed standard. Exposure to Coke Oven Emissions, 41 Fed. Reg. 46742, 46750 (1976).} OSHA stressed that the proposed standard was not ideal, as it would be if all risk were eliminated, but rather was the safest standard that could feasibly be implemented.\footnote{ See id. at 46755.} Given the knowledge uncertainties associated with carcinogenic risk assessments, there is no reason to assume OSHA could have shown a specified risk “more likely than not” existed. Thus, for coke oven emissions the Agency could not have met the burden of proof imposed in the benzene case.

2. *Vinyl chloride*

In the vinyl chloride proceeding cited by Justice Stevens, OSHA determined that the chemical was carcinogenic and reduced the permissible exposure limit from 50 ppm to 1 ppm.\footnote{ See Exposure to Vinyl Chloride, 39 Fed. Reg. 35890, 35892 (1974).} No reliable epidemiological data in the record demonstrated any human health effects at 50 ppm.\footnote{ See id.} Industry had submitted a study that purported to show no effects on humans from exposure to 200 ppm,\footnote{ See id.} but the Agency rejected it because of methodological deficiencies.\footnote{ See id.} OSHA made no estimate of the human health risk at 50 ppm; it did not construct a human dose-response curve for vinyl chloride; and it did not conduct studies at the 1 ppm PEL or at any intermediate exposure level to estimate the benefits achieved through regulation.\footnote{ See Exposure to Vinyl Chloride, 39 Fed. Reg. 35890-92 (1974).} OSHA relied on animal studies at exposures of 50 ppm to conclude that vinyl chloride should be regulated as a carcinogen,\footnote{ See id.} but the mode of analysis adopted by the Agency was entirely qualitative.

Justice Stevens thought the animal studies submitted in the vinyl chloride proceedings could be used to quantify disaggregated health risks:

In other proceedings, the Agency has had a good deal of data from
animal experiments on which it could base a conclusion on the significance of the risk. For example, the record on the vinyl chloride standard indicated that a significant number of animals had developed tumors of the liver, lung and skin when they were exposed to 50 ppm of vinyl chloride over a period of 11 months.\textsuperscript{305}

Justice Stevens did not distinguish between the use of animal test results to make qualitative judgments about the carcinogenic properties of a substance, and reliance on those results to derive quantitative risk estimates for humans at specified exposure levels. Several factors prohibit extrapolation from animal test results to human risk estimates. It would be very expensive to conduct animal studies at the low dosage levels typical of human exposures. For instance, at realistic dose levels a test of a single substance requires 10,000 animals to detect a carcinogenic risk of one in one hundred in a statistically valid manner.\textsuperscript{306} Yet, an occupational risk of one cancer for each hundred exposed workers would probably not be considered tolerable.\textsuperscript{307} To identify a lesser risk in a reliable manner would require a proportionately larger cohort of test animals.\textsuperscript{308} Most past experiments have exposed limited numbers of animals to high doses for relatively short time intervals,\textsuperscript{309} rather than to the low doses over extended periods characteristic of occupational exposure.

Another problem with reliance on animal studies is the absence of a generally accepted theory of extrapolation from animal test results at high doses to animal risks at low doses.\textsuperscript{310} There is also no recognized methodology for extrapolation from animal results to human health effects.\textsuperscript{311} The average duration and variability of latency periods for animals do not correspond with latency periods for humans.\textsuperscript{312} Animal studies do not reflect differences between the immunological systems and other body mechanisms of animals and humans.\textsuperscript{313} By the very nature of controlled experiments, variables such as age, nutrition, physiological condition and exposure to other toxic substances are tightly restricted in animal studies, unlike in human populations.\textsuperscript{314} For these

\begin{footnotes}
\item[305] 448 U.S. at 657 n.64.
\item[307] In attempting to illustrate the distinction between insignificant and significant risks, Justice Stevens suggested that odds of one in a thousand might well be significant. 448 U.S. at 655.
\item[308] See McGarity, supra note 2, at 734.
\item[309] Id.; see Generic Cancer Policy, 45 Fed. Reg. 5002, 5084 (1980).
\item[310] For extrapolation of animal effects, the same theories are debated as those applied to human effects. See Generic Cancer Policy, 45 Fed. Reg. 5002, 5182-88 (1980).
\item[311] See id. at 5190-95.
\item[312] See id. at 5192.
\item[313] See id. at 5190.
\item[314] See id.
\end{footnotes}
reasons, OSHA has concluded that animal studies cannot be employed to construct reliable dose-response curves applicable to human health effects.\textsuperscript{315}

In the vinyl chloride proceeding OSHA did not allege that extrapolations could be made from animal studies to human risks at the 50 ppm exposure level or any other. Rather, the Agency stated that quantification of risks at low doses was not scientifically possible at the time.\textsuperscript{316} OSHA used animal studies only to identify a carcinogenic risk, not to estimate the extent of that risk for humans or to determine if it was significant. Industry vigorously contested the assumption that observed effects in rats at a given exposure level could be correlated, even qualitatively, with human effects at the same exposure level.\textsuperscript{317} The Second Circuit Court of Appeals accepted a qualitative analysis and found no error in OSHA's reliance, under the prevailing scientific uncertainty, on animal studies to demonstrate some carcinogenic risk.\textsuperscript{318} However, OSHA's qualitative findings on vinyl chloride could not meet the requirement of quantitative risk assessments imposed in the Supreme Court's benzene decision.

