CHAPTER II

RISK ASSESSMENT, RISK MANAGEMENT, AND DISTRIBUTION OF ENVIRONMENTAL RISKS

1. RISK ASSESSMENT

Risk assessment is a "process in which information is analyzed to determine if an environmental hazard might cause harm to exposed persons and ecosystems." OFFICE OF SCI. ADVISOR, EPA, EXAMINATION OF EPA RISK MANAGEMENT PRACTICES 2 (2004), *available at* http://www.epa.gov/OSA/pdfs/ratf-final.pdf. It is inherently interdisciplinary in nature—drawing on such diverse fields as biology, toxicology, ecology, engineering, geology, statistics, and the social sciences—in an attempt to create a rational framework for evaluating environmental hazards. *Id*. Risk assessment is generally recognized as the first step in the regulatory process—a regulatory agency must first analyze the magnitude of an environmental risk before it can intelligently decide on whether and how much risk should be regulated—a process known as risk management.

The first section of this chapter addresses the process of risk assessment, focusing upon three principal themes: first, the feasibility and desirability of insulating risk assessment from politics; second, the uncertainties inherent in the risk assessment process; and third, the implications of the divergence between expert and lay perceptions of risk.

The article by William Ruckelshaus primarily addresses the first of these themes, arguing that a sharp distinction should be drawn between risk assessment and risk management. Ruckelshaus was the first administrator of the Environmental Protection Agency (EPA) in the early 1970s; in the 1980s, he was drafted to lead the agency again after the leadership of Anne Gorsuch had severely impaired its

credibility. He advocates keeping political consideration out of the risk assessment process—an approach that many believe EPA had not followed under Gorsuch's leadership. According to Ruckelshaus, the appropriate place for political decisions is at the risk management stage.

Ruckelshaus recognizes that risk assessment is dependent on a variety of assumptions and that these assumptions will reflect the values of the individuals responsible for the choice, whether they are scientists, civil servants, or politicians. He argues that the discretion of individual risk assessors should be constrained through generic policies governing recurring issues. Such policies were adopted in the early 1980s by EPA and a number of other federal agencies. One prescribes a no-threshold model for carcinogens, for example, so that any exposure to a carcinogen is assumed to increase the probability of cancer. Ruckelshaus argues that such policies make the process of risk assessment more uniform and less likely to be influenced by political considerations.

The next three readings address quantitative risk assessment, which as its name suggests, is a process by which human health risks attributable to environmental hazards are quantified. *Industrial Union Department, AFL-CIO v. American Petroleum Institute*, 448 U.S. 607 (1980), the *Benzene* case, is one of the Supreme Court's most important public health decisions. It involves a challenge to regulations promulgated by the Occupational Safety and Health Agency (OSHA), setting a standard for occupational exposure to benzene, a known carcinogen. The case is of great theoretical interest, illustrating the uncertainties inherent in the risk assessment of carcinogens at low doses, as well as the difficulties facing courts charged with reviewing the actions of an agency "working on the frontiers of science." In addition, the case is of great practical consequence. The plurality's insistence that OSHA's regulations be struck down for failure to demonstrate the existence of a significant risk to human health, prompted federal agencies to adopt the process of quantitative risk assessment in future rulemaking.

The article by Alon Rosenthal, George Gray, and John Graham describes each of the four stages of quantitative risk assessment primarily as it applies to carcinogens: hazard identification, dose-response evaluation, exposure assessment, and risk characterization.

Hazard identification—determining whether a substance is hazardous to human health—is conducted through human epidemiological studies or long-term animal bioassays. Epidemiological studies monitor the health of human populations that have been exposed to the substance (such as a community surrounding a factory from which the compound was accidentally released). In long-term animal bioassays, large doses of the substance are administered to controlled groups of animals, generally rodents, and the resulting reaction is monitored.

Dose-response evaluation involves determining the relationship between the dose of the substance to which human beings are exposed and the probability of adverse health effects. This determination is performed by extrapolating from the effects of the large doses to which rodents are exposed in animal bioassays to the far lower doses that a

plausible regulatory regime is likely to regard as permissible, as well as extrapolating from the effects on rodents to the likely effects on human beings.

Exposure assessment consists of determining the extent to which human populations are exposed to hazardous substances. For example, how much groundwater contaminated by a hazardous waste site do individuals in a surrounding community drink?

Finally, *risk characterization* involves providing a numerical estimate of the health risk. In the case of carcinogens, this number is often expressed as the increased probability of cancer from a lifetime exposure to the harmful substance.

The case of *Public Citizen Health Research Group v. Tyson*, 796 F.2d 1479 (D.C. Cir. 1986), serves as a counterpoint to the *Benzene* case. Like the *Benzene* case, it relates to a challenge to an OSHA rule limiting occupational exposure to a known carcinogen. Unlike in the *Benzene* case, however, EPA had conducted a quantitative risk assessment in support of its proposed rule. The differing outcomes of the two cases, decided some six years apart, demonstrates the deferential attitude courts are willing to afford agency decision-making in the event that an attempt is made to quantify the relevant risks.

The excerpt from the book by Justice Stephen Breyer, which was published shortly before his appointment to the Supreme Court, focuses upon the third theme of this section: the vast disparity between lay and expert perceptions of risk. This problem was made salient by the publication of two reports by EPA, in 1987 and 1990, which showed that problems that experts regarded as most serious, such as radon contamination in homes, were regarded as relatively unimportant by the public, whereas problems that experts ranked as far less serious, such as contamination from hazardous waste sites, were perceived by the public as most significant. Other studies confirm that lay and expert perceptions of risk are significantly different.

Justice Breyer explores the reasons why the public might have different reactions to risk than experts. In particular, human beings use heuristic devices as shortcuts to characterize risk, give greater prominence to unusual events than to everyday risks, have greater feelings of moral obligation toward those who are close to them, distrust experts, are reluctant to change their minds, and have difficulty understanding the mathematical probabilities involved in assessing risk. While some commentators have argued that the solution lies in more effective communication about risk, Justice Breyer is skeptical about whether such educative approaches are likely to significantly change the cognitive processes that lead to the gap between scientific and lay perceptions of risk.

A. NATURE OF RISK ASSESSMENT

William D. Ruckelshaus, Risk, Science, and Democracy

1 ISSUES SCI. & TECH. 19 (1985).*

"Risk" is the key concept here. It was hardly mentioned in the early years of EPA, and it does not have an important place in the Clean Air or Clean Water Acts passed in that period. Of the events that contributed to this change, the most important were the focus of public attention on PCBs [Polychlorinated Biphenyls] and asbestos (two substances that are ubiquitous in the American environment and that are capable of causing cancer) and the realization that exposure to a very large number of unfamiliar and largely untested chemicals is universal. The discovery by cancer epidemiologists that cancer rates vary with environment suggested that pollution might play a role in causing this disease. And finally, the cancer risk was pushed to the forefront by the emergence of abandoned dumps of toxic chemicals as a consuming public issue. As a direct result of this shift in attention, the relation of EPA to its science base was altered; the problem of uncertainty was moved from the periphery to the center.

This shift occurred because the risks of effects from typical environmental exposures to toxic substances—unlike the touchable, visible, and malodorous pollution that stimulated the initial environmental revolution—are largely constructs or projections based on scientific findings. We would know nothing at all about chronic risk attributable to most toxic substances if scientists had not detected and evaluated them. Our response to such risks, therefore, must be based on a set of scientific findings. Science, however, is hardly ever unambiguous or unanimous, especially when the data on which definitive science must be founded scarcely exist. The toxic effects on health of many of the chemicals EPA considers for regulation fall into this class.

"Risk assessment" is the device that government agencies such as EPA have adopted to deal with this quandary. It is the attempt to quantify the degree of hazard that might result from human activities—for example, the risks to human health and the environment from industrial chemicals. Essentially, it is a kind of pretense; to avoid the paralysis of protective action that would result from waiting for "definitive" data, we assume that we have greater knowledge than scientists actually possess and make decisions based on those assumptions.

Of course, not all risk assessment is on the controversial outer edge of science. We have been looking at the phenomenon of toxic risk from environmental levels of chemicals for a number of years, and as evidence has accumulated for certain chemicals, controversy has diminished and consensus among scientists has become easier to obtain. For other substances—and these are the ones that naturally figure most prominently in public debate—the data remain ambiguous.

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In such cases, risk assessment is something of an intellectual orphan. Scientists are uncomfortable with it when the method must use scientific information in a way that is outside the normal constraints of science. They are encroaching on political judgments and they know it. As Alvin Weinberg has written:

> Attempts to deal with social problems through the procedures of science hang on the answers to questions that can be asked of science and yet which cannot be answered by science. I propose the term *trans-scientific* for these questions. . . . Scientists have no monopoly on wisdom where this kind of trans-science is involved; they shall have to accommodate the will of the public and its representatives.

However, the representatives of the public, in this instance policy officials in protective agencies, have their problems with risk assessment as well. The very act of quantifying risk tends to reify dreaded outcomes in the public mind and may make it more difficult to gain public acceptance for policy decision or push those decisions in unwise directions. It is hard to describe, say, one cancer case in 70 years among a population of a million as an "acceptable risk" when such a description may too easily summon up for any individual the image of some close relative on his deathbed. Also, the use of risk assessment as a policy basis inevitably provokes endless arguments about the validity of the estimates, which can seriously disrupt the regulatory timetables such officials must live by.

Despite this uneasiness, there appears to be no substitute for risk assessment, in that some sort of risk finding is what tells us that there is any basis for regulatory action in the first place. The alternative to not performing risk assessment is to adopt a policy of either reducing all *potentially* toxic emissions to the greatest degree technology allows (of which more later) or banning all substances for which there is any evidence of harmful effect, a policy that no technological society could long survive. Beyond that, risk assessment is an irreplaceable tool for setting priorities among the tens of thousands of substances that could be subjects of control actions—substances that vary enormously in their apparent potential for causing disease. In my view, therefore, we must use and improve risk assessment with full recognition of its current shortcomings.

This accommodation would be much easier from a public policy viewpoint were it possible to establish for all pollutants the environmental levels that present zero risk. This is prevented, however, by an important limitation of the current technique; the difficulty of establishing definitive no-effect levels for exposure to most carcinogens. Consequently, whenever there is any exposure to such substances, there is a calculable risk of disease. The environmentalist ethos, which is reflected in many of our environmental laws, and which requires that zero-risk levels of pollutant exposure be established, is thus shown to be an impossible goal for an industrial society, as long as we retain the no-threshold model for carcinogenesis. . . .

This situation has given rise to two conflicting viewpoints on protection. The first, usually proffered by the regulated community, argues that regulation ought not to be based on a set of unprovable assumptions but only on connections between pollutants and health

effects that can be demonstrated under the canons of science in the strict sense. It points out that for the vast majority of chemical species, we have no evidence at all that suggests effects on human health from exposures at environmental levels. Because many important risk assessments are based on assumptions that are scientifically untestable, the method is too susceptible to manipulation for political ends and, the regulated community contends, it has been so manipulated by environmentalists.

The second viewpoint, which has been adopted by some environmentalists, counters that waiting for firm evidence of human health effects amounts to using the nation's people as guinea pigs, and that is morally unacceptable. It proposes that far from overestimating the risks from toxic substances, conventional risk assessments underestimate them, for there may be effects from chemicals in combination that are greater than would be expected from the sum effects of all chemicals acting independently. While approving of risk assessment as a priority-setting tool, this viewpoint rejects the idea that we can use risk assessment to distinguish between "significant" and "insignificant" risks. Any identifiable risk ought to be eliminated up to the capacity of available technology to do so.

It is impossible to evaluate the merits of these positions without first drawing a distinction between the assessment of risk and the process of deciding what to do about it, which is "risk management." The arguments in the form sketched here are really directed at both these processes, a common confusion that has long stood in the way of sensible policymaking.

Risk assessment is an exercise that combines available data on a substance's potency in causing adverse health effects with information about likely human exposure, and through the use of plausible assumptions, it generates an estimate of human health risk. Risk management is the process by which a protective agency decides what action to take in the face of such estimates. Ideally the action is based on such factors as the goals of public health and environmental protection, relevant legislation, legal precedent, and application of social, economic, and political values. *Risk Assessment in the Federal Government*, a National Research Council (NRC) document, recommends that regulatory agencies establish a strict distinction between the two processes, to allay any confusion between them. In my view Congress should do the same in all statutes seeking to deal with risk.

Returning now to the opposing viewpoints we see that both reflect the fear that risk assessment may be imbued with values repugnant to one or more of the parties involved. That is, some people in the regulated community believe that the structure of risk assessment inherently exaggerates risk, while many environmentalists believe that it will not capture all the risk that may actually exist. As we have seen, this disagreement is not resolvable in the short run through recourse to science. Risk assessment is necessarily dependent on choices made among a host of assumptions, and these choices will inevitably be affected by the values of the choosers, whether they be scientists, civil servants or politicians.

The NRC report suggests that this problem can be substantially alleviated by the establishment of formal public rules guiding the necessary inferences and assumptions. These rules should be based on the best available information concerning the underlying scientific mechanisms. Adoption of such guidelines reduces the possibility that an EPA administrator may manipulate the findings of some risk assessment so as to avoid making the difficult, and perhaps politically unpopular, choices involved in a risk-management decision. Both industry and environmentalists fear this manipulation—from different brands of administrator, needless to say. Although we cannot remove values from risk assessment, we can and should keep those values from shifting arbitrarily with the political winds.

The explicit and open codification suggested by the NRC will also ensure that the assumptions used in risk assessment will at least be uniform among all agencies that adopt them, will be plausible scientifically, and will reflect a predictable and relatively constant policy amid this complex and chaotic hybrid discipline. It also offers the possibility that one day all the protective agencies of government will speak with one voice when they address risks, so that estimates of risk will be comparable among agencies and the public at last will be able to make a fair comparison of the individual risk-management decisions of separate agencies.

The remaining points of both positions are really about risk management and on this issue both are flawed. At its extreme, the first position—that regulation should be based solely on scientifically provable connections between pollutants and health effects—would allow the release of unlimited quantities of substances that cause cancer in animals, on the assumption that there will be no analogous effect on people and that there must be thresholds for carcinogenesis. I expect that most Americans would reject that assumption as imprudent, given our current knowledge about carcinogenesis (for example, the similarity of cancer causing genes across species). At some level we have to regard the possibility that we are controlling somewhat in excess of the true risk as a kind of insurance, with the cost of control as its premium. The effort to reduce apprehension, even so-called unreasonable apprehension, about the future results of current practices is a valid social function. Risk-management agencies such as EPA could be chartered to do precisely that. If so, we had better make clear what we are doing, and establish rules for doing it.

The weakness of the second viewpoint, that any identifiable risk ought to be eliminated up to the capacity of available technology to do so, lies in the concept of a best available technology that must invariably be applied where risk is discovered. “Best” and “available” are terms as infinitely debatable as the assumptions of risk assessment. There is always a technology conceivable that is an improvement on a previous one, and as the last increments of pollution are removed, the cost of each successive fix goes up very steeply. Because, according to the no-threshold assumption, even minute quantities of carcinogens can be projected out to cause cases of disease, arguments about technology reduce in the end to arguments about risk and cost: technology A allows a residual risk of 10^{-5} and costs $1 million; technology B allows a residual risk of 10^{-6} and costs $10 million, and so on ad infinitum. It is

specious to pretend that costs do not matter, because it is always possible to show that at a certain level of removal, costs in fact do matter: technology Z allows residual risks of 10^{-15} and costs $1 trillion.

Once this is admitted, as it almost always is when we come down to debating actual regulations, the position is reduced to arguments about affordability. This too is treacherous ground. Firms vary in their ability to pay, and what is affordable for one may bankrupt another. If requirements are adjusted so as not to cripple the poorest firms, the policy amounts to an environmental subsidy to the less efficient players in our economy. . . .

My point is that in confronting any risk there is no way to escape the question "Is controlling it worth it?" We must ask this question not only in terms of the relationship of the risk reduced and the cost to the economy but also as it applies to the resources of the agency involved. Policy attention is the most precious commodity in government, and a regulation that marginally protects only 20 people may take up as much attention as a regulation that surely protects a million.

"Is it worth it?" That this question must be asked and asked carefully is a token of how the main force of the environmental idea has been modified by the recent focus on toxic risk to human health. In truth this question should always have been asked, but because the early goals of environmentalism were so obviously good, the requirement to ask, "Is it worth it?" was not firmly built into all our environmental laws. Who would dare to question the worth of saving Lake Erie? Environmentalism at its inception was a grand vision, one that nearly all Americans willingly shared. Somehow that vision of the essential unity of nature and of the need for bringing industrial society into harmony with it has been lost among the parts per billion, and with it we have lost the capacity to reach social consensus on environmental policy.

NOTES AND QUESTIONS

1. Risk Assessment and Risk Management. Why does Ruckelshaus want to distinguish between risk assessment and risk management? Why does he argue that the risk assessment process should be insulated from social policy trade-offs? What types of experts does Ruckelshaus think should conduct risk assessments? What disciplines are most relevant?

2. Blurring the Distinction. Is it possible to maintain a bright-line distinction between risk assessment and risk management? Consider the risk assessment of substances suspected of being carcinogens, in which there is generally less-than-conclusive evidence of carcinogenicity. Are risk management considerations relevant to the determination of whether the substance should be labeled a carcinogen? For example, imagine that risk assessments undertaken with respect to two substances concluded that each had a 95 percent probability of carcinogenicity. Given the prevailing statutory framework, the consequences of labeling the first substance a carcinogen would be to impose debilitating costs on industry, whereas (given the existence of close substitutes) the consequences of labeling the second a carcinogen would be next to non-existent? Is it appropriate that this discrepancy in costs borne by industry be factored into the risk assessment process? Would your answer change if the probability of

carcinogenicity for each substance was 99 percent? What if it were 50 percent? If, like Ruckelshaus, you do not favor the consideration of social policy tradeoffs at the risk assessment stage, how else should these decisions be made?

For an argument that, in the face of scientific uncertainty, social policy considerations should inform the risk assessment process, see Howard A. Latin, *Good Science, Bad Regulation, and Toxic Risk Assessment*, 5 YALE J. ON REG. 89 (1988).

3. Generic Policies. Does Ruckelshaus's reliance upon generic cancer policies—which provide a general framework for making assumptions in the risk assessment process—serve to bolster the clear distinction he draws between risk assessment and risk management? In *Science, Risk and Democracy*, Ruckelshaus advocates the use of generic policies in the face of uncertainty to reduce the politicization of risk assessments. How may this help resolve the tension inherent in the risk assessments of the two pollutants described above? Who does Ruckelshaus envisage setting these policies? To what extent is the setting of these policies likely to be insulated from the political process? What problems may arise as a consequence of a reliance on general policies?

