Syllabus

INDUSTRIAL UNION DEPARTMENT, AFL–CIO v. AMERICAN PETROLEUM INSTITUTE ET AL.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

No. 78–911. Argued October 10, 1979—Decided July 2, 1980*

The Occupational Safety and Health Act of 1970 (Act) delegates broad authority to the Secretary of Labor (Secretary) to promulgate standards to ensure safe and healthful working conditions for the Nation's workers (the Occupational Safety and Health Administration (OSHA) being the agency responsible for carrying out this authority). Section 3 (8) of the Act defines an "occupational safety and health standard" as a standard that is "reasonably necessary or appropriate to provide safe or healthful employment." Where toxic materials or harmful physical agents are concerned, a standard must also comply with § 6 (b) (5), which directs the Secretary to "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" When the toxic material or harmful physical agent to be regulated is a carcinogen, the Secretary has taken the position that no safe exposure level can be determined and that § 6 (b) (5) requires him to set an exposure limit at the lowest technologically feasible level that will not impair the viability of the industries regulated. In this case, after having determined that there is a causal connection between benzene (a toxic substance used in manufacturing such products as motor fuels, solvents, detergents, and pesticides) and leukemia (a cancer of the white blood cells), the Secretary promulgated a standard reducing the permissible exposure limit on airborne concentrations of benzene from the consensus standard of 10 parts benzene per million parts of air (10 ppm) to 1 ppm, and prohibiting dermal contact with solutions containing benzene. On pre-enforcement review, the Court of Appeals held the standard invalid because it was based on findings unsupported by the administrative record. The court concluded that OSHA had exceeded its standard-setting authority because it had not been shown that the 1 ppm exposure limit was "reasonably necessary or appropriate to provide safe and healthful employment" as required by § 3 (8), and that

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*Together with No. 78–1036, *Marshall, Secretary of Labor* v *American Petroleum Institute et al.*, also on certiorari to the same court.

§ 6 (b) (5) did not give OSHA the unbridled discretion to adopt standards designed to create absolutely risk-free workplaces regardless of cost.

Held. The judgment is affirmed. Pp. 630–662; 667–671, 672–688.

581 F 2d 493, affirmed.

MR. JUSTICE STEVENS, joined by MR. CHIEF JUSTICE BURGER, MR. JUSTICE STEWART, and MR. JUSTICE POWELL, concluded that the standard in question is invalid. Pp. 630–652, 658–659.

(a) The Court of Appeals was correct in refusing to enforce the 1 ppm exposure limit on the ground that it was not supported by appropriate findings. OSHA's rationale for lowering the permissible exposure limit from 10 ppm to 1 ppm was based, not on any finding that leukemia has ever been caused by exposure to 10 ppm of benzene and that it will *not* be caused by exposure to 1 ppm, but rather on a series of assumptions indicating that some leukemia might result from exposure to 10 ppm and that the number of cases might be reduced by lowering the exposure level to 1 ppm. Pp. 630–638.

(b) By empowering the Secretary to promulgate standards that are "reasonably necessary or appropriate to provide safe or healthful employment and places of employment" as required by § 3 (8), the Act implies that, before promulgating any standard, the Secretary must make a finding that the workplaces in question are not safe. But "safe" is not the equivalent of "risk-free." A workplace can hardly be considered "unsafe" unless it threatens the workers with a significant risk of harm. Therefore, before the Secretary can promulgate *any* permanent health or safety standard, he must make a threshold finding that the place of employment is unsafe in the sense that significant risks are present and can be eliminated or lessened by a change in practices. This requirement applies to permanent standards promulgated pursuant to § 6 (b) (5), as well as to other types of permanent standards, there being no reason why § 3 (8)'s definition of a standard should not be deemed incorporated by reference into § 6 (b) (5). Moreover, requiring the Secretary to make a threshold finding of significant risk is consistent with the scope of his regulatory power under § 6 (b) (5) to promulgate standards for "*toxic* materials" and "*harmful* physical agents." This interpretation is supported by other provisions of the Act, such as § 6 (g), which requires the Secretary, in determining the priority for establishing standards, to give due regard to the urgency of the need for mandatory safety and health standards for particular industries or workplaces, and § 6 (b) (8), which requires the Secretary, when he substantially alters an

existing consensus standard, to explain how the new rule will "better effectuate" the Act's purposes. Pp. 639–646.

(c) The Act's legislative history also supports the conclusion that Congress was concerned, not with absolute safety, but with the elimination of significant harm. Pp. 646–652.

(d) Where the Secretary relied on a special policy for carcinogens that imposed the burden on industry of proving the existence of a safe level of exposure, thereby avoiding his threshold responsibility of establishing the need for more stringent standards, he exceeded his power. Pp. 658–659.

MR. JUSTICE STEVENS, joined by MR. CHIEF JUSTICE BURGER and MR. JUSTICE STEWART, also concluded that:

1. The burden was on OSHA 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 material health impairment. Here, OSHA did not even attempt to carry such burden of proof. Imposing such a burden on OSHA will not strip it of its ability to regulate carcinogens, nor will it require it to wait for deaths to occur before taking any action. The requirement that a "significant" risk be identified is not a mathematical straitjacket; OSHA is not required to support its finding that a significant risk exists with anything approaching scientific certainty; and the record in this case and OSHA's own rulings on other carcinogens indicate that there are a number of ways in which OSHA can make a rational judgment about the relative significance of the risks associated with exposure to a particular carcinogen. Pp. 652–658.

2. OSHA did not make the required finding with respect to the dermal contact ban that the ban was "reasonably necessary and appropriate" to remove a significant risk of harm from such contact, but rather acted on the basis of the absolute, no-risk policy that it applies to carcinogens under the assumptions not only that benzene in small doses is a carcinogen but also that it can be absorbed through the skin in sufficient amounts to present a carcinogenic risk. These assumptions are not a proper substitute for the findings of significant risk of harm required by the Act. Pp. 659–662.

MR. JUSTICE POWELL, agreeing that neither the airborne concentration standard nor the dermal contact standard satisfied the Act's requirements, would not hold that OSHA did not even attempt to carry its burden of proof on the threshold question whether exposure to benzene at 10 ppm presents a significant risk to human health. He concluded that, even assuming OSHA had met such burden, the Act also requires OSHA to determine that the economic effects of its standard bear a

reasonable relationship to the expected benefits. A standard is neither "reasonably necessary" nor "feasible," as required by the Act, if it calls for expenditures wholly disproportionate to the expected health and safety benefits. Here, although OSHA did find that the "substantial costs" of the benzene regulations were justified, the record contains neither adequate documentation of this conclusion nor any evidence that OSHA weighed the relevant considerations. The agency simply announced its finding of cost-justification without explaining the method by which it determined that the benefits justified the costs and their economic effects. Pp. 667–671.

MR. JUSTICE REHNQUIST would invalidate, as constituting an invalid delegation of legislative authority to the Secretary, the relevant portion of § 6 (b) (5) of the Act as it applies to any toxic substance or harmful physical agent for which a safe level is, according to the Secretary, unknown or otherwise "infeasible." In the case of such substances, the language of § 6 (b) (5) gives the Secretary absolutely no indication where on the continuum of relative safety he should set the standard. Nor is there anything in the legislative history, the statutory context, or any other source traditionally examined by this Court that provides specificity to the feasibility criterion in § 6 (b) (5) Pp. 672–688.

STEVENS, J., announced the judgment of the Court and delivered an opinion, in which BURGER, C. J., and STEWART, J., joined, and in Parts I, II, III–A, III–B, III–C, and III–E of which POWELL, J., joined. BURGER, C. J., filed a concurring opinion, *post*, p. 662. POWELL, J., filed an opinion concurring in part and concurring in the judgment, *post*, p. 664. REHNQUIST, J., filed an opinion concurring in the judgment, *post*, p. 671. MARSHALL, J., filed a dissenting opinion, in which BRENNAN, WHITE, and BLACKMUN, JJ., joined, *post*, p. 688.

George H Cohen argued the cause for petitioner in No. 78–911. With him on the briefs were *Robert M Weinberg, J Albert Woll, Laurence Gold, Elliot Bredhoff,* and *George Kaufmann. William Alsup* argued the cause for petitioner in No. 78–1036. With him on the briefs were *Solicitor General McCree, Deputy Solicitor General Easterbrook, Benjamin W Mintz,* and *Dennis K. Kade.*

Edward W Warren argued the cause for respondents American Petroleum Institute et al. in both cases. With him on the brief were *Stark Ritchie, Martha Beauchamp, Neil J King,*

John H. Pickering, Robert R. Bonczek, John F Dickey, Robert L. Ackerly, and *Harold B. Scoggins, Jr Charles F Lettow* argued the cause for respondents Rubber Manufacturers Association, Inc., et al. in both cases. With him on the brief was *John C Murphy, Jr.*†

MR. JUSTICE STEVENS announced the judgment of the Court and delivered an opinion, in which THE CHIEF JUSTICE and MR. JUSTICE STEWART joined and in Parts I, II, III–A, III–B, III–C, and III–E of which MR. JUSTICE POWELL joined.

The Occupational Safety and Health Act of 1970 (Act), 84 Stat. 1590, 29 U S. C. § 651 *et seq.,* was enacted for the purpose of ensuring safe and healthful working conditions for every working man and woman in the Nation. This litigation concerns a standard promulgated by the Secretary of Labor to regulate occupational exposure to benzene, a substance which has been shown to cause cancer at high exposure levels. The principal question is whether such a showing is a sufficient basis for a standard that places the most stringent limitation on exposure to benzene that is technologically and economically possible.

The Act delegates broad authority to the Secretary to promulgate different kinds of standards. The basic definition

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†Briefs of *amici curiae* urging reversal were filed by *John A. Fillion* for the International Union, United Automobile, Aerospace and Agricultural Implement Workers of America, and by *Richard E. Ayres* for the Natural Resources Defense Council, Inc.

Briefs of *amici curiae* urging affirmance were filed by *Alfred V J Prather* for Anaconda Co., by *Anthony J Obadal* and *Stephen C. Yohay* for the Capital Legal Foundation, and by *Robert V Zener, Stephen A. Bokat,* and *William L. Kovacs* for the Chamber of Commerce of the United States.

Briefs of *amici curiae* were filed by *William J Kilberg, Thaddeus Holt,* and *Lawrence Z. Lorber* for ASARCO Inc., by *David B. Robinson* for the Chocolate Manufacturers Association; and by *James R. Richards* for Joseph Cimino et al.

of an "occupational safety and health standard" is found in § 3 (8), which provides:

> "The term 'occupational safety and health standard' means a standard which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment." 84 Stat. 1591, 29 U. S. C. § 652 (8).

Where toxic materials or harmful physical agents are concerned, a standard must also comply with § 6 (b)(5), which provides:

> "The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, 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 such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws." 84 Stat. 1594, 29 U S. C. § 655 (b)(5).[1]

[1] The second and third sentences of this section, which impose feasibility limits on the Secretary and allow him to take into account the best available evidence in developing standards, may apply to all health and safety standards. This conclusion follows if the term "subsection" used in the second sentence refers to the entire subsection 6 (b) (which sets out procedures for the adoption of all types of health and safety standards), rather than simply to the toxic materials subsection, § 6 (b)(5). While MR. JUSTICE MARSHALL, *post*, at 694, and respondents agree with this

Wherever the toxic material to be regulated is a carcinogen, the Secretary has taken the position that no safe exposure level can be determined and that § 6 (b)(5) requires him to set an exposure limit at the lowest technologically feasible level that will not impair the viability of the industries regulated. In this case, after having determined that there is a causal connection between benzene and leukemia (a cancer of the white blood cells), the Secretary set an exposure limit on airborne concentrations of benzene of one part benzene per million parts of air (1 ppm), regulated dermal and eye contact with solutions containing benzene, and imposed complex monitoring and medical testing requirements on employers whose workplaces contain 0.5 ppm or more of benzene. 29 CFR §§ 1910.1028 (c), (e) (1979)

On pre-enforcement review pursuant to 29 U S. C. § 655 (f), the United States Court of Appeals for the Fifth Circuit held the regulation invalid. *American Petroleum Institute* v *OSHA*, 581 F 2d 493 (1978) The court concluded that the Occupational Safety and Health Administration (OSHA) [2] had exceeded its standard-setting authority because it had not shown that the new benzene exposure limit was "reasonably necessary or appropriate to provide safe or healthful employment" as required by § 3 (8),[3] and because § 6 (b)(5)

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position, see Brief for Respondents American Petroleum Institute et al. 39; see also Currie, OSHA, 1976 Am. Bar Found. Research J. 1107, 1137, n. 151, the Government does not, see Brief for Federal Parties 58; see also Berger & Riskin, Economic and Technological Feasibility in Regulating Toxic Substances Under the Occupational Safety and Health Act, 7 Ecology L. Q. 285, 294 (1978). There is no need for us to decide this issue in these cases.

[2] OSHA is the administrative agency within the Department of Labor that is responsible for promulgating and enforcing standards under the Act. In this opinion, we refer to the "Secretary," "OSHA" and the "Agency" interchangeably

[3] "The Act imposes on OSHA the obligation to enact only standards that are reasonably necessary or appropriate to provide safe or healthful workplaces. If a standard does not fit in this definition, it is not one that OSHA is authorized to enact." 581 F 2d, at 502.

does "not give OSHA the unbridled discretion to adopt standards designed to create absolutely risk-free workplaces regardless of costs." [4] Reading the two provisions together, the Fifth Circuit held that the Secretary was under a duty to determine whether the benefits expected from the new standard bore a reasonable relationship to the costs that it imposed. *Id.*, at 503. The court noted that OSHA had made an estimate of the costs of compliance, but that the record lacked substantial evidence of any discernible benefits.[5]

We agree with the Fifth Circuit's holding that § 3 (8) requires the Secretary to find, as a threshold matter, that the

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[4] "Although 29 U. S. C. A. § 655 (b) (5) requires the goal of attaining the highest degree of health and safety protection for the employee, it does not give OSHA the unbridled discretion to adopt standards designed to create absolutely risk-free workplaces regardless of cost. To the contrary, that section requires standards to be feasible, and it contains a number of pragmatic limitations in the form of specific kinds of information OSHA must consider in enacting standards dealing with toxic materials. Those include 'the best available evidence,' 'research, demonstrations, experiments, and such other information as may be appropriate,' 'the latest available scientific data in the field,' and 'experience gained under this and other health and safety laws.' Moreover, in standards dealing with toxic materials, just as with all other occupational safety and health standards, the conditions and other requirements imposed by the standard must be 'reasonably necessary or appropriate to provide safe or healthful employment and places of employment.' 29 U. S. C. A. § 652 (8)." *Ibid.*

[5] "The lack of substantial evidence of discernable benefits is highlighted when one considers that OSHA is unable to point to any empirical evidence documenting a leukemia risk at 10 ppm even though that has been the permissible exposure limit since 1971. OSHA's assertion that benefits from reducing the permissible exposure limit from 10 ppm to 1 ppm are likely to be appreciable, an assumption based only on inferences drawn from studies involving much higher exposure levels rather than on studies involving these levels or sound statistical projections from the high-level studies, does not satisfy the reasonably necessary requirement limiting OSHA's action. *Aqua Slide* requires OSHA to estimate the extent of expected benefits in order to determine whether those benefits bear a reasonable relationship to the standard's demonstrably high costs." *Id.*, at 503–504.

toxic substance in question poses a significant health risk in the workplace and that a new, lower standard is therefore "reasonably necessary or appropriate to provide safe or healthful employment and places of employment." Unless and until such a finding is made, it is not necessary to address the further question whether the Court of Appeals correctly held that there must be a reasonable correlation between costs and benefits, or whether, as the federal parties argue, the Secretary is then required by § 6 (b)(5) to promulgate a standard that goes as far as technologically and economically possible to eliminate the risk.

Because these are unusually important cases of first impression, we have reviewed the record with special care. In this opinion, we (1) describe the benzene standard, (2) analyze the Agency's rationale for imposing a 1 ppm exposure limit, (3) discuss the controlling legal issues, and (4) comment briefly on the dermal contact limitation.

I

Benzene is a familiar and important commodity It is a colorless, aromatic liquid that evaporates rapidly under ordinary atmospheric conditions. Approximately 11 billion pounds of benzene were produced in the United States in 1976. Ninety-four percent of that total was produced by the petroleum and petrochemical industries, with the remainder produced by the steel industry as a byproduct of coking operations. Benzene is used in manufacturing a variety of products including motor fuels (which may contain as much as 2% benzene), solvents, detergents, pesticides, and other organic chemicals. 43 Fed. Reg. 5918 (1978).

The entire population of the United States is exposed to small quantities of benzene, ranging from a few parts per billion to 0.5 ppm, in the ambient air. Tr. 1029–1032. Over one million workers are subject to additional low-level exposures as a consequence of their employment. The majority of these employees work in gasoline service stations, benzene

production (petroleum refineries and coking operations), chemical processing, benzene transportation, rubber manufacturing, and laboratory operations.[6]

Benzene is a toxic substance. Although it could conceivably cause harm to a person who swallowed or touched it, the principal risk of harm comes from inhalation of benzene vapors. When these vapors are inhaled, the benzene diffuses through the lungs and is quickly absorbed into the blood.

[6] OSHA's figures indicate that 795,000 service station employees have some heightened exposure to benzene as a result of their employment. See 2 U. S. Dept. of Labor, OSHA, Technology Assessment and Economic Impact Study of an OSHA Regulation for Benzene, p. D–7 (May 1977) (hereinafter Economic Impact Statement), 11 Record, Ex. 5B, p. D–7 These employees are specifically excluded from the regulation at issue in this case. See *infra*, at 628. OSHA states that another 629,000 employees, who are covered by the regulation, work in the other industries described. 43 Fed. Reg. 5935 (1978).

It is not clear from the record or its explanation of the permanent standard how OSHA arrived at the estimate of 629,000 exposed employees. OSHA's consultant, Arthur D Little, Inc., estimated that there were 191,000 exposed employees, 30,000 of whom were exposed to 1 ppm or more of benzene. 1 Economic Impact Statement, p. 3–5, 11 Record, Ex. 5A, p. 3–5. In its explanation of the permanent standard OSHA stated that there were 1,440 exposed employees who worked in benzene plants, 98,000 in other petroleum refineries, 24,000 in coke ovens, 4,000 in light oil plants, 2,760 in the petrochemical industry, 52,345 who worked in bulk terminals, 23,471 drivers who loaded benzene from those terminals, 74,000 in oil and gas production, 17,000 in pipeline work, 100 at tank-car facilities, 200 at tank-truck facilities, 480 on barges, 11,400 in tire-manufacturing plants, and 13,050 in other types of rubber production. 43 Fed. Reg. 5936–5938 (1978). Although OSHA gave no estimate for laboratory workers, the A. D. Little study indicated that there were 25,000 exposed workers in that industry These figures add up to 347,246 exposed employees—approximately 282,000 less than the overall estimate of 629,000. It is possible that some or all of these employees work in the "other industries" briefly described in OSHA's explanation; these are primarily small firms that manufacture adhesives, paint and ink or that use benzene solvents. *Id.*, at 5939. No estimate of the number of exposed employees in those industries or the aggregate cost of compliance by those industries is given either by OSHA or by A. D Little in its consulting report.

Exposure to high concentrations produces an almost immediate effect on the central nervous system. Inhalation of concentrations of 20,000 ppm can be fatal within minutes, exposures in the range of 250 to 500 ppm can cause vertigo, nausea, and other symptoms of mild poisoning. 43 Fed. Reg. 5921 (1978) Persistent exposures at levels above 25–40 ppm may lead to blood deficiencies and diseases of the blood-forming organs, including aplastic anemia, which is generally fatal.

Industrial health experts have long been aware that exposure to benzene may lead to various types of nonmalignant diseases. By 1948 the evidence connecting high levels of benzene to serious blood disorders had become so strong that the Commonwealth of Massachusetts imposed a 35 ppm limitation on workplaces within its jurisdiction. In 1969 the American National Standards Institute (ANSI) adopted a national consensus standard of 10 ppm averaged over an 8-hour period with a ceiling concentration of 25 ppm for 10-minute periods or a maximum peak concentration of 50 ppm. *Id.*, at 5919. In 1971, after the Occupational Safety and Health Act was passed, the Secretary adopted this consensus standard as the federal standard, pursuant to 29 U S. C. § 655 (a) [7]

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[7] Section 6 (a) of the Act, as set forth in 29 U. S. C. § 655 (a), provides:

"Without regard to chapter 5 of Title 5 or to the other subsections of this section, the Secretary shall, as soon as practicable during the period beginning with the effective date of this chapter and ending two years after such date, by rule promulgate as an occupational safety or health standard any national consensus standard, and any established Federal standard, unless he determines that the promulgation of such a standard would not result in improved safety or health for specifically designated employees. In the event of conflict among any such standards, the Secretary shall promulgate the standard which assures the greatest protection of the safety or health of the affected employees."

In this case the Secretary complied with the directive to choose the most protective standard by selecting the ANSI standard of 10 ppm, rather than the 25 ppm standard adopted by the American Conference of Government Industrial Hygienists. 43 Fed. Reg. 5919 (1978).

As early as 1928, some health experts theorized that there might also be a connection between benzene in the workplace and leukemia.[8] In the late 1960's and early 1970's a number of epidemiological studies were published indicating that workers exposed to high concentrations of benzene were subject to a significantly increased risk of leukemia.[9] In a 1974 report recommending a permanent standard for benzene, the National Institute for Occupational Safety and Health

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[8] See Delore & Borgomano, Leucemie aiguë au cours de l'intoxication benzenique. Sur l'origine toxique de certaines leucemies aiguës et leurs relations avec les anemies graves, 9 Journal de Medécine de Lyon 227 (1928). A translation of that document appears in the benzene administrative record. 2 Record, Ex. 2–60. See also Hunter, Chronic Exposure to Benzene (Benzol). II. The Clinical Effects, 21 J. Ind. Hyg. & Toxicol. 331 (1939), 3 Record, Ex. 2–74, which refers to "leucemia" as a side effect of chronic exposure to benzene.

[9] Dr. Muzaffer Aksoy, a Turkish physician who testified at the hearing on the proposed benzene standard, did a number of studies concerning the effects of benzene exposure on Turkish shoemakers. The workers in Dr. Aksoy's studies used solvents containing large percentages of benzene and were constantly exposed to high concentrations of benzene vapors (between 150 and 650 ppm) under poorly ventilated and generally unhygienic conditions. See Aksoy, Acute Leukemia Due to Chronic Exposure to Benzene, 52 Am. J. of Medicine 160 (1972), 1 Record, Ex. 2–29; Aksoy, Benzene (Benzol) Its Toxicity and Effects on the Hematopoietic System, Istanbul Faculty of Medicine Monograph Series No. 51 (1970), 2 Record, Ex. 2–55, Aksoy, Erdem, & DinCol, Leukemia in Shoe-Workers Exposed Chronically to Benzene, 44 Blood 837 (1974), 2 Record, Ex. 2–53 (reporting on 26 shoeworkers who had contracted leukemia from 1967 to 1973, this represented an incidence of 13 per 100,000 rather than the 6 cases per 100,000 that would normally be expected).

Dr. Enrico Vigliani also reported an excess number of leukemia cases among Italian shoemakers exposed to glues containing a high percentage of benzene and workers in rotogravure plants who had been exposed over long periods of time to inks and solvents containing as much as 60% benzene. See Vigliani & Saita, Benzene and Leukemia, 271 New Eng. J. of Medicine 872–876 (1964), 1 Record, Ex. 2–27, Forni & Vigliani, Chemical Leukemogenesis in Man, 7 Ser. Haemat. 211 (1974), 2 Record, Ex. 2–50.

(NIOSH), OSHA's research arm,[10] noted that these studies raised the "distinct possibility" that benzene caused leukemia. But, in light of the fact that all known cases had occurred at very high exposure levels, NIOSH declined to recommend a change in the 10 ppm standard, which it considered sufficient to protect against nonmalignant diseases. NIOSH suggested that further studies were necessary to determine conclusively whether there was a link between benzene and leukemia and, if so, what exposure levels were dangerous.[11]

Between 1974 and 1976 additional studies were published which tended to confirm the view that benzene can cause leukemia, at least when exposure levels are high.[12] In an

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[10] Title 29 U. S. C. § 669 (a)(3) requires the Department of Health, Education, and Welfare (HEW) (now in part the Department of Health and Human Services) to develop "criteria" dealing with toxic materials and harmful physical agents that describe "exposure levels that are safe for various periods of employment." HEW's obligations under this section have been delegated to NIOSH, 29 U. S. C. § 671.

[11] See Dept. of HEW, NIOSH, Criteria for a Recommended Standard—Occupational Exposure to Benzene 74–75 (Pub. No. 74–137, 1974), 1 Record, Ex. 2–3. In response to a letter from the Director of the Office of Standards Division, NIOSH stated that its 10 ppm standard was designed to protect against leukemia, as well as other health risks. NIOSH noted, however, that further research was necessary in order to establish adequate dose-response data for benzene and leukemia. 12 Record, Ex. 32A, 32B.