3. Fourteen Carcinogenic Substances

The plurality's final example of how OSHA allegedly could determine the significance of carcinogenic risks also required extrapolation from animal studies:

Similarly, in a 1974 standard regulating 14 carcinogens, OSHA found that one of the substances had caused lung cancer in mice or rats at 1 ppm and even 0.1 ppm, while another had caused tumors in 80% of the animals subjected to high doses. [citations omitted].\textsuperscript{319}

For the fourteen substances, OSHA relied on animal experiments, supplemented in some instances by epidemiological data on aggregate health effects, to determine they were carcinogens.\textsuperscript{320} In each instance, this determination was qualitative rather than quantitative in nature. The first chemical cited by Justice Stevens, BCME,\textsuperscript{321} was the only one for which OSHA reported test results at low levels of exposure.\textsuperscript{322} However, as noted above, there is no recognized methodology for extrapolating from animal to human risks at particular exposure levels.

315. \textit{Id.} at 5200.
317. \textit{See id.} at 35891.
318. \textit{See Society of Plastics Indus., Inc. v. OSHA, 509 F.2d 1301, 1308 (2d Cir.), cert. denied, 421 U.S. 992 (1975).}
319. 448 U.S. at 657 n.64.
321. Bis (chloromethyl) ether (BCME) caused skin tumors and lung cancer in test animals. \textit{Id.} at 3757.
322. \textit{See id.}
The eighty percent toxicity of the other chemical cited, ethyleneimine, was observed after high doses were administered to test animals.\textsuperscript{323} The investigators in that study concluded "there was no way to predict whether man would be more or less susceptible to tumor induction."\textsuperscript{324} In none of the fourteen findings did OSHA attempt to quantify the human risk at any specified exposure level or to estimate the benefits that would result from the proposed regulatory standards. The Third Circuit opinions that upheld the regulations clearly accepted the Agency's qualitative analysis that the animal tests and scattered epidemiological data were sufficient to demonstrate carcinogenic risk, and that stringent regulatory standards were necessitated by the continuing scientific uncertainty.\textsuperscript{325} But again, the absence of disaggregated risk estimates in the record means OSHA could not meet the benzene decision's significance test for the fourteen carcinogens.

OSHA appears never to have submitted animal test results to predict human health effects at particular levels of exposure. The most that can be said for Justice Stevens' examples is that, in some cases, the Agency might be able on the basis of animal tests to characterize substances qualitatively as especially potent carcinogens. However, minimal or even negative results from animal studies at a given dosage do not demonstrate that a carcinogenic substance is relatively safe for humans. Where human metabolic and immunological processes differ from those of the test species\textsuperscript{326} or where a substance's carcinogenicity is aggravated by the presence of other chemicals,\textsuperscript{327} animal experiments will not reveal potentially severe risks for humans. In other words, animal test results may occasionally be useful to document qualitatively the presence of a severe hazard, but they cannot show the absence of a serious risk for humans. Controlled animal experiments have failed to demonstrate any degree of carcinogenic risk, much less a relatively serious one, from benzene or arsenic.\textsuperscript{328} In view of the clear correlation between these substances and excess cancer deaths, the Agency has not accepted the negative animal test results as proof of human safety.\textsuperscript{329} Surely, it would be inappropriate for the Supreme Court to do so on its own initiative.\textsuperscript{330}

\textsuperscript{323} See id.
\textsuperscript{324} Id.
\textsuperscript{327} See id. at 5135-37; 43 Fed. Reg. 5918, 5929 (1978).
\textsuperscript{330} See 448 U.S. at 663 (Burger, C.J., concurring).
Justice Stevens was essentially grasping at numerical straws in his selective references to the evidence on coke oven emissions, vinyl chloride and the fourteen carcinogens. These references, coupled with his treatment of industry’s assertion that a meaningful dose-response curve could be derived for benzene, reveal a misguided affinity for numerical claims without a realistic appreciation of the purposes for which these numbers were submitted or of their degree of reliability. If OSHA must prove that a specific level of exposure “more likely than not” presents “a significant risk of material health impairment,” neither the three examples cited by Justice Stevens nor any other rulemaking on carcinogens demonstrates that the Agency can do so in a scientifically valid manner.

In his caustic dissent, Justice Marshall correctly argued that the significance test would often require OSHA to do the impossible. The dissent criticized the plurality for imposing its own view of desirable regulatory policy, one characterized by “solicitude for the welfare of regulated industries.” Justice Marshall further observed that:

The consequence of the plurality’s approach would be to subject American workers to a continuing risk of cancer and other fatal diseases, and to render the Federal Government powerless to take protective action on their behalf. Such an approach would place the burden of medical uncertainty squarely on the shoulders of the American worker, the intended beneficiary of the Occupational Safety and Health Act.

The central flaw in the benzene case was the Court’s failure to analyze adequately the distinction between insignificant risks and uncertain risks. OSHA determined for benzene and for other toxic substances that quantification of carcinogenic risks at low levels of exposure was beyond the current state of scientific understanding. Yet, the plurality in the benzene case repeatedly emphasized the need for estimates of the risks posed by specific exposure levels. The legal alternatives are therefore clear: either OSHA must be allowed to regulate carcinogens despite prevailing knowledge uncertainties, which means the significance requirement must be abandoned in any rigorous

331. Id. at 653-54.
332. For the burden of proof imposed by the plurality, see 448 U.S. at 653; supra text accompanying note 63.
333. 448 U.S. at 714 (Marshall, J., dissenting).
334. 448 U.S. at 690; see also id. at 714 (Marshall, J., dissenting).
335. Id. at 690. This attack appears unwarranted, at least with respect to the plurality opinion’s author. Justice Stevens later joined the cotton dust majority that refused to require a balancing of regulatory costs against benefits, a position industry had vigorously espoused. See American Textile Mfrs. Inst., Inc. v. Donovan, 452 U.S. 490 (1981).
336. See id. at 688.
sense;\textsuperscript{339} or regulation must be postponed until the indefinite future when adequate knowledge can be acquired and the burden of proof imposed by the benzene decision can be met.\textsuperscript{340} This choice should be made through interpretation of the legislative policies in the applicable regulatory statute rather than through the imposition of a reductive burden of proof.