John D. Graham, Laura C. Green, and Marc J. Roberts are opposed to the broad adoption of generic policies, advocating instead the further tailoring of the risk assessment process to the characteristics of the chemical. JOHN D. GRAHAM ET AL., IN SEARCH OF SAFETY: CHEMICALS AND CANCER RISK (1988). They use the risk assessment of formaldehyde as a case study to highlight the policy choices that must be made in dose-response evaluation. The authors show that similar choices underlie other important components of the risk assessment process, such as the relationship between the dose administered in animal bioassays and the effective dose or dose actually reaching the target tissues. They come to two important conclusions. First, even the generic policies advocated by Ruckelshaus leave enormous room for policy judgments. Far from eliminating uncertainty, they shift it from more visible decisions, such as what model to use, to less visible ones. Second, the generic policies often lead to results inconsistent with the best scientific judgments.

Which position do you favor?

4. Interaction Between Risk Assessors and Risk Managers. What degree of interaction do you consider appropriate between risk assessors and risk managers in the performance of their respective tasks? Should a risk manager inquire about the risk assessor's degree of confidence in making a particular finding? Conversely, is it appropriate for risk assessors to inquire about the costs of the regulation required in the event of a particular finding? Would Ruckelshaus find such interactions desirable? Is it likely that such interactions take place in federal regulatory agencies?

5. Scientific Uncertainty. As Ruckelshaus notes, for many substances, there exists substantial scientific uncertainty concerning the relationship between exposure to the substance and the onset of adverse health effects. In the face of such uncertainty, there are two polar choices:

(a) not regulating until there is scientific certainty concerning this relationship; or

(b) regulating whenever there is at least some evidence linking the exposure to adverse health effects.

Adopting the former course of action means that, if the link is ultimately established, many individuals will have been exposed (perhaps for a period of several decades) to an unnecessary risk. Conversely, following the latter course of action means that, if the substance is ultimately found to be benign, pollution control costs will have been incurred needlessly. What criteria should be used in deciding between the two courses of action? Who should make the decision about the circumstances in which regulation is appropriate?

6. Justifications for Negative Risk Assessments. Consider two possible reasons for not regulating a particular substance:

(a) the risks associated with the substance are insignificant; and

(b) the risks are significant but regulation would impose unacceptably high costs on industry.

Which reason will a decisionmaker want to give the public? Is it inevitable that the decisionmaker will seek to influence the risk assessment process so as to be able to give the first reason?

B. QUANTITATIVE RISK ASSESSMENT

Industrial Union Department, AFL-CIO v. American Petroleum Institute

448 U.S. 607 (1980).

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

. . . This litigation concerns a standard promulgated by the Secretary of Labor [pursuant to the Occupational Safety and Health Act] 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 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).

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). . . .

II.

. . . Any discussion of the 1 ppm exposure limit must, of course, begin with the Agency's rationale for imposing that limit. 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. . . .

. . . 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. 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 10 ppm. 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.

Third, the Agency applied its standard policy with respect to carcinogens, concluding that, in the absence of definitive proof of a safe level, it must be assumed that any level above zero presents *some* increased risk of cancer. 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.

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. 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 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 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 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. . . .

III.

Our resolution of the issues in [this case] 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. . . ."

. . . [W]e 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. . . .

A.

Under the Government's view, § 3(8), if it has any substantive content at all, merely requires OSHA to issue standards that are reasonably calculated to produce a safer or more healthy work environment. 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. 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.

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. Moreover, requiring the 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." . . .

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. . . .

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. . . .

. . . 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. In some cases involving toxic substances, Congress has shifted the burden of providing that a particular substance is safe onto the party opposing the proposed rule. 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. . . .

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."

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, § 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. 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. . . .

■ JUSTICE MARSHALL, with whom JUSTICE BRENNAN, JUSTICE WHITE, and JUSTICE BLACKMUN join, dissenting:

. . . 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. Where, as here, the deficiency in 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.

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. 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. 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. 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 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 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. The definitional clause was not mentioned at all, an omission that would be incomprehensible if Congress intended by that clause to require the Secretary to quantify the risk he sought to regulate in order to demonstrate that it was "significant." . . .

. . . 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 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.

NOTES AND QUESTIONS

1. Non-Delegation Doctrine. Justice Rehnquist concurred with the judgment—albeit on different grounds—expressing the opinion 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." *Id*. at 671. Justice Rehnquist considered

> [t]he 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 . . . that legislatures are to make laws, not legislators.

Id. Do you agree with Justice Rehnquist's assessment that "[it would be] 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"? What could be the impact of this approach on other statutes?

Despite Justice Rehnquist's attempts to revive the non-delegation doctrine in *Benzene*, the doctrine has not been invoked by the Supreme Court as the basis for holding a statute unconstitutional since 1935. Following *Whitman v. American Trucking Associations*, 531 U.S. 457 (2001)

(discussed in Chapter V), it appears that the non-delegation doctrine will not be a fruitful avenue for challenging legislation that delegates authority to federal agencies.

2. Divided Court. In a portion of the case not excerpted above, Justice Powell concurred in part and concurred in the judgment, but refrained from joining Part III–D of the plurality opinion (addressing whether OSHA had attempted to carry its burden of proof on the question of whether exposure to benzene at 10 ppm presents a significant risk of material health impairment). Instead, Justice Powell considered the determinative question to be whether OSHA had successfully carried its burden on the basis of record evidence. In concluding that it had not, Justice Powell found that there was insufficient information to support OSHA's determination that the available quantification techniques were too imprecise, and that OSHA's finding of significant risks at current exposure levels was not supported by substantial evidence. *Id.* at 646. Given that the opinion of Justice Stevens was not supported by a majority of the Court, what is the holding of the case?

3. Question of Interpretation. In distinguishing between the holdings of the plurality and the dissent, evaluate first what is not in dispute. Consider the steps underpinning the dissenting opinion. First, the Agency acted properly in finding that benzene is a carcinogen, and that there does not exist a threshold level below which there would be no adverse human health effects. Second, for the purposes of § 6(b)(5), the standard that would "most adequately assure" that no employee would suffer material impairment from benzene would be 0 ppm. Finally, a standard promulgated at the level at which the Agency considered "feasible" for the purposes of § 6(b)(5)—1 ppm—would not result in the collapse of industry. Do the Justices in the plurality adopt a different approach to these matters?

If these matters are not in dispute, why would the dissent have upheld OSHA's regulation, whereas the plurality struck it down? The answer lies, in part, in the differing interpretations of the OSH Act. What roles do §§ 3(8) and 6(b)(5) play under the dissenting opinion? What roles do these sections play under the plurality opinion? Do you agree that § 3(8) should be considered to contain threshold requirements (in keeping with the plurality's preferred interpretation)?

In *Chevron v. NRDC*, 467 U.S. 837 (1984), decided four years after the *Benzene* case, the Supreme Court adopted a deferential attitude toward an agency's interpretation of its own statutory mandate. Do you think the *Benzene* case would have been decided differently post-*Chevron*?

4. Toward Quantitative Risk Assessment. The plurality explicitly recognized that "[t]he Agency had found it impossible to construct a dose-response curve that would predict with any accuracy the number of leukemias that could be expected to result from exposures at 10 ppm, at 1 ppm, or at any intermediate level." Why then was the plurality unwilling to accept the Agency's conclusion that "the benefits of the proposed standard are likely to be appreciable"?

After *Benzene*, what information is necessary to pass judicial review on a subsequent challenge to a permissible exposure limit (PEL)? Consider the following passage from the plurality opinion (not excerpted above):

> 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.

448 U.S. at 632. How should OSHA have sought to support its findings of significance?

5. Fate of the *Benzene* Regulations. Following the *Benzene* case, OSHA did not take immediate steps in formulating substitute standards. It was not until 1984, in response to a petition filed by labor organizations (seeking that OSHA be compelled to promulgate a new standard to fill the void created in the wake of the *Benzene* case) that the second rulemaking was initiated. In 1985, OSHA set forth a proposal for a rulemaking to modify the benzene standard within 14 months. In September 1987, OSHA issued the present rule for benzene regulation. Ironically, this standard provides similar protections to those struck down by the *Benzene* Court—most notably, the PEL for occupational exposure to benzene is set at 1 ppm with a short-term exposure limit of 5 ppm. The rule has not been subject to any further judicial scrutiny. For a detailed description of the history of benzene regulation in the United States and abroad, see Ilise L. Feitshans, *Law and Regulation of Benzene*, 82 ENVTL. HEALTH PERSP. 299 (1989).

Alon Rosenthal, George M. Gray & John D. Graham, Legislating Acceptable Cancer Risk from Exposure to Toxic Chemicals

19 ECOLOGY L.Q. 269 (1992).*

EPA uses risk assessment to predict the probability of developing cancer as a result of exposure to a particular agent. As currently practiced, risk assessment of a carcinogen takes place in four steps: hazard identification, dose-response evaluation, exposure assessment, and risk characterization.

The first step, hazard identification, is the process of determining whether an "agent" (for example, an industrial chemical, a natural product in the environment, or a particular lifestyle) increases a person's risk of developing cancer. The second step, dose-response evaluation, reveals how the likelihood of cancer changes with the level of exposure. A risk assessor might estimate, for example, how the probability of lung cancer changes with the number of cigarettes smoked. The third step, exposure assessment, quantifies the amount, or dose, of the carcinogen to which people may be exposed. This may be the amount of a chemical in the air near a factory, the concentration of radon in the basement of a home, or the amounts of various foods and beverages which an individual consumes each day.

After these quantitative inputs to a risk assessment have been determined, the numbers are combined to yield an overall estimate of risk, the basic component of the final step, risk characterization. A risk characterization is usually expressed numerically as the incremental lifetime risk of cancer due to a particular agent at a particular level of exposure (also referred to as an incremental risk). This is the number that a risk manager might compare to a legislated bright line. Good risk characterizations contain not only a final risk number but also a discussion of the uncertainties in and the assumptions behind the assessment, but unfortunately this step is rarely taken. . . .

Hazard Identification

The most definitive way to determine whether a compound can cause human cancer is through the science of epidemiology. Cancer epidemiology attempts to establish associations between human exposure to a suspected cancer causing agent and the frequency of cancer in the human population. The major drawback of epidemiological studies is that they cannot measure risks before those who are exposed develop cancer, but merely identify effects which have already occurred. Risk managers want to identify human carcinogens before cancer develops, before they can be discovered by epidemiology.

Furthermore, cancer epidemiology is fraught with interpretive difficulty. Cancer is a disease with a long latency period that arises from many causes, only some of which are known. Human exposures to potential carcinogens are often complex, uncertain, and poorly documented. If exposures are mismeasured, the epidemiologist will have a difficult time detecting any association between exposure and disease, even if one exists. Moreover, epidemiological studies are often plagued by confounding factors, such as smoking, by a lack of suitable control groups, and by alternative interpretations of data. Due to practical limitations on the size of studies and the large background risk of cancer, epidemiologists usually cannot detect modest cancer risks that would still be of concern to risk managers. While some epidemiological studies of animal carcinogens have been "negative," this may simply reflect the inadequate sample sizes in these studies. When epidemiologists do detect human cancer risks, they usually do so in occupational settings where historical levels of exposure have been quite high. If findings from the workplace are to be extrapolated to environmental settings, epidemiologists must resolve uncertainties about how to extrapolate tumors observed at relatively high doses to the tumors that might occur at low levels of environmental exposure.

Credible epidemiological studies, especially several showing the same positive result, are considered adequate evidence of human carcinogenicity. Such results are difficult to obtain except when studying very potent carcinogens or carcinogens which cause an unusual type of tumor. For example, epidemiological studies identified vinyl chloride as a human carcinogen because it causes liver angiosarcoma, an extremely rare type of tumor. By contrast, there is little consensus within the scientific community on how much weight to give negative epidemiological reports, or on how to resolve controversies when there are both positive and negative epidemiological studies of a compound. As a result, fewer than sixty chemicals and mixtures have been identified as known human carcinogens.

In light of the limits of epidemiology and the need to identify hazards before they cause serious harm, scientists have resorted to animal experiments in an effort to identify agents that are potential human carcinogens. The key laboratory test used in hazard identification is the long-term rodent bioassay, which is conducted on the assumption that a rodent carcinogen may also be a human carcinogen. In addition, laboratory tests of the biological properties of chemicals provide information which can help scientists assess a chemical's potential for human carcinogenicity.

The National Toxicology Program (the NTP) of the U.S. Department of Health and Human Services has established rigorous guidelines for the conduct of rodent carcinogen bioassays. Under the NTP's guidelines, a researcher must expose fifty animals of each sex of two species (usually rats and mice) to several dose levels of the suspected carcinogen for virtually their entire lives. The dose levels selected are the maximum tolerated dose (the MTD) and fractions thereof, usually MTD/2 or MTD/4. The MTD is the highest dose that the animals can tolerate without becoming so sick that the test will not be useful in detecting tumors. High dose levels are chosen to compensate for the small number of rodents, which are expensive to house and feed. Since most bioassays are performed with only fifty animals at each dose level, the animals must be given the highest dose that they can tolerate if the researchers are to maximize their chances of seeing a statistically significant response. However, the small number of animals used greatly limits the sensitivity of the assay. For example, if a dose of a carcinogen causes an increased cancer risk of one in 100 in a rodent's lifetime, it is unlikely to be detected in a cohort of fifty rodents.

Tumors observed at the MTD are considered relevant on the theory that cancer is a disease that can be caused by a single molecule of a carcinogen interacting with the DNA in a single cell, and therefore, the response of a carcinogen at the MTD can be extrapolated to the much lower levels of exposure that humans experience. However, there is controversy within the scientific community about whether results from rodent bioassays performed at or near the MTD are applicable to the much lower level of exposure typically faced by humans.

Several hundred compounds have been shown to cause cancer in animal tests. The usefulness of these studies in predicting human carcinogenicity depends on the accuracy of certain assumptions. These include the assumption that humans respond in a similar manner to rodents; the assumption that results of exposure to high doses over the relatively short lifetimes of animals are functionally equivalent to the results of exposure to low doses over human lifetimes; and the assumption that cross-species scaling methods accurately extrapolate doses given to small test animals to reflect comparable human doses. These assumptions are hotly contested within the scientific and regulatory communities, but a frequently stated rationale is that, while they may not be accurate, they are conservative—reliance upon them will minimize the chance that a carcinogen will be falsely exonerated. On the other hand, carcinogens are unlikely to be classified as carcinogens until enough high-quality, large-sample testing has been done in a variety of rodent strains and species to reveal their carcinogenic activity. . . .

Dose-Response Evaluation

Once a carcinogenic hazard has been identified, the second step in assessing cancer risks is the determination of the relationship between the dose of the agent and the probability of developing cancer. We will discuss dose response analysis of both carcinogens and noncarcinogens, since some scientists believe that, contrary to current agency practice, a similar method should be used to assess both types of toxic responses.

Toxicologists have for many years engaged in efforts to determine what dose of a chemical is safe and what is harmful. The data they have discovered describing these dose-response relationships have been used in occupational health, environmental protection, and medicine to protect people from the toxic effects of chemicals. Central to these efforts to determine a safe level of exposure is the concept of a response threshold.

The threshold is the dose of the toxicant below which no adverse effects will occur. Above the threshold, adverse effects do occur. There are two types of thresholds: population and individual. A population threshold is the dose of a compound below which absolutely no one in the population will show a response. An individual threshold is the dose below which an individual will not have a response. Individual thresholds vary from person to person and from toxin to toxin. The population threshold can be thought of as the threshold for the most sensitive individual in the population.

The dose-response relationship for a chemical is usually determined by tests on rodents, exposing them to a variety of doses of the compound and observing any toxic responses. The lowest dose producing an adverse effect on the animals is called the lowest observable adverse effect level (LOAEL), and the next tested dose below the LOAEL is called the no observable adverse effect level (NOAEL). The threshold dose in the experiments, then, is assumed to be somewhere between the LOAEL and the NOAEL, although its actual value is unknown.

When the rodent dose-response relationship is used to establish safe human doses, the NOAEL is divided by a safety factor. This safety factor accounts for potential differences in human and rodent response, protects potentially sensitive segments of the human population, and accounts for lack of knowledge of human response when there is little or no human data. The safety factor is usually 100 or 1000, which means that toxicologists set the safe level of exposure for humans at 1/100 or 1/1000 of the animal NOAEL.

Dose-response evaluation for carcinogens differs from that used in traditional toxicology. With suspected carcinogens, the threshold concept is essentially discarded—the threshold dose below which no risk may be seen is assumed to be zero. The no-threshold model, which is prominently used in cancer risk assessment, postulates that cancer can arise from a single change to the DNA of a single cell. In other words, theoretically, a single molecule of a carcinogen has some nonzero probability of causing cancer. For this reason, assessors of cancer risk assume that any dose of a carcinogen, however small, increases the probability of tumor formation.

Further complications arise in collecting and interpreting data from rodent tests of carcinogenicity. Chemicals may exhibit carcinogenic activity in some rodent species but not in others. The same chemical may even test positive in one strain of rats while testing negative in another strain of rats. Pathologists may disagree about the classification of tumors, especially when hyperplasia (a pretumor condition), benign tumors, and malignant tumors must be distinguished. Chemicals may cause tumors in one or more sites in the rodent's body which have no obvious human counterpart.

Scientists must make judgment calls to complete a dose-response evaluation of any particular animal carcinogen. The important judgments include (a) which set of animal data (e.g. which animal species response from which bioassay) to use in the modeling process; (b) which tumor types (e.g., benign and/or malignant) and tumor sites (e.g., liver and/or Zymbal gland) in the animal to count; (c) how to extrapolate the high-dose findings from animal bioassays or occupational epidemiology to the low doses humans encounter in daily life; and (d) how to scale the doses between species, adjust for different routes of exposure (e.g., ingestion in animals versus inhalation in humans), and account for variable durations or patterns of exposure. None of these judgments can currently be resolved solely on the basis of science. In the face of this uncertainty, agency scientists make quasi-policy judgments that reflect values about how protective or conservative they should be.

Perhaps the most contentious judgment in carcinogen risk assessment is how to extend the dose-response curve from the high doses to which animals are exposed in the laboratory to the lower doses to which humans are exposed in the environment. There are several well-known statistical models for fitting the animal data and extrapolating the dose-response curve to low doses. Often each model will fit the experimental animal data quite well and have at least some plausible basis in biology. The models nonetheless may yield low-dose risk estimates for the same chemical or even from the same data set, that vary enormously, by factors of hundreds or even of thousands.