[12] Aksoy published another study in 1976 reporting on an additional eight leukemia cases uncovered after 1973. In that article, he also noted that a 1969 ban on the use of benzene as a solvent had led to a decline in the number of reported leukemia cases beginning in 1974. Aksoy, Types of Leukemia in Chronic Benzene Poisoning, 55 Acta Haematologica 65 (1976), 1 Record, Ex. 2–30. Vigliani also noted a decline in leukemia cases in Italy after benzene was no longer used in glues and inks. See Vigliani & Forni, Benzene and Leukemia, 11 Environmental Res. 122 (1976), 1 Record, Ex. 2–15, Vigliani, Leukemia Associated with Benzene Exposure, 271 Annals N. Y. Acad. of Sciences 143 (1976), 2 Record, Ex. 2–49. In the latter study Vigliani noted that in the past 100% pure ben-

August 1976 revision of its earlier recommendation, NIOSH stated that these studies provided "conclusive" proof of a causal connection between benzene and leukemia. 1 Record, Ex. 2–5, p. 100. Although it acknowledged that none of the intervening studies had provided the dose-response data it had found lacking two years earlier, *id.*, at 9, NIOSH nevertheless recommended that the exposure limit be set as low as possible. As a result of this recommendation, OSHA contracted with a consulting firm to do a study on the costs to industry of complying with the 10 ppm standard then in effect or, alternatively, with whatever standard would be the lowest feasible. Tr. 505–506.

In October 1976, NIOSH sent another memorandum to OSHA, seeking acceleration of the rulemaking process and "strongly" recommending the issuance of an emergency temporary standard pursuant to § 6 (c) of the Act, 29 U S. C. § 655 (c),[13] for benzene and two other chemicals believed to

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zene solvents had been used and workers had been exposed on a prolonged basis to concentrations of 200–500 ppm, with peaks of up to 1500 ppm.

A number of epidemiological studies were also done among American rubber workers during this period. Dr. A. J. McMichael's studies indicated a ninefold increase in the risk of contracting leukemia among workers who were heavily exposed in the 1940's and 1950's to pure benzene used as a solvent. McMichael, Spirtas, Kupper, & Gamble, Solvent Exposure and Leukemia Among Rubber Workers: An Epidemiologic Study, 17 J. of Occup. Med. 234, 238 (1975), 2 Record, Ex. 2–37 See also Andjelkovic, Taulbee, & Symons, Mortality Experience of a Cohort of Rubber Workers, 1964–1973, 18 J. of Occup. Med. 387 (1976), 2 Record, Ex. 2–54 (also indicating an excess mortality rate from leukemia among rubber workers).

[13] Section 655 (c) provides:

"(1) The Secretary shall provide, without regard to the requirements of chapter 5 of title 5, for an emergency temporary standard to take immediate effect upon publication in the Federal Register if he determines (A) that employees are exposed to grave danger from exposure to substances or agents determined to be toxic or physically harmful or from

be carcinogens. NIOSH recommended that a 1 ppm exposure limit be imposed for benzene.[14] 1 Record, Ex. 2–6. Apparently because of the NIOSH recommendation, OSHA asked its consultant to determine the cost of complying with a 1 ppm standard instead of with the "minimum feasible" standard. Tr. 506–507 It also issued voluntary guidelines for benzene, recommending that exposure levels be limited to 1 ppm on an 8-hour time-weighted average basis wherever possible. 2 Record, Ex. 2–44.

In the spring of 1976, NIOSH had selected two Pliofilm plants in St. Marys and Akron, Ohio, for an epidemiological study of the link between leukemia and benzene exposure. In April 1977, NIOSH forwarded an interim report to OSHA indicating at least a fivefold increase in the expected incidence of leukemia for workers who had been exposed to ben-

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new hazards, and (B) that such emergency standard is necessary to protect employees from such danger.

"(2) Such standard shall be effective until superseded by a standard promulgated in accordance with the procedures prescribed in paragraph (3) of this subsection.

"(3) Upon publication of such standard in the Federal Register the Secretary shall commence a proceeding in accordance with subsection (b) of this section, and the standard as published shall also serve as a proposed rule for the proceeding. The Secretary shall promulgate a standard under this paragraph no later than six months after publication of the emergency standard as provided in paragraph (2) of this subsection."

[14] At the hearing on the permanent standard NIOSH representatives testified that they had selected 1 ppm initially in connection with the issuance of a proposed standard for vinyl chloride. In that proceeding they had discovered that 1 ppm was approximately the lowest level detectable through the use of relatively unsophisticated monitoring instruments. With respect to benzene, they also thought that 1 ppm was an appropriate standard because any lower standard might require the elimination of the small amounts of benzene (in some places up to 0.5 ppm) that are normally present in the atmosphere. Tr. 1142–1143. NIOSH's recommendation was *not* based on any evaluation of the feasibility, either technological or economic, of eliminating all exposures above 1 ppm. *Id.*, at 1156.

zene at the two plants from 1940 to 1949.[15] The report submitted to OSHA erroneously suggested that exposures in the two plants had generally been between zero and 15 ppm during the period in question.[16] As a result of this new evidence

[15] Seven fatalities from leukemia were discovered out of the 748 workers surveyed. However, Dr. Infante, who conducted the study, stated that his statistical techniques had probably underestimated the number of leukemia cases that had actually occurred. *Id.*, at 747 The normal expected incidence of leukemia in such a population would be 1.4. 2 Record, Ex. 2–51, p. 6.

[16] The authors' statement with respect to exposure levels was based on a 1946 report by the Ohio Industrial Commission indicating that, after some new ventilation equipment had been installed, exposures at the St. Marys plant had been brought within "safe" limits, in most instances ranging from zero to 10 to 15 ppm. *Id.*, at 3. As the authors later admitted, the level considered "safe" in 1946 was 100 ppm. Tr. 814–815. Moreover, only one of the seven workers who died of leukemia had begun working at St. Marys after 1946. Five of the others had worked at the Akron plant, which employed 310 of the 748 workers surveyed. *Id.*, at 2537–2538. A 1948 report by the Ohio Department of Health indicated exposure levels at the Akron plant of well over 100 ppm, with excursions in some areas up tc 1,000 ppm. 17 Record, Ex. 84A, App. A, pp. 61–62. Surveys taken in the intervening years, as well as testimony by St. Marys employees at the hearing on the proposed standard, Tr. 3432–3437, indicated that both of the plants may have had relatively high exposures through the 1970's.

Industry representatives argued at the hearing that this evidence indicated that the exposure levels had been very high, as they had been in the other epidemiological studies conducted in the past. See Post-Hearing Brief for American Petroleum Institute in No. H–059 (OSHRC), pp. 23–37, 31 Record, Ex. 217–33, pp. 23–37 NIOSH witnesses, however, simply stated that actual exposure levels for the years in question could not be determined, they did agree, however, that their study should *not* be taken as proof of a fivefold increase in leukemia risk at 10–15 ppm. Tr. 814–815. In its explanation of the permanent standard, OSHA agreed with the NIOSH witnesses that no dose-response relationship could be inferred from the study·

"Comments at the hearing demonstrated that there were area exposures during this study period exceeding these levels [10–15 ppm], at times reaching values of hundreds of parts per million. Since no personal moni-

and the continued prodding of NIOSH, 1 Record, Ex. 2–7, OSHA did issue an emergency standard, effective May 21, 1977, reducing the benzene exposure limit from 10 ppm to 1 ppm, the ceiling for exposures of up to 10 minutes from 25 ppm to 5 ppm, and eliminating the authority for peak concentrations of 50 ppm. 42 Fed. Reg. 22516 (1977) In its explanation accompanying the emergency standard, OSHA stated that benzene had been shown to cause leukemia at exposures below 25 ppm and that, in light of its consultant's report, it was feasible to reduce the exposure limit to 1 ppm. *Id.*, at 22517, 22521.

On May 19, 1977, the Court of Appeals for the Fifth Circuit entered a temporary restraining order preventing the emergency standard from taking effect. Thereafter, OSHA abandoned its efforts to make the emergency standard effective and instead issued a proposal for a permanent standard patterned almost entirely after the aborted emergency standard. *Id.*, at 27452.

In its published statement giving notice of the proposed permanent standard, OSHA did not ask for comments as to whether or not benzene presented a significant health risk at exposures of 10 ppm or less. Rather, it asked for comments as to whether 1 ppm was the minimum feasible exposure limit.[17] *Ibid.* As OSHA's Deputy Director of Health Standards, Grover Wrenn, testified at the hearing, this formulation

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toring data are available, any conclusion regarding the actual individual time-weighted average exposure is speculative. Because of the lack of definitive exposure data, OSHA cannot derive any conclusions linking the excess leukemia risk observed with any specific exposure level." 43 Fed. Reg. 5927 (1978).

[17] OSHA also sought public comment as to whether certain industries should be exempt from compliance, whether the proposed compliance procedures and labeling techniques were adequate, what the environmental and economic consequences of the regulation would be, and whether it was feasible to replace benzene in solvents and other products of which it constituted more than 1%.

of the issue to be considered by the Agency was consistent with OSHA's general policy with respect to carcinogens.[18] Whenever a carcinogen is involved, OSHA will presume that no safe level of exposure exists in the absence of clear proof establishing such a level and will accordingly set the exposure limit at the lowest level feasible.[19] The proposed 1 ppm ex-

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[18] It became clear at the hearing that OSHA had not promulgated the proposed standard in response to any new concern about the nonmalignant effects of low-level benzene exposure. See Tr. 126–127

"Is it accurate to say that the reason why the—why OSHA has proposed to reduce the exposure limits in the standard below the current levels is because of a perceived risk of leukemia, and not because of any new evidence it has received that the current standards are inadequate to protect against acute or chronic benzene toxicity, other than leukemia?

"MR. WRENN I think I will simply refer the part of my statement you were referring to, in which it says, it is however benzene's leukemogenicity which is of greatest concern to OSHA. That is certainly the central issue within the ETS [emergency temporary standard] and the proposed standard."

[19] Mr. Wrenn testified:

"The proposed standard requires that employee exposure to benzene in air be reduced to one part per million, with a five part per million ceiling allowable over any fifteen minute period during an eight hour work shift, and prohibits eye or prolonged skin contact with liquid benzene.

"This airborne exposure limit is based on OSHA's established regulatory policy, that in the absence of a demonstrated safe level, or a no effect level for a carcinogen, it will be assumed that none exist, and that the agency will attempt to limit employee exposure to the lowest level feasible." *Id.*, at 29–30.

See also:

"MR. WARREN Mr. Wrenn, in promulgating the emergency temporary, and proposed permanent, benzene standards, OSHA relies heavily, and I am quoting from your testimony now, on the regulatory policy that there is no safe level for carcinogens at any—for any exposed population, and the fact that leukemia, and a leukemogen is a carcinogen, is that correct?

"MR. WRENN I believe that I stated that slightly differently in my oral summary of the statement than it is stated in the statement itself. I said that in the absence of a known or demonstrated safe level or no

posure limit in this case thus was established not on the basis of a proven hazard at 10 ppm, but rather on the basis of "OSHA's best judgment at the time of the proposal of the feasibility of compliance with the proposed standard by the [a]ffected industries." Tr. 30. Given OSHA's cancer policy, it was in fact irrelevant whether there was any evidence at all of a leukemia risk at 10 ppm. The important point was that there was no evidence that there was *not* some risk, however small, at that level. The fact that OSHA did not ask for comments on whether there was a safe level of exposure for benzene was indicative of its further view that a demonstration of such absolute safety simply could not be made.[20]

Public hearings were held on the proposed standard, commencing on July 19, 1977 The final standard was issued on February 10, 1978. 29 CFR § 1910.1028 (1979).[21] In its final form, the benzene standard is designed to protect workers from whatever hazards are associated with low-level benzene

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effect level, our policy is to assume that none exists, and to regulate accordingly" *Id.*, at 48–49.

"MR. WRENN I would prefer to state it as I have on a couple of occasions already this morning, and that in the absence of a demonstrated safe level of exposure, we will assume that none exists for the purpose of regulatory policy." *Id.*, at 50.

[20] In answer to the question of what demonstration would suffice to establish a "safe level," Mr. Wrenn stated:

"I would like to draw a distinction, however, between what I have referred to as the demonstration that a safe level exists, and speculation or elaborate theories that one may make, and I think that the agency in its history and very likely its future regulatory policy, would, in the face of evidence demonstrating that a carcinogenic hazard does exist or did exist, in this particular set of circumstances, would be very reluctant to accept as the basis for its regulatory decisions, a theoretical argument that a safe level may, in fact, exist for a particular substance." *Id.*, at 51–52.

A NIOSH representative who testified later put it more succinctly, stating that " if benzene causes leukemia, and if leukemia is a cancer, then exposure really is almost moot." *Id.*, at 1007

[21] An amendment to the standard was promulgated on June 27, 1978. 43 Fed. Reg. 27962. See n. 22, *infra.*

exposures by requiring employers to monitor workplaces to determine the level of exposure, to provide medical examinations when the level rises above 0.5 ppm, and to institute whatever engineering or other controls are necessary to keep exposures at or below 1 ppm.

In the standard as originally proposed by OSHA, the employer's duty to monitor, keep records, and provide medical examinations arose whenever *any* benzene was present in a workplace covered by the rule.[22] Because benzene is omnipresent in small quantities, NIOSH and the President's Council on Wage and Price Stability recommended the use of an "action level" to trigger monitoring and medical examination requirements. Tr. 1030–1032, App. 121–133. OSHA accepted this recommendation, providing under the final standard that, if initial monitoring discloses benzene concentrations below 0.5 ppm averaged over an 8-hour work day, no further action is required unless there is a change in the company's practices.[23] If exposures are above the action

[22] Apart from its exclusion of gasoline storage and distribution facilities (an exclusion retained in the final rule, see text, at n. 25, *infra*), the proposed rule also excluded from coverage work operations in which liquid mixtures containing 1% or less benzene were used. After a year this exclusion was to be narrowed to operations where 0.1% benzene solutions were used. The rationale for the exclusion was that airborne exposures from such liquids would generally be within the 1 ppm limit. However, testimony at the hearing on the proposed rule indicated that there was no "consistent predictable relationship" between benzene content in a liquid and the resulting airborne exposure. Therefore, OSHA abandoned the idea of a percentage exclusion for liquid benzene in its final standard. 43 Fed. Reg. 5942 (1978).

OSHA later reconsidered its position and, in an amendment to the permanent standard, reinstated an exclusion for liquids, setting the level at 0.5%, to be reduced to 0.1% after three years, *id.*, at 27962.

[23] The exemption from the monitoring and medical testing portions of the standard for workplaces with benzene exposure levels below 0.5 ppm was not predicated on any finding that regulation of such workplaces was not feasible. OSHA's consultant, Arthur D Little, Inc., concluded that 1 ppm was a feasible exposure limit even assuming that there was no

level, but below the 1 ppm exposure limit, employers are required to monitor exposure levels on a quarterly basis and to provide semiannual medical examinations for their exposed employees. Neither the concept of an action level, nor the specific level selected by OSHA, is challenged in this proceeding.

Whenever initial monitoring indicates that employees are subject to airborne concentrations of benzene above 1 ppm averaged over an 8-hour workday, with a ceiling of 5 ppm for any 15-minute period, employers are required to modify their plants or institute work practice controls to reduce exposures within permissible limits. Consistent with OSHA's general policy, the regulation does not allow respirators to be used if engineering modifications are technologically feasible.[24] Employers in this category are also required to perform monthly monitoring so long as their workplaces remain above 1 ppm, provide semiannual medical examinations to exposed workers, post signs in and restrict access to "regulated areas" where the permissible exposure limit is exceeded, and conduct employee training programs where necessary

The standard also places strict limits on exposure to liquid

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action level (or, to put it another way, assuming that the action level was zero). Rather, it was, as NIOSH witnesses stated, a practical decision based on a determination that, where benzene exposures are below 0.5 ppm, they will be unlikely ever to rise above the permissible exposure level of 1 ppm. NIOSH was also concerned that, in the absence of an action level, employers who used sophisticated analytical equipment might be required to monitor and provide medical examinations simply because of the presence of benzene in the ambient air. Tr. 1030–1032, 1133–1134.

[24] Indeed, in its explanation of the standard OSHA states that an employer is required to institute engineering controls (for example, installing new ventilation hoods) even if those controls are insufficient, by themselves, to achieve compliance and respirators must therefore be used as well. 43 Fed. Reg. 5952 (1978). OSHA's preference for engineering modifications is based on its opinion that respirators are rarely used properly (because they are uncomfortable, are often not properly fitted, etc.) and therefore cannot be considered adequate protective measures.

benzene. As originally framed, the standard totally prohibited any skin or eye contact with any liquid containing any benzene. Ultimately, after the standard was challenged, OSHA modified this prohibition by excluding liquids containing less than 0.5% benzene. After three years, that exclusion will be narrowed to liquids containing less than 0.1% benzene.

The permanent standard is expressly inapplicable to the storage, transportation, distribution, sale, or use of gasoline or other fuels subsequent to discharge from bulk terminals.[25] This exception is particularly significant in light of the fact that over 795,000 gas station employees, who are exposed to an average of 102,700 gallons of gasoline (containing up to 2% benzene) annually, are thus excluded from the protection of the standard.[26]

As presently formulated, the benzene standard is an expensive way of providing some additional protection for a relatively small number of employees. According to OSHA's figures, the standard will require capital investments in engineering controls of approximately $266 million, first-year operating costs (for monitoring, medical testing, employee training, and respirators) of $187 million to $205 million and

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[25] It is also inapplicable to work operations involving 0.5% liquid benzene (0.1% after three years), see n. 22, *supra,* and to the handling of benzene in sealed containers or systems, except insofar as employers are required to provide cautionary notices and appropriate employee training.

[26] Prior to the introduction of the action-level concept, A. D Little estimated that compliance costs for the service station industry might be as high as $4 billion. Tr. 508–509. Moreover, A. D. Little's Economic Impact Statement indicated that service station employees were generally exposed to very low levels of benzene. 1 Economic Impact Statement, p. 4–21, 11 Record, Ex. 5A, p. 4–21. Still, in its explanation accompanying the permanent standard OSHA did not rule out regulation of this industry entirely, stating that it was in the process of studying whether and to what extent it should regulate exposures to gasoline in general. 43 Fed. Reg. 5943 (1978)

recurring annual costs of approximately $34 million.[27] 43 Fed. Reg. 5934 (1978). The figures outlined in OSHA's explanation of the costs of compliance to various industries indicate that only 35,000 employees would gain any benefit from the regulation in terms of a reduction in their exposure to benzene.[28] Over two-thirds of these workers (24,450) are employed in the rubber-manufacturing industry Compliance costs in that industry are estimated to be rather low with no capital costs and initial operating expenses estimated at only $34 million ($1,390 per employee), recurring annual costs would also be rather low, totaling less than $1 million. By contrast, the segment of the petroleum refining industry that produces benzene would be required to incur $24 million in capital costs and $600,000 in first-year operating expenses to provide additional protection for 300 workers ($82,000 per employee), while the petrochemical industry would be required to incur $20.9 million in capital costs and $1 million in initial operating expenses for the benefit of 552 employees ($39,675 per employee) [29] *Id.*, at 5936–5938.

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[27] OSHA's estimate of recurring annual costs was based on the assumption that the exposure levels it had projected would be confirmed by initial monitoring and that, after the first year, engineering controls would be successful in bringing most exposures within the 1 ppm limit. Under these circumstances, the need for monitoring, medical examinations, and respirators would, of course, be drastically reduced.

[28] Three hundred of these employees work in benzene plants, 5,000 in other petroleum refineries, 4,000 in light oil plants, 552 in the petrochemical industry, 156 in benzene transportation, 1,250 in laboratories, 11,400 in tire-manufacturing plants, and 13,050 in other rubber-manufacturing plants. OSHA also estimated that another 16,216 workers (5,000 in petroleum refineries, 1,104 in the petrochemical industry, 7,300 in bulk terminals, 312 in benzene transportation, and 2,500 in laboratories) would be exposed to 0.5 to 1 ppm of benzene and thus would receive a benefit in terms of more comprehensive medical examinations. *Id.*, at 5936–5938.

[29] The high cost per employee in the latter two industries is attributable to OSHA's policy of requiring engineering controls rather than allowing respirators to be used to reduce exposures to the permissible limit. The

Although OSHA did not quantify the benefits to each category of worker in terms of decreased exposure to benzene, it appears from the economic impact study done at OSHA's direction that those benefits may be relatively small. Thus, although the current exposure limit is 10 ppm, the actual exposures outlined in that study are often considerably lower. For example, for the period 1970–1975 the petrochemical industry reported that, out of a total of 496 employees exposed to benzene, only 53 were exposed to levels between 1 and 5 ppm and only 7 (all at the same plant) were exposed to between 5 and 10 ppm. 1 Economic Impact Statement, p. 4–6, Table 4–2, 11 Record, Ex. 5A, p. 4–6, Table 4–2. See also *id.*, Tables 4.3–4.8 (indicating sample exposure levels in various industries)

II

The critical issue at this point in the litigation is whether the Court of Appeals was correct in refusing to enforce the 1 ppm exposure limit on the ground that it was not supported by appropriate findings.[30]

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relatively low estimated cost per employee in the rubber industry is based on OSHA's assumption that other solvents and adhesives can be substituted for those that contain benzene and that capital costs will therefore not be required.

[30] The other issue before us is whether the Court of Appeals correctly refused to enforce the dermal contact ban. That issue is discussed in Part IV, *infra*.

In the court below respondents also challenged the monitoring and medical testing requirements, arguing that certain industries should have been totally exempt from them and that, as to other industries, the Agency had not demonstrated that all the requirements were reasonably necessary to ensure worker health and safety They also argued that OSHA's requirement that the permissible exposure limit be met through engineering controls rather than through respirators was not reasonably necessary under the Act. Because it invalidated the 1 ppm exposure limit, the Fifth Circuit had no occasion to deal with these issues, and they are not now before this Court.

Any discussion of the 1 ppm exposure limit must, of course, begin with the Agency's rationale for imposing that limit.[31] The written explanation of the standard fills 184 pages of the printed appendix. Much of it is devoted to a discussion of the voluminous evidence of the adverse effects of exposure to benzene at levels of concentration well above 10 ppm. This discussion demonstrates that there is ample justification for regulating occupational exposure to benzene and that the prior limit of 10 ppm, with a ceiling of 25 ppm (or a peak of 50 ppm) was reasonable. It does not, however, provide direct support for the Agency's conclusion that the limit should be reduced from 10 ppm to 1 ppm.

The evidence in the administrative record of adverse effects of benzene exposure at 10 ppm is sketchy at best. OSHA noted that there was "no dispute" that certain nonmalignant blood disorders, evidenced by a reduction in the level of red or white cells or platelets in the blood, could result from exposures of 25–40 ppm. It then stated that several studies had indicated that relatively slight changes in normal blood values could result from exposures below 25 ppm and perhaps below 10 ppm. OSHA did not attempt to make any estimate based on these studies of how significant the risk of nonmalignant disease would be at exposures of 10 ppm or less.[32] Rather, it stated that because of the lack of data concerning the linkage between low-level exposures and blood abnormalities, it was impossible to construct a dose-response

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[31] As we have often held, the validity of an agency's determination must be judged on the basis of the agency's stated reasons for making that determination. See *SEC* v. *Chenery Corp.*, 318 U. S. 80, 95 ("[A]n administrative order cannot be upheld unless the grounds upon which the agency acted in exercising its powers were those upon which its action can be sustained"), *FPC* v. *Texaco Inc.*, 417 U. S. 380, 397, *FTC* v. *Sperry & Hutchinson Co.*, 405 U. S. 233, 249.

[32] As OSHA itself noted, some blood abnormalities caused by benzene exposure may not have any discernible health effects, while others may lead to significant impairment and even death. 43 Fed. Reg. 5921 (1978).

curve at this time.[33] OSHA did conclude, however, that the studies demonstrated that the current 10 ppm exposure limit was inadequate to ensure that no single worker would suffer a nonmalignant blood disorder as a result of benzene exposure. Noting that it is "customary" to set a permissible exposure limit by applying a safety factor of 10–100 to the lowest level at which adverse effects had been observed, the Agency stated that the evidence supported the conclusion that the limit should be set at a point "substantially less than 10 ppm" even if benzene's leukemic effects were not considered. 43 Fed. Reg. 5924–5925 (1978). OSHA did not state, however, that the nonmalignant effects of benzene exposure justified a reduction in the permissible exposure limit to 1 ppm.[34]

OSHA also noted some studies indicating an increase in chromosomal aberrations in workers chronically exposed to

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[33] "A dose-response curve shows the relationship between different exposure levels and the risk of cancer [or any other disease] associated with those exposure levels. Generally, exposure to higher levels carries with it a higher risk, and exposure to lower levels is accompanied by a reduced risk." 581 F 2d, at 504, n. 24.

OSHA's comments with respect to the insufficiency of the data were addressed primarily to the lack of data at low exposure levels. OSHA did not discuss whether it was possible to make a rough estimate, based on the more complete epidemiological and animal studies done at higher exposure levels, of the significance of the risks attributable to those levels, nor did it discuss whether it was possible to extrapolate from such estimates to derive a risk estimate for low-level exposures.

[34] OSHA did not invoke the automatic rule of reducing exposures to the lowest limit feasible that it applies to cancer risks. Instead, the Secretary reasoned that prudent health policy merely required that the permissible exposure limit be set "sufficiently below the levels at which adverse effects have been observed to assure adequate protection for all exposed employees." 43 Fed. Reg. 5925 (1978). While OSHA concluded that application of this rule would lead to an exposure limit "substantially less than 10 ppm," it did not state either what exposure level it considered to present a significant risk of harm or what safety factor should be applied to that level to establish a permissible exposure limit.

concentrations of benzene "probably less than 25 ppm." [35] However, the Agency took no definitive position as to what these aberrations meant in terms of demonstrable health effects and stated that no quantitative dose-response relationship had yet been established. Under these circumstances, chromosomal effects were categorized by OSHA as an "adverse biological event of serious concern which may pose or reflect a potential health risk and as such, must be considered in the larger purview of adverse health effects associated with benzene. *Id.*, at 5932–5934.