III
INTERPRETATION OF THE OSH ACT

The OSH Act was intended "to assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources."\textsuperscript{341} For toxic substances, the Act directs OSHA to set the feasible standard which best assures that "no employee" will suffer material health impairment.\textsuperscript{342} Without disputing that employee protection was the preeminent concern of Congress, the plurality in the benzene case interpreted specific statutory provisions\textsuperscript{343} and legislative history\textsuperscript{344} for only one purpose: to demonstrate that the OSH Act does not mandate absolute safety. After articulating the threshold "significance" requirement, the plurality did not construe the statute to determine the outcome in cases where the risk is currently indeterminable and may or may not prove to be significant.

A. Preventive Purpose of the OSH Act

Congress was aware of the "lamentable lack of knowledge" about toxic health effects when it passed the OSH Act;\textsuperscript{345} the inadequacy of information was one of the most frequent observations in the legislative history.\textsuperscript{346} References were made, for example, to "unsuspected cause-and-effect relationships between occupational exposures and many of the so-called chronic diseases"\textsuperscript{347} and to "health hazards involving

\textsuperscript{339} See 448 U.S. at 715-17 (Marshall, J., dissenting).
\textsuperscript{340} OSHA recognized the uncertainty surrounding carcinogenic risk assessments and interpreted its own statutory mandate to say that it must not postpone effective regulation while awaiting definitive medical and scientific information. See 43 Fed. Reg. 5918, 5920, 5946 (1978).
\textsuperscript{343} See 448 U.S. at 639-45.
\textsuperscript{344} See id. at 646-49, 651.
\textsuperscript{345} See Leg. Hist., supra note 59, at 517.
\textsuperscript{346} E.g., id. at 142, 160, 339, 848-49.
\textsuperscript{347} Id. at 517.
complex, often synergistic, interactions of numerous physical and chemical agents.”

Congress recognized “due to the lack of information and records” that occupational health problems “may well be considerably worse than we currently know.”

In response to this uncertainty, Congress directed OSHA and HEW to sponsor research and to develop protective criteria; ordered OSHA to organize advisory committees with suitable expertise; created the National Institute of Occupational Safety and Health; imposed monitoring and record-keeping requirements on employers; and in section 6(b)(5) expressly allowed OSHA to set toxic substances standards on the basis of the best available evidence.

Although the Fifth Circuit’s benzene decision interpreted the “best available evidence” clause to limit OSHA’s authority by restricting the kind of information on which it must base regulatory standards, the legislative history reveals that the clause was intended to expand the Agency’s ability to act under uncertainty:

The Committee feels it is vital that when the Secretary sets an occupational health standard he do so on the basis of the best available professional evidence; it is not intended that the Secretary be paralyzed by debate surrounding diverse medical opinions.

In response to that congressional mandate, most judicial opinions have approved OSHA health standards promulgated on the basis of the “best available evidence.” After citing this clause, the majority in the cotton dust case held that OSHA’s “candor” in confessing uncertainty “should not precipitate a judicial review that nonetheless demands what the congressionally-delegated ‘expert’ says it cannot provide.” Yet that is precisely the effect of the significance test imposed in the benzene case. Given the current inability to extrapolate
from high dose-responses to health effects at low doses or from animal test results to human risks, evidence on disaggregated risks can only be acquired through controlled epidemiological studies at specified levels of exposure. Even in the best of circumstances, adequate studies would take many years to complete. The critical legal question, then, is whether Congress intended exposed employees to bear the burden of scientific uncertainty during the long period when evidence on the significance of disaggregated risks is lacking.

The proposition that Congress intended OSHA to postpone regulation indefinitely until the Agency can resolve scientific uncertainty is incompatible with the sense of urgency that prevailed when the OSH Act was passed. Congress recognized that workers are subject to toxic exposures "which have delayed or latent ill effects," that some toxic health problems result from a "cumulative buildup," and that many chemicals may turn out to be "killers in disguise." The legislative history stressed the inadequacy of knowledge about "materials long in industrial use," but placed equal or greater emphasis on "new materials and processes" that are "introduced into industry at a much faster rate than the present meager resources of occupational health can keep up with." The uncertainty associated with the introduction of "literally hundreds of new chemicals" was explicitly cited as a critical problem. If the congressional recognition that toxic substances often have delayed effects is juxtaposed with congressional concern over the dangers of new chemicals, for which long-term epidemiological data could not possibly exist, the section 6(b)(5) mandate that OSHA act on the basis of the best available evidence cannot be reconciled with the notion that the Agency should wait until information on disaggregated risks can be collected.

Justice Stevens did not allocate the burden of uncertainty in a manner consistent with the preventive purpose of the OSH Act at least in part because of two erroneous factual assumptions. He thought the

OSHA has repeatedly asserted its inability to quantify carcinogenic risks at low levels of exposure.


363. This is true because cancer typically involves a long latency period and many other toxic effects develop progressively as a result of cumulative exposures over an extended interval. See Generic Cancer Policy, 45 Fed. Reg. 5002, 5026, 5040 (1980).