As a default position based primarily on policy considerations, EPA requires use of the linearized multistage (LMS) model in all risk assessments. Agency risk assessors can choose another model only if there is persuasive evidence to support their choice; EPA guidelines do not indicate what sort of evidence would be persuasive. EPA favors the LMS model because it is generally considered to be a conservative method of estimating low-dose risks. Among biologically plausible models, few produce higher estimates of risks than does the LMS model. Scientists derive the critical low-dose potency parameter, the so-called q_1^*, by applying LMS to the tumor incidence data in rodents. The q_1^* is the upper ninety-five percent confidence limit on the linear term of the dose-response function. This linear term is produced by the LMS model's linearization of the data: the model assumes that the dose-response relationship is linear at low doses, regardless of the shape of the dose-response curve within the range of tested doses. The q_1^*, which EPA calls the "cancer potency factor" (the CPF), is an estimate of the carcinogenic strength of a compound based on the LMS model. The

cancer potency factor reflects the fact that not all carcinogenic agents are equal; CPF's differ by factors of as much as a million. . . .

Exposure Assessment

Exposure assessment is the phase of a risk assessment that determines just how much exposure to a carcinogen people actually confront. Exposure can occur through a variety of routes, including inhalation, dermal absorption, and ingestion of contaminated food or water. While some sources of pollution cause human exposure through more than one such pathway, EPA risk assessments do not always consider this possibility. More recent risk assessments, however, indicate a trend to account for as many sources and routes of exposure as possible.

Exposure assessment permits evaluation of two risk parameters: population risk (incidence) and maximum individual risk (MIR). Population risk is the traditional public health measure that reports the number of cases of disease in the population attributable to a specific source or contaminant. The person at maximum individual risk is the individual who suffers the largest incremental risk due to a particular source or contaminant. In theory, the MIR should reflect scientific information about variability in human exposure and sensitivity to chemical carcinogens.

Since little is known about which people are most sensitive to chemical carcinogens, EPA usually assumes that the person at MIR is the maximally exposed individual (the MEI). The MEI is the (usually hypothetical) person expected to receive the greatest lifetime exposure from a particular source. The MEI may be the resident living closest to a factory that emits the suspected carcinogen, or the resident who draws his or her drinking water from the well closest to a Superfund site that is leaking a suspected carcinogen.

EPA generally uses predictive models, rather than direct measurements, to calculate the exposure of the MEI. In the case of a resident at a factory fenceline, a mathematical dispersion model might estimate the air concentration of the carcinogen 200 meters from the source (EPA typically assumes in such scenarios that the fenceline, and the residence of the MEI, are 200 meters from the source). In addition, the models often assume that the MEI is outdoors breathing air at this predicted concentration twenty-four hours a day for seventy years. Although no one spends his or her entire life outdoors at the fenceline of the factory, and although few factories produce the same products, or even exist, for seventy years, the MEI calculation is designed to be conservative. By overstating probable actual exposure, it provides a safety margin, giving an upper bound on the true lifetime exposure.

Use of the hypothetical MEI to set standards is extremely controversial. Critics of MEI-based standards argue that it is unsound to regulate, often at very great cost, on the basis of an inflated exposure scenario that never occurs. Supporters argue that highly exposed people, even if they are few in number, have a right to protection, and that the conservatism in MEI scenarios may be appropriate given the other uncertainties in risk assessment. . . .

Risk Characterization

When a risk assessor has the three important pieces of information—an identified hazard, an estimate of the dose-response relationship q_1^*, and estimates of exposure (or dose)—he or she can make a numerical estimate of risk. Essentially all the assessor does is multiply the q_1^* the cancer potency factor derived from the LMS procedure, by the measured or predicted exposure. The q_1^* is usually expressed in units of increased lifetime probability of cancer per milligram of carcinogen per kilogram of body weight per day of exposure, and the exposure is expressed in units of milligrams of carcinogen per kilogram of body weight per day. The calculation therefore leads to an estimate of the increase in the lifetime probability of cancer from the particular level of exposure. For a properly performed risk-characterization, this number is only the beginning.

The meaning of EPA's risk estimates cannot be accurately conveyed except in light of the numerous assumptions that have been made. As two commentators have stated, risk estimates from analyses done according to EPA procedures "do not give certainty in the scientific sense, nor can they be used to establish precise numbers of persons who will be stricken with some disease." However, the number that comes from the risk characterization step is often reported and used without qualification. Advocates of risk assessment constantly call for analysts to quantify and report the full range of uncertainty in a risk assessment. In fact, because of the numerous conservative assumptions built into the EPA risk assessment process (so-called "compounded conservatism"), EPA has stated that a risk estimate produced in accord with its procedures should be regarded as a plausible upper bound on risk. That is, the actual risk will almost certainly lie somewhere between the EPA risk estimate and zero. The actual risk is very unlikely to be greater than the EPA risk estimate, is probably lower than the EPA estimate, and may even be zero.

Therefore, EPA states that, in addition to the risk number, a risk characterization should contain: (a) a discussion of the "weight of the evidence" for human carcinogenicity (e.g., the EPA carcinogen classification); (b) a summary of the various sources of uncertainty in the risk estimate, including those arising from hazard identification, dose-response evaluation, and exposure assessment; and (c) a report of the range of risk using EPA's risk estimate as the upper limit and zero as the lower limit.

NOTES AND QUESTIONS

1. Issues in the Risk Assessment of Potential Carcinogens. Consider the following issues regarding the risk assessment of potential carcinogens:

(a) Should negative epidemiological evidence of carcinogenicity be disregarded in light of positive evidence from long-term animal bioassays?

(b) Should benign tumors be aggregated with malignant tumors to determine the dose-response relationship?

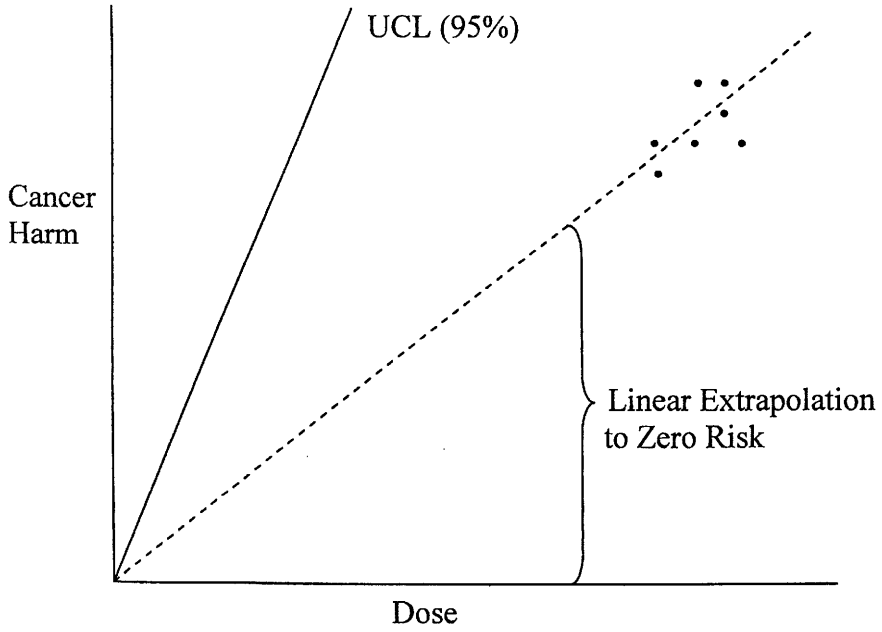
(c) What models should be used to extrapolate from high doses to low doses?

(d) What models should be used to extrapolate from rodents to human beings?

(e) How should inconsistent results in different species of rodents be treated?

There is no scientific consensus on these issues. How should a regulator reach a decision? For each issue, should a regulator always make a conservative assumption?

2. Distinguishing Between Scientific and Policy Decisions in Dose-Response Evaluation.



Above is a representation of a typical dose-response curve for a carcinogen. The data points in the upper-right of the graph represent observed responses from laboratory toxicological tests. In extrapolating from observed data to human responses at lower exposure levels, risk assessors must make several assumptions. First, an assumption must be made as to where to place the point at which there is no human harm: at zero (a no-threshold contaminant) or some higher dose (a threshold contaminant). Second, risk assessors must decide what type of relationship exists between the dose and the response and what curve best represents that relationship—linear, convex, or concave. Finally, they must decide the breadth of confidence they have in their extrapolation. The figure above depicts a no-threshold contaminant, a linear does-response relationship, and a 95 percent upper confidence level (UCL).

Which of these decisions are based on scientific analysis and which are based on policy determinations? What types of scientific analyses are they based on? Which are a combination of the two? Which experts are best suited to making these decisions?

3. Default Assumptions Under EPA's Guidelines. As noted by Rosenthal, EPA's Guidelines establish a number of default assumptions to guide risk assessments in the absence of observable data. One such

assumption is that chemical carcinogens exhibit risks at any dose. *See* EPA, GUIDELINES FOR CARCINOGEN RISK ASSESSMENT (2005), *available at* http://www.epa.gov/ttnatw01/cancer_guidelines_final_3-25-05.pdf. This no-threshold presumption is inherently conservative. It is based on the theory that a susceptible person can contract cancer from the absorption of a single molecule of a carcinogenic substance.

In addition, EPA's Guidelines also require that the agency adopt linear extrapolation to lower dose levels, as its default position. More specifically, the Guidelines prescribe the adoption of the linear extrapolation model in the following circumstances:

> Linear extrapolation should be used when there are data to indicate that the dose-response curve is expected to have a linear component below the [observable data range]. Agents that are generally considered to be linear in this region include:
>
> - agents that are DNA-reactive and have direct mutagenic activity, or
> - agents for which human exposures or body burdens are high and near doses associated with key precursor events in the carcinogenic process, so that background exposures to this and other agents operating through a common mode of action are in the increasing, approximately linear, portion of the dose-response curve.
>
> When the weight of evidence evaluation of all available data are insufficient to establish the mode of action for a tumor site and when scientifically plausible based on the available data, linear extrapolation is used as a default approach, because linear extrapolation generally is considered to be a health-protective approach. Nonlinear approaches generally should not be used in cases where [the relationship between the carcinogen and human health] has not been ascertained. Where alternative approaches with significant biological support are available for the same tumor response and no scientific consensus favors a single approach, an assessment may present results based on more than one approach.

Id. at 3–20. The Guidelines do not require, however, that the dose response be linear at high dose levels (in circumstances where more reliable data is available).

4. Nonparametric Dose-Response Estimation. One alternative to explicitly choosing a type of dose-response relationship (such as linear) is nonparametric estimation, where a functional form for the relationship isn't specified beforehand. Generally speaking, more data is needed for reliable nonparametric estimation because the data also supplies the structure of the model. While such an approach may yield productive results in the range of observed data, it may not be useful to extrapolate below the observed data. Can you see why? If there is no structure between the zero dose point and the lowest observation in the data, what is the estimate going to look like?

5. Distortion of Conservatism. Rosenthal, Gray, and Graham's article states that plausible models used to extrapolate from high doses to low doses may lead to estimates that vary by factors of hundreds or even thousands. Justice Breyer reports in his book *Breaking the Vicious Circle:*

Toward Effective Risk Regulation that "[t]wo scientifically plausible models for the risk associated with aflatoxin in peanuts or grain may show risk levels differing by a factor of 40,000." STEVEN BREYER, BREAKING THE VICIOUS CIRCLE: TOWARD EFFECTIVE RISK REGULATION 47 (1993). He further reports that, according to OMB, agencies "often overstate risks by factors of a thousand or even a million or more" because they pile conservative assumption upon conservative assumption. *Id.* In light of these disparities, is risk assessment at all useful? How should we address this problem?

6. Is "Conservative" Too Stringent? While regulatory agencies have frequently faced the criticism that conservative assumptions inexorably lead to regulations which are too stringent, the use of conservative assumptions for some parameters of a risk assessment do not *necessarily* lead to this result. *See* Adam M. Finkel, *Is Risk Assessment Really Too Conservative: Revising the Revisionists*, 14 COLUM. J. ENVT'L L. 427 (1989). First, choosing the most conservative of several options does not mean that the option chosen is biased upwards. *Id.* at 441–42. Second, not all choices made in a risk assessment will be conservative and different choices may have offsetting effects. *Id.* at 443–47. More generally, using conservative parameters in a risk assessment may correct for systematic defects or biases in other parts of the regulatory process. The risk assessment itself may omit pathways for human exposure or contain other flaws. *Id.* at 449–54. Regulatory steps after the risk assessment may be biased towards less stringent regulation, notably the estimation of costs. *Id.* at 457–59. In the absence of a systematic answer to all of these questions, is there independent value to risk assessments that are more accurate?

7. Distributional Consequences of Exposure Assessment. Which measure of exposure assessment is more relevant for risk assessment: population risk or maximum individual risk? Which measure should be used for risk management decisions? What are the possible distributional effects of ignoring maximum individual risk? Environmental justice advocates criticize risk assessment on the basis that it focuses on relatively small risks to large populations rather than on large risks to smaller sub-populations (such as minority and low-income communities). *See, e.g.*, Clifford Rechtschaffen & Eileen Guana, *Risk Assessment, in* ENVIRONMENTAL JUSTICE: LAW, POLICY & REGULATION 87–105 (2002); Carl F. Cranor, *Risk Assessment, Susceptible Subpopulations, and Environmental Justice, in* THE LAW OF ENVIRONMENTAL JUSTICE: THEORIES AND PROCEDURES TO ADDRESS DISPROPORTIONATE RISKS 307–56 (1999).

8. Issues in the Risk Assessment of Potential Carcinogens Revisited. Revisit questions 1–6 that follow the article by William Ruckelshaus, which address issues in the risk assessment process. Having read the *Benzene* decision and the article by Rosenthal, Gray and Graham, do you consider the line between scientific determinations and policy decisions to remain as clear cut as Ruckelshaus would desire?

Public Citizen Health Research Group v. Tyson

796 F.2d 1479 (D.C. Cir. 1986).

■ Before ROBINSON, CHIEF JUDGE, WRIGHT, CIRCUIT JUDGE, AND MCGOWAN, SENIOR CIRCUIT JUDGE.

■ MCGOWAN, SENIOR CIRCUIT JUDGE:

In these consolidated cases, we review the Occupational Safety and Health Administration's rule limiting exposure to ethylene oxide, a chemical widely used in manufacturing and in hospital instrument sterilization. . . .

. . . The final rule requires employers to ensure that their employees are not exposed to an airborne concentration of EtO [Ethylene Oxide] in excess of 1 ppm [parts per million] as an eight-hour TWA [time-weighted average]. Occupational Exposure to Ethylene Oxide, Final Standard, 49 Fed. Reg. 25,734, 25,796 (1984) (codified at 29 C.F.R. § 1910.1047 (1985)). Employers must monitor exposure levels regularly, depending on the concentration of EtO in the air and changes in work practices. The rule sets an "action level" of 0.5 ppm, which if detected, requires employers to engage in regular employee monitoring. . . .

OSHA models EtO's health effects by plotting a curve through known points and extrapolating into areas as yet untested. The model employs several assumptions about the relationship between EtO exposure and biological response. For example, OSHA chose to employ a linear, no-threshold model similar to that used by EPA's Carcinogen Assessment Group. This approach assumes that EtO exposure and biological response vary proportionately, and that there is no threshold level below which EtO exposure produces no adverse health effects.

AEOU [Association of Ethylene Oxide Users—a co-petitioner] challenges OSHA's model on two grounds. First, AEOU asserts that the model unlawfully assumes that there is no threshold level of EtO exposure. This assumption, AEOU argues, contravenes the teaching of the *Benzene* case. Second, AEOU claims that the model improperly translates breathing rates for rats into equivalent human terms.

In 29 C.F.R. § 1990 (1985) *et seq*., OSHA provides a framework for rulemaking treatment of occupational carcinogens. The regulations allow OSHA to infer a carcinogenic hazard from one or more positive human or animal studies. The regulations also provide that: "No determination will be made that a 'threshold' or 'no-effect' level of exposure can be established for a human population exposed to carcinogens in general, or to any specific substance." 29 C.F.R. § 1990.143(h) (1985).

AEOU presents a two-pronged attack on the threshold issue. First, AEOU charges that the no-threshold assumption violates the *Benzene* rule because it improperly assumes that EtO is harmful at low doses. Second, AEOU charges that OSHA improperly ignored evidence in the record that demonstrates that EtO does indeed have a threshold level. We treat these contentions in turn.

. . . AEOU asserts that OSHA's threshold position in this case is equivalent to OSHA's position on significant risk in the *Benzene* case, which the Supreme Court invalidated. In particular, AEOU argues that

"[t]he Supreme Court squarely rejected OSHA standard-setting based on 'probable' or 'suspected' risks." Petitioner AEOU Brief at 44. AEOU's implied assertion is that OSHA must *unequivocally prove* the scientific validity of each and every assumption it employs.

To the extent this argument asserts that OSHA cannot make any assumptions, even if they are supported by scientific thought, Congress has clearly come to the opposite conclusion. If Congress had intended to require the agency to "prove" all of its assumptions, Congress would not have allowed the agency to rely on the "best available evidence" and the "latest available scientific information." 29 U.S.C. § 655(b)(5) (1982).

Moreover, AEOU simply misconstrues the *Benzene* opinion. In that case, the Court carefully explained that, although OSHA may not act without some record basis, the agency also must be given leeway when regulatory subject matter is not subject to strict proof one way or the other. 448 U.S. at 656. The reason for this approach is clear: requiring strict proof would fatally cripple all of OSHA's regulatory efforts and run counter to the legislative branch's express delegation of hybrid rulemaking power to OSHA. Accordingly, in a passage critical to our inquiry here, the *Benzene* plurality stated: "[S]o 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." *Id.* . . .

The agency has gone to great lengths to calculate, within the bounds of available scientific data, the significance of the risk presented by EtO. The EtO proceeding thus stands in stark contrast to the agency's actions in regulating benzene exposure.

We think it clear from the above-quoted portion of the *Benzene* case that the Supreme Court intended to permit the very estimates that AEOU so vigorously attacks. Indeed, it would be anomalous for the Court to have required the agency to provide more than it has provided in regulating EtO. *See* American Textile Manufacturers Institute, Inc. v. Donovan, 452 U.S. 490, 528 n. 52 (1981) ("the agency's candor in confessing its own inability to achieve a more precise estimate should not precipitate a judicial review that nonetheless demands what the congressionally delegated 'expert' says it cannot provide"). . . .

AEOU points to one commenter who supports an EtO threshold. Dr. Thomas Darby theorized that "[w]ith ethylene oxide, like most substances, there appears to be a 'no effect dose'. . . ." . . .

AEOU argues that the Ethylene Oxide Industry Council (EOIC) supported Darby's position. EOIC stated that "no adverse health effect has been readily demonstrated in man following exposure to 10 ppm. . . ." EOIC Hazard Assessment at *v*, J.A. at 1445. AEOU also notes that OSHA admitted that the record contains no "direct evidence of an excess risk of cancer at chronic exposure levels below 14 ppm. . . ." Petitioner AEOU Brief at 15 (quoting Memorandum of Points and Authorities in Support of Defendants' Motion for Summary Judgment 19, *Public Citizen Health Research Group v. Auchter,* 554 F.Supp. 242 (D.D.C.1983)).