With respect to leukemia, evidence of an increased risk (*i. e.*, a risk greater than that borne by the general population) due to benzene exposures at or below 10 ppm was even sketchier. Once OSHA acknowledged that the NIOSH study it had relied upon in promulgating the emergency standard did not support its earlier view that benzene had been shown to cause leukemia at concentrations below 25 ppm, see n. 12, *supra*, there was only one study that provided any evidence of such an increased risk. That study, conducted by the Dow Chemical Co., uncovered three leukemia deaths, versus 0.2 expected deaths, out of a population of 594 workers; it appeared that the three workers had never been exposed to more than 2 to 9 ppm of benzene. The authors of the study, however, concluded that it could not be viewed as proof of a relationship between low-level benzene exposure and leukemia because all three workers had probably been occupationally exposed to a number of other potentially carcinogenic chemicals at other points in their careers and because no leukemia deaths had been uncovered among workers who had been exposed to much higher levels of benzene. In its explanation of the permanent standard, OSHA stated that the possibility that these three leukemias had been caused by benzene exposure could not be

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[35] While citing these studies, OSHA also noted that other studies of similarly exposed workers had not indicated any increased level of chromosome damage.

ruled out and that the study, although not evidence of an increased risk of leukemia at 10 ppm, was therefore "consistent with the findings of many studies that there is an excess leukemia risk among benzene exposed employees." 43 Fed. Reg. 5928 (1978) The Agency made no finding that the Dow study, any other empirical evidence, or any opinion testimony demonstrated that exposure to benzene at or below the 10 ppm level had ever in fact caused leukemia. See 581 F 2d, at 503, where the Court of Appeals noted that OSHA was "unable to point to any empirical evidence documenting a leukemia risk at 10 ppm. "

In the end OSHA's rationale for lowering the permissible exposure limit to 1 ppm was based, not on any finding that leukemia has ever been caused by exposure to 10 ppm of benzene and that it will *not* be caused by exposure to 1 ppm, but rather on a series of assumptions indicating that some leukemias might result from exposure to 10 ppm and that the number of cases might be reduced by reducing the exposure level to 1 ppm. In reaching that result, the Agency first unequivocally concluded that benzene is a human carcinogen.[36] Second, it concluded that industry had failed to prove that there is a safe threshold level of exposure to benzene below which no excess leukemia cases would occur. In reaching this conclusion OSHA rejected industry contentions that certain epidemiological studies indicating no excess risk of leukemia among workers exposed at levels below 10 ppm were sufficient to establish that the threshold level of safe exposure was at or above

[36] "The evidence in the record conclusively establishes that benzene is a human carcinogen. The determination of benzene's leukemogenicity is derived from the evaluation of all the evidence in totality and is not based on any one particular study OSHA recognizes, as indicated above that individual reports vary considerably in quality, and that some investigations have significant methodological deficiencies. While recognizing the strengths and weaknesses in individual studies, OSHA nevertheless concludes that the benzene record as a whole clearly establishes a causal relationship between benzene and leukemia." *Id.*, at 5931.

10 ppm.[37] It also rejected an industry witness' testimony that a dose-response curve could be constructed on the basis of the reported epidemiological studies and that this curve indicated that reducing the permissible exposure limit from 10 to 1 ppm would prevent at most one leukemia and one other cancer death every six years.[38]

Third, the Agency applied its standard policy with respect to carcinogens,[39] concluding that, in the absence of definitive

[37] In rejecting these studies, OSHA stated that: "Although the epidemiological method can provide strong evidence of a causal relationship between exposure and disease in the case of positive findings, it is by its very nature relatively crude and an insensitive measure." After noting a number of specific ways in which such studies are often defective, the Agency stated that it is "OSHA's policy when evaluating negative studies, to hold them to higher standards of methodological accuracy" *Id.*, at 5931–5932. Viewing the industry studies in this light, OSHA concluded that each of them had sufficient methodological defects to make them unreliable indicators of the safety of low-level exposures to benzene.

[38] OSHA rejected this testimony in part because it believed the exposure data in the epidemiological studies to be inadequate to formulate a dose-response curve. It also indicated that even if the testimony was accepted—indeed as long as there was any increase in the risk of cancer—the Agency was under an obligation to "select the level of exposure which is most protective of exposed employees." *Id.*, at 5941.

[39] In his dissenting opinion, MR. JUSTICE MARSHALL states that the Agency did not rely "blindly on some Draconian carcinogen 'policy'" in setting a permissible exposure limit for benzene. He points to the large number of witnesses the Agency heard and the voluminous record it compiled as evidence that it relied instead on the particular facts concerning benzene. With all due respect, we disagree with MR. JUSTICE MARSHALL'S interpretation of the Agency's rationale for its decision. After hearing the evidence, the Agency relied on the same policy view it had stated at the outset, see *supra*, at 623–625, namely, that, in the absence of clear evidence to the contrary, it must be assumed that no safe level exists for exposure to a carcinogen. The Agency also reached the entirely predictable conclusion that industry had not carried its concededly impossible burden, see n. 41, *infra*, of proving that a safe level of exposure exists for benzene. As the Agency made clear later in its proposed generic cancer policy, see n. 51, *infra*, it felt compelled to allow industry witnesses to go over the same ground in each regulation dealing with a carcinogen, despite

proof of a safe level, it must be assumed that *any* level above zero presents *some* increased risk of cancer.[40] As the federal parties point out in their brief, there are a number of scientists and public health specialists who subscribe to this view, theorizing that a susceptible person may contract cancer from the absorption of even one molecule of a carcinogen like benzene. Brief for Federal Parties 18–19.[41]

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its policy view The generic policy, which has not yet gone into effect, was specifically designed to eliminate this duplication of effort in each case by foreclosing industry from arguing that there is a safe level for the particular carcinogen being regulated. 42 Fed. Reg. 54154–54155 (1977).

[40] "As stated above, the positive studies on benzene demonstrate the causal relationship of benzene to the induction of leukemia. Although these studies, for the most part involve high exposure levels, it is OSHA's view that once the carcinogenicity of a substance has been established qualitatively, any exposure must be considered to be attended by risk when considering any given population. OSHA therefore believes that occupational exposure to benzene at low levels poses a carcinogenic risk to workers." 43 Fed. Reg. 5932 (1978)

[41] The so-called "one hit" theory is based on laboratory studies indicating that one molecule of a carcinogen may react in the test tube with one molecule of DNA to produce a mutation. The theory is that, if this occurred in the human body, the mutated molecule could replicate over a period of years and eventually develop into a cancerous tumor. See OSHA's Proposed Rule on the Identification, Classification and Regulation of Toxic Substances Posing a Potential Carcinogenic Risk, 42 Fed. Reg. 54148, 54165–54167 (1977). Industry witnesses challenged this theory, arguing that the presence of several different defense mechanisms in the human body make it unlikely that a person would actually contract cancer as a result of absorbing one carcinogenic molecule. Thus, the molecule might be detoxified before reaching a critical site, damage to a DNA molecule might be repaired, or a mutated DNA molecule might be destroyed by the body's immunological defenses before it could develop into a cancer. Tr. 2836.

In light of the improbability of a person's contracting cancer as a result of a single hit, a number of the scientists testifying 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. See, *e. g., id.*, at 1179–1181. The problem, however, is that individual susceptibility appears to vary greatly and there is at present no way to calculate each

Fourth, the Agency reiterated its view of the Act, stating that it was required by § 6 (b)(5) to set the standard either at the level that has been demonstrated to be safe or at the lowest level feasible, whichever is higher. If no safe level is established, as in this case, the Secretary's interpretation of the statute automatically leads to the selection of an exposure limit that is the lowest feasible.[42] Because of benzene's importance to the economy, no one has ever suggested that it would be feasible to eliminate its use entirely, or to try to limit exposures to the small amounts that are omnipresent. Rather, the Agency selected 1 ppm as a workable exposure level, see n. 14, *supra,* and then determined that compliance with that level was technologically feasible and that "the economic impact of [compliance] will not be such as to threaten the financial welfare of the affected firms or the general economy" 43 Fed. Reg. 5939 (1978). It therefore held that 1 ppm was the minimum feasible exposure level within the meaning of § 6 (b)(5) of the Act.

Finally, although the Agency did not refer in its discussion of the pertinent legal authority to any duty to identify the anticipated benefits of the new standard, it did conclude that some benefits were likely to result from reducing the exposure limit from 10 ppm to 1 ppm. This conclusion was based, again, not on evidence, but rather on the assumption that the risk of leukemia will decrease as exposure levels decrease. Although the Agency had found it impossible to construct a dose-response curve that would predict with any accuracy the

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and every person's threshold. Thus, even industry witnesses agreed that if the standard must ensure with absolute certainty that every single worker is protected from any risk of leukemia, only a zero exposure limit would suffice. *Id.,* at 2492, 2830.

[42] "There is no doubt that benzene is a carcinogen and must, for the protection and safety of workers, be regulated as such. Given the inability to demonstrate a threshold or establish a safe level, it is appropriate that OSHA prescribe that the permissible exposure to benzene be reduced to the lowest level feasible." 43 Fed. Reg. 5932 (1978).

number of leukemias that could be expected to result from exposures at 10 ppm, at 1 ppm, or at any intermediate level, it nevertheless "determined that the benefits of the proposed standard are likely to be appreciable." [43] 43 Fed. Reg. 5941 (1978). In light of the Agency's disavowal of any ability to determine the numbers of employees likely to be adversely affected by exposures of 10 ppm, the Court of Appeals held this finding to be unsupported by the record. 581 F 2d, at 503.[44]

It is noteworthy that at no point in its lengthy explanation did the Agency quote or even cite § 3 (8) of the Act. It made no finding that any of the provisions of the new standard were "reasonably necessary or appropriate to provide safe or healthful employment and places of employment." Nor did it allude to the possibility that any such finding might have been appropriate.

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[43] At an earlier point in its explanation, OSHA stated:

"There is general agreement that benzene exposure causes leukemia as well as other fatal diseases of the bloodforming organs. In spite of the certainty of this conclusion, there does not exist an adequate scientific basis for establishing the quantitative dose response relationship between exposure to benzene and the induction of leukemia and other blood diseases. The uncertainty in both the actual magnitude of expected deaths and in the theory of extrapolation from existing data to the OSHA exposure levels places the estimation of benefits on 'the frontiers of scientific knowledge.' While the actual estimation of the number of cancers to be prevented is highly uncertain, the evidence indicates that the number may be appreciable. There is general agreement that even in the absence of the ability to establish a 'threshold' or 'safe' level for benzene and other carcinogens, a dose response relationship is likely to exist; that is, exposure to higher doses carries with it a higher risk of cancer, and conversely, exposure to lower levels is accompanied by a reduced risk, even though a precise quantitative relationship cannot be established." *Id.*, at 5940.

[44] The court did, however, hold that the Agency's other conclusions—that there is *some* risk of leukemia at 10 ppm and that the risk would decrease by decreasing the exposure limit to 1 ppm—were supported by substantial evidence. 581 F 2d, at 503.

III

Our resolution of the issues in these cases turns, to a large extent, on the meaning of and the relationship between § 3 (8), which defines a health and safety standard as a standard that is "reasonably necessary and appropriate to provide safe or healthful employment," and § 6 (b)(5), which directs the Secretary in promulgating a health and safety standard for toxic materials to "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 "

In the Government's view, § 3 (8)'s definition of the term "standard" has no legal significance or at best merely requires that a standard not be totally irrational. It takes the position that § 6 (b)(5) is controlling and that it requires OSHA to promulgate a standard that either gives an absolute assurance of safety for each and every worker or reduces exposures to the lowest level feasible. The Government interprets "feasible" as meaning technologically achievable at a cost that would not impair the viability of the industries subject to the regulation. The respondent industry representatives, on the other hand, argue that the Court of Appeals was correct in holding that the "reasonably necessary and appropriate" language of § 3 (8), along with the feasibility requirement of § 6 (b)(5), requires the Agency to quantify both the costs and the benefits of a proposed rule and to conclude that they are roughly commensurate.

In our view, it is not necessary to decide whether either the Government or industry is entirely correct. For we think it is clear that § 3 (8) does apply to all permanent standards promulgated under the Act and that it requires the Secretary, before issuing any standard, to determine that it is reasonably necessary and appropriate to remedy a significant risk of material health impairment. Only after the Secretary has made the threshold determination that such a risk exists

with respect to a toxic substance, would it be necessary to decide whether § 6 (b)(5) requires him to select the most protective standard he can consistent with economic and technological feasibility, or whether, as respondents argue, the benefits of the regulation must be commensurate with the costs of its implementation. Because the Secretary did not make the required threshold finding in these cases, we have no occasion to determine whether costs must be weighed against benefits in an appropriate case.

A

Under the Government's view, § 3 (8), if it has any substantive content at all,[45] merely requires OSHA to issue stand-

[45] We cannot accept the argument that § 3 (8) is totally meaningless. The Act authorizes the Secretary to promulgate three different kinds of standards—national consensus standards, permanent standards, and temporary emergency standards. The only substantive criteria given for two of these—national consensus standards and permanent standards for safety hazards not covered by § 6 (b)(5)—are set forth in § 3. While it is true that § 3 is entitled "definitions," that fact does not drain each definition of substantive content. For otherwise there would be no purpose in defining the critical terms of the statute. Moreover, if the definitions were ignored, there would be no statutory criteria at all to guide the Secretary in promulgating either national consensus standards or permanent standards other than those dealing with toxic materials and harmful physical agents. We may not expect Congress to display perfect craftsmanship, but it is unrealistic to assume that it intended to give no direction whatsoever to the Secretary in promulgating most of his standards.

The structure of the separate subsection describing emergency temporary standards, 29 U. S. C. § 655 (c), quoted in n. 13, *supra*, supports this conclusion. It authorizes the Secretary to bypass the normal procedures for setting permanent standards if he makes two findings: (A) that employees are exposed to "grave danger" from exposure to toxic substances and (B) that an emergency standard is "necessary" to protect the employees from that danger. Those findings are to be compared with those that are implicitly required by the definition of the permanent standard—(A) that there be a significant—as opposed to a "grave"—risk, and (B) that additional regulation is "reasonably necessary or appropriate"—as opposed to "necessary" It would be anomalous for Congress to require specific find-

ards that are reasonably calculated to produce a safer or more healthy work environment. Tr. of Oral Arg. 18, 20. Apart from this minimal requirement of rationality, the Government argues that § 3 (8) imposes no limits on the Agency's power, and thus would not prevent it from requiring employers to do whatever would be "reasonably necessary" to eliminate all risks of any harm from their workplaces.[46] With respect to toxic substances and harmful physical agents, the Government takes an even more extreme position. Relying on § 6 (b)(5)'s direction to set a standard "which most adequately assures that no employee will suffer material impairment of health or functional capacity," the Government contends that the Secretary is required to impose standards that either guarantee workplaces that are free from any risk of material health impairment, however small, or that come as close as possible to doing so without ruining entire industries.

If the purpose of the statute were to eliminate completely and with absolute certainty any risk of serious harm, we would agree that it would be proper for the Secretary to interpret §§ 3 (8) and 6 (b)(5) in this fashion. But we think it is clear that the statute was not designed to require employers to provide absolutely risk-free workplaces whenever it is technologically feasible to do so, so long as the cost is not great enough to destroy an entire industry Rather, both the language and structure of the Act, as well as its legislative history, indicate that it was intended to require the elimination, as far as feasible, of significant risks of harm.

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ings for temporary standards but to give the Secretary a *carte blanche* for permanent standards.

[46] The Government does not concede that the feasibility requirement in the second sentence of § 6 (b)(5) applies to health and safety standards other than toxic substances standards. See n. 1, *supra*. However, even if it did, the Government's interpretation of the term "feasible," when coupled with its view of § 3 (8), would still allow the Agency to require the elimination of even insignificant risks at great cost, so long as an entire industry's viability would not be jeopardized.

B

By empowering the Secretary to promulgate standards that are "reasonably necessary or appropriate to provide safe or healthful employment and places of employment," the Act implies that, before promulgating any standard, the Secretary must make a finding that the workplaces in question are not safe. But "safe" is not the equivalent of "risk-free." There are many activities that we engage in every day—such as driving a car or even breathing city air—that entail some risk of accident or material health impairment, nevertheless, few people would consider these activities "unsafe." Similarly, a workplace can hardly be considered "unsafe" unless it threatens the workers with a significant risk of harm.

Therefore, before he can promulgate *any* permanent health or safety standard, the Secretary is required to make a threshold finding that a place of employment is unsafe—in the sense that significant risks are present and can be eliminated or lessened by a change in practices. This requirement applies to permanent standards promulgated pursuant to § 6 (b)(5), as well as to other types of permanent standards. For there is no reason why § 3 (8)'s definition of a standard should not be deemed incorporated by reference into § 6 (b)(5) The standards promulgated pursuant to § 6 (b)(5) are just one species of the genus of standards governed by the basic requirement. That section repeatedly uses the term "standard" without suggesting any exception from, or qualification of, the general definition, on the contrary, it directs the Secretary to select "*the* standard"—that is to say, one of various possible alternatives that satisfy the basic definition in § 3 (8)—that is most protective.[47] Moreover, requiring the

[47] Section 6 (b)(5) parallels § 6 (a) in this respect. Section 6 (a) requires the Secretary, when faced with a choice between two national consensus standards, to choose the more protective standard, see n. 7, *supra*. Just as § 6 (a) does not suggest that this more protective standard need not meet the definition of a national consensus standard set forth in § 3 (9),

Secretary to make a threshold finding of significant risk is consistent with the scope of the regulatory power granted to him by § 6 (b)(5), which empowers the Secretary to promulgate standards, not for chemicals and physical agents generally, but for *"toxic* materials" and *"harmful* physical agents." [48]

This interpretation of §§ 3 (8) and 6 (b)(5) is supported by the other provisions of the Act. Thus, for example, § 6 (g) provides in part that

> "[i]n determining the priority for establishing standards under this section, the Secretary shall give due regard to the urgency of the need for mandatory safety and health standards for particular industries, trades,

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so § 6 (b)(5) does not suggest that the most protective toxic material standard need not conform to the definition of a "standard" in § 3 (8).

[48] The rest of § 6 (b)(5), while requiring the Secretary to promulgate the standard that "most adequately assures that no employee will suffer material impairment of health or functional capacity," also contains phrases implying that the Secretary should consider differences in degrees of significance rather than simply a total elimination of all risks. Thus, the standard to be selected is one that "most adequately assures, to the extent feasible, on the basis of the best available evidence," that no such harm will result. The Secretary is also directed to take into account "research, demonstrations, experiments, and such other information as may be appropriate" and to consider "[i]n addition to the attainment of the highest degree of health and safety protection for the employee the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws."

MR. JUSTICE MARSHALL states that our view of § 3 (8) would make the first sentence in § 6 (b)(5) superfluous. We disagree. The first sentence of § 6 (b)(5) requires the Secretary to select a highly protective standard once he has determined that a standard should be promulgated. The threshold finding that there is a need for such a standard in the sense that there is a significant risk in the workplace is not unlike the threshold finding that a chemical is toxic or a physical agent is harmful. Once the Secretary has made the requisite threshold finding, § 6 (b)(5) directs him to choose the most protective standard that still meets the definition of a standard under § 3 (8), consistent with feasibility

crafts, occupations, businesses, workplaces or work environments."

The Government has expressly acknowledged that this section requires the Secretary to undertake some cost-benefit analysis before he promulgates any standard, requiring the elimination of the most serious hazards first.[49] If such an analysis must precede the promulgation of any standard, it seems manifest that Congress intended, at a bare minimum, that the Secretary find a significant risk of harm and therefore a probability of significant benefits before establishing a new standard.

Section 6 (b)(8) lends additional support to this analysis. That subsection requires that, when the Secretary substantially alters an existing consensus standard, he must explain how the new rule will "better effectuate" the purposes of the Act.[50] If this requirement was intended to be more than a meaningless formality, it must be read to impose upon the Secretary the duty to find that an existing national consensus standard is not adequate to protect workers from a continuing and significant risk of harm. Thus, in this case, the Secretary was required to find that exposures at the current permissible

[49] "First, 29 U. S. C. § 655 (g) requires the Secretary to establish priorities in setting occupational health and safety standards so that the more serious hazards are addressed first. In setting such priorities the Secretary must, of course, consider the relative costs, benefits and risks." Reply Brief for Federal Parties 13. The Government argues that the Secretary's setting of priorities under this section is not subject to judicial review. Tr. of Oral Arg. 23. While we agree that a court cannot tell the Secretary which of two admittedly significant risks he should act to regulate first, this section, along with §§ 3 (8) and 6 (b)(5), indicates that the Act does limit the Secretary's power to requiring the elimination of significant risks.

[50] Section 6 (b)(8), as set forth in 29 U. S. C. § 655 (b)(8), provides:

"Whenever a rule promulgated by the Secretary differs substantially from an existing national consensus standard, the Secretary shall, at the same time, publish in the Federal Register a statement of the reasons why the rule as adopted will better effectuate the purposes of this chapter than the national consensus standard."

exposure level of 10 ppm present a significant risk of harm in the workplace.

In the absence of a clear mandate in the Act, it is unreasonable to assume that Congress intended to give the Secretary the unprecedented power over American industry that would result from the Government's view of §§ 3 (8) and 6 (b)(5), coupled with OSHA's cancer policy Expert testimony that a substance is probably a human carcinogen—either because it has caused cancer in animals or because individuals have contracted cancer following extremely high exposures—would justify the conclusion that the substance poses some risk of serious harm no matter how minute the exposure and no matter how many experts testified that they regarded the risk as insignificant. That conclusion would in turn justify pervasive regulation limited only by the constraint of feasibility In light of the fact that there are literally thousands of substances used in the workplace that have been identified as carcinogens or suspect carcinogens, the Government's theory would give OSHA power to impose enormous costs that might produce little, if any, discernible benefit.[51]

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[51] OSHA's proposed generic cancer policy, 42 Fed. Reg. 54148 (1977), indicates that this possibility is not merely hypothetical. Under its proposal, whenever there is a certain quantum of proof—either from animal experiments, or, less frequently, from epidemiological studies—that a substance causes cancer at any exposure level, an emergency temporary standard would be promulgated immediately, requiring employers to provide monitoring and medical examinations and to reduce exposures to the lowest feasible level. A proposed rule would then be issued along the same lines, with objecting employers effectively foreclosed from presenting evidence that there is little or no risk associated with current exposure levels. *Id.*, at 54154–54155, 29 CFR, Part 1990 (1977).

The scope of the proposed regulation is indicated by the fact that NIOSH has published a list of 2,415 potential occupational carcinogens, NIOSH, Suspected Carcinogens: A Subfile of the Registry of Toxic Effects of Chemical Substances (HEW Pub. No. 77–149, 2d ed. 1976). OSHA has tentatively concluded that 269 of these substances have been proved to be carcinogens and therefore should be subject to full regulation. See OSHA Press Release, USDL 78–625 (July 14, 1978).

If the Government were correct in arguing that neither § 3 (8) nor § 6 (b)(5) requires that the risk from a toxic substance be quantified sufficiently to enable the Secretary to characterize it as significant in an understandable way, the statute would make such a "sweeping delegation of legislative power" that it might be unconstitutional under the Court's reasoning in *A. L. A. Schechter Poultry Corp.* v *United States,* 295 U S. 495, 539, and *Panama Refining Co.* v *Ryan,* 293 U S. 388. A construction of the statute that avoids this kind of open-ended grant should certainly be favored.

C

The legislative history also supports the conclusion that Congress was concerned, not with absolute safety, but with the elimination of significant harm. The examples of industrial hazards referred to in the Committee hearings and debates all involved situations in which the risk was unquestionably significant. For example, the Senate Committee on Labor and Public Welfare noted that byssinosis, a disabling lung disease caused by breathing cotton dust, affected as many as 30% of the workers in carding or spinning rooms in some American cotton mills and that as many as 100,000 active or retired workers were then suffering from the disease. It also noted that statistics indicated that 20,000 out of 50,000 workers who had performed insulation work were likely to die of asbestosis, lung cancer, or mesothelyioma as a result of breathing asbestos fibers. Another example given of an occupational health hazard that would be controlled by the Act was betanaphthylamine, a "chemical so toxic that any exposure at all is likely to cause the development of bladder cancer over a period of years." S. Rep. No. 91–1282, pp. 3–4 (1970), Legislative History of the Occupational Safety and Health Act of 1970 (Committee Print compiled for the Senate Committee on Labor and Public Welfare), pp. 143–144 (1971) (hereafter Leg. Hist.)

Moreover, Congress specifically amended § 6 (b)(5) to make

it perfectly clear that it does not require the Secretary to promulgate standards that would assure an absolutely risk-free workplace. Section 6 (b)(5) of the initial Committee bill provided that

> "[t]he Secretary, in promulgating standards under this subsection, shall set the standard which most adequately and feasibly assures, on the basis of the best available evidence, that no employee will suffer *any* impairment of health or functional capacity, or diminished life expectancy even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life." (Emphasis supplied.) S. 2193, 91st Cong., 2d Sess., p. 39 (1970), Leg. Hist. 242.