364. See LEG. HIST., supra note 59 at 141, 510-13, 857.

365. Id. at 895.

366. Id. at 339.

367. Id. at 517.

368. Id. at 142; see supra text accompanying notes 345-49.

369. LEG. HIST., supra note 59 at 142.

370. Id. at 849; see id. at 142, 159-60, 415, 517, 1048-49.

371. OSHA itself considered this potential construction of the OSH Act and explicitly rejected it. 43 Fed. Reg. 5918, 5920 (1978).
Agency often could estimate disaggregated risk levels for carcinogens, and that the consequences of promulgating too lenient a standard would be remediable:

It should also be noted that, in setting a permissible exposure level in reliance on less-than-perfect methods, OSHA would have the benefit of a backstop in the form of monitoring and medical testing. Thus, if OSHA properly determined that the permissible exposure limit should be set at 5 ppm, it could still require monitoring and medical testing for employees exposed to lower levels. By doing so, it could keep a constant check on the validity of the assumptions made in developing the evidentiary basis for decreasing the limit if it was initially set too high. Moreover, in this way it could ensure that workers who were unusually susceptible to benzene could be removed from exposure before they had suffered any permanent damage. (footnotes omitted).

Justice Stevens' emphasis on the utility of monitoring and medical testing was apparently premised on two of industry's debatable contentions. Industry had asserted workers will recover from nonmalignant blood disorders that are detected in time, and that nonmalignant disorders always precede the onset of leukemia. OSHA explicitly found those hypotheses unsupported by either the available epidemiological data or a reasonable consensus of scientific opinion.

Unlike progressive diseases such as byssinosis or nonmalignant blood disorders, cancer formation does not invariably depend on cumulative exposures. Leukemia is not detectable in many cases until years or decades after the fatal exposure occurs. Moreover, the discovery of occasional instances of leukemia among exposed workers would prove nothing because the disease occurs naturally in some people. Only a controlled long-term epidemiological study covering a large number of employees could identify a statistically valid incidence of excess cancers at an exposure limit that Justice Stevens conceded may be "initially set too high." By the time the results of such a

372. For a critique of the particular examples Justice Stevens cited, see supra text accompanying notes 278-305 and 315-330.
373. 448 U.S. at 657-58.
374. See supra text accompanying notes 165 & 169.
376. The existence of a dose-response curve simply indicates that the probability of contracting leukemia increases as the exposure is increased. A threshold level for benzene-induced leukemia means only that an individual must be exposed to at least that dose before he is at risk. If the person is exposed only once in his life to a sufficient dose of benzene and if that exposure initiates neoplastic alteration, leukemia may eventually result even when there are no subsequent periods of exposure. In other words, the degree of carcinogenic exposure is relevant to the incidence of disease, not to its severity once contracted. Implicit in OSHA's adoption of the one-hit theory, see supra note 239, is the possibility that some people may die from small and infrequent exposures.
378. See id. at 5926.
379. 448 U.S. at 657-58.
study were available, hundreds of thousands of workers would have been exposed to unnecessarily high levels of benzene. And because no cure is known for leukemia, the consequences of that exposure, whatever they may ultimately prove to be, will be irreversible.

The "backstop" argument represents another instance where Justice Stevens relied, perhaps unintentionally, on disputed scientific claims wholly outside his field of expertise. It is true, as the plurality opinion notes, that the Agency itself imposed a monitoring requirement. But OSHA did so at exposure levels below the strictest benzene standard that could feasibly be imposed on industry. In other words, OSHA chose to supplement its protective standard with a monitoring requirement applicable to even lower exposure levels. Justice Stevens assumed that monitoring could replace strict controls under conditions of uncertainty, a far less tenable judgment in light of the preventive purpose of the OSH Act.

The plurality's insistence on disaggregate risk estimates leads to an anomalous result. Only a few years before OSHA's benzene proceeding, industry voluntarily accepted a maximum exposure level of 10 ppm. Had industry continued to expose workers to 100 ppm or more of benzene, the Agency could probably have proved the risk was significant; the plurality acknowledged there was abundant evidence of toxicity at exposure levels "well above 10 ppm." The benzene case held that once a significant risk is found, section 6(b)(5) requires imposition of a highly protective standard. If OSHA had met the significance threshold at the 100 ppm level, it could then have required compliance with its stringent 1 ppm standard. Yet the same 1 ppm PEL was rejected by the benzene plurality because OSHA could not meet the significance test at industry's relatively new 10 ppm limit.

Suppose OSHA attempts to conduct epidemiological studies at the current 10 ppm PEL in order to document the need for a more stringent limit. If the long-term study at 10 ppm ultimately reveals a significant risk, then the Agency will be allowed to impose its proposed 1 ppm standard, the safest feasible PEL for benzene. If, a few years hence, industry agrees to reduce exposures to a maximum of 5 ppm, and the

381. 448 U.S. at 658 n.67.
382. See id. at 624-28.
383. Industry adopted a consensus limit of 10 ppm in 1969, and OSHA promulgated a national consensus standard at that level in 1971. Id. at 617. However, the plurality acknowledged that some plants may have continued "relatively high exposures through the 1970's." Id. at 622 n.16. Obviously, epidemiological data on benzene risks at low levels of exposure can only be acquired after industries actually reduce exposures to those levels.
384. Id. at 631.
385. Id. at 643 n.48.
386. This assumes that no significant technological innovations will be made in benzene control methods by the time the study is completed. It would, in reality, be possible for the
Agency chooses to promulgate an interim 5 ppm standard, an entirely new epidemiological study limited to exposures of 5 ppm and below will have to be initiated before the 1 ppm limit could be imposed. Positive results in the original 10 ppm study could not support a finding that 5 ppm presents a significant risk.\textsuperscript{387}

It seems, then, that OSHA should encourage industry to \textit{maximize} exposures, because that will simplify the task of demonstrating that the prevailing exposure level represents a significant risk. Once the Agency finds the current risk is significant, it can act to \textit{minimize} toxic exposures to the greatest extent feasible. Conversely, industry ought to reduce exposures to some intermediate point whenever it fears that OSHA may be able to prove significance at the previous exposure level. This absurd result flows directly from the plurality’s demand that OSHA produce proof of significance at specified exposure levels.