We find neither Dr. Darby's nor EOIC's comments sufficient to refute OSHA's no-threshold model. Although Dr. Darby advocated the

threshold concept, his conclusion was less than forceful. Moreover, contrary to AEOU's assertion, EOIC's cited comments do not unhesitatingly support Dr. Darby. . . .

Indeed, a number of participants (including OSHA) joined EOIC in calculating the risk presented by low EtO exposures. Many participants assessed health risks down to exposure levels at 1 ppm and below. *See* 49 Fed. Reg. at 25,756–63.

. . . The exercise of a dispute in the scientific community does not allow this court to choose a particular side as the "right" one. We have no special skills to aid in the resolution of these technical questions. Rather, our role is only to demand that OSHA review all sides of the issue and reasonably resolve the matter. OSHA has the expertise we lack and it has exercised that expertise by carefully reviewing the scientific data. Unlike the *Benzene* case, OSHA here expressly found risk at the 1 ppm level based on evidence submitted by a significant portion of the scientific community. We find the no-threshold assumption to be supported by substantial evidence. *See also* ASARCO, Inc. v. OSHA, 746 F.2d 483, 492–93 (9th Cir.1984) (no-threshold assumption upheld). . . .

Having established the basis for a quantitative risk assessment, OSHA set out to quantify the level of risk faced by workers exposed to EtO. OSHA then analyzed that risk to determine whether it met the test of significance set out in the *Benzene* case. Applying its model to the Bushy Run database, OSHA calculated the excess risk of death to workers exposed to EtO at various levels. At 50 ppm, OSHA estimated that EtO exposure would cause 634 to 1093 excess deaths per 10,000 workers. 49 Fed. Reg. at 25,762. At 1 ppm, OSHA estimated 12–23 excess deaths per 10,000 workers exposed to EtO. *Id*. [In the Bushy Run study, researchers at the Bushy Run Research Center in Pittsburgh exposed rats to EtO at concentrations of 100, 33, and 10 ppm for 6 hours per day, 5 days per week. This study produced a number of significant results, indicating that EtO exposure was related to the development of various types of cancers.]

OSHA found that 634 to 1093 excess deaths at 50 ppm exposure levels is a significant risk within the meaning of the *Benzene* case. *Id*. at 25,764. The agency further found that reducing the PEL from 50 ppm to 1 ppm is reasonably necessary and appropriate to remedying the risk at 50 ppm. *Id*. These particular findings (significant risk and necessity) are not directly challenged on appeal.

OSHA further found that EtO exposure at 1 ppm (12–23 excess deaths estimated) poses a significant risk itself. The agency set the PEL at 1 ppm, however, not because no excess deaths would occur at that level, but because it could not show that any lower long-term limit would be feasible. *Id*. at 25,772. AEOU does not challenge OSHA's finding that the 1 ppm PEL is the lowest feasible limit.

AEOU instead charges that OSHA's estimates inflate the number of excess deaths attributable to EtO exposure. AEOU proffers two related reasons for the allegedly inflated figures. First, AEOU echoes OMB's [Office of Management and Budget] objection that OSHA mistakenly assessed the current exposure patterns of hospital workers. . . . AEOU repeats a second OMB objection as well. OMB

charges that OSHA erred in assuming that workers are exposed for eight hours per day, five days per week. A more realistic exposure pattern postulates only intermittent exposure. Had OSHA assumed the latter exposure pattern, the 1 ppm PEL would avoid only 125 cancer deaths, rather than OSHA's final estimate of 634 to 1093 detailed above. *Id*.

Assuming *arguendo* that these two challenges have merit, they do not undermine the validity of OSHA's final standard. OSHA expressly found that the 12–23 excess deaths still caused by EtO exposure at the 1 ppm PEL is a significant risk within the meaning of the *Benzene* case. That finding is unchallenged here. Assuming 12 deaths are significant, 125 deaths are *a fortiori* significant. Thus, even if AEOU correctly argues that the current standard allows only 125 excess deaths, the argument is irrelevant. We need not decide, therefore, whether OSHA erred in its risk calculation. Even if it did, the error is insufficient to affect the validity of the outcome. . . .

NOTES AND QUESTIONS

1. *Benzene* and *Tyson*. What process did OSHA undertake in *Tyson* that it had not undertaken in the *Benzene* case? What statutory finding did the Agency make in *Tyson* that it had not made in the *Benzene* case?

Pursuant to what standard of review did the court review OSHA's EtO standard? Was this the same standard in operation in the *Benzene* case? What then accounts for the different outcomes in *Benzene* and *Tyson*?

2. Significant Risk and *Tyson*. What was the Agency's finding of significance in the *Tyson* case? How did the Agency justify this finding? Did the Agency consider the risk posed by an EtO standard of 1 ppm to be significant? If so, on what basis did it justify setting the standard at this level?

3. No-Threshold Assumption. In *Tyson*, industry groups challenged the assumption by OSHA that EtO should be considered a no-threshold carcinogen. Why did the court find that the general cancer policy favored by OSHA should trump the AEOU's contention that a threshold characterization would better fit the data?

4. Limitations on the Use of EPA's Cancer Policy. When is there sufficient information to justify abandonment of the cancer policy? Consider *Chlorine Chemistry Council v. EPA*, 206 F.3d 1286 (D.C.Cir. 2000), in which the D.C. Circuit held EPA's regulations of chloroform to be arbitrary and capricious and inconsistent with the Safe Drinking Water Act because EPA's default assumption of linearity and zero threshold "openly overrode the 'best available' scientific evidence, which suggested that chloroform is a threshold carcinogen." Of key importance was a "Notice of Data Availability" published by EPA in the Federal Register, which concluded that chloroform exhibited a "nonlinear mode of carcinogenic action" and a draft report which supported these conclusions. *Id*. at 1288–89. Consider the reasons why Ruckelshaus supported the use of general policy guidelines. Would he likely support deviation in this instance?

5. Dioxin and Linearity. EPA has been assessing the carcinogenic effects of dioxin since the mid-1980s. In 2003, EPA issued a draft risk assessment for review by the National Academy of the Sciences. EPA, DRAFT DIOXIN REASSESSMENT, NATIONAL ACADEMY OF SCIENCES (NAS)

REVIEW DRAFT (2003). While the draft assessment did not contain a formal recommendation, the National Academy of Sciences report made the following comment:

> The committee unanimously agrees that the current weight of evidence on [dioxin] carcinogenicity favors the use of nonlinear methods for extrapolation [at low doses]. However, the committee recognizes that it is not scientifically possible to exclude totally a linear response at [low doses], so it recommends that EPA provide risk estimates using both approaches and describing their scientific strengths and weaknesses to inform risk managers of the importance of choosing a linear vs. nonlinear method of extrapolation. To the extent that EPA favors using default assumptions for regulating dioxin as though it were a linear carcinogen, such a conclusion should be made as part of risk management. EPA should strictly adhere to the distinction between risk assessment, which is a scientific activity, and risk management, which takes into account other factors.

COMMITTEE ON EPA'S EXPOSURE AND HUMAN HEALTH REASSESSMENT OF TCDD AND RELATED COMPOUNDS, NATIONAL RESEARCH COUNCIL, HEALTH RISKS FROM DIOXIN AND RELATED COMPOUNDS: EVALUATION OF THE EPA REASSESSMENT 135 (2006). If EPA assumed a linear dose-response relationship and a zero threshold for dioxin, would this openly override the best available scientific evidence? Does it matter that such a relationship cannot be totally ruled out? Could a court be persuaded that such an assumption was a justifiable risk management decision?

6. Scientific Uncertainty and Judicial Review. Should one judge's opinion outweigh the accumulated expertise of an expert governmental agency? In the 1970s, as the D.C. Circuit was confronted with an increasing number of highly technical environmental disputes, Judges Bazelon and Leventhal engaged in a discussion of the proper role of the judiciary in reviewing agency decision-making. Part of this on-going discussion is contained in concurring opinions each judge filed in *Ethyl Corp. v. EPA*, 541 F.2d 1 (D.C. Cir. 1976), *cert. denied*, 426 U.S. 941 (1976). Judge Bazelon believed that

> in cases of great technological complexity, the best way for courts to guard against unreasonable or erroneous administrative decisions is not for the judges themselves to scrutinize the technical merits of each decision. Rather, it is to establish a decision-making process that assures a reasoned decision that can be held up to the scrutiny of the scientific community and the public. . . . The process making a de novo evaluation of the scientific evidence inevitably invites judges of opposing views to make plausible-sounding, but simplistic, judgments of the relative weight to be afforded various pieces of technical data.

Id. at 66. Judge Leventhal on the other hand advocated a more robust judicial review, premised on the theory that

> in the case of agency decision-making the courts have an additional responsibility set by Congress. . . . Our present system of review assumes judges will acquire whatever technical knowledge is necessary as background for decision of the legal questions. . . . The substantive review of administrative action is

> modest, but it cannot be carried out in a vacuum of understanding. Better no judicial review at all than a charade that gives the imprimatur without the substance of judicial confirmation that the agency is not acting unreasonably.

Id. at 68–69. What do you consider to be the appropriate role of the courts in reviewing agency rulemaking actions in areas where scientific expertise is required?

7. Vulnerability of Risk Assessment to Manipulation. Given the inherent uncertainty in the risk assessment process, there exists scope for manipulation. One potential solution to political manipulation at the risk assessment stage is regulatory peer review. Proposals for a peer review system that would examine the basis of regulatory decisions have garnered interest from industry and government officials alike. Would the benefits of such a check be worth the expense and time necessarily involved in such a process? James Salzman and J. B. Ruhl argue that regulatory peer review should be applied by a random sampling technique to both help define the scope of the problem of agency overstatement of scientific support and to induce agencies to pay more attention to clearly articulating where science ends and policy judgment begins in the justification of their decisions. J. B. Ruhl & James Salzman, *In Defense of Regulatory Peer Review*, 84 WASH. U. L. REV. 1 (2006).

C. EXPERT V. LAY PERCEPTIONS OF RISK

Stephen Breyer, Breaking the Vicious Circle: Toward Effective Risk Regulation

33–39 (1993).*

Study after study shows that the public's evaluation of risk problems differs radically from any consensus of experts in the field. Risks associated with toxic waste dumps and nuclear power appear near the bottom of most expert lists; they appear near the top of the public's list of concerns, which more directly influences regulatory agendas. . . . To some extent, these differences may reflect that the public fears certain risks more than others with the same probability of harm. As previously pointed out, of two equal risks, one could rationally dislike or fear more the risk that is involuntarily suffered, new, unobservable, uncontrollable, catastrophic, delayed, a threat to future generations, or likely accompanied by pain or dread.

Still, these differences in the source, quality, or nature of a risk may not account for the different ranking by the public and the experts. A typical member of the public would like to minimize risks of death to himself, to his family, to his neighbors; he would normally prefer that regulation buy more safety for a given expenditure or the same amount of safety for less. Not many of us would like to shift resources to increase overall risks of death significantly in order to increase the likelihood that death will occur on a bicycle or in a fire, rather than through disease. There is a far simpler explanation for the public's aversion to toxic waste dumps than an enormous desire for supersafety,

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or a strong aversion to the tiniest risk of harm—namely, the public does not *believe* that the risks are tiny. The public's "nonexpert" reactions reflect not different values but different understandings about the underlying risk-related facts.

My assumption that the public assigns "rational" values to risks, however, does not entail rational public reactions to risk. Psychologists have found several examples of thinking that impede rational understanding, but may have helped us survive as we lived throughout much of prehistory, in small groups of hunter-gatherers, depending upon grain, honey, and animals for sustenance. The following, rather well-documented aspects of risk perception are probably familiar.

1. Rules of thumb. In daily life most of us do not weigh all the pros and cons of feasible alternatives. We use rules of thumb, more formally called "heuristic devices." . . . The resulting categorizations do not always accurately describe another person or circumstance, but they help us make quick decisions, most of which prove helpful. This kind of quick decision-making may help cut a swath through the modern information jungle, but it oversimplifies dramatically and thereby inhibits an understanding of risks, particularly small risks.

2. Prominence. People react more strongly, and give greater importance, to events that stand out from the background. Unusual events are striking. We more likely notice the (low-risk) nuclear waste disposal truck driving past the school than the (much higher-risk) gasoline delivery trucks on their way to local service stations. . . .

3. Ethics. The strength of our feelings of ethical obligation seems to diminish with distance. That is to say, feelings of obligation are stronger (or we have different, more time-consuming obligations) toward family, neighbors, friends, community, and those with whom we have direct contact, those whom we see, than toward those who live in distant places, whom we do not see but only read or hear about.

4. Trust in experts. People cannot easily judge between experts when those experts disagree with each other. The public, since the mid-1960s, has shown increasing distrust of experts and the institutions, private, academic, or governmental, that employ them.

5. Fixed decisions. A person who has made up his or her mind about something is very reluctant to change it.

6. Mathematics. Most people have considerable difficulty understanding the mathematical probabilities involved in assessing risk. . . . People consistently overestimate small probabilities. What is the likelihood of death by botulism? (One in two million.) They underestimate large ones. What is the likelihood of death by diabetes? (One in fifty thousand.) People cannot detect inconsistencies in their own risk-related choices. . . .

These few, near-commonsense propositions, with strong statistical support in the technical literature, verify Oliver Wendell Holmes's own observation that "most people think dramatically, not quantitatively." They also have important consequences. . . .

When we think about nuclear power controversies, we should take account of the fact that hearing about an accident is what psychologists tell us is an heuristic "tip-off" of danger, whether or not anyone is hurt.

We have "seen" Chernobyl and Three Mile Island, and we may therefore doubt nuclear power's safety, whether or not experts tell us that the reactor at Chernobyl was not properly designed, that the accident at Three Mile Island hurt no one, that military weapons, not electric power generators, are responsible for 99 percent of all nuclear waste, that nuclear power's risks are minuscule compared to the risks of coal-generated power. . . .

[This suggests] that better "risk communications," such as efforts to explain risks to the public at open meetings, may not suffice to alleviate risk regulation problems. It is not surprising that, after the EPA Administrator William Ruckelshaus spent days at such meetings in Tacoma, Washington, explaining why an ASARCO chemical plant that was leaking small amounts of arsenic could remain open, he was misunderstood, criticized, and accused of trying to drive a wedge between environmentalists and blue collar workers. . . .

There is little reason to hope for better risk communication over time. To the contrary, as science improves, scientists may more easily detect and identify ever tinier risks—the risk associated, for example, with the migration of a single molecule of plastic from a container into a soft drink; they may more easily identify geographical areas near toxic waste dumps with higher than average cancer rates. As international communications improve, the press will have an ever larger pool of unusual, and therefore more interesting, accident stories to write about. Why should we not expect an outcry from a public that reads about Love Canal, Times Beach, Alar, Chilean grapes laced with cyanide, and the leaflet of Villejuif, whether or not such examples reflect meaningful danger? (At the same time, how can one expect public reaction to potentially greater but more mundane problems, of which it is unaware?)

It is hard to make the normal human mind grapple with this inhuman type of problem. To change public reaction, one would either have to institute widespread public education in risk analysis or generate greater public trust in some particular group of experts or the institutions that employ them. The first alternative seems unlikely. The second, over the past thirty years, has not occurred. . . .

NOTES AND QUESTIONS

1. Characteristics That Affect Lay Perceptions of Risk. Justice Breyer's theoretical discussion about the discrepancy between expert and lay perceptions of risk is derived from a large academic literature on the subject. Representative works include Baruch Fischhoff, *Managing Risk Perceptions*, 2 ISSUES SCI. & TECH. 83 (1985); Roger G. Noll & James E. Krier, *Some Implications of Cognitive Psychology for Risk Regulation*, 19 J. LEGAL STUD. 747 (1990); Paul Slovic, *Perception of Risk*, 236 SCIENCE 280 (1987); Paul Slovic, Baruch Fischhoff & Sarah Lichtenstein, *Rating the Risks*, 21 ENV'T 14 (1979).

Slovic and his colleagues define eight characteristics that affect lay perceptions of risk:

(a) *voluntariness of risk*: involuntary risks are perceived as more serious;

(b) *immediacy of effect*: risks with delayed effects (such as cancer) are perceived as more serious;

(c) *knowledge about risk*: unknown risks are perceived as more serious;

(d) *control over risk*: risks that individuals cannot reduce through their own actions are perceived as more serious;

(e) *newness*: new risks are perceived as more serious;

(f) *chronic/catastrophic*: catastrophic risks—risks that kill large numbers of people at once—are perceived as more serious;

(g) *common/dread*: dread risks—risks that people have not learned to deal with—are perceived as more serious; and

(h) *severity of consequences*: fatal risks are perceived as more serious.

Given these factors, for what types of environmental risks would you expect lay perceptions to be greater than expert perceptions?

2. *Unfinished Business.* Justice Breyer's factual views about the discrepancy between expert and lay evaluations of risk are informed to a large extent by two EPA reports: *Unfinished Business: A Comparative Assessment of Environmental Problems*, published in 1987, and *Reducing Risk: Setting Priorities and Strategies for Environmental Protection*, published in 1990.

Unfinished Business is the report of a special taskforce of senior career managers and technical experts at EPA, commissioned by the administrator to compare the risks of different environmental problems. The group chose to focus on thirty-one problems and, for each problem, considered four types of risks: cancer risks, non-cancer health risks, ecological risks and welfare risks (such as visibility impairment and material damage). The study reached two important conclusions:

> The [group's] rankings by risk . . . do not correspond well with EPA's current program priorities. Areas of relatively high risk but low EPA effort include: indoor radon; indoor air pollution; stratospheric ozone depletion; global warming; non-point sources; discharges to estuaries, coastal waters and oceans; other pesticide risks; accidental releases of toxics; consumer products; and worker exposures. Areas of high EPA effort but relatively low or medium risks include: RCRA sites; Superfund; underground storage tanks; and municipal non-hazardous waste sites.

EPA, UNFINISHED BUSINESS: A COMPARATIVE ASSESSMENT OF ENVIRONMENTAL PROBLEMS / OVERVIEW REPORT, at xix–xx (1987). Second, the group concluded:

> Overall, EPA's priorities appear more closely aligned with public opinion than with our estimated risks. Recent national polling data ranks areas of public concern about environmental issues as follows:
>
> *High*: chemical waste disposal, water pollution, chemical plant accidents, and air pollution;
>
> *Medium*: oil spills, worker exposure, pesticides, and drinking water;

> *Low*: indoor air pollution, consumer products, genetic radiation (except nuclear power), and global warming.

Id. at xx. What prescriptions for regulation should one draw from these conclusions?