On the floor of the Senate, Senator Dominick questioned the wisdom of this provision, stating:

> "How in the world are we ever going to live up to that? What are we going to do about a place in Florida where mosquitoes are getting at the employee—perish the thought that there may be mosquitoes in Florida? But there are black flies in Minnesota and Wisconsin. Are we going to say that if employees get bitten by those for the rest of their lives they will not have been done any harm at all? Probably they will not be, but do we know?" 116 Cong. Rec. 36522 (1970), Leg. Hist. 345.

He then offered an amendment deleting the entire subsection.[52]

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[52] In criticizing the Committee bill, Senator Dominick also made the following observations:

"It is unrealistic to attempt, as this section apparently does, to establish a utopia free from any hazards. Absolute safety is an impossibility and it will only create confusion in the administration of this act for the Congress to set clearly unattainable goals." 116 Cong. Rec. 37614 (1970), Leg. Hist. 480.

"But I ask, Mr. President, just thinking about that language, let us take a fellow who is a streetcar conductor or a bus conductor at the present time. How in the world, in the process of the pollution we have in the streets

After discussions with the sponsors of the Committee bill, Senator Dominick revised his amendment. Instead of deleting the first sentence of § 6 (b)(5) entirely, his new amendment limited the application of that subsection to toxic materials and harmful physical agents and changed "any" impairment of health to "material" impairment.[53] In discussing this change, Senator Dominick noted that the Committee's bill read as if a standard had to "assure that, no matter what anybody was doing, the standard would protect him for the rest of his life against any foreseeable hazard." Such an "unrealistic standard," he stated, had not been intended by the sponsors of the bill. Rather, he explained that the intention of the bill, as implemented by the amendment, was to require the Secretary

> "to use his best efforts to promulgate the best available standards, and in so doing, he should take into account that anyone working in toxic agents and physical

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or in the process of the automobile accidents that we have all during a working day of any one driving a bus or trolley car, or whatever it may be, can we set standards that will make sure he will not have any risk to his life for the rest of his life? It is totally impossible for this to be put in a bill, and yet it is in the committee bill." 116 Cong. Rec., at 37337, Leg. Hist. 423.

As an opponent of the legislation, Senator Dominick may have exaggerated the significance of the problem since the language in § 3 (8) already was sufficient to prevent the Secretary from trying "to establish a utopia free from any hazards." Nevertheless, the fact that Congress amended the bill to allay Senator Dominick's concern demonstrates that it did not intend the statute to achieve "clearly unattainable goals."

[53] Senator Dominick had also been concerned that the placement of the word "feasibly" could be read to require the Secretary to "ban all occupations in which there remains *some* risk of injury, impaired health, or life expectancy," since the way to most "adequately" and "feasibly" assure absolute protection might well be to prohibit the occupation entirely 116 Cong. Rec., at 36530, Leg. Hist. 366–367 In his final amendment, he attempted to cure this problem by relocating the feasibility requirement, changing "the standard which most adequately and feasibly assures" to "the standard which most adequately assures, to the extent feasible."

> agents which might be harmful may be subjected to such conditions for the rest of his working life, so that we can get at something which might not be toxic now, if he works in it a short time, but if he works in it the rest of his life might be very dangerous, and we want to make sure that such things are taken into consideration in establishing standards." 116 Cong. Rec., at 37622–37623, Leg. Hist. 502–503.[54]

Senator Williams, one of the sponsors of the Committee bill, agreed with the interpretation, and the amendment was adopted.

In their reply brief the federal parties argue that the Dominick amendment simply means that the Secretary is not required to eliminate threats of insignificant harm, they argue that § 6 (b)(5) still requires the Secretary to set standards that ensure that not even one employee will be subject to any risk of serious harm—no matter how small that risk may be.[55]

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[54] MR. JUSTICE MARSHALL argues that Congress could not have thought § 3 (8) had any substantive meaning inasmuch as § 6 (b)(5), as originally drafted, applied to all standards and not simply to standards for toxic materials and harmful physical substances. However, as this legislative history indicates, it appears that the omission of the words "toxic substances" and "harmful physical agents" from the original draft of § 6 (b)(5) was entirely inadvertent. As Senator Dominick noted, the Committee had always intended that subsection to apply only to that limited category of substances. 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 § 6 (b)(5).

[55] Reply Brief for Federal Parties 24–26. While it is true that some of Senator Dominick's comments were concerned with the relative unimportance of minor injuries (see his "fly" example quoted *supra*, at 647), it is

This interpretation is at odds with Congress' express recognition of the futility of trying to make all workplaces totally risk-free. Moreover, not even OSHA follows this interpretation of § 6 (b)(5) to its logical conclusion. Thus, if OSHA is correct that the only no-risk level for leukemia due to benzene exposure is zero and if its interpretation of § 6 (b)(5) is correct, OSHA should have set the exposure limit as close to zero as feasible. But OSHA did not go about its task in that way Rather, it began with a 1 ppm level, selected at least in part to ensure that employers would not be required to eliminate benzene concentrations that were little greater than the so-called "background" exposures experienced by the population at large. See n. 14, *supra*. Then, despite suggestions by some labor unions that it was feasible for at least some industries to reduce exposures to well below 1 ppm,[56] OSHA decided to apply the same limit to all, largely as a matter of administrative convenience. 43 Fed. Reg. 5947 (1978).

OSHA also deviated from its own interpretation of § 6 (b)(5) in adopting an action level of 0.5 ppm below which monitoring and medical examinations are not required. In light of OSHA's cancer policy, it must have assumed that some employees would be at risk because of exposures below 0.5 ppm. These employees would thus presumably benefit from medical examinations, which might uncover any benzene-related problems. OSHA's consultant advised the Agency that it was technologically and economically feasible to require that such examinations be provided. Nevertheless, OSHA adopted an action level, largely because the insignificant ben-

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clear that he was also concerned with the remote possibility of major injuries, see n. 52, *supra*.

[56] One union suggested a 0.5 ppm permissible exposure limit for oil refineries and a 1 ppm ceiling (rather than a time-weighted average) exposure for all other industries, with no use of an action level, Tr. 1250, 1257 Another wanted a 1 ppm ceiling limit for all industries, *id.*, at 3375–3376.

efits of giving such examinations and performing the necessary monitoring did not justify the substantial cost.[57]

OSHA's concessions to practicality in beginning with a 1 ppm exposure limit and using an action level concept implicitly adopt an interpretation of the statute as not requiring regulation of insignificant risks.[58] It is entirely consistent with this interpretation to hold that the Act also requires the Agency to limit its endeavors in the standard-setting area to eliminating significant risks of harm.

Finally, with respect to the legislative history, it is important to note that Congress repeatedly expressed its concern about allowing the Secretary to have too much power over American industry Thus, Congress refused to give the Secretary the power to shut down plants unilaterally because of an imminent danger, see *Whirlpool Corp.* v *Marshall,* 445 U S. 1, and narrowly circumscribed the Secretary's power to issue temporary emergency standards.[59] This effort by

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[57] "A need for an action level is also suggested by the record evidence that some minimal exposure to benzene occurs naturally from animal and plant matter (Tr. 749–750; 759–760). Naturally occurring benzene concentrations, it appears, may range from 0.02 to 15 parts per billion (Ex. 117, p. 1). Additionally, it was suggested by certain employers that their operations be exempted from the requirements of the standard because these operations involve only intermittent and low level exposures to benzene. The use of the action level concept should accommodate these concerns in all cases where exposures are indeed extremely low since it substantially reduces the monitoring of employees who are below the action level and removes for these employees the requirements for medical surveillance. At the same time, employees with *significant* overexposure are afforded the full protection of the standard." (Emphasis added.) 43 Fed. Reg. 5942 (1978).

[58] The Government also states that it is OSHA's policy to attempt to quantify benefits wherever possible. While this is certainly a reasonable position, it is not consistent with OSHA's own view of its duty under § 6 (b)(5). In light of the inconsistencies in OSHA's position and the legislative history of the Act, we decline to defer to the Agency's interpretation.

[59] In *Florida Peach Growers Assn., Inc.* v *U S. Dept. of Labor,* 489 F 2d 120, 130, and n. 16 (CA5 1974), the court noted that Congress intended

Congress to limit the Secretary's power is not consistent with a view that the mere possibility that some employee somewhere in the country may confront some risk of cancer is a sufficient basis for the exercise of the Secretary's power to require the expenditure of hundreds of millions of dollars to minimize that risk.

D

Given the conclusion that the Act empowers the Secretary to promulgate health and safety standards only where a significant risk of harm exists, the critical issue becomes how to define and allocate the burden of proving the significance of the risk in a case such as this, where scientific knowledge is imperfect and the precise quantification of risks is therefore impossible. The Agency's position is that there is substantial evidence in the record to support its conclusion that there is no absolutely safe level for a carcinogen and that, therefore, the burden is properly on industry to prove, apparently beyond a shadow of a doubt, that there *is* a safe level for benzene exposure. The Agency argues that, because of the uncertainties in this area, any other approach would render it helpless, forcing it to wait for the leukemia deaths that it believes are likely to occur [60] before taking any regulatory action.

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to restrict the use of emergency standards, which are promulgated without any notice or hearing. It held that, in promulgating an emergency standard, OSHA must find not only a danger *of* exposure or even some danger *from* exposure, but also a grave danger from exposure necessitating emergency action. Accord, *Dry Color Mfrs. Assn., Inc.* v. *U S. Dept. of Labor*, 486 F 2d 98, 100 (CA3 1973) (an emergency standard must be supported by something more than a possibility that a substance may cause cancer in man).

Congress also carefully circumscribed the Secretary's enforcement powers by creating a new, independent board to handle appeals from citations issued by the Secretary for noncompliance with health and safety standards. See 29 U. S. C. §§ 659–661.

[60] As noted above, OSHA acknowledged that there was no empirical evidence to support the conclusion that there was any risk whatsoever of deaths due to exposures at 10 ppm. What OSHA relied upon was a theory

We disagree. 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 material health impairment. Ordinarily, it is the proponent of a rule or order who has the burden of proof in administrative proceedings. See 5 U. S. C. § 556 (d). In some cases involving toxic substances, Congress has shifted the burden of proving that a particular substance is safe onto the party opposing the proposed rule.[61] The fact that Congress did not follow this course in enacting the Occupational Safety and Health Act indicates that it intended the Agency to bear the normal burden of establishing the need for a proposed standard.

In this case OSHA did not even attempt to carry its burden of proof. The closest it came to making a finding that benzene presented a significant risk of harm in the workplace was its statement that the benefits to be derived from lowering the permissible exposure level from 10 to 1 ppm were "likely" to be "appreciable." The Court of Appeals held that this finding was not supported by substantial evidence. Of greater importance, even if it were supported by substantial evidence, such a finding would not be sufficient to satisfy the Agency's obligations under the Act.

The inadequacy of the Agency's findings can perhaps be

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that, because leukemia deaths had occurred at much higher exposures, some (although fewer) were also likely to occur at relatively low exposures. The Court of Appeals specifically held that its conclusion that the number was "likely" to be appreciable was unsupported by the record. See *supra*, at 638.

[61] See *Environmental Defense Fund, Inc.* v *EPA*, 179 U. S. App. D. C. 43, 49, 57–63, 548 F. 2d 998, 1004, 1012–1018 (1977), cert. denied, 431 U. S. 925, where the court rejected the argument that the EPA has the burden of proving that a pesticide is unsafe in order to suspend its registration under the Federal Insecticide, Fungicide, and Rodenticide Act. The court noted that Congress had deliberately shifted the ordinary burden of proof under the Administrative Procedure Act, requiring manufacturers to establish the continued safety of their products.

illustrated best by its rejection of industry testimony that a dose-response curve can be formulated on the basis of current epidemiological evidence and that, even under the most conservative extrapolation theory, current exposure levels would cause at most two deaths out of a population of about 30,000 workers every six years. See n. 38, *supra*. In rejecting this testimony, OSHA made the following statement:

> "In the face of the record evidence of numerous actual deaths attributable to benzene-induced leukemia and other fatal blood diseases, OSHA is unwilling to rely on the hypothesis that at most two cancers every six years would be prevented by the proposed standard. By way of example, the Infante study disclosed seven excess leukemia deaths in a population of about 600 people over a 25-year period. While the Infante study involved higher exposures then those currently encountered, the incidence rates found by Infante, together with the numerous other cases reported in the literature of benzene leukemia and other fatal blood diseases, make it difficult for OSHA to rely on the [witness'] hypothesis to assure the statutorily mandated protection of employees. In any event, due to the fact that there is no safe level of exposure to benzene and that it is impossible to precisely quantify the anticipated benefits, OSHA must select the level of exposure which is most protective of exposed employees." 43 Fed. Reg. 5941 (1978)

There are three possible interpretations of OSHA's stated reason for rejecting the witness' testimony: (1) OSHA considered it probable that a greater number of lives would be saved by lowering the standard from 10 ppm, (2) OSHA thought that saving two lives every six years in a work force of 30,000 persons is a significant savings that makes it reasonable and appropriate to adopt a new standard, or (3) even if the small number is not significant and even if the savings may be even smaller, the Agency nevertheless believed it had

a statutory duty to select the level of exposure that is most protective of the exposed employees if it is economically and technologically feasible to do so. Even if the Secretary did not intend to rely entirely on this third theory, his construction of the statute would make it proper for him to do so. Moreover, he made no express findings of fact that would support his 1 ppm standard on any less drastic theory Under these circumstances, we can hardly agree with the Government that OSHA discharged its duty under the Act.

Contrary to the Government's contentions, imposing a burden on the Agency of demonstrating a significant risk of harm will not strip it of its ability to regulate carcinogens, nor will it require the Agency to wait for deaths to occur before taking any action. First, the requirement that a "significant" risk be identified is not a mathematical straitjacket. It is the Agency's responsibility to determine, in the first instance, what it considers to be a "significant" risk. Some risks are plainly acceptable and others are plainly unacceptable. If, for example, the odds are one in a billion that a person will die from cancer by taking a drink of chlorinated water, the risk clearly could not be considered significant. On the other hand, if the odds are one in a thousand that regular inhalation of gasoline vapors that are 2% benzene will be fatal, a reasonable person might well consider the risk significant and take appropriate steps to decrease or eliminate it. Although the Agency has no duty to calculate the exact probability of harm, it does have an obligation to find that a significant risk is present before it can characterize a place of employment as "unsafe." [62]

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[62] In his dissenting opinion, *post,* at 706, MR. JUSTICE MARSHALL states: "[W]hen the question involves determination of the acceptable level of risk, the ultimate decision must necessarily be based on considerations of policy as well as empirically verifiable facts. Factual determinations can at most define the risk in some statistical way; the judgment whether that risk is tolerable cannot be based solely on a resolution of

Second, OSHA is not required to support its finding that a significant risk exists with anything approaching scientific certainty. Although the Agency's findings must be supported by substantial evidence, 29 U. S. C. § 655 (f), § 6 (b)(5) specifically allows the Secretary to regulate on the basis of the "best available evidence." As several Courts of Appeals have held, this provision requires a reviewing court to give OSHA some leeway where its findings must be made on the frontiers of scientific knowledge. See *Industrial Union Dept., AFL–CIO* v *Hodgson*, 162 U. S. App. D. C. 331, 340, 499 F. 2d 467, 476 (1974); *Society of the Plastics Industry, Inc.* v *OSHA*, 509 F. 2d 1301, 1308 (CA2 1975), cert. denied, 421 U. S. 992. Thus, so long as they are supported by a body of reputable scientific thought, the Agency is free to use conservative assumptions in interpreting the data with respect to carcinogens, risking error on the side of overprotection rather than underprotection.[63]

Finally, the record in this case and OSHA's own rulings on other carcinogens indicate that there are a number of ways in which the Agency can make a rational judgment about the

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the facts." We agree. Thus, 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.

[63] MR. JUSTICE MARSHALL states that, under our approach, the Agency must either wait for deaths to occur or must "deceive the public" by making a basically meaningless determination of significance based on totally inadequate evidence. MR. JUSTICE MARSHALL's view, however, rests on the erroneous premise that the only reason OSHA did not attempt to quantify benefits in this case was because it could not do so in any reasonable manner. As the discussion of the Agency's rejection of an industry attempt at formulating a dose-response curve demonstrates, however, see *supra*, at 653–655, the Agency's rejection of methods such as dose-response curves was based at least in part on its view that nothing less than absolute safety would suffice.

relative significance of the risks associated with exposure to a particular carcinogen.[64]

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 monitor-

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[64] For example, in the coke-oven emissions standard, 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 41 Fed. Reg. 46742, 46750 (1976), upheld in *American Iron & Steel Inst.* v *OSHA,* 577 F 2d 825 (CA3 1978), cert. granted, *post,* p. 909. 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 population of 14,000 workers, as a result of the proposed standard. Although noting that the range of benefits would vary depending on the assumptions 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 benefits against the projected costs.

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. One hundred out of 200 animals died during that period. 39 Fed. Reg. 35890, 35891 (1974). 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. *Id.,* at 3756, 3757, upheld in *Synthetic Organic Chemical Mfrs. Assn.* v. *Brennan,* 503 F 2d 1155 (CA3 1974), cert. denied, 420 U. S. 973, and *Synthetic Organic Chemical Mfrs. Assn.* v. *Brennan,* 506 F 2d 385 (CA3 1974), cert. denied, 423 U. S. 830.

In this case the Agency did not have the benefit of animal studies, because scientists have been unable as yet to induce leukemia in experimental animals as a result of benzene exposure. It did, however, have a fair amount of epidemiological evidence, including both positive and negative studies. Although the Agency stated that this evidence was insufficient to construct a precise correlation between exposure levels and cancer risks, it would at least be helpful in determining whether it is more likely than not that there is a significant risk at 10 ppm.

ing 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.[65] By doing so, it could keep a constant check on the validity of the assumptions made in developing the permissible exposure limit, giving it a sound evidentiary basis for decreasing the limit if it was initially set too high.[66] Moreover, in this way it could ensure that workers who were unusally susceptible to benzene could be removed from exposure before they had suffered any permanent damage.[67]

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Because our review of these cases has involved a more detailed examination of the record than is customary, it must

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[65] See *GAF Corp.* v *Occupational Safety and Health Review Comm'n*, 183 U S. App. D. C. 20, 561 F 2d 913 (1977), where the court upheld the asbestos standard insofar as it required employers to provide medical examinations for employees exposed to any asbestos fibers, even if they were exposed to concentrations below the permissible exposure limit.

The respondent industry representatives have never disputed OSHA's power to require monitoring and medical examinations in general, although they did object to some of the specific requirements imposed in this case. See n. 30, *supra*. Because of our disposition of the case, we have no occasion to pass on these specific objections or to determine what cost-benefit considerations, if any, should govern the Agency's imposition of such requirements.

[66] This is precisely the type of information-gathering function that Congress had in mind when it enacted § 6 (b) (7), which empowers the Secretary to require medical examinations to be furnished to employees exposed to certain hazards and potential hazards "in order to most effectively determine whether the health of such employees is adversely affected by such exposure." See S. Rep. No. 91–1282, p. 7 (1970), Leg. Hist. 147

[67] In its explanation of the final standard OSHA noted that there was some testimony that blood abnormalities would disappear after exposure had ceased. 43 Fed. Reg. 5946 (1978). Again, however, OSHA refused to rely on the hypothesis that this would always occur. Yet, in requiring medical examinations of employees exposed to between 0.5 ppm and 1 ppm, OSHA was essentially providing itself with the same kind of backstop.

be emphasized that we have neither made any factual determinations of our own, nor have we rejected any factual findings made by the Secretary We express no opinion on what factual findings this record might support, either on the basis of empirical evidence or on the basis of expert testimony; nor do we express any opinion on the more difficult question of what factual determinations would warrant a conclusion that significant risks are present which make promulgation of a new standard reasonably necessary or appropriate. The standard must, of course, be supported by the findings actually made by the Secretary, not merely by findings that we believe he might have made.

In this case the record makes it perfectly clear that the Secretary relied squarely on a special policy for carcinogens that imposed the burden on industry of proving the existence of a safe level of exposure, thereby avoiding the Secretary's threshold responsibility of establishing the need for more stringent standards. In so interpreting his statutory authority, the Secretary exceeded his power.

IV

Throughout the administrative proceedings, the dermal contact issue received relatively little attention. In its proposed rule OSHA recommended a total ban on skin and eye contact with liquid benzene on the basis of its policy that "in dealing with a carcinogen, all potential routes of exposure (i. e., inhalation, ingestion, and skin absorption) [should] be limited to the extent feasible." 43 Fed. Reg. 5948 (1978) There was little opposition to this requirement at the hearing on the proposed rule, apparently because the proposed rule also excluded from both the permissible exposure level and the dermal contact ban work operations involving liquid mixtures containing 1% (and after one year, 0.1%) or less benzene.

In its final standard, however, OSHA eliminated the percentage exclusion for liquid benzene, on the ground that there was no predictable correlation between the percentage of ben-

zene in a liquid and the airborne exposure arising from it. See n. 22, *supra*. Although the extent to which liquid benzene is absorbed through the skin is concededly unknown, OSHA also refused to exempt any liquids, no matter how little benzene they contained, from the ban on dermal contact. In support of this position it stated that there was no evidence to "suggest that the absorption rate depends on the amount of benzene present in the liquid." 43 Fed. Reg. 5948–5949 (1978).

After the permanent standard was promulgated, OSHA received a number of requests from various industries that the percentage exclusion for liquids containing small amounts of benzene be reinstated. Those concerned with airborne exposures argued that they should not be required to monitor workplaces simply because they handled petroleum-based products in which benzene is an unavoidable contaminant. Others concerned with the dermal contact ban made similar arguments. In particular, tire manufacturers argued that it was impossible for them to comply with the ban because gloves cannot be worn during certain tire-building operations in which solvents are used and solvents containing absolutely no benzene are not commercially available.

Because of these requests, OSHA held a new series of hearings and promulgated an amendment to the rule, reinstating the percentage exclusion, but lowering it from the proposed 1% to 0.5%. The Agency did, however, provide for a 3-year grace period before the exclusion dropped to 0.1%, rather than the one year that had originally been proposed. In explaining its amendment, OSHA reiterated its policy with respect to carcinogens, stating that, because there is no absolutely safe level for any type of exposure, exposures by whatever route must be limited to the extent feasible. For airborne exposures, a zero permissible exposure limit had not been feasible. However, in most industries a ban on any dermal contact was feasible since compliance could be achieved simply by the use of protective clothing, such as impermeable

gloves. The Agency recognized that the dermal contact ban could present a problem for tire manufacturers, but stated that the percentage exclusion would alleviate the problem, because solvents containing 0.5% or less benzene were available in sufficient quantities. Although it noted that solvents containing 0.1% or less benzene were not then available in quantity, the Agency stated that a 3-year grace period would be sufficient to "allow time for increased production of solvents containing lower amounts of benzene and for development and evaluation of alternative methods of compliance with the standard's dermal provision." *Id.*, at 27968–27969.

The Court of Appeals struck down the dermal contact prohibition on two grounds. First, it held that the record did not support a finding that the ban would result in quantifiable benefits in terms of a reduced leukemia risk; therefore, it was not "reasonably necessary" within the meaning of § 3 (8) of the Act. Second, the court held that the Agency's conclusion that benzene may be absorbed through the skin was not based on the best available evidence as required by § 6 (b)(5) 581 F 2d, at 505–506. On the second ground, the court noted that the evidence on the issue of absorption of benzene through the skin was equivocal, with some studies indicating that it could be absorbed and some indicating that it could not. All of these studies were relatively old and the only expert who had testified on the issue stated that a simple test was now available to determine, with a great deal of accuracy, whether and to what extent absorption will result. In light of § 6 (b)(5), which requires the Agency to promulgate standards on the basis of the "best available evidence" and "the latest available scientific data in the field," the court held that where there is uncontradicted testimony that a simple test will resolve the issue, the Agency is required to acquire that information before "promulgating regulations which would require an established industry to change long-followed work processes that are not demonstrably unsafe." 581 F 2d, at 508.

While the court below may have been correct in holding that, under the peculiar circumstances of this case, OSHA was required to obtain more information, there is no need for us to reach that issue. For, in order to justify a ban on dermal contact, the Agency must find that such a ban is "reasonably necessary and appropriate" to remove a significant risk of harm from such contact. The Agency did not make such a finding, but rather acted on the basis of the absolute, no-risk policy that it applies to carcinogens. Indeed, on this issue the Agency's position is even more untenable, inasmuch as it was required to assume not only that benzene in small doses is a carcinogen, but also that it can be absorbed through the skin in sufficient amounts to present a carcinogenic risk. These assumptions are not a proper substitute for the findings of a significant risk of harm required by the Act.

The judgment of the Court of Appeals remanding the petition for review to the Secretary for further proceedings is affirmed.

It is so ordered.

MR. CHIEF JUSTICE BURGER, concurring.

These cases press upon the Court difficult unanswered questions on the frontiers of science and medicine. The statute and the legislative history give ambiguous signals as to how the Secretary is directed to operate in this area. The opinion by MR. JUSTICE STEVENS takes on a difficult task to decode the message of the statute as to guidelines for administrative action.