The absurdity is compounded by the requirement that OSHA demonstrate “significant” benefits will accrue from imposition of the strictest feasible standard.\textsuperscript{388} In the absence of a valid theory of extrapolation, only epidemiological studies can define the extent of disaggregated risks. However, epidemiological evidence could not possibly be obtained until after a new standard is implemented. Thus, it is impossible to see how OSHA could prove that significant benefits will result from a proposed regulation. It would be more consistent with the preventive purpose of the OSH Act to allow OSHA to regulate on the bases of a qualitative demonstration of toxicity derived from scientific experiments and documented aggregate health effects.

Although the significance test is not objectionable as a statement of abstract principle, it was articulated without any real understanding of the uncertainty that prevents meaningful estimation of carcinogenic risks or of the long period of time that must pass before OSHA could resolve that uncertainty. The practical consequences of the significance requirement are to deny many workers the protection against toxic substances that Congress intended and to convert workers into guinea pigs subjected to unnecessarily high levels of exposure before strict controls can be justified.

\textbf{B. Diseases Cited in the Legislative History}

Congress intended the OSH Act to control a wide range of occupa-
tional risks, but the severe health effects of exposure to carcinogens, asbestos, and cotton dust were repeatedly cited in the legislative history as examples of the pressing need for federal action. Justice Stevens characterized those hazards as exactly the types of problems that Congress meant to regulate. The question here is whether OSHA could strictly regulate those recognized health risks in compliance with the plurality's significance test. Carcinogenic risk assessment has already been examined at length; asbestos is a carcinogen and also causes the progressively disabling disease asbestosis. OSHA promulgated a regulatory standard that lowered the PEL for asbestos from five fibers per cubic milliliter of air to two fibers. The District of Columbia Circuit Court of Appeals reviewed the evidence in support of that decision in Industrial Union Department, AFL-CIO v. Hodgson.

The critical factual issues in the asbestos and benzene proceedings were precisely the same: given demonstrable aggregate health effects, what specific level of exposure is safe? The available data on the relationship between asbestos exposure and particular health effects had serious deficiencies. It would be difficult to acquire data on disaggregated risks because of uncertainty about past exposure levels at workplaces. There was relatively little scientific understanding of the causal relationship between asbestos exposure and various diseases. Indeed, with respect to the comparison of risks at the existing and proposed PELs, the record indicated that "no precise prediction of increased harm can be made at this time." Data and conflicting expert testimony were introduced to support possible standards ranging from twelve fibers down to zero exposure, but there was no indication that disaggregated risk levels could be estimated reliably. The Court of Appeals concluded "it is fair to say that the evidence did not establish any one position as clearly correct." In view of this uncertainty, Judge McGowan approved OSHA's decision to resolve the doubt in favor of greater protection for exposed workers.

389. E.g., Leg. Hist., supra note 59, at 142; see 448 U.S. at 692 n.4 (Marshall, J., dissenting).
391. E.g., id. at 143.
392. See 448 U.S. at 646.
393. See Industrial Union Dep't, AFL-CIO v. Hodgson, 499 F.2d 467, 471 n.7 (D.C. Cir. 1974).
394. See id. at 478-79.
395. 499 F.2d 467 (D.C. Cir. 1974).
396. See id. at 475, 485.
397. See id. at 487.
398. See id.
399. Id. at 479.
400. See id. at 479 & n.27.
401. Id. at 478-79.
402. Id. at 475, 479.
terized the disputed factual issues as "on the frontiers of scientific knowledge," and held that the determination of such issues "depends to a greater extent upon policy judgments and less upon purely factual analysis." The Court held the Agency should be allowed broad discretion, when scientific knowledge is deficient, to formulate a solution to the best of its ability on the basis of available information. Because protection of employee health is OSHA's "overriding concern," the Agency's determination was found to be a legitimate exercise of its discretion.

This analysis is plainly inconsistent with the reasoning of the plurality in the benzene case. OSHA repeatedly stated that it could not quantify either the risk posed by low level exposure to benzene or the benefits from reducing that risk. However, in one passage in the record, the Agency hypothesized that the benefits were "likely to be appreciable." Justice Stevens stated that a finding of "likely" benefits, even if supported by substantial evidence, would not satisfy the Agency's burden of proof. According to the plurality, OSHA must show it is "at least more likely than not" that an existing standard poses a significant risk of material health impairment. In light of the inconclusive evidence on asbestos reviewed in Hodgson, the Agency could not possibly have demonstrated that the five-fiber standard presented a significant risk that would be appreciably reduced by lowering the permissible exposure limit to two fibers. The Court of Appeals in the asbestos case was able to approve the lower standard only because the benzene decision's significance test had not yet been imposed. The different results in the asbestos and benzene cases cannot be explained by the quality of the evidence available to the decisionmakers in each case. Rather, the disparate outcomes were pro-

403. Id. at 474.
404. Id. at 474-75 n.18.
405. Id. at 475, 479.
406. The Fifth Circuit explicitly recognized the inconsistency of its benzene decision with the Hodgson line of analysis. See American Petroleum Inst. v. OSHA, 581 F.2d 493, 505 (5th Cir. 1978). However, Justice Stevens cited Hodgson approvingly, without acknowledging the incompatibility between Judge McGowan's reasoning and his own. See 448 U.S. at 656.
408. The Court of Appeals held OSHA had failed to provide substantial evidence that "appreciable" benefits were likely. See 448 U.S. at 638, citing 581 F.2d 493, 503 (5th Cir. 1978).
409. 448 U.S. at 653.
410. Id.
duced solely by the adoption of antithetical modes of legal analysis. Judge McGowan ruled that OSHA must be granted wide discretion in situations where uncertainty would otherwise frustrate regulation of toxic risks, whereas Justice Stevens imposed a reductive burden of proof without recognizing the Agency's inability to meet that burden in many instances.