Unfinished Business is more agnostic than Justice Breyer about whether regulatory attention should be more closely aligned with expert perceptions of risk. The report states:

> This divergence between what we found in terms of relative risks and EPA's priorities is not necessarily inappropriate. Some problems appear to be relatively low risks precisely because of the high levels of program effort that have been devoted to controlling them. And these high levels of attention may remain necessary in order to hold risks to current levels.

Id. at xix. Air pollution and water pollution control, the first two large-scale environmental programs, probably fall in this category.

Moreover, the report expressly declined to consider the economic or technological controllability of the risks. Also, in some of the areas studied by the report—particularly consumer products and worker exposure to toxic chemicals—EPA shared jurisdiction with other government agencies, and for other areas—particularly stratospheric ozone depletion and global warming—international coordination is necessary for successful response.

Is it inconsistent with the economic perspective for regulation to focus on less serious risks rather than on other more serious risks? For further discussion, see W. Kip Viscusi, *Equivalent Frames of Reference for Judging Risk Regulation Policies*, 3 N.Y.U. ENVTL. L.J. 431 (1995). What additional information would you need to determine whether EPA's priorities are appropriate?

3. ***Reducing Risk.*** The second EPA study, *Reducing Risk*, was undertaken by EPA's Science Advisory Board (SAB). The SAB was asked to review the findings in *Unfinished Business* and to develop recommendations for prioritizing EPA's efforts. Most importantly, the SAB called on EPA to "target its environmental protection efforts on the basis of opportunities for the greatest risk reduction." EPA SCI. ADVISORY BD., REDUCING RISK: SETTING PRIORITIES AND STRATEGIES FOR ENVIRONMENTAL PROTECTION 6 (1990). Why is this objective desirable? Should the relative costs of achieving different risk reductions be taken into account? Should it matter whether the risks are voluntary or involuntary? Should it matter whether the environmental problem is fully internalized, as is the case for indoor radon in owner-occupied houses?

Elsewhere in the report, the SAB formulates these recommendations in two other ways. First, it states: "We should set priorities for environmental protection based on an explicit comparison of the relative risk posed by different environmental problems, and more specifically, the opportunities for cost effective risk reduction." *Id*. at 28. Second, it states: "[T]o the extent that EPA has discretion to emphasize one environmental protection program over another, it should emphasize the program that reduces the most environmental risk at the lowest overall cost to society." *Id*. Are these three formulations consistent? Under the third formulation, is it necessarily the case that the most serious risks would be addressed first?

The process of comparing risks so as to address the most serious ones first has come to be known as comparative risk assessment or comparative risk analysis (CRA). For academic criticism of CRA, see D. Hattis & R. Goble, *Current Priority-Setting Methodology: Too Little Rationality or Too Much?*, *in* WORST THINGS FIRST?: THE DEBATE OVER RISK-BASED NATIONAL ENVIRONMENTAL PRIORITIES 107 (Adam M. Finkel & Dominic Golding eds., 1994); Donald T. Hornstein, *Reclaiming Environmental Law: A Normative Critique of Comparative Risk Analysis*, 92 COLUM. L. REV. 562 (1992); Ellen K. Silbergeld, *The Risks of Comparing Risks*, 3 N.Y.U. ENVTL. L.J. 405 (1995).

4. Addressing the Divide in Regulation. If it cannot do both, should environmental regulation address risks that experts think are serious or risks that the public thinks are serious? What is the economic perspective's view on this question? What would Mark Sagoff say? The economic and non-economic perspectives on environmental degradation are discussed in Chapter I. If people are being compensated for exposure to risk, to what extent are public perceptions likely to affect the amount of compensation?

5. Should Lay Perceptions of Risk Count in Risk Assessments? Is the divergence between lay and expert perceptions of risk a case of public misperception that should be solved by changing the public's perceptions? Or should the regulatory system accept the divergence and seek to adjust the decision-making process to accommodate the differing perceptions? In particular, should lay perceptions of risk count in risk assessments? For discussion, see James S. Freeman & Rachel D. Godsil, *The Question of Risk: Incorporating Community Perceptions Into Environmental Risk Assessments*, 21 FORDHAM URB. L.J. 547 (1994).

6. Judicial Response to the Divide. In some areas of the law, the courts have tried to address the divergence between lay and expert perceptions of risk by, for example, prohibiting awards of damages in nuisance cases for loss of property value due to scientifically unfounded fear of contamination. Should the response of the legislative and administrative processes be different from the response of the courts?

7. Can Communication Adequately Bridge the Gap? Do you think that risk communication can significantly narrow the difference between expert and lay perceptions of risk? Have your views about risk changed as a result of the readings in this section?

8. Risk Assessment in the European Union. In its Communication on the Precautionary Principle, the Commission of European Communities devised an approach for how to assess, appraise, manage and communicate risks that science is not yet able to fully evaluate. *Communication from the Commission on the Precautionary Principle*, at 2 COM (2000) 1 final (Feb. 2, 2000). According to this communication, "[a] scientific evaluation of the potential adverse effects should be undertaken based on the available data when considering whether measures are necessary to protect the environment, the human, animal or plant health."

In *Pfizer Animal Health SA v. Council of European Union*, Case t–13/99, 2002 E.C.R. II–03305, the European Court of First Instance analyzed the enactment of a Council regulation that withdrew the authorizations of four antibiotics used as additives in feedingstuffs. The Council had found a risk that the effectiveness of certain human medicinal

products could be compromised as a result of the use of the additives. *See id.* ¶ 112.

The Council adopted that decision even though at that time neither the existence nor the seriousness of the risk had been scientifically proven. *Id.* ¶ 113. Pfizer challenged the Council decision on the grounds that the Community institutions had erred in their risk assessment and management. *Id.* ¶ 107. In particular, it argued that the Community institutions could not take preventive measures until they had carried out a scientific assessment of the risks allegedly associated with the product or procedure concerned. *Id.* ¶ 129. The European Union Court of First Instance explained:

> [T]he Court of Justice has already had occasion to note that in matters relating to additives in feedingstuffs the Community institutions are responsible for carrying out complex technical and scientific assessments. . . .
>
> [I]t must be borne in mind that, when the precautionary principle is applied, the fact that there is scientific uncertainty and that it is impossible to carry out a full risk assessment in the time available does not prevent the competent public authority from taking preventive protective measures if such measures appear essential, regard being had to the level of risk to human health which the public authority has decided is the critical threshold above which it is necessary to take preventive measures.
>
> The precautionary principle allows the competent public authority to take, on a provisional basis, preventive protective measures on what is as yet an incomplete scientific basis, pending the availability of additional scientific evidence. . . . [T]he competent public authority must weigh up its obligations and decide either to wait until the results of more detailed scientific research become available or to act on the basis of the scientific information available. Having taken account, first, of the seriousness of the repercussions should the risk of streptogramin resistance being transferred from animals to humans become a reality and, second, of the results of the scientific research examined above, the Court concludes that the Community institutions did not make a manifest error of assessment when they came to weigh up their obligations.

Id. ¶¶ 154, 382, 387. What kind of scientific evidence did the Court require to justify the withdrawal of the authorization? Is a risk assessment required? *See* Case t–70/99, *Alpharma Inc. v. Council of European Union*, 2002 E.C.R. II–3495, ¶ 316–17 (upholding the ban of an antibiotic used in animal feed based only on evidence regarding other antibiotics and on the reports of various international bodies). Compare this approach to the one adopted in the United States. Which approach is more desirable? Should the regulatory agency wait to have more conclusive evidence? For a discussion of risk assessment in the European Union and in the United States, see Jonathan B. Wiener, *Convergence, Divergence, and Complexity in US and European Risk Regulation, in* GREEN GIANTS? ENVIRONMENTAL POLICIES OF THE UNITED STATES AND THE EUROPEAN UNION 73–109 (Norman J. Vig & Michael G. Faure eds., 2004); Theofanis Christoforou, *The Precautionary Principle, Risk Assessment, and the Comparative Role of*

Science in the European Community and the US Legal System, in GREEN GIANTS?, *supra*, at 17–51.

2. RISK MANAGEMENT

A. RISK MANAGEMENT FRAMEWORKS

Risk management is the process by which regulators make decisions about which risks are worth addressing and about the extent to which these risks should be controlled. As discussed in the previous section on risk assessment, risk management is generally seen as a second step in the regulatory process, following the completion of a risk assessment. At the risk management stage, regulators have an estimate of the magnitude of the environmental risks and must decide about the extent, if any, to which these risks should be controlled.

This section will begin by presenting an overview of the risk management frameworks in the major federal environmental statutes, tracing the trend—which began in the early 1980s—toward the application of cost-benefit analysis.

The federal environmental statutes employ a variety of risk management frameworks, often combining several of the categories described above. For example, the National Ambient Air Quality Standards (NAAQS) under the Clean Air Act (CAA), which apply to criteria pollutants (as opposed to hazardous pollutants), must be set at the levels that, "allowing an adequate margin of safety, are requisite to protect the public health." 42 U.S.C. § 7409(b)(1). Pursuant to this standard, EPA has employed a "critical populations, critical effects" approach, seeking to protect the most sensitive members of the population against every adverse health effect. Moreover, the courts have held that the costs of pollution reduction cannot be taken into account in setting these standards. Thus, at least in theory the NAAQS are set by reference to a no-risk framework. (The practical problems with this approach are discussed in Chapter V.) Technology-based standards are also employed, but primarily as a mechanism to allocate the pollution control burden required by the NAAQS.

The CAA takes a different approach with respect to hazardous air pollutants. The pollutants are currently controlled by means of technology-based standards. Over the course of the next decade, however, EPA must promulgate more stringent standards if the technology-based standards "do not reduce lifetime excess cancer risks to the individual most exposed to emissions . . . to less than one in one million." 42 U.S.C. § 7412(f)(2)(A). These more stringent standards correspond to a negligible risk framework (a variant of a no-risk framework). The resulting standards are therefore the more stringent of those that would result from the technology-based and negligible risk frameworks, respectively.

Under the Safe Drinking Water Act (SDWA), a different two-part procedure is used. EPA first sets maximum contaminant level goals "at the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety." 42 U.S.C. § 300g-1(b)(4)(A). Next, EPA promulgates the national primary drinking water regulations, which constitute the enforceable standard,

"as close to the maximum contaminant level goal as is feasible." The statute defines "feasible" as "feasible with the use of the best technology . . . [taking cost into consideration]." 42 U.S.C. § 300g–1(b)(4)(D). Thus, these standards are the less stringent of those that would result from the technology-based and risk threshold frameworks, respectively.

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provides that pesticides can be marketed only if they "will not generally cause unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5)(d). Such effects, in turn, are defined as "unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits." *Id.* § 136(bb). This approach has elements of both the risk-risk framework, in that it takes into account both environmental costs and benefits of the pesticide and of the risk-benefit framework, in that it considers both the benefits and burdens of regulation.

Since the early 1980s, the risk management frameworks of the various federal environmental statutes have been significantly affected by Executive Order 12,291, which was promulgated by President Reagan and remained in effect during the George H. W. Bush administration. Procedurally, it established a centralized process for the prepromulgation review of any major rule (defined as a rule with an annual effect on the economy of $100 million or more) by OMB. Substantively, it required that, "to the extent permitted by law," "[r]egulatory action . . . not be undertaken unless the potential benefits to society of the regulation outweigh the potential costs to society," "[r]egulatory objectives . . . be chosen to maximize the net benefits to society," and "[a]mong alternative approaches to any given regulatory objective, the alternative involving the least net cost to society . . . be chosen." Exec. Order No. 12,291, 46 Fed. Reg. 13,193 (1981). Executive Order 12,291 vested in OMB an unprecedented level of control over the administrative apparatus and established the essential architecture of central review of agency action that remains in place to this day.

President Clinton replaced this order with Executive Order 12,866, which retains the centralized review by OMB, and provides, consistent with the approach of its predecessor, that "in choosing among alternative regulatory approaches, agencies should select those approaches that maximize net benefits . . . unless a statute requires another regulatory approach." Exec. Order No. 12,866, 58 Fed. Reg. 51,735 (1993). In response to criticisms about how agency decisions were being reviewed, the latter order imposes enhanced disclosure requirements, specifically required that agencies weigh "qualitative measures," including "distributive impacts" and "equity," when engaging in cost-benefit analysis, and set deadlines on review in an attempt to prevent the indefinite stalling of a regulation. The effect of these orders has been to push EPA in the direction of cost-benefit analysis, except in those instances, such as the promulgation of NAAQS under the CAA, where the statute prohibits the application of this framework.

In January 2007, President George W. Bush announced revisions to Executive Order 12,866, further centralizing control of administrative agencies. *See* Exec. Order No. 13,422, 72 Fed. Reg. 2763 (2007). Key revisions include a requirement that agencies identify a "market

failure" before they move forward with proposed regulations and a requirement that guidance documents (in addition to actual regulations) be subject to the OMB review process. In addition, the revised order places political appointees in the agencies as Regulatory Policy Review Officers, further cementing presidential control over the bureaucracy. For a detailed description of the growth of cost-benefit analysis as the predominant risk management framework in federal environmental decision-making, see RICHARD L. REVESZ & MICHAEL A. LIVERMORE, RETAKING RATIONALITY: HOW COST-BENEFIT ANALYSIS CAN BETTER PROTECT THE ENVIRONMENT AND OUR HEALTH (2008).

President Obama issued an executive order which did not replace the main aspects of the Clinton and Bush executive orders but introduced some minor but potentially important changes. *See* Exec. Order No. 13,563, 76 Fed. Reg. 3,821 (2011). This order emphasized public participation, agency coordination, flexible regulatory approaches, and scientific integrity. Perhaps most significantly, the order introduced retrospective analyses of existing regulations as a routine part of an agency's mission. However, the order did not pre-judge how a retrospective analysis would be used. It stated that such review would "determine whether any such regulations should be modified, streamlined, expanded, or repealed. . . ." President Obama accompanied this executive order with memoranda to agencies, directing them to make more information available on websites in a searchable form and to consider measures to reduce regulatory burdens on small businesses.

During the last few decades, economists have developed different techniques for the valuation of environmental benefits. These benefits can be categorized as benefits to human life and health on the one hand and benefits to the environment on the other. The latter, in turn, are generally subdivided into three categories: use values, option values, and existence values. Use values arise with respect to environmental resources, for example, pristine lakes that one values because one plans to actually use them. Option values arise with respect to resources that one does not currently use but that one may want to use in the future. Existence values, sometimes called non-use values, arise with respect to resources that one does not currently use or expect to use in the future but the existence of which nonetheless gives rise to utility. For example, one can derive utility from knowing that a wilderness area that one never plans to visit will remain pristine.

For the purposes of cost-benefit analysis, the standard technique for valuing lives is the "willingness-to-pay" approach. Typically, this approach first identifies jobs that are similar except for different exposures to risk. Second, it determines the wage premium obtained by workers at the riskier jobs, controlling for other relevant determinants of the worker and the job. Third, it estimates the additional probability of death that results from the riskier jobs. Finally, it extrapolates, from the wage premium obtained for this additional probability of death, to the value of a life. In turn, use values for environmental resources such as parks are often estimated through the travel-cost method. This method estimates the expenditures, in terms of time and out-of-pocket disbursements, that individuals are willing to incur in order to visit the site. Finally, option and existence values are generally ascertained by

means of the contingent valuation methodology (CVM). Under CVM, individual valuations are determined by means of surveys, and the resulting figures are multiplied by the number of affected individuals.

Lester B. Lave, The Strategy of Social Regulation: Decision Frameworks for Policy

9–27 (1981).*

Six frameworks for making regulatory decisions are currently being used and two have been proposed. The frameworks range, roughly, from those requiring the least theory, data, and analysis and offering the least flexibility to those at the opposite pole; they include market regulation, no-risk, technology-based standards, risk-risk (proposed), risk-benefit, cost-effectiveness, regulatory budget (proposed), and benefit cost.

Market Regulation

Economic theory has formalized the 200-year-old insight of Adam Smith that competitive markets are efficient. In particular (under a set of stringent assumptions including complete information, no transaction costs, rational consumers and producers, no economies of scale in production, and no externalities), a competitive market produces an efficient (or Pareto optimal) equilibrium in the sense that no one can be made better off without making at least one person worse off. This efficiency principle also holds for situations involving risk, such as hazardous products or jobs, although still more stringent assumptions are needed.

Each person in such an economy presumably would decide what is best for him by looking at the array of available products and jobs. Since risk is an undesirable attribute, all risky products and jobs having no compensating attributes would be eliminated, and individuals would scrutinize those risky products and jobs that offered higher pay or some other advantage to determine which should be taken. Under the restrictive assumptions, government regulation would be unnecessary.

Clearly the U.S. economy does not satisfy the host of restrictive assumptions; both buyers and sellers can often influence price, many effects are transmitted outside the marketplace, and often buyers and sellers are woefully ignorant of the health and safety implications of a product. Market equilibrium is inefficient and a case can be made for government intervention. Some economists caution Americans to eschew perfection, arguing that they would be better off in the long run by tolerating these relatively minor evils instead of erecting a huge, self-defeating regulatory structure. Regulation requires resources, but more important, it is virtually impossible to regulate so that incentives are not distorted, and this often leads to even greater inefficiency than in the unregulated market—for example, transportation regulation, particularly of airlines and trains. Many economists argue that regulation is justified only when serious violations of the assumptions occur, and then only if the regulation can be relatively efficient. . . .

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In summary, the decision to use the market to regulate risk puts faith in consumer information and judgments. It sees the costs of bureaucracy constraining private decisions as larger than costs arising from market imperfections and advises accepting current imperfections rather than creating a regulatory morass.

No-Risk

The philosophy behind the Delaney Clause of the Food, Drug, and Cosmetic Act, and food additive amendments generally, is that the public should be exposed to no additional or unnecessary risk. Carcinogens cannot be added to foods or remain as residuals in meat since this might increase the risk of cancer; according to the Clean Air Act Amendments of 1970, air pollution levels must be sufficiently low to protect the population from adverse effects, presumably even the most sensitive members.

This approach has great appeal as rhetoric. To argue that carcinogens ought to be permitted in the food supply is to argue that society must allow higher than necessary risks of cancer. Why should any unnecessary exposure be tolerated, even if the risk appears to be small?

The no-risk framework has the advantage of requiring little data and analysis and precludes agonizing about the decision to be made. According to the Delaney Clause, the only question is whether a food additive has been shown to be a carcinogen in humans or animals. Thus data (on the quality, variety, and price of food) concerning the consequences of banning may not be considered. The Delaney Clause has a simple, straightforward answer to a complicated question: ban a substance if there is evidence of carcinogenicity. Frameworks other than market regulation require answers to a set of complicated questions: What level of risks are acceptable? What benefits would serve to offset the risks? Can animal bioassays be relied on to demonstrate human carcinogenicity? Can the potency of a substance for humans be demonstrated under current exposure levels? If one requires simple answers to these questions or distrusts the complicated answers given by experts, no-risk offers an appealing solution.