To comply with statutory requirements, the Secretary must bear the burden of "finding" that a proposed health and safety standard is "reasonably necessary or appropriate to provide safe or healthful employment and places of employment." This policy judgment entails the subsidiary finding that the pre-existing standard presents a "significant risk" of material health impairment for a worker who spends his entire employment life in a working environment where ex-

posure remains at maximum permissible levels. The Secretary's factual finding of "risk" must be "quantified sufficiently to enable the Secretary to characterize it as significant in an understandable way" *Ante*, at 646. Precisely what this means is difficult to say But because these mandated findings were not made by the Secretary, I agree that the 1 ppm benzene standard must be invalidated. However, I would stress the differing functions of the courts and the administrative agency with respect to such health and safety regulation.

The Congress is the ultimate regulator, and the narrow function of the courts is to discern the meaning of the statute and the implementing regulations with the objective of ensuring that in promulgating health and safety standards the Secretary "has given reasoned consideration to each of the pertinent factors" and has complied with statutory commands. *Permian Basin Area Rate Cases*, 390 U S. 747, 792 (1968) Our holding that the Secretary must retrace his steps with greater care and consideration is not to be taken in derogation of the scope of legitimate agency discretion. When the facts and arguments have been presented and duly considered, the Secretary must make a policy judgment as to whether a specific risk of health impairment is significant in terms of the policy objectives of the statute. When he acts in this capacity, pursuant to the legislative authority delegated by Congress, he exercises the prerogatives of the legislature—to focus on only one aspect of a larger problem, or to promulgate regulations that, to some, may appear as imprudent policy or inefficient allocation of resources. The judicial function does not extend to substantive revision of regulatory policy That function lies elsewhere—in Congressional and Executive oversight or amendatory legislation—although to be sure the boundaries are often ill-defined and indistinct.

Nevertheless, when discharging his duties under the statute, the Secretary is well admonished to remember that a heavy responsibility burdens his authority Inherent in this statutory scheme is authority to refrain from regulation of

insignificant or *de minimis* risks. See *Alabama Power Co.* v *Costle*, 204 U S. App. D C. 51, 88–89, 636 F 2d 323, 360–361 (1979) (opinion of Leventhal, J). 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.

MR. JUSTICE POWELL, concurring in part and concurring in the judgment.

I join Parts I, II, III–A, III–B, III–C, and III–E of the plurality opinion.[1] The Occupational Safety and Health Administration relied in large part on its "carcinogen policy"—which had not been adopted formally—in promulgating the benzene exposure and dermal contact regulation at issue in these cases.[2] For the reasons stated by the plurality, I agree that §§ 6 (b)(5) and 3 (8) of the Occupational Safety and Health Act of 1970, 29 U S. C. §§ 655 (b)(5) and 652 (8), must be read together. They require OSHA to make a threshold finding that proposed occupational health standards are reasonably necessary to provide safe workplaces. When OSHA acts to reduce existing national consensus standards,

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[1] These portions of the plurality opinion primarily address OSHA's special carcinogen policy, rather than OSHA's argument that it also made evidentiary findings. I do not necessarily agree with every observation in the plurality opinion concerning the presence or absence of such findings. I also express no view on the question whether a different interpretation of the statute would violate the nondelegation doctrine of *A. L. A. Schechter Poultry Corp.* v. *United States*, 295 U. S. 495 (1935), and *Panama Refining Co.* v *Ryan*, 293 U. S. 388 (1935). See *post*, at 672–687 (REHNQUIST, J., concurring in judgment).

[2] The Secretary of Labor promulgated the relevant standard pursuant to his statutory authority Since OSHA is the agency responsible for developing such regulations under the Secretary's direction, this opinion refers to "OSHA" or "the agency" as the decisionmaker most directly concerned.

therefore, it must find that (i) currently permissible exposure levels create a significant risk of material health impairment, and (ii) a reduction of those levels would significantly reduce the hazard.

Although I would not rule out the possibility that the necessary findings could rest in part on generic policies properly adopted by OSHA, see McGarity, Substantive and Procedural Discretion in Administrative Resolution of Science Policy Questions: Regulating Carcinogens in EPA and OSHA, 67 Geo. L. J 729, 754–759 (1979), no properly supported agency policies are before us in these cases.[3] I therefore agree with the plurality that the regulation is invalid to the extent it rests upon the assumption that exposure to known carcinogens always should be reduced to a level proved to be safe or, if no such level is found, to the lowest level that the affected industry can achieve with available technology

I

If the disputed regulation were based exclusively on this "carcinogen policy," I also would agree that we need not consider whether the Act requires OSHA to determine that the benefits of a proposed standard are reasonably related to the costs of compliance. *Ante,* at 615. As the Court of Appeals for the Fifth Circuit recognized, however, OSHA takes the "fall-back position" that its regulation is justified by specific findings based upon the voluminous evidentiary record compiled in this case. *American Petroleum Institute* v *OSHA,* 581 F 2d 493, 503. OSHA found, for example, that the num-

[3] OSHA has adopted a formal policy for regulating carcinogens effective April 21, 1980. 45 Fed. Reg. 5282 (1980) (to be codified at 29 CFR, Part 1990). But no such policy was in effect when the agency promulgated its benzene regulation. Moreover, neither the factual determinations nor the administrative judgments upon which the policy rests are supported adequately on this record alone. Accordingly, we have no occasion to consider the extent to which valid agency policies may supply a basis for a finding that health risks exist in particular cases.

ber of cancers prevented by reducing permissible exposure levels from 10 ppm to 1 ppm "may be appreciable," that "the benefits of the proposed standard are likely to be appreciable," and that the "substantial costs [of the new standard] are justified in light of the hazards." 43 Fed. Reg. 5940–5941 (1978) Thus, OSHA found—at least generally—that the hazards of benzene exposure at currently permissible levels are serious enough to justify an expenditure of hundreds of millions of dollars. For me, that finding necessarily subsumes the conclusion that the health risk is "significant." If OSHA's conclusion is supported by substantial evidence, the threshold requirement discussed in the plurality opinion would be satisfied.

As I read its opinion, the plurality does not consider whether the agency's findings are supported by substantial evidence. The Court of Appeals found them insufficient because OSHA failed "to estimate the extent of expected benefits. " 581 F 2d, at 504. That court apparently would have required OSHA to supply a specific numerical estimate of benefits derived through mathematical techniques for "risk quantification" or "cost-effectiveness analysis." *Id.*, at 504, n. 23, see *id.*, at 504–505. I do not agree with the Court of Appeals' conclusion that the statute requires quantification of risk in every case.

The statutory preference for the "best available evidence," 29 U S. C. § 655 (b)(5), implies that OSHA must use the best known techniques for the accurate estimation of risks and benefits when such techniques are available. But neither the statute nor the legislative history suggests that OSHA's hands are tied when reasonable quantification cannot be accomplished by any known methods. See *post,* at 693 (MARSHALL, J., dissenting) In this litigation, OSHA found that "it is impossible to precisely quantify the anticipated benefits. " 43 Fed. Reg. 5941 (1978). If this finding is supported by substantial evidence, the statute does not prevent the Secretary from finding a significant health hazard on the

basis of the weight of expert testimony and opinion. I do not understand the plurality to hold otherwise. See *ante*, at 662.

For the foregoing reasons, I would not hold that "OSHA did not even attempt to carry its burden of proof" on the threshold question whether exposure to benzene at 10 ppm presents a significant risk to human health. *Ante*, at 653. In my view, the question is whether OSHA successfully carried its burden on the basis of record evidence. That question in turn reduces to two principal issues. First, is there substantial evidence supporting OSHA's determination that available quantification techniques are too imprecise to permit a reasonable numerical estimate of risks? If not, then OSHA has failed to show that its regulation rests on the "best available evidence." Second, is OSHA's finding of significant risks at current exposure levels supported by substantial evidence? If not, then OSHA has failed to show that the new regulation is reasonably necessary to provide safe and healthful workplaces.

II

Although I regard the question as close, I do not disagree with the plurality's view that OSHA has failed, on this record, to carry its burden of proof on the threshold issues summarized above. But even if one assumes that OSHA properly met this burden, see *post*, at 697–701, 713–714 (MARSHALL, J., dissenting), I conclude that the statute also requires the agency to determine that the economic effects of its standard bear a reasonable relationship to the expected benefits. An occupational health standard is neither "reasonably necessary" nor "feasible," as required by statute, if it calls for expenditures wholly disproportionate to the expected health and safety benefits.

OSHA contends that § 6 (b)(5) not only permits but actually requires it to promulgate standards that reduce health risks without regard to economic effects, unless those effects

would cause widespread dislocation throughout an entire industry.[4] Under the threshold test adopted by the plurality today, this authority will exist only with respect to "significant" risks. But the plurality does not reject OSHA's claim that it must reduce such risks without considering economic consequences less serious than massive dislocation. In my view, that claim is untenable.

Although one might wish that Congress had spoken with greater clarity, the legislative history and purposes of the statute do not support OSHA's interpretation of the Act.[5]

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[4] OSHA argues that § 6 (b) (5) requires it to promulgate standards that are "feasible" only in the sense that they are "capable of achievement"; that is, achievable "at bearable cost with available technology." Brief for Federal Parties 57. The lower courts have indicated that a standard is not "infeasible" under OSHA's test unless it would precipitate "massive economic dislocation" in the affected industry. See, *e. g., American Federation of Labor* v *Brennan*, 530 F. 2d 109, 123 (CA3 1975). In this case, OSHA simply asked a consulting firm to ascertain the costs of complying with a 1 ppm standard. See *ante*, at 621. OSHA then concluded that "the economic impact of [compliance] will not threaten the financial welfare of the affected firms or the general economy." 43 Fed. Reg. 5939 (1978). The cost of complying with a standard may be "bearable" and still not reasonably related to the benefits expected. A manufacturing company, for example, may have financial resources that enable it to pay the OSHA-ordered costs. But expenditures for unproductive purposes may limit seriously its financial ability to remain competitive and provide jobs.

[5] I will not repeat the detailed summary of the legislative history contained in the plurality opinion. *Ante*, at 646–652. Many of the considerations that the plurality relies upon to show Congress' concern with significant harms persuade me that Congress did not intend OSHA to reduce each significant hazard without regard to economic consequences. Senator Williams, a sponsor of the legislation, stated: "Our bill is fair and reasonable. It is a good-faith effort to balance the need of workers to have a sa[f]e and healthy work environment against the requirement of industry to function without undue interference." 116 Cong. Rec. 37342 (1970), Legislative History of the Occupational Safety and Health Act of 1970 (Committee Print compiled for the Senate Committee on Labor and Public Welfare), p. 435 (1971). There could be no such "balance" if OSHA were

It is simply unreasonable to believe that Congress intended OSHA to pursue the desirable goal of risk-free workplaces to the extent that the economic viability of particular industries—or significant segments thereof—is threatened. As the plurality observes, OSHA itself has not chosen to carry out such a self-defeating policy in all instances. *Ante,* at 650. If it did, OSHA regulations would impair the ability of American industries to compete effectively with foreign businesses and to provide employment for American workers.[6]

I therefore would not lightly assume that Congress intended OSHA to require reduction of health risks found to be significant *whenever* it also finds that the affected indus-

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authorized to impose standards without regard to economic consequences short of serious dislocation.

Senator Dominick described a preliminary version of § 6 (b)(5) as follows:

"What we were trying to do in the bill was to say that when we are dealing with toxic agents or physical agents, we ought to take such steps as are *feasible and practical* to provide an atmosphere within which a person's health or safety would not be affected. Unfortunately, we had language providing that anyone [*sic*] would be assured that no one would have a hazard.

"It was an unrealistic standard. " 116 Cong. Rec. 37622 (1970), Legislative History, *supra,* at 502 (emphasis added).

Senator Dominick's objection to the "unrealistic" standard of the forerunner of § 6 (b)(5) does not imply that he thought § 3 (8) of the Act lacked substantive content. See *post,* at 710–711 (MARSHALL, J., dissenting). The Senator hardly would have proposed that § 6 (b)(5) be deleted entirely, see *ante,* at 647, if he had not thought that other sections of the Act required health regulations that were reasonable and practical.

[6] Congress has assigned OSHA an extremely difficult and complex task, and the guidance afforded OSHA is considerably less than clear. The agency's primary responsibility, reflected in its title, is to minimize health and safety risks in the workplace. Yet the economic health of our highly industrialized society requires a high rate of employment and an adequate response to increasingly vigorous foreign competition. There can be little doubt that Congress intended OSHA to balance reasonably the societal interest in health and safety with the often conflicting goal of maintaining a strong national economy

try can bear the costs. See n. 4, *supra*. Perhaps more significantly, however, OSHA's interpretation of § 6 (b)(5) would force it to regulate in a manner inconsistent with the important health and safety purposes of the legislation we construe today Thousands of toxic substances present risks that fairly could be characterized as "significant." Cf. *ante*, at 645, n. 51. Even if OSHA succeeded in selecting the gravest risks for earliest regulation, a standard-setting process that ignored economic considerations would result in a serious misallocation of resources and a lower effective level of safety than could be achieved under standards set with reference to the comparative benefits available at a lower cost.[7] I would not attribute such an irrational intention to Congress.

In these cases, OSHA did find that the "substantial costs" of the benzene regulations are justified. See *supra*, at 665–666. But the record before us contains neither adequate documentation of this conclusion, nor any evidence that OSHA weighed the relevant considerations. The agency simply announced its finding of cost-justification without explaining the method by which it determines that the benefits justify the costs and their economic effects. No rational system of regulation can permit its administrators to make policy judgments without explaining how their decisions effectuate the purposes of the governing law, and nothing in the statute authorizes such laxity in these cases.[8] Since neither the air-

[7] For example, OSHA's reading of § 6 (b) (5) could force the depletion of an industry's resources in an effort to reduce a single risk by some speculative amount, even though other significant risks remain unregulated.

[8] The decision that costs justify benefits is largely a policy judgment delegated to OSHA by Congress. When a court reviews such judgments under the "substantial evidence" standard mandated by 29 U. S. C. § 655 (f), the court must determine whether the responsible agency has "careful[ly] identifi[ed] the reasons why [it] chooses to follow one course rather than another" as the most reasonable method of effectuating the purposes of the applicable law. *Industrial Union Dept.* v. *Hodgson*, 162 U. S. App. D. C. 331, 339–340, 499 F 2d 467, 475–476 (1974). Since OSHA failed to identify its reasons in these cases, I express no

borne concentration standard nor the dermal contact standard for exposure to benzene satisfies the requirements of the governing statute, I join the Court's judgment affirming the judgment of the Court of Appeals.

MR. JUSTICE REHNQUIST, concurring in the judgment.

The statutory provision at the center of the present controversy, § 6 (b)(5) of the Occupational Safety and Health Act of 1970, states, in relevant part, that the Secretary of Labor

> " in promulgating standards dealing with toxic materials or harmful physical agents 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 such standard for the period of his working life." 84 Stat. 1594, 29 U S. C. § 655 (b)(5) (emphasis added)

According to the Secretary, who is one of the petitioners herein, § 6 (b)(5) imposes upon him an absolute duty, in regulating harmful substances like benzene for which no safe level is known, to set the standard for permissible exposure at the lowest level that "can be achieved at bearable cost with available technology" Brief for Federal Parties 57 While the Secretary does not attempt to refine the concept of "bearable cost," he apparently believes that a proposed standard is economically feasible so long as its impact "will not be such as to threaten the financial welfare of the affected firms or the general economy" 43 Fed. Reg. 5939 (1978).

Respondents reply, and the lower court agreed, that § 6 (b)(5) must be read in light of another provision in the

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opinion as to the standard of review that may be appropriate in other situations.

same Act, § 3 (8), which defines an "occupational health and safety standard" as

> " a standard which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment." 84 Stat. 1591, 29 U S. C. § 652 (8)

According to respondents, § 6 (b)(5), as tempered by § 3 (8), requires the Secretary to demonstrate that any particular health standard is justifiable on the basis of a rough balancing of costs and benefits.

In considering these alternative interpretations, my colleagues manifest a good deal of uncertainty, and ultimately divide over whether the Secretary produced sufficient evidence that the proposed standard for benzene will result in any appreciable benefits at all. This uncertainty, I would suggest, is eminently justified, since I believe that this litigation presents the Court with what has to be one of the most difficult issues that could confront a decisionmaker: whether the statistical possibility of future deaths should ever be disregarded in light of the economic costs of preventing those deaths. I would also suggest that the widely varying positions advanced in the briefs of the parties and in the opinions of MR. JUSTICE STEVENS, THE CHIEF JUSTICE, MR. JUSTICE POWELL, and MR. JUSTICE MARSHALL demonstrate, perhaps better than any other fact, that Congress, the governmental body best suited and most obligated to make the choice confronting us in this litigation, has improperly delegated that choice to the Secretary of Labor and, derivatively, to this Court.

I

In his Second Treatise of Civil Government, published in 1690, John Locke wrote that "[t]he power of the legislative, being derived from the people by a positive voluntary grant and institution, can be no other than what that positive

grant conveyed, which being only to make laws, and not to make legislators, the legislative can have no power to transfer their authority of making laws and place it in other hands." [1] Two hundred years later, this Court expressly recognized the existence of and the necessity for limits on Congress' ability to delegate its authority to representatives of the Executive Branch. "That Congress cannot delegate legislative power to the President is a principle universally recognized as vital to the integrity and maintenance of the system of government ordained by the Constitution." *Field* v *Clark*, 143 U S. 649, 692 (1892) [2]

The rule against delegation of legislative power is not, however, so cardinal a principle as to allow for no exception. The Framers of the Constitution were practical statesmen, who saw that the doctrine of separation of powers was a two-sided coin. James Madison, in Federalist Paper No. 48, for example, recognized that while the division of authority among the various branches of government was a useful principle, "the degree of separation which the maxim requires, as essential to a free government, can never in practice be duly maintained." The Federalist No. 48, p. 308 (H. Lodge ed. 1888).

This Court also has recognized that a hermetic sealing-off of the three branches of government from one another could easily frustrate the establishment of a National Government

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[1] J. Locke, Second Treatise of Civil Government, in the Tradition of Freedom, ¶ 141, p. 244 (M. Mayer ed. 1957). In the same treatise, Locke also wrote that "[t]he legislative cannot transfer the power of making laws to any other hands; for it being but a delegated power from the people, they who have it cannot pass it over to others." *Ibid.*

[2] As early as 1812, this Court had considered and rejected an argument that a statute authorizing the President to terminate a trade embargo on Britain and France if those two nations ceased violating "the neutral commerce of the United States" delegated too much discretion to the Executive Branch. See *The Brig Aurora* v. *United States*, 7 Cranch 382, 383, 386, 388.

capable of effectively exercising the substantive powers granted to the various branches by the Constitution. Mr. Chief Justice Taft, writing for the Court in *J. W. Hampton & Co.* v *United States*, 276 U. S. 394 (1928), noted the practicalities of the balance that has to be struck:

> "[T]he rule is that in the actual administration of the government Congress or the Legislature should exercise the legislative power, the President or the State executive, the Governor, the executive power, and the Courts or the judiciary the judicial power, and in carrying out that constitutional division into three branches it is a breach of the National fundamental law if Congress gives up its legislative power and transfers it to the President, or to the Judicial branch, or if by law it attempts to invest itself or its members with either executive power or judicial power. This is not to say that the three branches are not co-ordinate parts of one government and that each in the field of its duties may not invoke the action of the two other branches in so far as the action invoked shall not be an assumption of the constitutional field of action of another branch. In determining what it may do in seeking assistance from another branch, the extent and character of that assistance must be fixed according to common sense and the inherent necessities of the governmental co-ordination." *Id.*, at 406.

During the third and fourth decades of this century, this Court within a relatively short period of time struck down several Acts of Congress on the grounds that they exceeded the authority of Congress under the Commerce Clause or under the nondelegation principle of separation of powers, and at the same time struck down state statutes because they violated "substantive" due process or interfered with interstate commerce. See generally R. Jackson, The Struggle for Judicial Supremacy 48–123 (1949). When many of these decisions were later overruled, the principle that Congress

could not simply transfer its legislative authority to the Executive fell under a cloud. Yet in my opinion decisions such as *Panama Refining Co.* v *Ryan,* 293 U S. 388 (1935), suffer from none of the excesses of judicial policymaking that plagued some of the other decisions of that era. The many later decisions that have upheld congressional delegations of authority to the Executive Branch have done so largely on the theory that Congress may wish to exercise its authority in a particular field, but because the field is sufficiently technical, the ground to be covered sufficiently large, and the Members of Congress themselves not necessarily expert in the area in which they choose to legislate, the most that may be asked under the separation-of-powers doctrine is that Congress lay down the general policy and standards that animate the law, leaving the agency to refine those standards, "fill in the blanks," or apply the standards to particular cases. These decisions, to my mind, simply illustrate the above-quoted principle stated more than 50 years ago by Mr. Chief Justice Taft that delegations of legislative authority must be judged "according to common sense and the inherent necessities of the governmental co-ordination."

Viewing the legislation at issue here in light of these principles, I believe that it fails to pass muster. Read literally, the relevant portion of § 6 (b)(5) is completely precatory, admonishing the Secretary to adopt the most protective standard if he can, but excusing him from that duty if he cannot. In the case of a hazardous substance for which a "safe" level is either unknown or impractical, the language of § 6 (b)(5) gives the Secretary absolutely no indication where on the continuum of relative safety he should draw his line. Especially in light of the importance of the interests at stake, I have no doubt that the provision at issue, standing alone, would violate the doctrine against uncanalized delegations of legislative power. For me the remaining question, then, is whether additional standards are ascertainable from the legislative history or statutory context of § 6 (b)(5) or, if not, whether

such a standardless delegation was justifiable in light of the "inherent necessities" of the situation.

II

One of the primary sources looked to by this Court in adding gloss to an otherwise broad grant of legislative authority is the legislative history of the statute in question. The opinions of MR. JUSTICE STEVENS and MR. JUSTICE MARSHALL, however, give little more than a tip of the hat to the legislative origins of § 6 (b)(5) Such treatment is perhaps understandable, since the legislative history of that section, far from shedding light on what important policy choices Congress was making in the statute, gives one the feeling of viewing the congressional purpose "by the dawn's early light."

The precursor of § 6 (b)(5) was placed in the Occupational Safety and Health Act of 1970 while that bill was pending in the House Committee on Education and Labor. At that time, the section read.

> "The Secretary, in promulgating standards under this subsection, shall set the standard which most adequately assures, on the basis of the best available professional evidence, that no employee will suffer any impairment of health, or functional capacity, or diminished life expectancy even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life." § 7 (a)(4), H. R. 16785, 91st Cong., 2d Sess., 49 (1970), Legislative History of the Occupational Safety and Health Act of 1970 (Committee Print compiled for the Senate Committee on Labor and Public Welfare), p. 943 (1971) (hereinafter Leg. Hist.).

Three aspects of this original proposal are particularly significant. First, and perhaps most importantly, as originally introduced the provision contained no feasibility limitation, providing instead that the Secretary "shall set the standard which most adequately assures" that no employee will suffer

harm. Second, it would have required the Secretary to protect employees from "any" impairment of health or functional capacity Third, on its face, although perhaps not in its intent, the provision applied to both health and safety standards promulgated under the Act.[3]

There can be little doubt that, at this point in its journey through Congress, § 6 (b)(5) would have required the Secretary, in regulating toxic substances, to set the permissible level of exposure at a safe level or, if no safe level was known, at zero. When the Senate Committee on Labor and Public Welfare considered a provision identical in almost all respects to the House version, however, Senator Javits objected that the provision in question "might be interpreted to require absolute health and safety in all cases, regardless of feasibility " S. Rep. No. 91–1282, p. 58 (1970), Leg. Hist. 197 See also 116 Cong. Rec. 37327 (1970), Leg. Hist. 418. The Committee therefore amended the bill to provide that the Secretary "shall set the standard which most adequately *and feasibly*" assured that no employee would suffer any impairment of health. S. 2193, 91st Cong., 2d Sess., p. 39 (1970), Leg. Hist. 242 (emphasis added) The only additional explanation for this change appeared in the Senate Report accompanying the bill to the Senate floor. There, the Committee explained.

> "[S]tandards promulgated under section 6 (b) shall represent *feasible requirements,* which, where appropriate, shall be based on research, experiments, demonstrations, past experience, and the latest available scientific

[3] Respondents argue that, despite its seemingly general application, the original version of § 6 (b)(5) actually referred only to health hazards as opposed to safety hazards. See Addendum B to Brief for Respondents American Petroleum Institute et al. 5b–6b. In support of this proposition, they cite a portion of the legislative history where the House Committee on Education and Labor stated that the proposed version of § 6 (b)(5) would apply when the Secretary set an "occupational health standard." H. R. Rep. No. 91–1291, p. 18 (1970), Leg. Hist. 848.

data. Such standards should be directed at assuring, *so far as possible,* that no employee will suffer impaired health or functional capacity or diminished life expectancy, by reason of exposure to the hazard involved, even though such exposure may be over the period of his entire working life." S. Rep. No. 91–1282, p. 7 (1970), Leg. Hist. 147 (emphasis added)

Despite Senator Javits' inclusion of the words "and feasibly" in the provision, participants in the floor debate immediately characterized § 6 (b)(5) as requiring the Secretary "to establish a utopia free from any hazards" and to "assure that there will not be any risk at all." 116 Cong. Rec. 37614 (1970), Leg. Hist. 480–481 (remarks of Sen. Dominick). Senator Saxbe stated.

> "When we come to saying that an employer must guarantee that such an employee is protected from any possible harm, I think it will be one of the most difficult areas we are going to have to ascertain.
>
> "I believe the terms that we are passing back and forth are going to have to be identified." 116 Cong. Rec., at 26522, Leg. Hist. 345.