Unlike benzene and asbestos, cotton dust has not been shown to cause cancer but does cause the progressively disabling disease of byssinosis. Based on epidemiological data for textile mill workers, OSHA was able to construct a dose-response curve applicable to cotton dust. The Agency then adopted the safest standard feasible, a decision approved by the District of Columbia Circuit Court of Appeals and affirmed by the Supreme Court. OSHA also sought to extrapolate from the observed health effects on textile workers to the risks for workers in nontextile industries. The Agency conceded that "in the absence of detailed dose-response data, the risk to workers from cotton dust generated in many segments of the non-textile industry cannot be precisely defined." The author of the dose-response curve for textile workers expressed reservations about the PEL imposed in the nontextile industries, but concluded it was "not an unreasonable approach" pending further study. Judge Bazelon approved the nontextile standard under the same line of analysis in the asbestos decision. He noted that adequate knowledge was not yet available on the causal mechanism for byssinosis, that the evidence of toxic effects is conclusive for textile workers, and that courts must defer to agency determinations on the frontiers of scientific and medical knowledge.

It is doubtful that the cotton dust standard for nontextile workers would be upheld under the plurality's analysis in the benzene case. The Fifth Circuit, in *Texas Independent Ginners Ass'n v. Marshall*,


417. *Id.* at 666.

418. *Id.* at 666 n.81 (D.C. Cir. 1979); see *id.* at 644-45.

419. *Id.* at 666.

420. *Id.* at 668 & n.191.

421. 630 F.2d 398 (5th Cir. 1980).
refused to approve a similar cotton dust standard for cotton gin workers. The Court rejected OSHA's attempt to extrapolate from textile industry data because the work conditions of cotton gin and textile mill workers differ, the typical duration of exposure is considerably less for gin workers, and no estimate of the risk under prevailing industry practices was presented. Following the benzene decision's reasoning, the Court of Appeals found OSHA had failed to prove a significant risk existed for cotton gin workers. The Texas Ginners opinion suggests that significance must be demonstrated separately for each affected industry, at least where arguably different levels or conditions of exposure exist. Given the scientific uncertainties that prevent reliable extrapolations from health effects at known exposure levels to risks under other circumstances, this reading of the significance requirement presents another serious obstacle to effective regulation by OSHA.

The OSH Act's legislative history specifically identified carcinogens, asbestos and cotton dust as causes of particularly severe occupational health problems. As a consequence of inadequate data and scientific understanding, OSHA concluded that it could not reliably estimate the risks posed by low-level exposures to asbestos, benzene, other carcinogens, and even cotton dust in some occupational settings. Yet the benzene case plurality's significance test requires just such estimates. However accurate the plurality's perception that Congress did not contemplate absolute safety, the significance requirement prevents the Agency from strictly controlling the very health problems that impelled Congress to pass the OSH Act.

C. Special Concern for Toxic Substances

Congress's special concern for protection against toxic sub-

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422. Id. at 406-09.
423. Id. at 407-09. The Fifth Circuit Court's reasoning is similar to that unsuccessfully advanced by nontextile industries in AFL-CIO v. Marshall, 617 F.2d 636, 666 (D.C. Cir. 1979), aff'd sub nom. American Textile Mfrs. Inst., Inc. v. Donovan, 452 U.S. 490 (1981). Nontextile industries argued that their workers were exposed to different work processes, dust compositions and levels or conditions of exposure than textile mill workers. AFL-CIO v. Marshall, 617 F.2d 636, 666 (D.C. Cir. 1979).
425. Even if the levels of toxic exposure are comparable in two industries, such factors as dust composition, ventilation, worker turnover, intrafirm job mobility and seasonal variations in exposure could lead to different dose-response curves for those industries. The Fifth Circuit based its decision on these types of factors. In future cases, the Fifth Circuit either must on its own initiative decide which factors are substantial enough to defeat OSHA's attempt to extrapolate from one set of industrial data to the health risks in other industries, or must require the Agency to consider these factors in each separate industrial setting. The first alternative is wholly outside judicial competence and would undoubtedly lead to inconsistent results within and among Circuits. The latter alternative may be institutionally rational, but it would greatly limit OSHA's ability to regulate toxic substances effectively.
426. See supra notes 289-391.
stances reinforces the proposition that the plurality’s treatment of uncertainty was inconsistent with the legislative policy of the OSH Act. The plurality based its significance requirement on section 3(8), which states that standards must be “reasonably necessary or appropriate to provide safe or healthful employment.” Justice Stevens interpreted section 3(8) to apply to all occupational standards, but failed to examine adequately the relation between that section and section 6(b)(5). The initial version of section 6(b)(5) authorized elimination of any occupational risk of health impairment. Because that provision could be read to require absolute safety, Senator Dominick attempted to delete it. His proposal was not accepted but, in response to the criticisms he and other Senators expressed, the provision was revised to apply to toxic risks of material health impairment. OSHA’s regulatory authority was also restricted by a feasibility requirement. In the benzene case Justice Marshall and Justice Rehnquist, representing between them a majority of the Court, noted that this revision was thought necessary despite the presence of section 3(8) in early versions of the bill. Both Justices concluded that Congress did not believe the general definitional language in section 3(8) limited the more specific mandate in section 6(b)(5).