Unfortunately the answers are too simple. Virtually all “natural” foods contain trace elements of carcinogens, including biological contaminants and pesticides. The Food and Drug Administration treats natural foods differently than food additives; apparently it is less troublesome to die from a cancer induced by a natural food than from one induced by a food additive. Does anyone seriously propose to ban all foods with trace levels of carcinogens? Does it make sense to treat those with trace amounts in the same way as those with large amounts of potent carcinogens? . . .

The three principal objections to this framework are the current misallocation of resources, the closing of the door to future solutions, and the inconsistency in government policy. In addition this framework cannot distinguish between a toxin that is extremely weak and to which few people are exposed and a potent carcinogen to which nearly the entire population is exposed. Insofar as there are many carcinogens and it is costly to ban at least some of them, this framework does not help to develop priorities—which substance should be treated first?—or

guidelines—what level of safety ought to be sought where banning is infeasible? Instead, it sends regulators scurrying off to devote much of their attention to relatively benign substances by giving all toxins equal priority. Thus the framework is a pernicious guide to regulators confronted with complicated problems.

Although Congress has written the no-risk framework into legislation, it is a straw man unworthy of serious consideration. Even the attempt to maintain the facade is increasingly recognized by the regulatory agencies to be impossible. For example, the Food and Drug Administration has attempted to define a "negligible" risk level; any risk below a level of one in one million lifetimes would be considered to be zero for regulatory purposes. . . .

Technology-Based Standards

Recognizing the difficulty of attempting to estimate the health and safety effects of a proposed standard (much less the problem of quantifying these effects), a number of agencies have placed their reliance on engineering judgments. The best available control technology has been required extensively by the Environmental Protection Agency in regulating air and water pollution. This framework has the simplicity of requiring the estimation of neither benefits nor costs. The data and analysis required are for identifying a hazard and then for making the engineering judgment as to the best available control technology. This framework requires a second set of information for determining the best available control technology in addition to the carcinogenicity data required for the no-risk framework.

In practice, however, there is never a best technology but only successively more expensive and stringent technologies. For example, the effectiveness of an electrostatic precipitator in removing suspended particles from air is proportional to the collector plate area; effectiveness can be increased by increasing the area. In practice, engineering judgment defines best available control technology as a finite collector plate area, even though further increases in plate area would improve (minutely) the effectiveness of collection. At some point additional abatement is unwarranted because social costs exceed social benefits; but even then technology is available that would abate emissions further. In practice, best available control technology embodies implicit assumptions about the benefits and costs of further abatement.

The crucial issue in implementing this framework at present is the financial burden each industry can bear. As long as an industry is not in danger of bankruptcy, a technology that lowered emissions would be considered acceptable. Sufficient uncertainty exists about what cost level would endanger an industry that regulators rarely impose standards that come close to doing so.

In summary, the primary advantage of technology-based standards is that they require no formal evidence on costs or benefits; the only data required are those necessary for good engineering judgments. The resulting standard, however, will depend on regulators' perceptions of industry profitability. If an area is populated by an industry teetering on the brink of bankruptcy, best available control technology will be weak and few emissions will be abated. If the industry is profitable, it

will require large expenditures. There is more than a theoretical possibility that the first regulation in an industry would press it to the limit of its ability to afford regulation, leaving no financial resources to handle later regulations that might be far more important. Rather than being a framework for lowering risk or even for using engineering judgments, technology-based standards is a framework for regulating economic activity through imposing costs arbitrarily among industries until all are at the same minimal level of profit.

Risk-Risk: Direct

Even if maximum protection were desired, the Delaney Clause would be a poor framework because it requires banning carcinogens. Some toxic substances, such as food additives and fungicides, prevent contamination of food, and thus it is desirable to weigh one risk against the other, as recognized by the Food and Drug Administration and the Department of Agriculture in the proposed risk-risk analysis. Balancing the toxicity of a substance against the enhanced protection it brings can be done from either of two perspectives. The narrow perspective is that of balancing the risk to the consumer of the additive against the direct health benefits. Sodium nitrite may be a carcinogen, but it protects against botulism; the risk of cancer must be balanced against that of botulism. The broad perspective takes account of both producers and consumers as shown below.

Since the risk-risk framework allows beneficial health effects to be considered along with adverse health effects, it is more flexible than no-risk. It and the remaining frameworks are qualitatively different from no-risk in that they require quantification of risk and at least partial estimation of benefits. If quantification were impossible, this framework could not be implemented because there would be no method for balancing unmatched risks (for example, chronic respiratory disease versus broken legs). Quantification is particularly difficult for the effects of toxic substances; thus this and the remaining frameworks are subject to the caution of those who contend that potency cannot be estimated from animal bioassays, or at least that potency for humans at low doses cannot be inferred reliably. . . .

While the risk-risk framework provides somewhat greater flexibility, it still precludes consideration of nonhealth effects. Conceptually it is a small step since it merely includes both the health risks and health benefits of a proposal. In practice it appears to be a major improvement over the no-risk framework—where it is applicable. Cases such as sodium nitrite where the risk-risk framework is invaluable, are the exception. Few substances offer a direct health benefit to the consumer other than drugs, products for which the Food and Drug Administration already uses this framework. The framework is of limited interest because it is of such limited applicability.

Risk-Risk: Indirect

The advantage of the risk-risk framework over the no-risk framework is that it permits wider analysis of risks. One way of stating the objective is that society desires to minimize the adverse health effects associated with a given food such as bacon. Thus society would permit nitrite in bacon if the improvement in the health of consumers from botulism protection exceeded the decrement in health from the

risk of cancer. Yet it is evident that the direct risk-risk framework takes only the first step of considering the health of the person consuming the food. People are also associated with the production and distribution of food; society desires to minimize the adverse health effects associated with producing as well as consuming bacon (for a fixed level of production). Workers would not countenance a regulation that offered consumers a small amount of protection at the cost of a large increase in risk to workers.

Since every human activity is risky, a regulation that requires more man-hours to produce a unit of food would increase the exposure and presumably the occupational risk of workers. The indirect risk-risk framework includes occupational risks associated with each additive or contaminant. . . .

Risk-Benefit

Unlike the risk-benefit framework, the three previous ones do not allow consideration of nonhealth effects. The folly of refusing to consider these effects is illustrated by examining one's own choices. For example, most people are willing to risk the minute chance of biological contamination rather than to be bothered with boiling drinking water. They are willing to undertake additional risks in order to get rewards such as additional income and recreational stimulation. For example, there is a risk premium in the pay of workers in hazardous occupations to attract them in the face of the higher risks. These premiums can be extremely high, as for test pilots, steeplejacks, and divers working deep in the ocean. If the effect of a regulation is to lower risk minutely at the cost of a vast increase in price, a lessening of choice or convenience, harm to the environment, or a sacrifice in social goals generally, society should not be satisfied. The frameworks previously mentioned suffer from their lack of recognition of other social goals such as the ecosystem, endangered species, and individual freedoms.

Under the risk-benefit framework, regulators would be enjoined to balance the general benefits of a proposed regulation against its general risks. This framework is intended to be somewhat vague, with all effects being enumerated, but with full quantification and valuation being left to the general wisdom of the regulators. The framework may account for cost, convenience, and even preferences in an attempt to balance benefits against risks. A vast array of frameworks can come under the risk-benefit heading, from balancing health risks against health benefits (like the risk-risk indirect framework) to consideration of all risks, costs, and benefits. The framework has an immediate appeal to congressmen and regulators since it is a general instruction to consider all social factors in arriving at a decision. While no one can oppose considering all relevant factors, no one has specified precisely how this is to be done.

The intellectual difficulty with this framework is its lack of precise definition. Are only health risks to be considered, or are risks to the present and future environment (air, water, louseworts, snail darters, and tundra) relevant? If they are not, the framework is no more complete than the previous one, and if they are, how can the risks to louseworts be added to those to the health of our great grandchildren and of current workers? Similarly, there is no guidance about how to

quantify benefits: what is the value of an increase in the supply of food or electricity? . . .

Cost-Effectiveness

Many organizations, private and public, find themselves attempting to increase output even though their current budget is fixed. The intellectual contributions in defining this problem and developing rules to solve it have come from the Department of Defense. Although cost-effectiveness is often thought erroneously to refer to getting some specific project done at lowest cost, the concept is much broader, referring to accomplishing some general objective at lowest cost. President Eisenhower's secretary of defense, Charles Wilson, described the goal succinctly as an attempt to "get the most bang for the buck."

How can a goal be achieved within a fixed budget? For example, the goal of the National Cancer Institute is to lower the cancer death rate. It might achieve this goal by devoting resources to basic research, clinical trials testing new treatment techniques, public education, prevention by lowering the amounts of carcinogens in the environment, early detection of cancer, or the provision of more treatment. How should the fixed budget be allocated among these competing programs to lower both the incidence of cancer and the occurrence of death and lesser effects?

Mathematically, this is a problem of maximization under constraints; the solution is to equate the effectiveness of the last dollar spent on each activity. For this example, the National Cancer Institute ought to allocate funds among the programs (taking care that the most effective projects are done first within each program) by testing the effectiveness of each dollar. The first increment of funds should be given to the program where it would be estimated to save the most lives. The second increment of funds should be allocated by the same criterion, perhaps going to the same program. As each successive increment of funds is allocated, the number of lives it saves should fall (since the best projects were done first). When all funds have been allocated, it should be true that the last increment of funds to each program would be expected to save approximately the same number of lives. If not, then funds should be reallocated by recalling them from the program where they are least effective and giving them to the program where they are most effective. Mathematically, the ratio of lives saved to dollars expended (for the last increment of funds) should be equal across programs when all funds have been allocated. As long as the ratios are not equal, additional lives could be saved for the same budget by removing funds from the program with the lowest ratio and adding them to the program with the highest ratio. . . .

Cost-effectiveness offers a major advantage over benefit-cost analysis in that it does not require an explicit value for the social cost of premature death (or other untraded goods). Assumptions about these values are built into the goal and budget (for example, maximize lives saved for a fixed budget) but need not be stated explicitly. The flip side of this advantage, however, is that errors in stating the goal or in determining the budget can lead to bad decisions, and there is no internal mechanism for showing the errors in these decisions and the changes in goals or budget that are necessary.

Regulatory Budget

Cost-effectiveness is a good framework if the relevant costs are being measured in the analysis. Unfortunately when the only costs considered are those of the regulatory agency, the framework will misallocate resources because only one subset of the total costs of the regulation to the entire economy is being considered. The agencies have little or no reason to consider the costs that their regulations impose on others unless the costs are so high that industry bankruptcy is a relevant possibility. The agencies are instructed to protect the environment, consumers, or workers without any apparent limits on their ability to impose costs on others. That the resulting regulations are not universally perceived as desirable can be judged from the comments of the affected companies and the fact that the federal government has often exempted itself from the regulations or has been slow in implementing them.

An idea originating in the Council of Economic Advisers under Charles Schultze was to give each regulatory agency an implementation budget in the form of a limit on the total annual costs that its regulations could impose. For example, the Environmental Protection Agency might be given an implementation budget of $10 billion a year, which would mean that the costs of implementing its air, water, solid waste, radiation, and pesticide regulations could not exceed $10 billion in that year. Each agency would develop an implementation budget request, just as it currently develops its operating budget request. The administration would coordinate and impose priorities on the agencies, and then Congress would react to these requests, modifying them as necessary.

The regulatory budget is one method of implementing cost-effectiveness analysis. The goals needed for the framework are stated in the legislation for each agency, supplemented by whatever informal instructions arise from hearings, appropriations, Office of Management and Budget directives, or presidential intervention. The internal and implementation budgets would be considered and approved by Congress, based on each agency's data on effectiveness. A major advantage of the framework is that it would elicit from the agencies a clearer indication of their priorities and would enable Congress to make more intelligent decisions regarding social values.

The principal difficulties with the framework are in estimating the costs and effects of each regulation. Where a control device must be added to a smokestack, there is debate about the cost of the device and about its expected lifetime, maintenance, and reliability. For a new piece of technology, these difficulties might perhaps introduce a factor-of-two difference in estimated costs. When the regulation will require a change in process or result in banning a substance, the costs become much more uncertain. If there is a factor-of-five-or-ten difference between reasonable high and low estimates of implementation costs, the regulatory budget cannot provide a helpful constraint. . . .

Benefit-Cost

This framework is similar to the general balancing of risks against benefits; the principal difference is that it is more quantitative and formal. In addition to enumerating the various benefits of the

regulation and then subjectively balancing benefits against costs, this framework would require quantification of the extent to which the benefits and costs vary with the level of regulation, and then would require each of these effects to be translated into dollars.

There are many controversial aspects to its application, including putting an explicit value on prolonging a life, quantifying other benefits, deciding the rate at which effects in the future are discounted to make them equivalent to current effects, and redistributing income. Valuing benefits, or even deciding what is a benefit, runs into the diversity of cultural backgrounds, personal goals, fears, and time horizons. . . .

Benefit-cost analysis is a sufficiently broad framework to be adapted to consider virtually any aspect of a regulation or public decision. The implications for those who gain or lose can be folded into the analysis. None of the objections to the framework have the effect of showing an inherent bias or blind spot in the analysis.

In practice, however, the picture is quite different. Benefit-cost analysis is often viewed, correctly, as a tool for defending the status quo. It is rarely used to consider who benefits or pays, and it focuses on the present, giving short shrift to even the near-term future with no importance for events more than a few decades in the future. Adjustment costs are often estimated to be higher than would be observed, reflecting a prejudice that the current situation must be the best one (when adjustment costs are not considered, the analysis is biased toward change). Finally, a number of simplifying assumptions are made that bias the analysis against change. . . .

A Comparison of Frameworks

. . . Four criteria might be used to compare frameworks:

The first is comprehensiveness. Are all the relevant issues encompassed within the framework? No-risk considers only carcinogenesis (or other health attributes); risk-risk considers all health consequences either to the consumer (direct) or more generally (indirect). Cost-effectiveness and the regulatory budget require examination of costs as well as health, but they can be considered only within the goals of the agency. Benefit-cost and risk-benefit are the most encompassing, although even they are not used in practice to address equity questions.

The second criterion is the intellectual foundation required of each framework. One can be most certain about the foundation for the simple frameworks, but drawing in additional considerations requires more knowledge, assumptions, and value judgments. The wider coverage comes at a price. In some cases there is insufficient knowledge to be able to quantify or even explore these other considerations; if so, there is no alternative to a simple framework or an ad hoc decision.

The third criterion is the resources required to implement the framework. The more complicated frameworks require exploitation of further aspects of the problem, which in turn requires more data collection and analysis. Generally the resources available to analyze alternative regulations constitute a small proportion of those available for drafting and defending the regulations, and a minuscule proportion of the cost of carrying out the regulation. If additional analysis can result in even a tiny improvement in the quality of the regulation, the

reduction in implementation and other costs should more than pay for the effort.

The fourth criterion is felicitousness. The world is complicated; it changes so rapidly that an agency rarely gets to second-order priority issues. The most important issues must be treated first, and they must be raised in easily comprehended fashion. If the issues are posed in a confused or obscure manner, the decision is likely to be made on an ad hoc basis. The felicitousness of the framework is more important than its comprehensiveness.

None of these frameworks is sufficiently complete and sound to serve as an automatic way of making decisions. The current Delaney Clause framework would appear to be the most concrete; even it, however, becomes mired in controversy over proving carcinogenicity. . . .

The other frameworks have the more difficult task of quantifying risk and of attempting to quantify other aspects of the issue (for example the value of greater choice). In all cases judgment is required to examine the suitability of the quantification, the factors that could not be quantified, and the valuation of the aspects that were quantified. These issues are far too complicated for a mechanical decision-making framework to be appropriate—for example one of pursuing a project if and only the estimated benefits exceed costs.

The real question is the extent to which each of these frameworks can prove helpful in informing the decisionmaker. Must all effects be quantified accurately and all valuations be agreed upon before benefit-cost analysis is helpful? If complete quantification is not possible or if there are difficulties in estimating risk, is it better to slip back to a less demanding framework, possibly back to the no-risk framework? The answer depends on both the amount of uncertainty and the extent to which the general nature of the uncertainty is known. No analysis of health and safety regulations has managed to quantify all aspects of the issue, and it is evident that no future analysis can be expected to be complete. If this lack of completeness is deemed fatal, there is no point in considering benefit-cost analysis further.

NOTES AND QUESTIONS

1. Choosing Among Frameworks. Simplistic solutions to risk management problems are likely to be undesirable. A no-risk command might be unattractive if there is a competing alternative that poses only slightly greater risk but is far less costly. Similarly, setting a standard so that the probability of some important adverse consequence is lower than a given threshold (say one in a million) might lead to an undesirable outcome if an alternative standard, with a probability only slightly above this threshold, would be far less costly. Also problematic is a fixed value trade-off between cost and risk. For example, one might be willing to pay more to reduce a unit of risk when risk is high than when it is low. *See* BARUCH FISCHHOFF ET AL., ACCEPTABLE RISK 5–7 (1981). Does the rejection of the no-risk and risk threshold approaches lead inevitably in the direction of cost-benefit analysis? Are there circumstances in which the level of costs, or the cost-risk trade-off, should just not matter? Does the rejection of fixed value tradeoffs between cost and risk imply a rejection of cost-benefit analysis?

2. Market Regulation. Consider the following instances of market regulation:

(a) buying a more expensive house rather than one that is cheaper but closer to a hazardous waste site, to a highway, or to a mental hospital;

(b) buying a more expensive car that provides more protection in the event of a crash;

(c) paying more to avoid flying on a commuter airline; and

(d) receiving a higher wage to take a job with higher workplace risks.

Which, if any, of these forms of market regulation are desirable?

3. Limits to Market Regulation. There is typically a cut-off or threshold below which we will not allow market regulation. Consider the *Benzene* case in which OSHA had been directed to set a limit on workplace exposure to benzene. Why did Congress not consider it adequate that workers exposed to high levels of benzene in the workplace are usually compensated by way of higher wages? Similarly, why does Congress set minimum safety requirements for automobiles, in circumstances in which consumers may prefer to pay less for less secure cars? Why is regulatory intervention warranted under these circumstances? Is it that these risks are considered unacceptable according to societal values? If the risk is borne only by the consumer, why should the government intervene in market regulation?

4. Range of Debate. A standard limiting to one-in-a-million the lifetime probability of getting cancer from exposure to an environmental risk is generally considered stringent and is often advocated by environmentalist groups, whereas a one-in-ten-thousand standard is generally considered lax and is often advocated by industry groups. Why do these numbers so often frame the range for mainstream debate? For further discussion, see Alon Rosenthal, George M. Gray & John D. Graham, *Legislating Acceptable Cancer Risk from Exposure to Toxic Chemicals*, 19 ECOLOGY L.Q. 269 (1992).