In response to these concerns, Senator Dominick introduced a substitute for the proposed provision, deleting the sentence at issue here entirely He explained that his amendment would delete

> "the requirement in section 6 (b)(5) that the Secretary will establish occupational safety and health standards which most adequately and feasibly assure to the extent possible that *no* employee will suffer *any* impairment of health or functional capacity, or diminished life expectancy even if the employee has regular exposure to the hazard dealt with by the standard for the period of his working life.
>
> "This requirement is inherently confusing and unrealistic. It could be read to require the Secretary to ban all

occupations in which there remains *some* risk of injury, impaired health, or life expectancy In the case of all occupations, it will be impossible to eliminate all risks to safety and health. Thus, the present criteria could, if literally applied, close every business in this nation. In addition, in many cases, the standard which might most 'adequately' and 'feasibly' assure the elimination of the danger would be the prohibition of the occupation itself.

"If the provision is intended as no more than an admonition to the Secretary to do his duty, it seems unnecessary and could, if deemed advisable be included in the legislative history" (Emphasis in original.) 116 Cong. Rec., at 36530, Leg. Hist. 367

Eventually, Senator Dominick and his supporters settled for the present language of § 6 (b)(5) This agreement resulted in three changes from the original version of the provision as amended by Senator Javits. First, the provision was altered to state explicitly that it applied only to standards for "toxic materials or harmful physical agents," in apparent contrast with safety standards. Second, the Secretary was no longer admonished to protect employees from "any" impairment of their health, but rather only from "material" impairments. Third, and most importantly for our purposes, the phrase "most adequately and feasibly assures" was revamped to read "most adequately assures, to the extent feasible."

We have been presented with a number of different interpretations of this shift. According to the Secretary, Senator Dominick recognized that he could not delete the seemingly absolute requirements of § 6 (b)(5) entirely, and instead agreed to limit its application to toxic materials or harmful physical agents and to specify that the Secretary was only to protect employees from material impairment of their health. Significantly, the Secretary asserts that his mandate to set such standards at the safest level technologically and eco-

nomically achievable remained unchanged by the Dominick amendment. According to the Secretary, the change in language from "most adequately and feasibly assures" to "most adequately assures, to the extent feasible," represented only a slight shift in emphasis, perhaps suggesting "a preference for health protection over cost." App. to Brief for Federal Parties 7a, n. 2. See also Brief for Federal Parties 59.

MR. JUSTICE MARSHALL reads this history quite differently In his view, the version of § 6 (b)(5) that reached the Senate floor did not "clearly embod[y] the feasibility requirement" and thus was soundly criticized as being unrealistic. See *post,* at 693. It was only as a result of the floor amendments, which replaced "most adequately and feasibly assures" with "most adequately assures, to the extent feasible," that the Secretary clearly was authorized to reject a standard if it proved technologically or economically infeasible. See also *post,* at 710, and 720–721, n. 34.

Respondents cast yet a third light on these events, focusing upon a few places in the legislative history where the words "feasible" and "reasonable" were used more or less interchangeably See S. Rep. No. 91–2193, pp. 8–10 (1969), Leg. Hist. 38–40, 115 Cong. Rec. 22517 (1969) (Sen. Javits). It is their contention that, when Congress said "feasible," it meant cost-justified. According to respondents, who agree in this regard with the Secretary, the meaning of the feasibility requirement did not change substantially between the version that left the Senate Committee on Labor and Public Welfare and the version that was ultimately adopted as part of the Act.

To my mind, there are several lessons to be gleaned from this somewhat cryptic legislative history First, as pointed out by MR. JUSTICE MARSHALL, to the extent that Senator Javits, Senator Dominick, and other Members were worried about imposing upon the Secretary the impossible burden of assuring absolute safety, they did not view § 3 (8) of the Act

as a limitation on that duty I therefore find it difficult to accept the conclusion of the lower court, as embellished by respondents, that § 3 (8) acts as a general check upon the Secretary's duty under § 6 (b)(5) to adopt the most protective standard feasible.

Second, and more importantly, I believe that the legislative history demonstrates that the feasibility requirement, as employed in § 6 (b)(5), is a legislative mirage, appearing to some Members but not to others, and assuming any form desired by the beholder. I am unable to accept MR. JUSTICE MARSHALL's argument that, by changing the phrasing of § 6 (b)(5) from "most adequately and feasibly assures" to "most adequately assures, to the extent feasible," the Senate injected into that section something that was not already there.[4] If I am correct in this regard, then the amendment introduced by Senator Javits to relieve the Secretary of the duty to create a risk-free workplace left Senator Dominick free to object to the amended provision on the same grounds. Perhaps Senator Dominick himself offered the aptest description of the feasibility requirement as "no more than an admonition to the Secretary to do his duty " 116 Cong. Rec. 36530 (1970), Leg. Hist. 367

In sum, the legislative history contains nothing to indicate that the language "to the extent feasible" does anything other

[4] The legislative history indicates strongly that Senator Dominick himself saw little, if any, difference between the phrases "most adequately and feasibly assures" and "most adequately assures, to the extent feasible." In the course of his earlier attempt to delete the first sentence of § 6 (b)(5) entirely, he paraphrased the unamended version of that section as requiring the Secretary to promulgate standards that "most adequately and feasibly assure *to the extent possible*" that no employee would suffer harm. See 116 Cong. Rec. 36530 (1970), Leg. Hist. 367 (emphasis added). Unless Senator Dominick found a significant difference between the words "possible" and "feasible," it is clear that there is little difference between Senator Dominick's perception of what the unamended section required in the way of feasibility and what that section required after his amendment.

than render what had been a clear, if somewhat unrealistic, standard largely, if not entirely, precatory There is certainly nothing to indicate that these words, as used in § 6 (b)(5), are limited to technological and economic feasibility When Congress has wanted to limit the concept of feasibility in this fashion, it has said so, as is evidenced in a statute enacted the same week as the provision at issue here.[5] I also question whether the Secretary wants to assume the duties such an interpretation would impose upon him. In these cases, for example, the Secretary actually declined to adopt a standard lower than 1 ppm for some industries, not because it was economically or technologically infeasible, but rather because "different levels for different industries would result in serious administrative difficulties." 43 Fed. Reg. 5947 (1978) See also *ante*, at 650 (plurality opinion) If § 6 (b)(5) authorizes the Secretary to reject a more protective standard in the interest of administrative feasibility, I have little doubt that he could reject such standards for any reason whatsoever, including even political feasibility

III

In prior cases this Court has looked to sources other than the legislative history to breathe life into otherwise vague delegations of legislative power. In *American Power & Light Co.* v *SEC*, 329 U S. 90, 104 (1946), for example, this Court concluded that certain seemingly vague delegations "derive[d] much meaningful content from the purpose of the Act, its factual background and the statutory context in which they appear." Here, however, there is little or nothing in the

[5] Sections 211 (c)(2)(A) and (B) of the Clean Air Act, as amended on Dec. 31, 1970, 84 Stat. 1698, authorize the Environmental Protection Agency to regulate, control, or prohibit automotive fuel additives after "consideration of other *technologically or economically feasible* means of achieving emission standards. " 42 U S. C. § 7545 (c)(2)(A) (1976 ed., Supp. II) (emphasis added).

remaining provisions of the Occupational Safety and Health Act to provide specificity to the feasibility criterion in § 6 (b) (5) It may be true, as suggested by MR. JUSTICE MARSHALL, that the Act as a whole expresses a distinct preference for safety over dollars. But that expression of preference, as I read it, falls far short of the proposition that the Secretary must eliminate marginal or insignificant risks of material harm right down to an industry's breaking point.

Nor are these cases like *Lichter* v *United States,* 334 U S. 742, 783 (1948), where this Court upheld delegation of authority to recapture "excessive profits" in light of a pre-existing administrative practice. Here, the Secretary's approach to toxic substances like benzene could not have predated the enactment of § 6 (b)(5) itself. Moreover, there are indications that the postenactment administrative practice has been less than uniform. For example, the Occupational Safety and Health Review Commission (OSHRC), the body charged with adjudicating citations issued by the Secretary under the Act, apparently does not agree with the definition of "feasibility," advanced in these cases by the Secretary In *Continental Can Co.,* 4 OSHC 1541, 1976–1977 OSHD ¶ 21,009 (1976), the Commission reasoned.

> "Clearly, employers have finite resources available for use to abate health hazards. And just as clearly if they are to be made to spend without limit for abatement of this hazard their financial ability to abate other hazards, including life threatening hazards, is reduced." *Id.,* at 1547, 1976–1977 OSHD, p. 25,256.

Furthermore, the record in these cases contains at least one indication that the Secretary himself was, at one time, quite uncertain what limits § 6 (b)(5) placed upon him. In announcing the proposed 1 ppm standard and discussing its economic ramifications, the Secretary explained that "[w]hile the precise meaning of feasibility is not clear from the Act, it is

OSHA's view that the term may include the economic ramifications of requirements imposed by standards." 43 Fed. Reg. 5934 (1978). This candid and tentative statement falls far short of the Secretary's present position that economic and technological considerations set the only limits on his duty to adopt the most protective standard. Finally, as noted earlier, the Secretary has failed to apply his present stringent view uniformly, rejecting in these cases a lower standard for some industries on the grounds of administrative convenience.

In some cases where broad delegations of power have been examined, this Court has upheld those delegations because of the delegatee's residual authority over particular subjects of regulation. In *United States* v *Curtiss-Wright Export Corp.*, 299 U. S. 304, 307 (1936), this Court upheld a statute authorizing the President to prohibit the sale of arms to certain countries if he found that such a prohibition would "contribute to the reestablishment of peace." This Court reasoned that, in the area of foreign affairs, Congress "must often accord to the President a degree of discretion and freedom from statutory restriction which would not be admissible were domestic affairs alone involved." *Id.*, at 320. Similarly, *United States* v *Mazurie*, 419 U. S. 544 (1975), upheld a broad delegation of authority to various Indian tribes to regulate the introduction of liquor into Indian country. According to *Mazurie* limitations on Congress' authority to delegate legislative power are "less stringent in cases where the entity exercising the delegated authority itself possesses independent authority over the subject matter." *Id.*, at 556–557. In the present cases, however, neither the Executive Branch in general nor the Secretary in particular enjoys any independent authority over the subject matter at issue.

Finally, as indicated earlier, in some cases this Court has abided by a rule of necessity, upholding broad delegations of authority where it would be "unreasonable and impracticable

to compel Congress to prescribe detailed rules" regarding a particular policy or situation. *American Power & Light Co.* v *SEC,* 329 U. S., at 105. See also *Buttfield* v *Stranahan,* 192 U. S. 470, 496 (1904). But no need for such an evasive standard as "feasibility" is apparent in the present cases. In drafting § 6 (b)(5), Congress was faced with a clear, if difficult, choice between balancing statistical lives and industrial resources or authorizing the Secretary to elevate human life above all concerns save massive dislocation in an affected industry That Congress recognized the difficulty of this choice is clear from the previously noted remark of Senator Saxbe, who stated that "[w]hen we come to saying that an employer must guarantee that such an employee is protected from any possible harm, I think it will be one of the most difficult areas we are going to have to ascertain." 116 Cong. Rec. 36522 (1970), Leg. Hist. 345. That Congress chose, intentionally or unintentionally, to pass this difficult choice on to the Secretary is evident from the spectral quality of the standard it selected and is capsulized in Senator Saxbe's unfulfilled promise that "the terms that we are passing back and forth are going to have to be identified." *Ibid.*

IV

As formulated and enforced by this Court, the nondelegation doctrine serves three important functions. First, and most abstractly, it ensures to the extent consistent with orderly governmental administration that important choices of social policy are made by Congress, the branch of our Government most responsive to the popular will. See *Arizona* v *California,* 373 U S. 546, 626 (1963) (Harlan, J., dissenting in part), *United States* v *Robel,* 389 U S. 258, 276 (1967) (BRENNAN, J., concurring in result). Second, the doctrine guarantees that, to the extent Congress finds it necessary to delegate authority, it provides the recipient of that authority with an

"intelligible principle" to guide the exercise of the delegated discretion. See *J. W. Hampton & Co.* v *United States*, 276 U. S., at 409; *Panama Refining Co.* v *Ryan*, 293 U. S., at 430. Third, and derivative of the second, the doctrine ensures that courts charged with reviewing the exercise of delegated legislative discretion will be able to test that exercise against ascertainable standards. See *Arizona* v *California*, *supra*, at 626 (Harlan, J., dissenting in part); *American Power & Light Co.* v *SEC*, *supra*, at 106.

I believe the legislation at issue here fails on all three counts. The decision whether the law of diminishing returns should have any place in the regulation of toxic substances is quintessentially one of legislative policy. For Congress to pass that decision on to the Secretary in the manner it did violates, in my mind, John Locke's caveat—reflected in the cases cited earlier in this opinion—that legislatures are to make laws, not legislators. Nor, as I think the prior discussion amply demonstrates, do the provisions at issue or their legislative history provide the Secretary with any guidance that might lead him to his somewhat tentative conclusion that he must eliminate exposure to benzene as far as technologically and economically possible. Finally, I would suggest that the standard of "feasibility" renders meaningful judicial review impossible.

We ought not to shy away from our judicial duty to invalidate unconstitutional delegations of legislative authority solely out of concern that we should thereby reinvigorate discredited constitutional doctrines of the pre-New Deal era. If the nondelegation doctrine has fallen into the same desuetude as have substantive due process and restrictive interpretations of the Commerce Clause, it is, as one writer has phrased it, "a case of death by association." J. Ely, Democracy and Distrust, A Theory of Judicial Review 133 (1980). Indeed, a number of observers have suggested that this Court should once more take up its burden of ensuring that Congress does not unnecessarily delegate important choices of social policy to po-

litically unresponsive administrators.[6] Other observers, as might be imagined, have disagreed.[7]

If we are ever to reshoulder the burden of ensuring that Congress itself make the critical policy decisions, these are surely the cases in which to do it. It is difficult to imagine a more obvious example of Congress simply avoiding a choice which was both fundamental for purposes of the statute and yet politically so divisive that the necessary decision or compromise was difficult, if not impossible, to hammer out in the legislative forge. Far from detracting from the substantive authority of Congress, a declaration that the first sentence of § 6 (b)(5) of the Occupational Safety and Health Act constitutes an invalid delegation to the Secretary of Labor would preserve the authority of Congress. If Congress wishes to legislate in an area which it has not previously sought to enter, it will in today's political world undoubtedly run into opposition no matter how the legislation is formulated. But that is the very essence of legislative authority under our system. It is the hard choices, and not the filling in of the blanks, which must be made by the elected representatives of the people. When fundamental policy decisions underlying important legislation about to be enacted are to be made, the buck stops with Congress and the President insofar as he exercises his constitutional role in the legislative process.

I would invalidate the first sentence of § 6 (b)(5) of the Occupational Safety and Health Act of 1970 as it applies to

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[6] See J. Ely, Democracy and Distrust, A Theory of Judicial Review 131–134 (1980), J. Freedman, Crisis and Legitimacy, The Administrative Process and American Government 78–94 (1978), T. Lowi, The End of Liberalism: Ideology, Policy, and the Crisis of Public Authority 129–146, 297–299 (1969), Wright, Beyond Discretionary Justice, 81 Yale L. J. 575, 582–587 (1972), Waist-Deep in Regulation, Washington Post, Nov 3, 1979, p. A10, col. 1. Cf. W Douglas, Go East, Young Man 217 (1974).

[7] See K. Davis, Discretionary Justice: A Preliminary Inquiry 49–51 (1969), Stewart, The Reformation of American Administrative Law, 88 Harv L. Rev 1669, 1693–1697 (1975). Cf. Jaffe, The Illusion of the Ideal Administration, 86 Harv L. Rev 1183, 1190, n. 37 (1973)

any toxic substance or harmful physical agent for which a safe level, that is, a level at which "no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to [that hazard] for the period of his working life," is, according to the Secretary, unknown or otherwise "infeasible." Absent further congressional action, the Secretary would then have to choose, when acting pursuant to § 6 (b)(5), between setting a safe standard or setting no standard at all.[8] Accordingly, for the reasons stated above, I concur in the judgment of the Court affirming the judgment of the Court of Appeals.

MR. JUSTICE MARSHALL, with whom MR. JUSTICE BRENNAN, MR. JUSTICE WHITE, and MR. JUSTICE BLACKMUN join, dissenting.

In cases of statutory construction, this Court's authority is limited. If the statutory language and legislative intent are plain, the judicial inquiry is at an end. Under our jurisprudence, it is presumed that ill-considered or unwise legislation will be corrected through the democratic process, a court is not permitted to distort a statute's meaning in order to make it conform with the Justices' own views of sound social policy. See *TVA* v *Hill*, 437 U. S. 153 (1978).

Today's decision flagrantly disregards these restrictions on judicial authority. The plurality ignores the plain meaning of the Occupational Safety and Health Act of 1970 in order to bring the authority of the Secretary of Labor in line with the plurality's own views of proper regulatory policy. The unfortunate consequence is that the Federal Government's efforts to protect American workers from cancer and other crippling diseases may be substantially impaired.

[8] This ruling would not have any effect upon standards governing toxic substances or harmful physical agents for which safe levels are feasible, upon extant standards promulgated as "national consensus standards" under § 6 (a), nor upon the Secretary's authority to promulgate "emergency temporary standards" under § 6 (c).

The first sentence of § 6 (b)(5) of the Act provides:

> "The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, 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 such standard for the period of his working life." 29 U. S. C. § 655 (b)(5)

In this case the Secretary of Labor found, on the basis of substantial evidence, that (1) exposure to benzene creates a risk of cancer, chromosomal damage, and a variety of non-malignant but potentially fatal blood disorders, even at the level of 1 ppm, (2) no safe level of exposure has been shown, (3) benefits in the form of saved lives would be derived from the permanent standard, (4) the number of lives that would be saved could turn out to be either substantial or relatively small, (5) under the present state of scientific knowledge, it is impossible to calculate even in a rough way the number of lives that would be saved, at least without making assumptions that would appear absurd to much of the medical community; and (6) the standard would not materially harm the financial condition of the covered industries. The Court does not set aside any of these findings. Thus, it could not be plainer that the Secretary's decision was fully in accord with his statutory mandate "most adequately [to] assur[e] that no employee will suffer material impairment of health or functional capacity "

The plurality's conclusion to the contrary is based on its interpretation of 29 U S. C. § 652 (8), which defines an occupational safety and health standard as one "which requires conditions reasonably necessary or appropriate to provide safe or healthful employment. " According to the plurality, a standard is not "reasonably necessary or appropriate"

unless the Secretary is able to show that it is "at least more likely than not," *ante*, at 653, that the risk he seeks to regulate is a "significant" one. *Ibid.* Nothing in the statute's language or legislative history, however, indicates that the "reasonably necessary or appropriate" language should be given this meaning. Indeed, both demonstrate that the plurality's standard bears no connection with the acts or intentions of Congress and is based only on the plurality's solicitude for the welfare of regulated industries. And the plurality uses this standard to evaluate not the agency's decision in this case, but a strawman of its own creation.

Unlike the plurality, I do not purport to know whether the actions taken by Congress and its delegates to ensure occupational safety represent sound or unsound regulatory policy The critical problem in cases like the ones at bar is scientific uncertainty While science has determined that exposure to benzene at levels above 1 ppm creates a definite risk of health impairment, the magnitude of the risk cannot be quantified at the present time. The risk at issue has hardly been shown to be insignificant, indeed, future research may reveal that the risk is in fact considerable. But the existing evidence may frequently be inadequate to enable the Secretary to make the threshold finding of "significance" that the Court requires today If so, 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. It is fortunate indeed that at least a majority of the Justices reject the view that the Secretary is prevented from taking regulatory action when the magnitude of a health risk cannot be quantified on the basis of current techniques. See *ante*, at 666 (POWELL, J., concurring in part

and concurring in judgment), see also *ante*, at 656, and n. 63 (plurality opinion)

Because today's holding has no basis in the Act, and because the Court has no authority to impose its own regulatory policies on the Nation, I dissent.

I

Congress enacted the Occupational Safety and Health Act as a response to what was characterized as "the grim history of our failure to heed the occupational health needs of our workers." [1] The failure of voluntary action and legislation at the state level, see S. Rep. No. 91–1282, p. 4 (1970), Leg. Hist. 144, had resulted in a "bleak" and "worsening" [2] situation in which 14,500 persons had died annually as a result of conditions in the workplace. In the four years preceding the Act's passage, more Americans were killed in the workplace than in the contemporaneous Vietnam War, S. Rep. No. 91–1283, at 2, Leg. Hist. 142. The Act was designed as "a safety bill of rights for close to 60 million workers." [3] Its stated purpose is "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." 29 U S. C. § 651 (b). See *Atlas Roofing Co.* v *Occupational Safety and Health Review Comm'n*, 430 U S. 442, 444–445 (1977).

The Act is enforced primarily through two provisions. First, a "general duty" is imposed upon employers to furnish employment and places of employment "free from recognized hazards that are causing or are likely to cause death or serious physical harm. " 29 U S. C. § 654 (a)(1). Second, the Secretary of Labor is authorized to set "occupational safety

[1] Legislative History of the Occupational Safety and Health Act of 1970 (Committee Print compiled for the Senate Committee on Labor and Public Welfare), p. iii (1971) (Foreword by Sen. Williams) (hereinafter Leg. Hist.).

[2] S. Rep. No. 91–1282, p. 2 (1970), Leg. Hist. 142.

[3] Leg. Hist. iii.

and health standards," defined as standards requiring "conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment." 29 U S. C. § 652 (8)

The legislative history of the Act reveals Congress' particular concern for health hazards of "unprecedented complexity" that had resulted from chemicals whose toxic effects "are only now being discovered." S. Rep. No. 91–1282, *supra,* at 2, Leg. Hist. 142. "Recent scientific knowledge points to hitherto unsuspected cause-and-effect relationships between occupational exposures and many of the so-called chronic diseases—cancer, respiratory ailments, allergies, heart disease, and others." *Ibid.* Members of Congress made repeated references to the dangers posed by carcinogens and to the defects in our knowledge of their operation and effect.[4] One of the primary purposes of the Act was to ensure regulation of these "insidious 'silent' killers." [5]

This special concern led to the enactment of the first sentence of 29 U S. C. § 655 (b)(5), which, as noted above, provides:

> "The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, 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 such standard for the period of his working life."

This directive is designed to implement three legislative pur-

[4] S. Rep. No. 91–1282, p. 2 (1970), Leg. Hist. 142; 116 Cong. Rec. 37326 (1970), Leg. Hist. 415 (Sen. Williams), H. R. Rep. No. 91–1291, p. 19 (1970), Leg. Hist. 849; 116 Cong. Rec. 38392–38393 (1970), Leg. Hist. 1049 (Rep. Karth)

[5] 116 Cong. Rec. 38375 (1970), Leg. Hist. 1003 (Sen. Daniels).

poses. First, Congress recognized that there may be substances that become dangerous only upon repeated or frequent exposure.[6] The Secretary was therefore required to provide protection even from substances that would cause material impairment only upon exposure occurring throughout an employee's working life. Second, the requirement that the Secretary act on the basis of "the best *available* evidence" was intended to ensure that the standard-setting process would not be destroyed by the uncertainty of scientific views. Recognizing that existing knowledge may be inadequate, Congress did not require the Secretary to wait until definitive information could be obtained. Thus "it is not intended that the Secretary be paralyzed by debate surrounding diverse medical opinions." H. R. Rep. No. 91–1291, p. 18 (1970), Leg. Hist. 848. Third, Congress' special concern for the "silent killers" was felt to justify an especially strong directive to the Secretary in the standard-setting process. 116 Cong. Rec. 37622 (1970), Leg. Hist. 502 (Sen. Dominick).

The authority conferred by § 655 (b)(5), however, is not absolute. The subsection itself contains two primary limitations. The requirement of "material" impairment was designed to prohibit the Secretary from regulating substances that create a trivial hazard to affected employees.[7] Moreover, all standards promulgated under the subsection must be "feasible." During the floor debates Congress expressed concern that a prior version of the bill, not clearly embodying the feasibility requirement, would require the Secretary to close down whole industries in order to eliminate risks of impairment. This standard was criticized as unrealistic.[8]

[6] 116 Cong. Rec., at 37623, Leg. Hist. 503 (Sen. Dominick), H. R. No. 91–1291, p. 28 (1970), Leg. Hist. 858.

[7] See n. 34, *infra*.

[8] An earlier version of the bill had provided:

"The Secretary, in promulgating standards under this subsection, shall set the standard which most adequately and feasibly assures, on the basis of the best available evidence, that no employee will suffer any impairment

The feasibility requirement was imposed as an affirmative limit on the standard-setting power.

The remainder of § 655 (b)(5), applicable to all safety and health standards, requires the Secretary to base his standards "upon research, demonstrations, experiments, and such other information as may be appropriate." In setting standards, the Secretary is directed to consider "the attainment of the highest degree of health and safety protection for the employee" and also "the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws."

The Act makes provision for judicial review of occupational safety and health standards promulgated pursuant to § 655 (b)(5) The reviewing court must uphold the Secretary's

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of health or functional capacity, or diminished life expectancy even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life." S. 2193, 91st Cong., 2d Sess., 39 (1970), Leg. Hist. 242.