The plurality opinion relied heavily on Senator Dominick’s statutory interpretations despite his opposition to the Act. However, in describing the compromise version of section 6(b)(5), Senator Dominick concluded that “we would be . . . setting a standard or criterion which would not result in harm.” He added: “what we are doing now is to say that the Secretary has got to use his best efforts to promulgate the best available standards” for “toxic agents or physical agents which might be harmful . . .” There was no intimation in Senator Dominick’s comments that toxic substances regulation should be limited only to situations in which OSHA can show a particular disaggregated risk is more likely than not significant. Rather, for toxic risks, the final version of section 6(b)(5) requires the “highest” feasible degree of

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427. 448 U.S. at 692-93 (Marshall, J., dissenting).
429. 448 U.S. at 676-77 (Rehnquist, J., concurring in the judgment).
430. Id. at 678-79.
432. See id.; 448 U.S. at 679 (Rehnquist, J., concurring in the judgment); id. at 711 (Marshall, J., dissenting).
434. See 448 U.S. at 680-81 (Rehnquist, J., concurring in the judgment); id. at 711 (Marshall, J., dissenting).
435. See id. at 647-50 & nn.52-55.
436. See id. at 647-48 n.52.
437. LEG. HIST., supra note 59, at 502.
438. Id. at 503 (emphasis added).
Justice Stevens attributed the inclusion of a separate provision for toxic substances solely to the long-term nature of the resulting health hazards:

The reason that Congress drafted a special section for these substances was not, as Mr. Justice Marshall suggests, because it thought that there was a need for special protection in these areas. Rather, it was because Congress recognized that there were special problems in regulating health risks as opposed to safety risks. In the latter case, the risks are generally immediate and obvious, while in the former, the risks may not be evident until a worker has been exposed for long periods of time to particular substances. It was to ensure that the Secretary took account of these long-term risks that Congress enacted Sec. 6(b)(5).

This assertion cannot bear careful scrutiny. Congress did recognize the problems posed by delayed or latent harmful effects and by cumulative exposures. However, toxic substances such as benzene can be immediately debilitating or fatal in some cases. Nothing in section 6(b)(5) or the legislative history indicates that Congress intended to discriminate between immediate and deferred toxic consequences. In addition to the long-term problems posed by many toxic chemicals, Congress was concerned with the characteristic seriousness of toxic health hazards, the pervasive uncertainty surrounding them, and the inability of workers to protect themselves from toxic exposures. Moreover, the section 6(b)(5) directive that OSHA consider experience gained “under other health and safety laws” suggests that Congress considered this provision part of a broader campaign to control toxic health hazards. In light of the general legislative pattern of strict regulatory controls for toxic substances, there

440. 448 U.S. at 649 n.54 (1980).
441. See Leg. Hist., supra note 59, at 415, 859.
442. See id. at 338-39, 858.
444. Leg. Hist., supra note 59, at 415:
   A particularly urgent concern repeatedly brought out during our hearings is the frequent exposure of many workers to a great variety of toxic materials or harmful physical agents. They are often unaware of the nature of such exposure or of its extent. In some cases, the consequences of over-exposure may be severe and immediate; in other cases, effects may be delayed or latent.
445. See id. at 142-44, 510, 517, 849.
446. See supra text accompanying notes 345-49 & 364-70.
is no reason to believe Congress meant something other than what it explicitly stated in section 6(b)(5): to the extent feasible, no employee should suffer material health impairment from toxic exposures.

Justice Stevens' characterization of section 6(b)(5) also appears incompatible with his allocation of the burden of proof. If Congress adopted that provision exclusively in response to the long-term nature of toxic problems, congressional intent would not be served by allowing greater than necessary carcinogenic exposures until OSHA can validly estimate disaggregated risks. If, as seems much more likely, section 6(b)(5) was a product of Congress' special concern for control of toxic health hazards, the legislative purpose will best be promoted by allowing the Agency to err on the side of safety when regulating known toxic substances under conditions of uncertainty about the risks associated with particular exposure levels.

Following the benzene case, several elements must be proven before OSHA can regulate a toxic substance. Exposure to occupational health hazards is a prerequisite for subject-matter jurisdiction under the OSH Act. The Agency must also make a threshold determination that an occupational risk is presented by "toxic" materials or harmful physical agents before it can promulgate standards under section 6(b)(5). There is no reason to doubt that OSHA should bear the burden of proof on these initial findings. Neither the "best available evidence" clause nor Congress' special concern for protection against toxic substances are relevant until section 6(b)(5) is determined to apply. The statutory interpretation in the preceding discussion was limited to the decisive issue in the benzene case: given known occupational exposures to a known toxic substance, should OSHA be required to ascertain the degree of toxicity at particular levels of exposure? When the Agency finds that disaggregated risks cannot be estimated in a meaningful way, the imposition on OSHA of any additional burden of proof would be inconsistent with the protective policy of the OSH Act.

The reductive analysis in the benzene case placed the burden of production and proof for all substantive issues on OSHA. Consequently the Supreme Court correctly assigned the burden to the Agency on the threshold issues of toxicity and occupational exposure, but incorrectly required the Agency to estimate disaggregated risks.