5. Technology-Based Standards. In general, technology-based standards under the environmental statutes are set by reference to the best available technology that has been adequately demonstrated, taking costs into account. The consideration of costs has generally been taken to mean costs that a particular industry as a whole could bear and survive, even though particular firms might not survive. Is it sensible to regulate up to the point at which the industry as a whole is about to disappear? If not, what level of profit should the industry be able to keep? How should this tension affect the assessment of technology-based standards?

6. Features of Technology-Based Standards. Consider the following features of using technology-based standards as the means for determining the level of environmental protection:

(a) more stringent standards would be imposed on more profitable industries;

(b) more stringent standards would be imposed on industries that face less foreign competition; and

(c) more stringent standards would be imposed on industries that manufacture products for which there are no substitutes.

Are these features desirable?

7. Technology-Based Standards v. Cost-Benefit Analysis. Compare the relative environmental protection that results from technology-based standards on the one hand and from cost-benefit analysis on the other. Which should environmentalists prefer? Which should labor unions prefer? Are these answers case specific? *See* Jonathan S. Masur & Eric A. Posner, *Against Feasibility Analysis*, 77 U. CHI. L. REV. 657, 697–98 (2010). Why do environmentalists generally prefer technology-based standards?

8. Market Entry and Technology-Based Standards. If technology-based standards are the sole mechanism for determining the level of environmental quality, this level will vary depending on the rate of entry of new firms. Is this desirable? Should these standards be altered when new firms enter the market (or firms exit from the market)? Frequent changes, however, could be undesirable because they would render worthless substantial investments in pollution control technology. What is the solution?

9. Different Applications of Technology-Based Standards. Under the various environmental statutes, technology-based standards are sometimes used to determine the level of environmental protection, as discussed by Lave, but in other instances are used as the means to allocate among various polluters the pollution control burden that is determined through the use of a different framework. For example, under the CAA, technology-based standards for automobiles, new stationary sources, and certain types of existing sources are used as the means of meeting the National Ambient Air Quality Standards, which are nominally set by reference to the no-risk framework (as is discussed at greater length in Chapter V). Is the evaluation of technology-based standards different in this latter context?

10. Media Quality-Based Approaches v. Technology-Based Approaches. One commentator draws a distinction between media quality-based approaches on the one hand, such as ambient air quality standards, and technology-based approaches on the other. *See* Thomas O. McGarity, *Media-Quality, Technology, and Cost-Benefit Balancing Strategies for Health and Environmental Regulation*, LAW & CONTEMP. PROBS., Summer 1983, at 159. He suggests that:

> [T]he general preference of Congress and especially of implementing agencies for the technology-based approach . . . is warranted by an almost universal recognition that citizens of this country have a "right" to a healthy environment and workplace, at least insofar as the societal pursuit of that right is not technologically impossible or prohibitively expensive.

Id. at 161. Is this position compelling?

11. Risk-Risk Framework. Under a risk-risk framework should the regulatory decision be simply to minimize the aggregate risk (in the Lave example, the sum of the risk of the carcinogenic food additive and the risk of botulism)? Alternatively, should man-made risks be weighted differently from natural risks? In this connection, consider the discussion of risk perceptions in the previous section. Is this example one in which market

regulation, coupled with informational requirements, would achieve the best results? For example, the food product could be classified as organic or nonorganic and the relative risks could be disclosed. For an illuminating discussion of this framework, see RISK VS. RISK: TRADEOFFS IN PROTECTING HEALTH & THE ENVIRONMENT (John D. Graham & Jonathan B. Wiener eds., 1995).

12. Trade-Offs Under Risk-Risk Analysis. Under an indirect risk-risk framework, how should the health of workers be traded-off against the health of consumers? Consider the relevance of the following factors:

(a) whether workers are receiving a higher wage to reflect the additional risk to which they are exposed;

(b) whether consumers are sufficiently informed of the risks to make informed decisions; and

(c) whether there are less risky substitutes for the product.

13. Risk-Risk Analysis and Ancillary Benefits. The literature on risk-risk analysis has been predicated on the assumption that ancillary effects are negative. Should ancillary benefits also be considered in risk-risk analysis? For example, in conducting risk-risk analysis into the use of aspirin as a treatment of headaches, should the ancillary benefit of heart attack prevention be taken into account? Are there examples of ancillary environmental benefits? For further discussion of the treatment of ancillary risks and benefits, see Samuel J. Rascoff & Richard L. Revesz, *The Biases of Risk Tradeoff Analysis: Towards Parity in Regulatory Policy*, 69 U. CHI. L. REV. 1763 (2002) (challenging the common assumption that ancillary effects are always negative).

14. Risk-Benefit Analysis. The risk-benefit framework discussed by Lave typically balances the risks that remain under different levels of regulation with the resulting costs. Therefore risk-cost, or cost-risk, might be a more appropriate term. This term would also be more parallel to cost-benefit, which is simply a special case in which the benefits of regulation are quantified. Under the risk-benefit framework, how should one decide whether it is worth spending $100 million to save thirty lives, or to restore fish to a polluted river?

15. Risk-Benefit Analysis v. Cost-Benefit Analysis. The primary difference between the risk-benefit and cost-benefit frameworks is the lack of economic quantification of environmental benefits under the risk-benefit analysis approach. How useful then is the risk-benefit analysis in practice? How would it discern between the following regulatory responses: Response A which would save 100 lives and cost $500 million, and Response B which would save 110 lives and cost $600 million? How would cost-benefit analysis evaluate these policy responses?

16. Cost-Effectiveness and Regulatory Budget Approaches. Are the cost-effectiveness and regulatory budget approaches risk management frameworks, if risk management is understood to be the process by which society chooses the risk that it wishes to bear? Under the cost-effectiveness approach, on what basis should the underlying objective be chosen? Under a regulatory budget approach, how should the budget be set?

17. Cost-Benefit Analysis and the Status Quo. Why does Lave believe that benefit-cost analysis is a tool for defending the status quo? If this criticism is valid, how could this bias be eliminated?

18. Criteria for Discerning Between Frameworks. Evaluate the four criteria advanced by Lave to make comparative decisions among the different frameworks. Are other criteria relevant as well?

Compare the various risk management frameworks using Lave's criteria. Is one framework always favored? Does one framework do poorly? For further discussion of alternative decisional frameworks, see V. Kerry Smith, *A Conceptual Overview of the Foundations of Benefit-Cost Analysis*, *in* BENEFITS ASSESSMENT: THE STATE OF THE ART (Judith D. Bentkover et al. eds., 1986).

19. Risk Management Frameworks in Federal Environmental Statutes. Consider the hybrid decisional frameworks of the federal environmental statutes, which are discussed in the introduction to this section. What is the justification for the approach of the SDWA? Is this hybrid more or less stringent than what would result from a pure technology-based standard with the same definition of feasibility?

Under the hazardous air pollutant provision of the CAA, if one-in-a-million probability is considered the desirable goal, what is the justification for not weakening the technology-based standards if they would result in a lower probability of cancer?

Compare the CAA's approach to hazardous air pollutants to that of the SDWA. Under the former, a technology-based standard constitutes the first stage in the regulatory process; a health-based standard is the second step, which does not become effective until years later. In contrast, under the latter, the starting point is the health-based standard; at the second stage in the regulatory process, the enforceable, technology-based standard is promulgated. What factors might account for this different structure? For further discussion of risk management standards under the environmental statutes, see Harold P. Green, *The Role of Congress in Risk Management*, 16 ENVTL. L. REP. 10,220 (1986); *see also* Alon Rosenthal, George M. Gray & John D. Graham, *supra*.

What might explain the multiplicity of risk management frameworks under the federal environmental laws? Would some standardization be desirable?

20. An Attack on Cost-Benefit Analysis. Steven Kelman questions the frequent use of cost-benefit analysis in environmental, safety and health regulation. Steven Kelman, *Cost-Benefit Analysis: An Ethical Critique*, REGULATION, Jan–Feb 1981, at 33. First, he argues that the methods used by economists to perform these valuations are invariably subject to criticism on technical grounds. Second, he challenges the valuation of benefits by ascertaining an individual's willingness to pay (WTP) for an environmental amenity, a measure which he argues is likely to understate the true value of the resource. In support of this position, he relies upon studies which suggest that one's WTP for a resource is inevitably lower than one's willingness to accept (WTA) compensation to give up a resource already in one's possession. Third, Kelman argues that it is inappropriate to use WTP values in making public policy, because there exists a difference between the attitudes that people express in public and in private. Fourth, he argues that the mere act of pricing certain non-market commodities reduces their value.

Assess the strength of Kelman's critique of cost-benefit analysis. What decisional framework do you think he favors? Other critiques of cost-benefit

analysis, from different perspectives, include Duncan Kennedy, *Cost-Benefit Analysis of Entitlement Problems: A Critique*, 33 STAN. L. REV. 387 (1981); Richard B. Stewart, *Regulation in a Liberal State: The Role of Non-Commodity Values*, 92 YALE L.J. 1537 (1983).

One of Kelman's primary objections is directed toward the monetization of environmental benefits. Should he then favor the risk-benefit (risk-cost) approach? Under this approach, how could he decide whether a particular expenditure is worthwhile if it saves a certain number of lives?

21. Risk Management and the Value of Human Life. Should a regulatory system attempt to value human life? If not, on what basis should it decide to regulate an environmental risk?

Even if human life is not explicitly valued in the regulatory process, one can determine what value was "imputed" to life (at least in cases in which there are no additional benefits to the environment) by dividing the cost of the regulation by the number of lives that it expects to save. Studies show that there is a wide disparity across regulatory programs, ranging from $10,000 to over $100 million. *See* STEPHEN BREYER, BREAKING THE VICIOUS CIRCLE: TOWARD EFFECTIVE RISK REGULATION 92 (1993). In light of these results, is it appropriate to insist on more stringent regulation for programs in which the imputed valuation is low, and less stringent regulation for programs in which it is high? Is such an inquiry a disguised form of cost-benefit analysis? Is consistency desirable? In this connection, consider the factors, discussed in the previous section, that affect risk perceptions. *See* Lewis A. Kornhauser, *The Value of Life*, 38 CLEV. ST. L. REV. 209 (1990).

22. Willingness to Pay as a Value of Human Life. Consider the willingness-to-pay approach to valuing lives. How does one determine that two jobs are identical in all respects except for the risk level? How does one determine the additional risk of one of the jobs? Is it likely to be an expert or a lay assessment? How many people are induced to take risky jobs as a result of wage premiums? Are there problems with extrapolating to the population as a whole? Why is this issue significant? As discussed in the previous section, studies show that individuals undervalue voluntary risks relative to involuntary risks. How does this phenomenon affect the valuations? Consider the following criticism advanced by Kelman—that individuals who take risky jobs are likely to have unusually low valuations of risk, either because of unusually weak aversions to risk or unusually strong constraints on their choices. For discussion of the willingness-to-pay procedure, see W. Kip Viscusi, *The Value of Risks to Life and Health*, 31 J. ECON. LITERATURE 1912 (1993); Richard Zeckhauser, *Procedures for Valuing Lives*, 23 PUB. POL'Y 419 (1975).

23. Existence Values. While the concept of existence values is now well established in the economic literature, consider the following attack:

> Perhaps the greatest conceptual problem with existence value is deciding which goods and service . . . of the world have an existence value. For example, why not expand the concept to continued . . . existence of the great American farmer. . . .
>
> The family farm is also just the tip of the iceberg for an expanded list of possible existence values. Other candidates include . . . coal mining jobs in West Virginia, automobile manufacturing jobs in

> Detroit, or jobs anywhere. Because of existence values, trade barriers may start to look more efficient as they generate large economic values by preserving the existence of readily identifiable American jobs. But then, of course, there is also an existence value to reducing poverty in Third World nations that may offset the existence value gains closer to home.

Donald H. Rosenthal & Robert H. Nelson, *Why Existence Value Should Not Be Used in Cost-Benefit Analysis*, 11 J. POL'Y ANALYSIS & MGM'T 116, 118 (1992).

How would you respond? *See* Raymond J. Kopp, *Why Existence Value Should Be Used in Cost-Benefit Analysis*, 11 J. POL'Y ANALYSIS & MGM'T 123 (1992). If people value jobs or the reduction of poverty, why should these factors not enter a cost-benefit analysis?

The procedure generally employed for valuing existence values, the contingent valuation methodology (CVM), is highly controversial. What are possible concerns? The issues are summarized in Paul R. Portney, *The Contingent Valuation Debate: Why Economists Should Care*, 8 J. ECON. PERSP. 3 (1994). *See also* RICHARD L. REVESZ & MICHAEL A. LIVERMORE, RETAKING RATIONALITY 125–26 (2008).

B. BALANCING ENVIRONMENTAL BENEFITS AND OTHER SOCIAL GOALS

Environmental Defense Fund, Inc. v. Environmental Protection Agency

548 F.2d 998 (D.C. Cir. 1976), *cert. denied*, 431 U.S. 925 (1977).

■ Before LEVENTHAL, ROBINSON, and WILKEY, CIRCUIT JUDGES.

■ LEVENTHAL, CIRCUIT JUDGE:

This case involves the pesticides heptachlor and chlordane. Consolidated petitions seek review of an order of the Environmental Protection Agency (EPA) suspending the registration of those pesticides under the [Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)] for certain uses. The Administrator of EPA issued an order on December 24, 1975. The order prohibited further production of these pesticides for the suspended uses, but permitted the pesticides' continued production and sale for limited minor uses. Even as to the suspended uses, the Order tempered its impact in certain respects: It delayed until August 1, 1976, the effective date of the prohibition of production for use on corn pests; and it permitted the continued sale and use of existing stocks of registered products formulated prior to July 29, 1975.

One petition to review was filed by Earl L. Butz, Secretary of Agriculture of the United States (U.S.D.A.). Secretary Butz and intervenor Velsicol Chemical Corporation, the sole manufacturer of heptachlor and chlordane, urge that the EPA order as to chlordane be set aside on both substantive and procedural grounds. They contend that substantial evidence does not support the Administrator's conclusion that continued use of chlordane poses an "imminent hazard" to human health, and that the Administrator made critical errors in

assessing the burden of proof and in weighing the benefits against the risks of continued use of chlordane.

The other petition, filed by Environmental Defense Fund, urges that the Order did not go far enough to protect against the hazards of heptachlor and chlordane use. EDF sought an injunction against the provisions permitting continued production and use of the pesticides on corn pests until August 1, 1976. EDF also challenges the Administrator's decision to allow continued use of the stocks of the two pesticides existing as of July 29, 1975, contending that EPA should have provided for retrieval and controlled disposal of such stocks. EDF also contends that the Administrator erred in failing to suspend certain "minor uses" of chlordane and heptachlor.

I. Statutory Framework and Standard of Review

The issues posed by administrative action pursuant to FIFRA are not new to this court, and we have previously extensively described the statutory framework for such actions. What is involved here is a suspension of registration of two pesticides during the pendency of the more elaborate cancellation of registration proceeding, initiated in this case by a November 18, 1974, notice of intent to cancel. This 1974 notice stated that there existed "substantial questions of safety amounting to an unreasonable risk to man and the environment" from continued use of heptachlor and chlordane. Public cancellation hearings pursuant to that notice were not expected to commence for some time. On July 29, 1975, the Administrator issued a Notice of Intent to Suspend the registrations of most uses of the two pesticides. The Administrator then commented on that expected delay in completing the cancellation hearings, and cited "new evidence . . . which confirms and heightens the human cancer hazard posed by these pesticides." On August 4, 1975, registrant Velsicol Chemical Corporation requested an expedited adversary hearing on the suspension question pursuant to § 6 of FIFRA, 7 U.S.C. § 136d(c). Administrative Law Judge Herbert L. Perlman presided over the cancellation hearings beginning August 12. Evidence was limited to human health issues and the benefits of continued use of heptachlor and chlordane. The record was closed December 4, 1975, and on December 12, the ALJ recommended against suspension, stating that he was unable to find that "heptachlor and chlordane are conclusively carcinogens in laboratory animals." The Administrator reversed that decision on December 24, 1975, and suspended most uses of chlordane and heptachlor.

The Administrator is authorized to suspend the registration of a pesticide where he determines that an "imminent hazard" is posed by continued use during the time required for cancellation. Section 6(c) of FIFRA, 7 U.S.C. § 136d(c)(1). An "imminent hazard" exists where continued use during the time required for the cancellation proceeding would be likely to result in "unreasonable adverse effects on the environment." Section 2(*l*) of FIFRA, 7 U.S.C. § 136(*l*). The term "unreasonable adverse effects on the environment" is, in turn, defined as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." Section 2(bb) of FIFRA, 7 U.S.C.§ 136(bb). . . .

II. Substantial Evidence Support for the Administrator's Decision

To evaluate whether use of a pesticide poses an "unreasonable risk to man or the environment," the Administrator engages in a cost-benefit analysis that takes "into account the economic, social, and environmental costs and benefits of the use of any pesticide." 7 U.S.C. § 136(bb). We have previously recognized that in the "preliminary assessment of probabilities" involved in a suspension proceeding, "it is not necessary to have evidence on . . . a specific use or area in order to be able to conclude on the basis of substantial evidence that the use of [a pesticide] in general is hazardous." EDF v. EPA, 489 F.2d at 1254, quoted in EDF v. EPA [Shell Chemical Co.], 510 F.2d at 1301. "Reliance on general data, consideration of laboratory experiments on animals, etc." has been held a sufficient basis for an order cancelling or suspending the registration of a pesticide. *Id*. Once risk is shown, the responsibility to demonstrate that the benefits outweigh the risks is upon the proponents of continued registration. Conversely, the statute places a "heavy burden" of explanation on an Administrator who decides to permit the continued use of a chemical known to produce cancer in experimental animals. Applying these principles to the evidence adduced in this case, we conclude that the Administrator's decision to suspend most uses of heptachlor and chlordane and not to suspend others is supported by substantial evidence and is a rational exercise of his authority under FIFRA. . . .

[Velsicol and USDA argued that the laboratory tests on mice and rats do not "conclusively" demonstrate that chlordane is carcinogenic to those animals; that mice are too prone to tumors to be used in carcinogenicity testing in any case; and that human exposure to chlordane is insufficient to create a cancer risk. After evaluating the data presented, the Court affirmed the Administrator's conclusions, stating "[w]e have previously held that it is not necessary to have evidence on a specific use to be able to conclude that the use of a pesticide in general is hazardous. Once the initial showing of hazard is made for one mode of exposure in a suspension proceeding, and the pesticide is shown to be present in human tissues, the burden shifts to the registrant to rebut the inference that other modes of exposure may also pose a carcinogenic hazard for humans. Velsicol has totally failed to meet that burden here."] . . .