This standard, it was feared, "could be read to require the Secretary to ban all occupations in which there remains *some* risk of injury, impaired health, or life expectancy In the case of all occupations, it will be impossible to eliminate all risks to safety and health. Thus, the present criteria could, if literally applied, close every business in this nation. In addition, in many cases, the standard which might most 'adequately' and 'feasibly' assure the elimination of the danger would be the prohibition of the occupation itself." 116 Cong. Rec. 36530 (1970), Leg. Hist. 367 (Statement on Amendment of Sen. Dominick) In explaining the present language, Senator Dominick stated:

"What we were trying to do in the bill—unfortunately, we did not have the proper wording or the proper drafting—was to say that when we are dealing with toxic agents or physical agents, we ought to take such steps as are feasible and practical to provide an atmosphere within which a person's health or safety would not be affected. Unfortunately, we had language providing that anyone would be assured that no one would have a hazard so that no one would have any problem for the rest of his working life.

"It was an unrealistic standard. As modified, we would be approaching the problem by looking at the problem and setting a standard or criterion which would not result in harm." 116 Cong. Rec., at 37622, Leg. Hist. 502.

determinations if they are supported by "substantial evidence in the record considered as a whole." 29 U. S. C. § 655 (f). It is to that evidence that I now turn.

II

The plurality's discussion of the record in this case is both extraordinarily arrogant and extraordinarily unfair. It is arrogant because the plurality presumes to make its own factual findings with respect to a variety of disputed issues relating to carcinogen regulation. See, *e. g.*, *ante*, at 656–657, and n. 64. It should not be necessary to remind the Members of this Court that they were not appointed to undertake independent review of adequately supported scientific findings made by a technically expert agency.[9] And the plurality's discussion is unfair because its characterization of the Secretary's report bears practically no resemblance to what the Secretary actually did in this case. Contrary to the plurality's suggestion, the Secretary did not rely blindly on some Draconian carcinogen "policy." See *ante*, at 624–625, 635–636. If he had, it would have been sufficient for him to have observed that

[9] I do not, of course, suggest that it is appropriate for a federal court reviewing agency action blindly to defer to the agency's findings of fact and determinations of policy. Under *Citizens to Preserve Overton Park, Inc.* v. *Volpe*, 401 U. S. 402, 416 (1971), courts must undertake a "searching and careful" judicial inquiry into those factors. Such an inquiry is designed to require the agency to take a "hard look," *Kleppe* v. *Sierra Club*, 427 U. S. 390, 410, n. 21 (1976) (citation omitted), by considering the proper factors and weighing them in a reasonable manner. There is also room for especially rigorous judicial scrutiny of agency decisions under a rationale akin to that offered in *United States* v. *Carolene Products Co.*, 304 U. S. 144, 152, n. 4 (1938). See *Environmental Defense Fund* v. *Ruckelshaus*, 142 U. S. App. D. C. 74, 439 F. 2d 584 (1971).

I see no basis, however, for the approach taken by the plurality today, which amounts to nearly *de novo* review of questions of fact and of regulatory policy on behalf of institutions that are by no means unable to protect themselves in the political process. Such review is especially inappropriate when the factual questions at issue are ones about which the Court cannot reasonably be expected to have expertise.

benzene is a carcinogen, a proposition that respondents do not dispute. Instead, the Secretary gathered over 50 volumes of exhibits and testimony and offered a detailed and evenhanded discussion of the relationship between exposure to benzene at all recorded exposure levels and chromosomal damage, aplastic anemia, and leukemia. In that discussion he evaluated, and took seriously, respondents' evidence of a safe exposure level. See also *ante*, at 666 (POWELL, J., concurring in part and in judgment)

The hearings on the proposed standard were extensive, encompassing 17 days from July 19 through August 10, 1977 The 95 witnesses included epidemiologists, toxicologists, physicians, political economists, industry representatives, and members of the affected work force. Witnesses were subjected to exhaustive questioning by representatives from a variety of interested groups and organizations.

Three basic positions were presented at the hearings. The first position was that the proposed 1 ppm standard was necessary because exposure to benzene would cause material impairment of the health of workers no matter how low the exposure level. Some direct evidence indicated that exposure to benzene had caused chromosomal damage, blood disorders, and leukemia at or below the 10 ppm level itself. More important, it was suggested that the recorded effects of benzene at higher levels required an inference that leukemia and other disorders would result at levels of 1 ppm and lower, especially after the prolonged exposure typical in industrial settings. Therefore, the standard should be set at the lowest feasible level, which was 1 ppm.

The second position was that a 1 ppm exposure level would itself pose an unwarranted threat to employee health and safety and that the available evidence necessitated a significantly lower level. An exposure limit below 1 ppm, it was argued, would be feasible. There were suggestions that benzene was gradually being replaced in many of the affected

industries and that most companies were already operating at or below the 1 ppm level.

The third position was that the 1971 standard should be retained. Proponents of this position suggested that evidence linking low levels of benzene exposure to leukemia was uncertain, that the current exposure limit was sufficiently safe, and that the benefits of the proposed standard would be insufficient to justify the standard's costs. In addition, there was testimony that the expenses required by the proposed standard would be prohibitive.

The regulations announcing the permanent standard for benzene are accompanied by an extensive statement of reasons summarizing and evaluating the results of the hearings. The Secretary found that the evidence showed that exposure to benzene causes chromosomal damage, a variety of nonmalignant blood disorders, and leukemia. 43 Fed. Reg. 5921 (1978). He concluded that low concentrations imposed a hazard that was sufficiently grave to call for regulatory action under the Act.

Evidence of deleterious effects. The Secretary referred to studies which conclusively demonstrated that benzene could damage chromosomes in blood-forming cells. *Id.*, at 5932. There was testimony suggesting a causal relationship between chromosomal damage and leukemia, although it could not be determined whether and to what extent such damage would impair health. *Id.*, at 5933.[10] Some studies had suggested chromosomal damage at exposure levels of 10–25 ppm and lower.[11] No quantitative dose-response curve, showing the relationship between exposure levels and incidence of chromosomal damage, could yet be established. *Id.*, at 5933–5934. The evidence of chromosomal damage was, in the Secretary's view, a cause for "serious concern." *Id.*, at 5933.

The most common effect of benzene exposure was a de-

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[10] Tr. 258–259, 1039.

[11] *Id.*, at 148, 200–201, 258.

crease in the levels of blood platelets and red and white blood cells. If sufficiently severe, the result could be pancytopenia or aplastic anemia, noncancerous but potentially fatal diseases. There was testimony that some of the nonmalignant blood disorders caused by benzene exposure could progress to, or represented, a preleukemic stage which might eventually evolve into a frank leukemia. *Id.*, at 5922.[12]

Considerable evidence showed an association between benzene and nonmalignant blood disorders at low exposure levels. Such an association had been established in one study in which the levels frequently ranged from zero to 25 ppm with some concentrations above 100 ppm, *ibid.*, in another they ranged from 5 to 30 ppm, *id.*, at 5923. Because of the absence of adequate data, a dose-response curve showing the relationship between benzene exposure and blood disorders could not be constructed. There was considerable testimony, however, that such disorders had resulted from exposure to benzene at or near the current level of 10 ppm and lower.[13] The Secretary concluded that the current standard did not provide adequate protection. He observed that a "safety factor" of 10 to 100 was generally used to discount the level at which a causal connection had been found in existing studies.[14] Under this approach, he concluded that, quite apart from any leukemia risk, the permissible exposure limit should be set at a level considerably lower than 10 ppm.

Finally, there was substantial evidence that exposure to benzene caused leukemia. The Secretary concluded that the evidence established that benzene was a carcinogen. A causal relationship between benzene and leukemia was first reported in France in 1897, and since that time similar results had been found in a number of countries, including Italy, Turkey, Japan, Switzerland, the Soviet Union, and the United

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[12] *Id.*, at 145, 173–174, 352, 1227, 1928, 3206, 15 Record, Ex. 43B, p. 166.
[13] *Id.*, at 149, 360–361, 997, 1023, 2543, 2689, 3203; 11 Record, Ex. 3.
[14] Tr. 149, 1218, 2692, 2847

States. The latest study, undertaken by the National Institute for Occupational Safety and Health (NIOSH) in the 1970's, reported a fivefold excess over the normal incidence of leukemia among workers exposed to benzene at industrial plants in Ohio. There was testimony that this study seriously understated the risk.[15]

The Secretary reviewed certain studies suggesting that low exposure levels of 10 ppm and more did not cause any excess incidence of leukemia. Those studies, he suggested, suffered from severe methodological defects, as their authors frankly acknowledged.[16] Finally, the Secretary discussed a study suggesting a statistically significant excess in leukemia at levels of 2 to 9 ppm. *Ibid.*[17] He found that, despite certain deficiencies in the study, it should be considered as consistent with other studies demonstrating an excess leukemia risk among employees exposed to benzene. *Id.*, at 5928.

Areas of uncertainty. The Secretary examined three areas

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[15] *Id.*, at 308, 314, 747, 768, 769–770, 874, 2445. As the Secretary observed, the issue of the exposure level in the NIOSH study was extensively debated during the hearings. A report from the Industrial Commission of Ohio suggested that concentrations generally ranged from zero to 10 or 15 ppm. But the Secretary concluded that evidence at the hearings showed that area exposures during the study period had sometimes substantially exceeded that level. Because of the conflicting evidence and the absence of monitoring data, he found that the excess leukemia risk observed in the NIOSH study could not be linked to any particular exposure level.

[16] As to the study on which industry relied most heavily, for example, the Secretary, largely repeating the author's own admissions, observed that (1) a number of employees included in the sample may not have been exposed to benzene at any time; (2) there was inadequate followup of numerous employees, so that persons who may have contracted leukemia were not included in the data, (3) the diagnoses were subject to serious question, and cases of leukemia may have gone unnoticed; (4) no determination of exposure levels had been made; and (5) the occupational histories of the workers were admittedly incomplete. 43 Fed. Reg. 5928 (1978).

[17] Tr. 1023–1024, 1227, 22A Record, Ex. 154.

of uncertainty that had particular relevance to his decision. First, he pointed to evidence that the latency period for benzene-induced leukemia could range from 2 to over 20 years. *Id.*, at 5930. Since lower exposure levels lead to an increase in the latency period, it would be extremely difficult to obtain evidence showing the dose-response relationship between leukemia and exposure to low levels of benzene. Because there has been no adequate monitoring in the past, it would be practically impossible to determine what the exposure levels were at a time sufficiently distant so that the latency period would have elapsed. The problem was compounded by the difficulty of conducting a suitable study Because exposure levels approaching 10 ppm had been required only recently, direct evidence showing the relationship between leukemia and exposure levels between 1 and 10 ppm would be unavailable in the foreseeable future.

Second, the Secretary observed that individuals have differences in their susceptibility to leukemia. *Ibid.* Among those exposed to benzene was a group of unknown but possibly substantial size having various "predisposing factors" whose members were especially vulnerable to the disease. *Id.*, at 5930, 5946. The permanent standard was designed to minimize the effects of exposure for these susceptible individuals as well as for the relatively insensitive, *id.*, at 5946, and also to facilitate early diagnosis and treatment. *Id.*, at 5930.

The Secretary discussed the contention that a safe level of exposure to benzene had been demonstrated. From the testimony of numerous scientists, he concluded that it had not. *Id.*, at 5932.[18] He also found that although no dose-response curve could be plotted, *id.*, at 5946,[19] the extent of the risk

[18] The testimony of Dr. Aksoy, one of the world's leading experts, was typical. "[E]ven one ppm causes leukemia." Tr. 204. See also *id.*, at 30, 150, 262, 328, 351–352, 363–364, 394, 745–746, 1057, 1210, 2420; 9 Record, Ex. 2.8–272, p. 1.

[19] Tr. 130, 360, 414–415, 416–417, 760–761, 781–782, 925, 1055–1056; 17 Record, Ex. 75, p. 2; 1 Record, Ex. 2–4, p. 11.

would decline with the exposure level. *Ibid.*[20] Exposure at a level of 1 ppm would therefore be less dangerous than exposure at one of 10 ppm. The Secretary found that the existing evidence justified the conclusion that he should not "wait for answers" while employees continued to be exposed to benzene at hazardous levels.

Finally, the Secretary responded to the argument that the permissible exposure level should be zero or lower than 1 ppm. *Id.*, at 5947[21] Even though many industries had already achieved the 1 ppm level, he found that a lower level would not be feasible. *Ibid.*

Costs and benefits. The Secretary offered a detailed discussion of the role that economic considerations should play in his determination. He observed that standards must be "feasible," both economically and technologically In his view the permanent standard for benzene was feasible under both tests. The economic impact would fall primarily on the more stable industries, such as petroleum refining and petrochemical production. *Id.*, at 5934. These industries would be able readily to absorb the costs or to pass them on to consumers. None of the 20 affected industries, involving 157,000 facilities and 629,000 exposed employees, *id.*, at 5935, would be unable to bear the required expenditures, *id.*, at 5934. He concluded that the compliance costs were "well within the financial capability of the covered industries." *Id.*, at 5941. An extensive survey of the national economic impact of the standard, undertaken by a private contractor, found first-year operating costs of between $187 and $205 million, recurring annual costs of $34 million, and investment in engineering controls of about $266 million.[22] Since respondents have not at-

[20] Tr. 382, 401, 405, 1372, 2846, 2842–2843.

[21] *Id.*, at 148–149 ("the permissible exposure limit for benzene should be zero") (testimony of Dr. Aksoy). See also *id.*, at 1251 *et seq.*, 3506 *et seq.*

[22] The plurality's estimate of the amount of expenditure per employee, see *ante*, at 629, is highly misleading. Most of the costs of the benzene

tacked the Secretary's basic conclusions as to cost, the Secretary's extensive discussion need not be summarized here.

Finally, the Secretary discussed the benefits to be derived from the permanent standard. During the hearings, it had been argued that the Secretary should estimate the health benefits of the proposed regulation. To do this he would be required to construct a dose-response curve showing, at least in a rough way, the number of lives that would be saved at each possible exposure level. Without some estimate of benefits, it was argued, the Secretary's decisionmaking would be defective. During the hearings an industry witness attempted to construct such a dose-response curve. Restricting himself to carcinogenic effects, he estimated that the proposed standard would save two lives every six years and suggested that this relatively minor benefit would not justify the regulation's costs.

The Secretary rejected the hypothesis that the standard would save only two lives in six years. This estimate, he concluded, was impossible to reconcile with the evidence in the record. *Ibid.*[23] He determined that, because of numer-

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standard would be incurred only once and would thus protect an unascertainable number of employees in the future; that number will be much higher than the number of employees currently employed.

[23] The projection, designed as an extrapolation from an amalgamation of existing studies, was dependent on a number of assumptions which the Secretary could reasonably view as questionable. Indeed, the witness himself stated that his estimate was based on "a lousy set of data," was "slightly better than a guess," Tr. 2772, and that there was "no real basis," *id.*, at 2719, for a dose-response curve on which the estimate was wholly dependent.

The witness' assumptions were severely tested during the hearings, see *id.*, at 2795 *et seq.*, and the Secretary could reasonably reject them on the basis of the evidence in the record. For example: (1) The witness appeared to assume that in previous tests leukemia had been contracted after a lifetime of exposure; the evidence afforded no basis for that assumption, and the duration of exposure may have been quite short for particular employees. If the duration period was short, the witness' estimate would have been much too low (2) The witness assumed that exposure levels in the NIOSH study were around 100 ppm. The Secretary

ous uncertainties in the existing data, it was impossible to construct a dose-response curve by extrapolating from those data to lower exposure levels.[24] More generally, the Secre-

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found, however, that no such assumption could be made, and there was evidence that exposure levels had generally been between zero and 10–15 ppm. (3) The witness assumed that the dose-response curve was linear at all levels, but there was no basis for that assumption. In the case of vinyl chloride (another carcinogen for which the Secretary has promulgated exposure standards), recent evidence suggested that the dose-response curve rises steeply at low doses and becomes less steep as the levels are increased. (4) Twenty-five percent of the workers in the NIOSH study had not been found, and the witness assumed that they were still alive and would not contract leukemia. Six hundred additional workers exposed in that study were still alive; the witness assumed they too would not contract leukemia. There was considerable testimony that, for these and other reasons, the NIOSH study significantly underestimated the risk. The witness assumes that it had not. (5) The NIOSH study found a fivefold excess risk from benzene exposure; the witness assumed that the excess was much lower, despite the NIOSH finding and the testimony that that finding was a significant understatement of the risk. In light of these uncertainties, the Secretary could conclude that the witness' estimate was unsupportable.

[24] Witnesses testifying to the inability to construct a dose-response curve referred primarily to the impossibility of correlating the incidence of leukemia, blood disorders, and chromosomal damage with the levels and duration of exposure in past studies. Thus Dr. Herman Kraybill of the National Cancer Institute testified:

"[W]e like to estimate risk factors. This has been done, as many of you recall, with vinyl chloride several years ago.

" [T]o estimate the risk factors on [the basis of] experimental data, this presupposes if you have good toxicity data. When I say toxicity data, I mean good dose-response data on vinyl chloride, which indeed we did have that.

"But with benzene, it appeared that we didn't have this situation, so therefore, most of us gave up.

" With benzene, we sort of struck out." *Id.*, at 760–761.

Because of the enormous uncertainties in levels and duration of exposure in prior studies, any assumptions would necessarily be arbitrary The possible range of assumptions was so great that the ultimate conclusion would be entirely uninformative. See *id.*, at 360, 415, 1055–1056.

tary observed that it had not been established that there was a safe level of exposure for benzene. Since there was considerable testimony that the risk would decline with the exposure level, *id.*, at 5940, the new standard would save lives. The number of lives saved "may be appreciable," but there was no way to make a more precise determination.[25] The question was "on the frontiers of scientific knowledge." *Ibid.*

The Secretary concluded that, in light of the scientific uncertainty, he was not required to calculate benefits more precisely *Id.*, at 5941. In any event he gave "careful consideration" to the question of whether the admittedly substantial costs were justified in light of the hazards of benzene exposure. He concluded that those costs were "necessary" in order to promote the purposes of the Act.

III

A

This is not a case in which the Secretary found, or respondents established, that no benefits would be derived from a permanent standard, or that the likelihood of benefits was insignificant. Nor was it shown that a quantitative estimate of benefits could be made on the basis of "the best available evidence." Instead, the Secretary concluded that benefits will result, that those benefits "may" be appreciable, but that the dose-response relationship of low levels of benzene

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[25] At one point the Secretary did indicate that appreciable benefits were "likely" to result. The Court of Appeals held that this conclusion was unsupported by substantial evidence. The Secretary's suggestion, however, was made in the context of a lengthy discussion intended to show that appreciable benefits "may" be predicted but that their likelihood could not be quantified. The suggestion should not be taken as a definitive statement that appreciable benefits were more probable than not.

For reasons stated *infra*, there is nothing in the Act to prohibit the Secretary from acting when he is unable to conclude that appreciable benefits are more probable than not.

exposure and leukemia, nonmalignant blood disorders, and chromosomal damage was impossible to determine. The question presented is whether, in these circumstances, the Act permits the Secretary to take regulatory action, or whether he must allow continued exposure until more definitive information becomes available.

As noted above, the Secretary's determinations must be upheld if supported by "substantial evidence in the record considered as a whole." 29 U S. C. § 655 (f) This standard represents a legislative judgment that regulatory action should be subject to review more stringent than the traditional "arbitrary and capricious" standard for informal rulemaking. We have observed that the arbitrary and capricious standard itself contemplates a searching "inquiry into the facts" in order to determine "whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Citizens to Preserve Overton Park* v *Volpe,* 401 U S. 402, 416 (1971) Careful performance of this task is especially important when Congress has imposed the comparatively more rigorous "substantial evidence" requirement. As we have emphasized, however, judicial review under the substantial evidence test is ultimately deferential. See, *e. g., Richardson* v *Perales,* 402 U S. 389, 401 (1971), *Consolo* v *Federal Maritime Comm'n,* 383 U S. 607, 618–621 (1966) The agency's decision is entitled to the traditional presumption of validity, and the court is not authorized to substitute its judgment for that of the Secretary If the Secretary has considered the decisional factors and acted in conformance with the statute, his ultimate decision must be given a large measure of respect. *Id.,* at 621.

The plurality is insensitive to three factors which, in my view, make judicial review of occupational safety and health standards under the substantial evidence test particularly difficult. First, the issues often reach a high level of technical complexity In such circumstances the courts are required to immerse themselves in matters to which they are unaccus-

tomed by training or experience. Second, the factual issues with which the Secretary must deal are frequently not subject to any definitive resolution. Often "the factual finger points, it does not conclude." *Society of Plastics Industry, Inc.* v *OSHA*, 509 F 2d 1301, 1308 (CA2) (Clark, J), cert. denied, 421 U S. 992 (1975). Causal connections and theoretical extrapolations may be uncertain. Third, when the question involves determination of the acceptable level of risk, the ultimate decision must necessarily be based on considerations of policy as well as empirically verifiable facts. Factual determinations can at most define the risk in some statistical way; the judgment whether that risk is tolerable cannot be based solely on a resolution of the facts.

The decision to take action in conditions of uncertainty bears little resemblance to the sort of empirically verifiable factual conclusions to which the substantial evidence test is normally applied. Such decisions were not intended to be unreviewable, they too must be scrutinized to ensure that the Secretary has acted reasonably and within the boundaries set by Congress. But a reviewing court must be mindful of the limited nature of its role. See *Vermont Yankee Nuclear Power Corp.* v *NRDC*, 435 U S. 519 (1978) It must recognize that the ultimate decision cannot be based solely on determinations of fact, and that those factual conclusions that have been reached are ones which the courts are ill-equipped to resolve on their own.

Under this standard of review, the decision to reduce the permissible exposure level to 1 ppm was well within the Secretary's authority The Court of Appeals upheld the Secretary's conclusions that benzene causes leukemia, blood disorders, and chromosomal damage even at low levels, that an exposure level of 10 ppm is more dangerous than one of 1 ppm, and that benefits will result from the proposed standard. It did not set aside his finding that the number of lives that would be saved was not subject to quantification.

Nor did it question his conclusion that the reduction was "feasible."

In these circumstances, the Secretary's decision was reasonable and in full conformance with the statutory language requiring that he "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 such standard for the period of his working life." 29 U S. C. § 655 (b) (5) On this record, the Secretary could conclude that regular exposure above the 1 ppm level would pose a definite risk resulting in material impairment to some indeterminate but possibly substantial number of employees. Studies revealed hundreds of deaths attributable to benzene exposure. Expert after expert testified that no safe level of exposure had been shown and that the extent of the risk declined with the exposure level. There was some direct evidence of incidence of leukemia, nonmalignant blood disorders, and chromosomal damage at exposure levels of 10 ppm and below Moreover, numerous experts testified that existing evidence required an inference that an exposure level above 1 ppm was hazardous. We have stated that "well-reasoned expert testimony—based on what is known and uncontradicted by empirical evidence—may in and of itself be 'substantial evidence' when first-hand evidence on the question is unavailable." *FPC* v *Florida Power & Light Co.*, 404 U S. 453, 464–465 (1972). Nothing in the Act purports to prevent the Secretary from acting when definitive information as to the quantity of a standard's benefits is unavailable.[26] Where, as here, the deficiency in

[26] This is not to say that the Secretary is prohibited from examining relative costs and benefits in the process of setting priorities among hazardous substances, or that systematic consideration of costs and benefits is not to be attempted in the standard-setting process. Efforts to quantify costs and benefits, like statements of reasons generally, may help to promote informed consideration of decisional factors and facilitate

knowledge relates to the extent of the benefits rather than their existence, I see no reason to hold that the Secretary has exceeded his statutory authority

B

The plurality avoids this conclusion through reasoning that may charitably be described as obscure. According to the plurality, the definition of occupational safety and health standards as those "reasonably necessary or appropriate to provide safe or healthful working conditions" requires the Secretary to show that it is "more likely than not" that the risk he seeks to regulate is a "significant" one. *Ante*, at 653. The plurality does not show how this requirement can be plausibly derived from the "reasonably necessary or appropriate" clause. Indeed, the plurality's reasoning is refuted by the Act's language, structure, and legislative history, and it is foreclosed by every applicable guide to statutory construction. In short, the plurality's standard is a fabrication bearing no connection with the acts or intentions of Congress.

At the outset, it is important to observe that "reasonably necessary or appropriate" clauses are routinely inserted in regulatory legislation, and in the past such clauses have uniformly been interpreted as general provisos that regulatory actions must bear a reasonable relation to those statutory purposes set forth in the statute's substantive provisions. See, *e. g.*, *FCC* v *National Citizens Committee for Broadcasting*, 436 U. S. 775, 796–797 (1978), *Mourning* v *Family Publications Service, Inc.*, 411 U. S. 356, 369 (1973), *Thorpe*

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judicial review. See *Dunlop* v. *Bachowski*, 421 U. S. 560, 571–574 (1975). The Secretary indicates that he has attempted to quantify costs and benefits in the past. See 43 Fed. Reg. 54354, 54427–54431 (1978) (lead), *id.*, at 27350, 27378–27379 (cotton dust).

It is not necessary in the present litigation to say whether the Secretary must show a reasonable relation between costs and benefits. Discounting for the scientific uncertainty, the Secretary expressly—and reasonably—found such a relation here.

v *Housing Authority of City of Durham*, 393 U S. 268, 280–281 (1969) The Court has never—until today—interpreted a "reasonably necessary or appropriate" clause as having a substantive content that supersedes a specific congressional directive embodied in a provision that is focused more particularly on an agency's authority This principle, of course, reflects the common understanding that the determination of whether regulations are "reasonably necessary" may be made only by reference to the legislative judgment reflected in the statute, it must not be based on a court's own, inevitably subjective view of what steps should be taken to promote perceived statutory goals.