450. See McGarity, supra note 2, at 795.
451. 29 U.S.C. § 652(8) (1976). In approving the concept of a labelling requirement for products containing benzene, the Fifth Circuit concluded that the OSH Act was meant to protect all employees, not just those of benzene manufacturers. American Petroleum Inst. v. OSHA, 581 F.2d 493, 508-10 (5th Cir. 1978), aff'd on other grounds sub nom. Industrial Union Dep't, AFL-CIO v. American Petroleum Inst., 448 U.S. 607 (1980).
453. 448 U.S. at 643.
The opposite reductive doctrine would shift the responsibility entirely to industry, correctly assigning the burden of proof on disaggregated risks but misallocating the burden on the issue of toxicity. The evident conclusion is that neither reductive treatment would be satisfactory for regulation under the OSH Act. The preferable approach to legal decisionmaking under uncertainty is to assign the burdens of production and proof separately for discrete factual issues in the manner that best achieves the purposes of the organic legislation.

CONCLUSION

The incorrect result in the benzene case stemmed from three analytical deficiencies: failure to distinguish between insignificant health risks and uncertain risks, failure to accept the Agency’s determination that it cannot estimate disaggregated risks for benzene and other carcinogens, and failure to allocate the burden of uncertainty in a manner compatible with the legislative policy in the OSH Act. The ramifications of the benzene decision are likely to be both widespread and unfortunate. In response to the plurality’s analysis, OSHA amended its generic cancer policy to provide that only significant risks will be regulated. However, no occupational standards for carcinogens have been promulgated since the plurality opinion was published and the Agency has yet to explain how it hopes to prove “significance” in compliance with the Supreme Court’s insistence on disaggregated risk estimates. Congress emphasized the uncertainty surrounding hundreds of potentially toxic substances and the need for protecting employees against these “killers in disguise.” Yet under the benzene decision, OSHA generally will not be able to achieve that congressional objective even after a chemical has been positively identified as carcinogenic. It seems astonishing that the Supreme Court plurality reached this result without attempting to resolve the problems created by uncertainty through a careful interpretation of the OSH Act itself.

Prior to the benzene decision, the dominant judicial response to uncertainty emphasized great deference to agency decisionmaking “on the frontiers of scientific knowledge.” This formulation encourages judicial deference whether or not agencies exercise their discretion in a

455. This inaction cannot be blamed entirely on the benzene decision; the Reagan Administration has assigned a low priority to the promulgation of new standards for carcinogens. See OSHA Shifts Direction on Health Standards, 212 Sci. 1482, 1483 (1981).
456. See supra text accompanying notes 345-59 & 364-70.
457. LEG. HIST., supra note 59, at 517.
458. See, e.g., Ethyl Corp. v. EPA, 541 F.2d 1, 28 (D.C. Cir.) (en banc), cert. denied, 426 U.S. 941 (1976); Society of Plastics Indus., Inc. v. OSHA, 509 F.2d 1301, 1308 (2d Cir. 1975), cert. denied, 421 U.S. 992 (1975); Amoco Oil Co. v. EPA, 501 F.2d 722, 741 (D.C. Cir. 1974); Industrial Union Dep’t. AFL-CIO v. Hodgson, 499 F.2d 467, 474 (D.C. Cir. 1974).
manner that promotes the objectives of the organic legislation.\textsuperscript{459} With regard to the OSH Act, for example, Congress directed that OSHA should not be "paralyzed by debate surrounding diverse medical opinions."\textsuperscript{460} To serve this clear congressional intent, reviewing courts should be deferential when the Agency attempts to promulgate toxic standards despite scientific uncertainty. However, it does not follow that courts should be equally deferential if OSHA demonstrates through a pattern of inaction that it will regulate toxic risks only after all uncertainty is eliminated.\textsuperscript{461} The proper question for reviewing courts is what treatment of uncertainty best comports with the legislative purposes and priorities in particular regulatory programs. Because legislative policies, factual issues and the capabilities of parties vary widely in different regulatory contexts, no reductive treatment of legal decisionmaking under uncertainty can prove acceptable.

\textsuperscript{459} The cases cited in note 495\textsuperscript{supra} involved controversies where regulatory agencies acted aggressively to prevent potential health hazards despite factual uncertainty. \textit{See, e.g.}, Ethyl Corp. v. EPA, 541 F.2d 1, 28 (D.C. Cir.) (\textit{en banc}), cert. denied, 426 U.S. 941 (1976): Where a statute is precautionary in nature, the evidence difficult to come by, uncertain, or conflicting because it is on the frontiers of scientific knowledge, the regulations designed to protect the public health, and the decision that of an expert administrator, we will not demand rigorous step-by-step proof of cause and effect.


\textsuperscript{460} \textit{Leg. Hist.}, supra note 59, at 848.

\textsuperscript{461} OSHA's Director recently justified the Agency's reluctance to promulgate new toxic standards partly on the basis of inadequate knowledge about toxic effects and economic costs. \textit{OSHA Shifts Direction on Health Standards}, 212 \textit{Sci.} 1482, 1483 (1981). Deliberate inaction in the face of uncertainty would conflict with the preventive purpose of the OSH Act, in which Congress recognized the need for strict regulation of toxic substances despite uncertainty, and should be subject to judicial review. \textit{See} NRDC v. Train, 519 F.2d 287 (D.C. Cir. 1975) (EPA required to fully explain its failure to promulgate standards for toxic water pollutants). OSHA's cautious policy has been sharply criticized by J. Donald Millar, director of the National Institute of Occupational Safety and Health, who told OSHA's deputy assistant secretary that the policy is "bad news indeed for those who are interested in preventing work-related cancer." 217 \textit{Sci.} 233 (1982). Millar argued that if OSHA requires evidence of cancer in humans before taking regulatory action, it would be particularly unfortunate for the estimated 1.6 million workers "potentially at risk from exposure to formaldehyde." \textit{Id.}