The plurality suggests that under the "reasonably necessary" clause, a workplace is not "unsafe" unless the Secretary is able to convince a reviewing court that a "significant" risk is at issue. *Ante*, at 642. That approach is particularly embarrassing in this case, for it is contradicted by the plain language of the Act. The plurality's interpretation renders utterly superfluous the first sentence of § 655 (b)(5), which, as noted above, requires the Secretary to set the standard "which most adequately assures that no employee will suffer material impairment of health." Indeed, the plurality's interpretation reads that sentence out of the Act. By so doing, the plurality makes the test for standards regulating toxic substances and harmful physical agents substantially identical to the test for standards generally—plainly the opposite of what Congress intended. And it is an odd canon of construction that would insert in a vague and general definitional clause a threshold requirement that overcomes the specific language placed in a standard-setting provision. The most elementary principles of statutory construction demonstrate that precisely the opposite interpretation is appropriate. See, *e. g.*, *FPC* v *Texaco Inc.*, 417 U S. 380, 394–395 (1974), *Clark* v *Uebersee Finanz-Korp.*, 332 U S. 480, 488–489 (1947). In short, Congress could have provided that the Secretary may not take regulatory action until the existing

scientific evidence proves the risk at issue to be "significant," [27] but it chose not to do so.

The plurality's interpretation of the "reasonably necessary or appropriate" clause is also conclusively refuted by the legislative history While the standard-setting provision that the plurality ignores received extensive legislative attention, the definitional clause received *none at all.* An earlier version of the Act, see n. 8, *supra,* did not embody a clear feasibility constraint and was not restricted to toxic substances or to "material" impairments. The "reasonably necessary or appropriate" clause was contained in this prior version of the bill, as it was at all relevant times. In debating this version, Members of Congress repeatedly expressed concern that it would require a risk-free universe. See, *e. g., ante,* at 646–649. The definitional clause was not mentioned at all, an omission that would be incomprehensible if Congress intended

[27] It is useful to compare the Act with other regulatory statutes in which Congress has required a showing of a relationship between costs and benefits or of an "unreasonable risk." In some statutes Congress has expressly required cost-benefit analysis or a demonstration of some reasonable relation between costs and benefits. See 33 U. S. C. § 701a (Flood Control Act of 1936), 42 U. S. C. § 7545 (c) (2) (B) (1976 ed., Supp. II) (Clean Air Act), 33 U. S. C. § 1314 (b) (4) (B) (1976 ed., Supp. II) (Clean Water Act). In others Congress has imposed two independent requirements: that administrative action be "feasible" and justified by a balancing of costs and benefits, *e. g.,* 43 U. S. C. § 1347 (b) (1976 ed., Supp. II) (Outer Continental Shelf Lands Act), 42 U. S. C. § 6295 (a) (2) (D) (1976 ed., Supp. II) (Energy Policy and Conservation Act). This approach demonstrates a legislative awareness of the difference between a feasibility constraint and a constraint based on weighing costs and benefits. See *infra,* at 719–720. In still others Congress has authorized regulation of "unreasonable risk," a term which has been read by some courts to require a balancing of costs and benefits. See, *e. g., Aqua Slide 'N' Dive Corp.* v *Consumer Product Safety Comm'n,* 569 F 2d 831 (CA5 1978) (construing 15 U. S. C. § 2058 (c) (2) (A) (Consumer Product Safety Act)), *Forester* v. *Consumer Product Safety Comm'n,* 182 U. S. App. D. C. 153, 559 F 2d 774 (1977) (construing 15 U. S. C. § 1261 (s) (Child Protection and Toy Safety Act)).

by that clause to require the Secretary to quantify the risk he sought to regulate in order to demonstrate that it was "significant."

The only portions of the legislative history on which the plurality relies, see *ibid.*, have nothing to do with the "reasonably necessary or appropriate" clause from which the "threshold finding" requirement is derived. Those portions consisted of criticisms directed toward the earlier version of the statute *which already contained the definitional clause.* These criticisms, in turn, were met by subsequent amendments that limited application of the strict "no employee will suffer" clause to toxic substances, inserted an explicit feasibility constraint, and modified the word "impairment" by the adjective "material." It is disingenuous at best for the plurality to suggest that isolated statements in the legislative history, expressing concerns that were met by subsequent amendments not requiring any "threshold" finding, can justify reading such a requirement into a "reasonably necessary" clause that was in the Act all along.[28]

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[28] The plurality also relies on its perception that if the "reasonably necessary" clause were not given the meaning it ascribes to it, there would be no guidance for "standards other than those dealing with toxic materials and harmful physical agents." *Ante,* at 640, n. 45. For two reasons this argument is without force. First, even if the "reasonably necessary" clause does have independent content, and even if that content is as the plurality describes it, it cannot under any fairminded reading supersede the express language of § 655 (b)(5) for toxic substances and harmful physical agents.

Second, as noted above, an earlier version of the bill applied the "no employee will suffer" language to all substances. At that time, there was no "gap," and accordingly it could not be argued that the "reasonably necessary or appropriate" clause had the content the plurality ascribes to it. In this light, the plurality's reasoning must be that when Congress amended the bill to apply the strict § 655 (b)(5) requirements only to toxic substances, the definitional clause gained an independent meaning that in turn comprehended all standards. But surely this argument turns congressional purposes on their head. It reasons that when

The plurality's various structural arguments are also unconvincing. The fact that a finding of "grave danger" is required for temporary standards, see *ante,* at 640, n. 45, hardly implies that the Secretary must show for permanent standards that it is more probable than not that the substance to be regulated poses a "significant" risk. Nor is the reference to *"toxic* materials," *ante,* at 643, in any way informative. And the priority-setting provision, *ante,* at 643–644, cannot plausibly be read to condition the Secretary's standard-setting authority on an ability to meet the Court's "threshold" requirement.

The plurality ignores applicable canons of construction, apparently because it finds their existence inconvenient. But as we stated quite recently, the inquiry into statutory purposes should be "informed by an awareness that the regulation is entitled to deference unless it can be said not to be a reasoned and supportable interpretation of the Act." *Whirlpool Corp.* v *Marshall,* 445 U S. 1, 11 (1980). Can it honestly be said that the Secretary's interpretation of the Act is "unreasoned" or "unsupportable"? And as we stated in the same case, "safety legislation is to be liberally construed to effectuate the congressional purpose." *Id.,* at 13. The plurality's disregard of these principles gives credence to the frequently voiced criticism that they are honored only when the Court finds itself in substantive agreement with the agency action at issue.

In short, today's decision represents a usurpation of decisionmaking authority that has been exercised by and properly belongs with Congress and its authorized representatives.

Congress singled out toxic substances for special regulation, it simultaneously created a more lenient ("reasonably necessary") test for standards generally, and that once that more lenient test was applicable, it somehow superseded the strict requirements for toxic substances. That reasoning is both illogical and circular. Nor is there any basis for the plurality's suggestion, see *ante,* at 649, n. 54, that the original bill's application to all standards was "entirely inadvertent."

The plurality's construction has no support in the statute's language, structure, or legislative history. The threshold finding that the plurality requires is the plurality's own invention. It bears no relationship to the acts or intentions of Congress, and it can be understood only as reflecting the personal views of the plurality as to the proper allocation of resources for safety in the American workplace.

C

The plurality is obviously more interested in the consequences of its decision than in discerning the intention of Congress. But since the language and legislative history of the Act are plain, there is no need for conjecture about the effects of today's decision. "It is not for us to speculate, much less act, on whether Congress would have altered its stance had the specific events of this case been anticipated." *TVA* v *Hill*, 437 U. S., at 185. I do not pretend to know whether the test the plurality erects today is, as a matter of policy, preferable to that created by Congress and its delegates: the area is too fraught with scientific uncertainty, and too dependent on considerations of policy, for a court to be able to determine whether it is desirable to require identification of a "significant" risk before allowing an administrative agency to take regulatory action. But in light of the tenor of the plurality opinion, it is necessary to point out that the question is not one-sided, and that Congress' decision to authorize the Secretary to promulgate the regulation at issue here was a reasonable one.

In this case the Secretary found that exposure to benzene at levels above 1 ppm posed a definite albeit unquantifiable risk of chromosomal damage, nonmalignant blood disorders, and leukemia. The existing evidence was sufficient to justify the conclusion that such a risk was presented, but it did not permit even rough quantification of that risk. Discounting for the various scientific uncertainties, the Secretary gave

"careful consideration to the question of whether th[e] substantial costs" of the standard "are justified in light of the hazards of exposure to benzene," and concluded that "these costs are necessary in order to effectuate the statutory purpose and to adequately protect employees from the hazards of exposure to benzene." 43 Fed. Reg. 5941 (1978).

In these circumstances it seems clear that the Secretary found a risk that is "significant" in the sense that the word is normally used. There was some direct evidence of chromosomal damage, nonmalignant blood disorders, and leukemia at exposures at or near 10 ppm and below In addition, expert after expert testified that the recorded effects of benzene exposure at higher levels justified an inference that an exposure level above 1 ppm was dangerous. The plurality's extraordinarily searching scrutiny of this factual record reveals no basis for a conclusion that quantification is, on the basis of "the best available evidence," possible at the present time. If the Secretary decided to wait until definitive information was available, American workers would be subjected for the indefinite future to a possibly substantial risk of benzene-induced leukemia and other illnesses. It is unsurprising, at least to me, that he concluded that the statute authorized him to take regulatory action now

Under these circumstances, the plurality's requirement of identification of a "significant" risk will have one of two consequences. If the plurality means to require the Secretary realistically to "quantify" the risk in order to satisfy a court that it is "significant," the record shows that the plurality means to require him to do the impossible. But regulatory inaction has very significant costs of its own. The adoption of such a test would subject American workers to a continuing risk of cancer and other serious diseases, it would disable the Secretary from regulating a wide variety of carcinogens for which quantification simply cannot be undertaken at the present time.

There are encouraging signs that today's decision does not extend that far.[29] My Brother POWELL concludes that the Secretary is not prevented from taking regulatory action "when reasonable quantification cannot be accomplished by any known methods." See *ante,* at 666. The plurality also indicates that it would not prohibit the Secretary from promulgating safety standards when quantification of the benefits is impossible. See *ante,* at 656–657, and n. 63. The Court might thus allow the Secretary to attempt to make a very rough quantification of the risk imposed by a carcinogenic substance, and give considerable deference to his finding that the risk was significant. If so, the Court would permit the Secretary to promulgate precisely the same regulation involved in these cases if he had not relied on a carcinogen "policy," but undertaken a review of the evidence and the

[29] The plurality suggests that it is for the agency "to determine, in the first instance, what it considers to be a 'significant' risk," and that the agency "is free to use conservative assumptions in interpreting the data. " *Ante,* at 655, 656. Moreover, my Brother POWELL would not require "quantification of risk in every case." *Ante,* at 666 (opinion concurring in part and concurring in judgment). As I read his opinion, MR. JUSTICE POWELL would have permitted the Secretary to promulgate the standard at issue here if the Secretary had provided a more carefully reasoned explanation of his conclusion that the risk at issue justified the admittedly significant costs of the benzene standard. MR. JUSTICE POWELL also suggests that such a conclusion would be subject to relatively deferential review. *Ante,* at 670–671, n. 8.

In this respect, the differences between my approach and that of MR. JUSTICE POWELL may be comparatively narrow. We are agreed on two propositions that I regard as critical to a fairminded interpretation of the Act: (1) the Secretary may regulate risks that are not subject to quantification on the basis of the "best available evidence"; and (2) the Secretary's judgment that a particular health risk merits regulatory action is subject to limited judicial scrutiny It is encouraging that at least five Members of the Court accept these basic propositions.

For reasons stated in the text, however, I disagree with my Brother POWELL's conclusion that it is appropriate to hold in these cases that the Act requires the Secretary to show a reasonable relationship between costs and benefits.

expert testimony and concluded, on the basis of conservative assumptions, that the risk addressed is a significant one. Any other interpretation of the plurality's approach would allow a court to displace the agency's judgment with its own subjective conception of "significance," a duty to be performed without statutory guidance.

The consequences of this second approach would hardly be disastrous, indeed, it differs from my own principally in its assessment of the basis for the Secretary's decision in these cases. It is objectionable, however, for three reasons. First, the requirement of identification of a "significant" risk simply has no relationship to the statute that the Court today purports to construe. Second, if the "threshold finding" requirement means only that the Secretary must find "that there is a need for such a standard," *ante,* at 643, n. 48, the requirement was plainly satisfied by the Secretary's express statement that the standard's costs "are necessary in order to effectuate the statutory purpose and to adequately protect employees from the hazards of exposure to benzene." 43 Fed. Reg. 5941 (1978) Third, the record amply demonstrates that in light of existing scientific knowledge, no purpose would be served by requiring the Secretary to take steps to quantify the risk of exposure to benzene at low levels. Any such quantification would be based not on scientific "knowledge" as that term is normally understood, but on considerations of policy For carcinogens like benzene, the assumptions on which a dose-response curve must be based are necessarily arbitrary To require a quantitative showing of a "significant" risk, therefore, would either paralyze the Secretary into inaction or force him to deceive the public by acting on the basis of assumptions that must be considered too speculative to support any realistic assessment of the relevant risk. See McGarity, Substantive and Procedural Discretion in Administrative Resolution of Science Policy Questions. Regulating Carcinogens in EPA and OSHA, 67 Geo. L. J 729, 806 (1979) It is encouraging that the Court appears willing

not to require quantification when it is not fairly possible. See *ante,* at 656–657, and n. 63.

Though it is difficult to see how a future Congress could be any more explicit on the matter than was the Congress that passed the Act in 1970, it is important to remember that today's decision is subject to legislative reversal. Congress may continue to believe that the Secretary should not be prevented from protecting American workers from cancer and other fatal diseases until scientific evidence has progressed to a point where he can convince a federal court that the risk is "significant." Today's decision is objectionable not because it is final, but because it places the burden of legislative inertia on the beneficiaries of the safety and health legislation in question in these cases. By allocating the burden in this fashion, the Court requires the American worker to return to the political arena and to win a victory that he won once before in 1970. I am unable to discern any justification for that result.

D

Since the plurality's construction of the "reasonably necessary or appropriate" clause is unsupportable, I turn to a brief discussion of the other arguments that respondents offer in support of the judgment below

First, respondents characterize the Act as a pragmatic statute designed to balance the benefits of a safety and health regulation against its costs. Respondents observe that the statute speaks in terms of relative protection by providing that safety must be assured "so far as possible," 29 U S. C. § 651 (b), and by stating that the "no material impairment" requirement is to be imposed only "to the extent feasible." [30]

[30] Finding obscurity in the word "feasible," my Brother REHNQUIST invokes the nondelegation doctrine, which was last used to invalidate an Act of Congress in 1935. *A. L. A. Schecter Poultry Corp.* v. *United States,* 295 U. S. 495 (1935). While my Brother REHNQUIST eloquently argues that there remains a place for such a doctrine in our jurisprudence, I am frankly puzzled as to why the issue is thought to be of any relevance

Respondents contend that the term "feasible" should be read to require consideration of the economic burden of a standard, not merely its technological achievability I do not understand the Secretary to disagree. But respondents present no argument that the expenditure required by the benzene standard is not feasible in that respect. The Secretary concluded on the basis of substantial evidence that the costs of the standard would be readily absorbed by the 20 affected industries. One need not define the feasibility requirement with precision in order to conclude that the benzene standard is "feasible" in the sense that it will not materially harm the financial condition of the regulated industries.

Respondents suggest that the feasibility requirement should be understood not merely to refer to a standard's expense, but also to mandate a finding that the benefits of an occupational safety and health standard bear a reasonable relation

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here. The nondelegation doctrine is designed to assure that the most fundamental decisions will be made by Congress, the elected representatives of the people, rather than by administrators. Some minimal definiteness is therefore required in order for Congress to delegate its authority to administrative agencies.

Congress has been sufficiently definite here. The word "feasible" has a reasonably plain meaning, and its interpretation can be informed by other contexts in which Congress has used it. See n. 27, *supra*. Since the term is placed in the same sentence with the "no employee will suffer" language, it is clear that "feasible" means technologically and economically achievable. Under the Act, the Secretary is afforded considerably more guidance than are other administrators acting under different regulatory statutes. In short, Congress has made "the critical policy decisions" in these cases, see *ante*, at 687 (REHNQUIST, J., concurring in judgment).

The plurality's apparent suggestion, see *ante*, at 646, that the nondelegation doctrine might be violated if the Secretary were permitted to regulate definite but nonquantifiable risks is plainly wrong. Such a statute would be quite definite and would thus raise no constitutional question under *Schechter Poultry*. Moreover, Congress could rationally decide that it would be better to require industry to bear "feasible" costs than to subject American workers to an indeterminate risk of cancer and other fatal diseases.

to its costs. I believe that the statute's language, structure, and legislative history foreclose respondents' position. In its ordinary meaning an activity is "feasible" if it is capable of achievement, not if its benefits outweigh its costs. See Webster's Third New International Dictionary 831 (1976) Moreover, respondents' interpretation would render § 655 (b)(5) internally inconsistent by reading into the term "feasible" a requirement irreconcilable with the express language authorizing the Secretary to set standards assuring that "no employee will suffer material impairment. " Respondents' position would render that language merely hortatory As noted above, no cost-benefit analysis is referred to at any point in the statute or its legislative history, an omission which cannot be deemed inadvertent in light of the explicit cost-benefit requirements inserted into other regulatory legislation.[31] Finally, the legislative history of the feasibility requirement, see n. 8, *supra,* demonstrates that Congress' sole concern was that standards be economically and technologically achievable. The legislative intent was to prevent the Secretary from materially harming the financial condition of regulated industries in order to eliminate risks of impairment. Congress did not intend to preclude the Secretary from taking regulatory action where, as here, no such threat to industry is posed.[32]

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[31] See n. 27, *supra.*

[32] Congress' antipathy toward cost-benefit balancing is evident throughout the legislative history of the Act. For example:

"The costs that will be incurred by employers in meeting the standards of health and safety to be established under this bill are, in my view, reasonable and necessary costs of doing business. Whether we, as individuals, are motivated by simple humanity or by simple economics, we can no longer permit profits to be dependent upon an unsafe or unhealthy worksite." 116 Cong. Rec. 41766 (1970), Leg. Hist. 1150–1151 (Sen. Eagleton).

Similarly, Senator Yarborough stated:

"We are talking about people's lives, not the indifference of some cost accountants. We are talking about assuring the men and women who

In order to decide these cases, however, it is not necessary to resolve the question whether the term "feasible" may contemplate some balancing of the costs and benefits of regulatory action.[33] Taking into account the uncertainties in existing knowledge, the Secretary made an express finding that the hazards of benzene exposure were sufficient to justify the regulation's costs. 43 Fed. Reg. 5941 (1978) Any requirement to balance costs and benefits cannot be read to invalidate this wholly rational conclusion. A contrary result, forcing the Secretary to wait for quantitative data that may not be available in the foreseeable future, would run directly counter to the protective purposes of the Act.[34]

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work in our plants and factories that they will go home after a day's work with their bodies intact. We are talking about assuring our American workers who wo[r]k with deadly chemicals that when they have accumulated a few year's seniority they will not have accumulated lung congestion and poison in their bodies, or something that will strike them down before they reach retirement age." 116 Cong. Rec., at 37625, Leg. Hist. 510.

[33] Nor need I discuss the possibility, raised by counsel for the federal parties in oral argument, that a decision to regulate a substance posing a negligible threat to health and safety could itself be challenged as arbitrary and capricious under the Administrative Procedure Act. See Tr. of Oral Arg. 23.

[34] Respondents also rely on the statutory requirement that the Secretary may act only to prevent "material" impairment. They contend that the standard promulgated here does not fall within that category because the risk is so low This interpretation derives no support from the statute or its legislative history The statute itself states that standards should ensure that no employee will suffer "material impairment," not material *risk* of impairment.

The language is consistent with the legislative history In an early version of the Act, the word "impairment" was modified by "any" rather than "material." See n. 8, *supra*. The feasibility and materiality requirements were added simultaneously as part of an effort to qualify the original language authorizing the Secretary to ensure that "no employee will suffer any impairment of health or functional capacity, or diminished life expectancy" Senator Dominick was concerned that the

Finally, respondents suggest broadly that the Secretary did not fulfill his statutory responsibility to act on the basis of "research, demonstrations, experiments," and to consider "the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws." 29 U S. C. § 655 (b)(5) Here, they contend, the Secretary based his decision solely on "views and arguments." Brief for Respondents American Petroleum Institute et al. 52. I disagree. The Secretary compiled an extensive record composed of over 50 volumes of exhibits. Most of those exhibits are the reported results of research and demonstrations representing "the latest available scientific data." The Secretary offered a careful discussion of these data in the statement accompanying the permanent standard. His ultimate conclusions were grounded in extensive findings of fact. Where, as here, there are gaps in existing knowledge, the Secretary's decision must necessarily be based on considerations of policy as well as on empirically verifiable facts.

In passing the Occupational Safety and Health Act of 1970, Congress was aware that it was authorizing the Secretary to regulate in areas of scientific uncertainty But it intended to require stringent regulation even when definitive information was unavailable. In reducing the permissible level of exposure to benzene, the Secretary applied proper legal standards. His determinations are supported by substantial evi-

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phrase "any" impairment would require the Secretary to prevent insect bites. 116 Cong. Rec. 36522 (1970), Leg. Hist. 345.

The respondents' construction would pose an enormous obstacle to efforts to regulate toxic substances under § 655 (b)(5). The probability of contracting cancer will in most contexts be quite small with respect to any particular employee. If the statute were read to authorize the Secretary to act only to assure that "no employee will suffer material risk of impairment," the Secretary would be disabled from regulating substances which poses a small risk with respect to any particular employee but which will nonetheless result in the death of numerous members of the employee pool.

dence. The Secretary's decision was one, then, which the governing legislation authorized him to make.[35]

IV

In recent years there has been increasing recognition that the products of technological development may have harmful effects whose incidence and severity cannot be predicted with certainty The responsibility to regulate such products has fallen to administrative agencies. Their task is not an enviable one. Frequently no clear causal link can be established between the regulated substance and the harm to be averted. Risks of harm are often uncertain, but inaction has considerable costs of its own. The agency must decide whether to take regulatory action against possibly substantial risks or to wait until more definitive information becomes available—a judg-

[35] Although the Court of Appeals accepted the Secretary's finding that dermal contact with benzene could cause leukemia, it set aside the dermal contact standard because of the Secretary's failure to perform an experiment recommended by an industry witness. The failure to conduct this test, according to the court, violated the statutory requirement that the Secretary act on the basis of "the best available evidence" and "the latest available scientific data in the field."

In the hearings before the agency, respondents presented no substantial challenge to the position that benzene could be absorbed through the skin, and there was evidence in the record to support that position. Both animal and human studies had found such absorption. In these circumstances, the Secretary was not obligated to undertake additional studies simply because a witness testified that such studies would be informative. The imposition of such a requirement would paralyze the standard-setting process. The Secretary's mandate is to act on the basis of "available" evidence, not evidence which may become available in the future.

In setting aside the dermal contact standard, the Court of Appeals also relied on its conclusion that the Secretary had not shown that quantifiable benefits would result from the standard. As the discussion above indicates, the court applied incorrect legal standards in so holding.

ment which by its very nature cannot be based solely on determinations of fact.[36]

Those delegations, in turn, have been made on the understanding that judicial review would be available to ensure that the agency's determinations are supported by substantial evidence and that its actions do not exceed the limits set by Congress. In the Occupational Safety and Health Act, Congress expressed confidence that the courts would carry out this important responsibility But in these cases the plurality has far exceeded its authority The plurality's "threshold finding" requirement is nowhere to be found in the Act and is antithetical to its basic purposes. "The fundamental policy questions appropriately resolved in Congress are *not* subject to re-examination in the federal courts under the guise of judicial review of agency action." *Vermont Yankee Nuclear Power Corp.* v *NRDC,* 435 U S., at 558 (emphasis in original) Surely this is no less true of the decision to ensure safety for the American worker than the decision to proceed with nuclear power. See *ibid.*

Because the approach taken by the plurality is so plainly irreconcilable with the Court's proper institutional role, I am certain that it will not stand the test of time. In all likelihood, today's decision will come to be regarded as an extreme reaction to a regulatory scheme that, as the Members of the plurality perceived it, imposed an unduly harsh burden on regulated industries. But as the Constitution "does not enact Mr. Herbert Spencer's Social Statics," *Lochner* v *New York,* 198 U S. 45, 75 (1905) (Holmes, J., dissenting), so the responsibility to scrutinize federal administrative action does not authorize this Court to strike its own balance between the

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[36] See W Lowrance, Of Acceptable Risk: Science and the Determination of Safety (1976), Stewart, Paradoxes of Liberty, Integrity and Fraternity· The Collective Nature of Environmental Quality and Judicial Review of Administrative Action, 7 Environ. L. 463, 469–472 (1977).

costs and benefits of occupational safety standards. I am confident that the approach taken by the plurality today, like that in *Lochner* itself, will eventually be abandoned, and that the representative branches of government will once again be allowed to determine the level of safety and health protection to be accorded to the American worker.