B. Benefits

Velsicol and USDA challenge the Administrator's finding that the benefits derived from the suspended uses of chlordane do not outweigh the harms done. EDF urges that the Administrator's decision to continue some uses was not justified by evidence that the risk of harm was outweighed by benefits from the continued uses.

1. Use on Corn

Heptachlor and chlordane were used on an estimated 3.5% of the total corn acreage in the United States in 1975, largely in an effort to control black cutworm. Cutworms sporadically infest 2 to 8% of total U.S. corn farms, and occur most often in lowland, river bottom areas. Chlordane and heptachlor are used as preplant treatments to insure against possible infestations. The Administrator found, with record

support, that no macroeconomic impact will occur as a result of suspending those pesticides. He also found that crop surveillance or "scouting" for infestations during the early weeks of plant growth, together with application of post-emergence baits or sprays where necessary, provide an effective alternative to the more indiscriminate prophylactic use of chlordane and heptachlor. Velsicol urges that this approach is not as effective as the persistent protection provided by chlordane. Especially in the absence of proof of a serious threat to the nation's corn, there is no requirement that a pesticide can be suspended only if alternatives to its use are absolutely equivalent in effectiveness. The Administrator reasonably took into account that a transition period would be necessary to implement post-emergent techniques of control and concluded that the challenged pesticides could continue in use for corn protection until August 1, 1976. This evaluation of alternatives and the time required to implement them is supported by substantial evidence, and we find no basis to disturb the Administrator's balancing of costs and benefits.

2. Miscellaneous Agricultural Uses

The Administrator suspended a number of agricultural uses where the record was insufficient to support any finding that benefits outweigh costs of continued use of heptachlor or chlordane on these crops. Possibly the lack of benefits evidence reflected readily available alternatives, possibly a relative lack of interest in lesser-volume uses. In any event, the registrant's failure to carry its burden of adducing sufficient evidence on benefits in effect leaves the Administrator nothing to weigh in his cost-benefit analysis except the evidence that the use of the challenged pesticides in general is hazardous. That evidence of general hazard is sufficient to support a suspension of uses.

3. Non-Agricultural Uses Suspended by the Administrator

Chlordane is a common household, lawn, garden, and ornamental turf insecticide, with over 7.5 million pounds (36% of total use) so employed in 1974. The ALJ and Administrator found on the basis of substantial evidence that the "efficaciousness of the substitutes for control of household and lawn insects is not really at issue" and that when lack of evidence of substantial benefits from continued use is weighed against the special hazards of exposure presented by the possibilities of inhalation, dermal absorption, and the increased dangers associated with improper handling, suspension of those uses was justified. Similarly, on the basis of evidence in the record, the Administrator could reasonably find that the residual capacity of chlordane was not necessary to control either structural pests or ticks and chiggers, given the existence of effective alternatives to each of those uses.

4. The Administrator's Refusal to Suspend Certain Uses

EDF challenges the Administrator's refusal to suspend use of chlordane or heptachlor on strawberries, for seed treatment, pineapples, the white fringed beetle, Florida citrus, white grubs in Michigan, narcissi bulbs, harvester ants, imported fire ant, Japanese beetle quarantine, and black vine weevil quarantine in Michigan. Following the recommendations of the ALJ, the Administrator found that for each use the benefits outweighed the risks for the limited time

under consideration, effective alternatives were generally not available, and that the exposure risk arising from the use was minimal. EDF counters that the total exposure resulting from these "minor" uses is in fact significant, and that the Administrator continued these uses whenever a "colorable" case of benefits had been made out.

Once the Administrator has found that a risk inheres in the use of a pesticide, he has an obligation to explain how the benefits of continued use outweigh that risk. We are satisfied that he has met that obligation here, and that substantial evidence supports his decision. We note, however, that we come to this conclusion in the context of a suspension proceeding where perforce the Administrator is engaged in making a "preliminary assessment" of the evidence; a more careful exploration of economic impact and available alternatives would be required to support continued registration in a cancellation proceeding.

C. Continued Sale and Use of Existing Stocks of Chlordane and Heptachlor for Suspended Uses

Although we have no doubt that the Administrator has the power under FIFRA to exempt from a suspension order the use of existing stocks (in this case stocks existing as of July 29, 1975), the Administrator acted arbitrarily when he failed to even inquire into the amount of stocks left, and the problem of returning and disposing of them. *Some* evidence must be adduced before an exemption decision is made, and it is the responsibility of the registrant to provide it. It may be that the lapse of time has lessened the current significance of this issue but we are in no position to do other than remand for further consideration.

We affirm the Agency's suspension order of December 24, 1975, as clarified by the order of January 19, 1976, except for the exemption of the sale and use of existing stocks. The record is remanded for further consideration of that issue.

NOTES AND QUESTIONS

1. "Imminent Hazard" and "Unreasonable Adverse Effects" Under FIFRA. How does FIFRA define an "imminent hazard"? How does FIFRA define "unreasonable adverse effects on the environment"? On what basis did EPA engage in cost-benefit analysis to determine whether heptachlor and chlordane gave rise to "unreasonable adverse effects on the environment"?

2. Adequacy of EPA's Cost-Benefit Analysis. What was the subject of controversy in this case? On what basis did Velsicol and USDA challenge EPA's finding that the benefits derived from the suspended uses of chlordane did not outweigh the resulting harms? On what basis did EDF argue that EPA's decisions to allow the continuation of other uses were not justified?

Compare, for example, EPA's findings on corn crops with those on strawberry crops. On what basis did EPA find that the costs of using the pesticides on corn crops outweighed its benefits? Why did EPA reach the opposite conclusion with respect to strawberries? Why, in both cases, did the court uphold the Agency's findings? In either case, did the Agency

quantify the costs and benefits of the proposed regulation? If not, on what basis was a comparison made? Was this of concern to the court?

3. Impact of Executive Order 12,291. Recall that this decision predated the promulgation of Executive Order 12,291 (described in the previous section) by President Reagan in 1981. Would this order, and the subsequent order promulgated by President Clinton, have had an impact on the manner in which the Agency conducted its various cost-benefit analyses in this case?

Corrosion Proof Fittings v. Environmental Protection Agency

947 F.2d 1201 (5th Cir. 1991).

■ Before BROWN, SMITH, and WIENER, CIRCUIT JUDGES.

■ SMITH, CIRCUIT JUDGE:

The Environmental Protection Agency (EPA) issued a final rule under section 6 of the Toxic Substances Control Act (TSCA) to prohibit the future manufacture, importation, processing, and distribution of asbestos in almost all products. . . .

Asbestos is a naturally occurring fibrous material that resists fire and most solvents. Its major uses include heat-resistant insulators, cements, building materials, fireproof gloves and clothing, and motor vehicle brake linings. Asbestos is a toxic material, and occupational exposure to asbestos dust can result in mesothelioma, asbestosis, and lung cancer. . . .

An EPA-appointed panel reviewed over one hundred studies of asbestos and conducted several public meetings. Based upon its studies and the public comments, the EPA concluded that asbestos is a potential carcinogen at all levels of exposure, regardless of the type of asbestos or the size of the fiber. The EPA concluded in 1986 that exposure to asbestos "poses an unreasonable risk to human health" and thus proposed at least four regulatory options for prohibiting or restricting the use of asbestos, including a mixed ban and phase-out of asbestos over ten years; a two-stage ban of asbestos, depending upon product usage; a three-stage ban on all asbestos products leading to a total ban in ten years; and labeling of all products containing asbestos. *Id*. at 29,460–61.

Over the next two years, the EPA updated its data, received further comments, and allowed cross-examination on the updated documents. In 1989, the EPA issued a final rule prohibiting the manufacture, importation, processing, and distribution in commerce of most asbestos-containing products. Finding that asbestos constituted an unreasonable risk to health and the environment, the EPA promulgated a staged ban of most commercial uses of asbestos. The EPA estimates that this rule will save either 202 or 148 lives, depending upon whether the benefits are discounted, at a cost of approximately $450–800 million, depending upon the price of substitutes. *Id.* at 29,468. . . .

. . . TSCA provides that a reviewing court "shall hold unlawful and set aside" a final rule promulgated under § 6(a) "if the court finds that

the rule is not supported by substantial evidence in the rulemaking record . . . taken as a whole." 15 U.S.C. § 2618(c)(1)(B)(i).

. . . An agency may exercise its judgment without strictly relying upon quantifiable risks, costs, and benefits, but it must "cogently explain why it has exercised its discretion in a given manner" and "must offer a 'rational connection between the facts found and the choice made.' " *Id.* (quoting Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins., 463 U.S. 29 (1983)). . . .

TSCA provides, in pertinent part, as follows:

> (a) Scope of regulation.—If the Administrator finds that there is a *reasonable basis* to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents or will present an *unreasonable risk of injury* to health or the environment, the Administrator shall by rule apply one or more of the following requirements to such substance or mixture to the extent necessary to *protect adequately* against such risk using the *least burdensome* requirements.

Id. (emphasis added). As the highlighted language shows, Congress did not enact TSCA as a zero-risk statute. The EPA, rather, was required to consider both alternatives to a ban and the costs of any proposed actions and to "carry out this chapter in a reasonable and prudent manner [after considering] the environmental, economic, and social impact of any action." 15 U.S.C. § 2601(c).

We conclude that the EPA has presented insufficient evidence to justify its asbestos ban. We base this conclusion upon two grounds: the failure of the EPA to consider all necessary evidence and its failure to give adequate weight to statutory language requiring it to promulgate the least burdensome, reasonable regulation required to protect the environment adequately. Because the EPA failed to address these concerns, and because the EPA is required to articulate a "reasoned basis" for its rules, we are compelled to return the regulation to the agency for reconsideration.

1. Least Burdensome and Reasonable.

TSCA requires that the EPA use the least burdensome regulation to achieve its goal of minimum reasonable risk. This statutory requirement can create problems in evaluating just what is a "reasonable risk." Congress's rejection of a no-risk policy, however, also means that in certain cases, the least burdensome yet still adequate solution may entail somewhat more risk than would other, known regulations that are far more burdensome on the industry and the economy. The very language of TSCA requires that the EPA, once it has determined what an acceptable level of non-zero risk is, choose the least burdensome method of reaching that level.

In this case, the EPA banned, for all practical purposes, all present and future uses of asbestos—a position the petitioners characterize as the "death penalty alternative," as this is the *most* burdensome of all possible alternatives listed as open to the EPA under TSCA. TSCA not only provides the EPA with a list of alternative actions, but also provides those alternatives in order of how burdensome they are. The

regulations thus provide for EPA regulation ranging from labeling the least toxic chemicals to limiting the total amount of chemicals an industry may use. Total bans head the list as the most burdensome regulatory option.

By choosing the harshest remedy given to it under TSCA, the EPA assigned to itself the toughest burden in satisfying TSCA's requirement that its alternative be the least burdensome of all those offered to it. Since, both by definition and by the terms of TSCA, the complete ban of manufacturing is the most burdensome alternative—for even stringent regulation at least allows a manufacturer the chance to invest and meet the new, higher standard—the EPA's regulation cannot stand if there is any other regulation that would achieve an acceptable level of risk as mandated by TSCA. . . .

The EPA considered, and rejected, such options as labeling asbestos products, thereby warning users and workers involved in the manufacture of asbestos-containing products of the chemical's dangers, and stricter workplace rules. . . .

The EPA presented two comparisons in the record: a world with no further regulation under TSCA, and a world in which no manufacture of asbestos takes place. The EPA rejected calculating how many lives a less burdensome regulation would save, and at what cost. Furthermore the EPA, when calculating the benefits of its ban, explicitly refused to compare it to an improved workplace in which currently available control technology is utilized. *See* 54 Fed. Reg. at 29,474. This decision artificially inflated the purported benefits of the rule by using a baseline comparison substantially lower than what currently available technology could yield. . . .

This comparison of two static worlds is insufficient to satisfy the dictates of TSCA. While the EPA may have shown that a world with a complete ban of asbestos might be preferable to one in which there is only the current amount of regulation, the EPA has failed to show that there is not some intermediate state of regulation that would be superior to both the currently-regulated and the completely-banned world. Without showing that asbestos regulation would be ineffective, the EPA cannot discharge its TSCA burden of showing that its regulation is the least burdensome available to it.

Upon an initial showing of product danger, the proper course for the EPA to follow is to consider each regulatory option, beginning with the least burdensome, and the costs and benefits of regulation under each option. The EPA cannot simply skip several rungs, as it did in this case, for in doing so, it may skip a less-burdensome alternative mandated by TSCA. Here, although the EPA mentions the problems posed by intermediate levels of regulation, it takes no steps to calculate the costs and benefits of these intermediate levels. *See* 54 Fed. Reg. at 29,462, 29,474. Without doing this it is impossible, both for the EPA and for this court on review, to know that none of these alternatives was less burdensome than the ban in fact chosen by the agency. . . .

2. The EPA's Calculations.

Furthermore, we are concerned about some of the methodology employed by the EPA in making various of the calculations that it did

perform. In order to aid the EPA's reconsideration of this and other cases, we present our concerns here. . . .

Although various commentators dispute whether it ever is appropriate to discount benefits when they are measured in human lives, we note that it would skew the results to discount only costs without according similar treatment to the benefits side of the equation. Adopting the position of the commentators who advocate not discounting benefits would force the EPA similarly not to calculate costs in present discounted real terms, making comparisons difficult. Furthermore, in evaluating situations in which different options incur costs at varying time intervals, the EPA would not be able to take into account that soon-to-be-incurred costs are more harmful than postponable costs. Because the EPA must discount costs to perform its evaluations properly, the EPA also should discount benefits to preserve an apples-to-apples comparison, even if this entails discounting benefits of a non-monetary nature. *See What Price Posterity?*, The Economist, March 23, 1991, at 73 (explaining use of discount rates for non-monetary goods).

When the EPA does discount costs or benefits, however, it cannot choose an unreasonable time upon which to base its discount calculation. Instead of using the time of injury as the appropriate time from which to discount, as one might expect, the EPA instead used the time of exposure.

The difficulties inherent in the EPA's approach can be illustrated by an example. Suppose two workers will be exposed to asbestos in 1995, with worker X subjected to a tiny amount of asbestos that will have no adverse health effects, and worker Y exposed to massive amounts of asbestos that quickly will lead to an asbestos-related disease. Under the EPA's approach, which takes into account only the time of exposure rather than the time at which any injury manifests itself, both examples would be treated the same. The EPA's approach implicitly assumes that the day on which the risk of injury occurs is the same day the injury actually occurs. Such an approach might be proper when the exposure and injury are one and the same, such as when a person is exposed to an immediately fatal poison, but is inappropriate for discounting toxins in which exposure often is followed by a substantial lag time before manifestation of injuries.

Of more concern to us is the failure of the EPA to compute the costs and benefits of its proposed rule past the year 2000, and its double-counting of the costs of asbestos use. In performing its calculus, the EPA only included the number of lives saved over the next thirteen years, and counted any additional lives saved as simply "unquantified benefits." 54 Fed.Reg. at 29,486. The EPA and intervenors now seek to use these unquantified lives saved to justify calculations as to which the benefits seem far outweighed by the astronomical costs. For example, the EPA plans to save about three lives with its ban of asbestos pipe, at a cost of $128–227 million (*i.e.*, approximately $43–76 million per life saved). Although the EPA admits that the price tag is high, it claims that the lives saved past the year 2000 justify the price. *See generally id.* at 29,473 (explaining use of unquantified benefits).

Such calculations not only lessen the value of the EPA's cost analysis, but also make any meaningful judicial review impossible.

While TSCA contemplates a useful place for unquantified benefits beyond the EPA's calculation, unquantified benefits never were intended as a trump card allowing the EPA to justify any cost calculus, no matter how high. . . .

Unquantified benefits can, at times, permissibly tip the balance in close cases. They cannot, however, be used to effect a wholesale shift on the balance beam. Such a use makes a mockery of the requirements of TSCA that the EPA weigh the costs of its actions before it chooses the least burdensome alternative.

We do not today determine what an appropriate period for the EPA's calculations would be, as this is a matter better left for agency discretion. *See Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 53. We do note, however, that the choice of a thirteen-year period is so short as to make the unquantified period so unreasonably large that any EPA reliance upon it must be displaced. . . .

3. Reasonable Basis.

In addition to showing that its regulation is the least burdensome one necessary to protect the environment adequately, the EPA also must show that it has a reasonable basis for the regulation. 15 U.S.C. § 2605(a). . . .

Most problematical to us is the EPA's ban of products for which no substitutes presently are available. In these cases, the EPA bears a tough burden indeed to show that under TSCA a ban is the least burdensome alternative, as TSCA explicitly instructs the EPA to consider "the benefits of such substance or mixture for various uses and the availability of substitutes for such uses." *Id*. § 2605(c)(1)(C). These words are particularly appropriate where the EPA actually has decided to ban a product, rather than simply restrict its use, for it is in these cases that the lack of an adequate substitute is most troubling under TSCA.

As the EPA itself states, "[w]hen no information is available for a product indicating that cost-effective substitutes exist, the estimated cost of a product ban is very high." 54 Fed. Reg. at 29,468. Because of this, the EPA did not ban certain uses of asbestos, such as its use in rocket engines and battery separators. The EPA, however, in several other instances, ignores its own arguments and attempts to justify its ban by stating that the ban itself will cause the development of low-cost, adequate substitute products.

As a general matter, we agree with the EPA that a product ban can lead to great innovation, and it is true that an agency under TSCA, as under other regulatory statutes, "is empowered to issue safety standards which require improvements in existing technology or which require the development of new technology." Chrysler Corp. v. Department of Transp., 472 F.2d 659, 673 (6th Cir. 1972). As even the EPA acknowledges, however, when no adequate substitutes currently exist, the EPA cannot fail to consider this lack when formulating its own guidelines. Under TSCA, therefore, the EPA must present a stronger case to justify the ban, as opposed to regulation, of products with no substitutes. . . .

We also are concerned with the EPA's evaluation of substitutes even in those instances in which the record shows that they are

available. The EPA explicitly rejects considering the harm that may flow from the increased use of products designed to substitute for asbestos, even where the probable substitutes themselves are known carcinogens. *Id.* at 29,481–83. The EPA justifies this by stating that it has "more concern about the continued use and exposure to asbestos than it has for the future replacement of asbestos in the products subject to this rule with other fibrous substitutes." *Id.* at 29,481. The agency thus concludes that any "[r]egulatory decisions about asbestos which poses well-recognized, serious risks should not be delayed until the risk of all replacement materials are fully quantified." *Id.* at 29,483.

This presents two problems. First, TSCA instructs the EPA to consider the relative merits of its ban, as compared to the economic effects of its actions. The EPA cannot make this calculation if it fails to consider the effects that alternate substitutes will pose after a ban.

Second, the EPA cannot say with any assurance that its regulation will increase workplace safety when it refuses to evaluate the harm that will result from the increased use of substitute products. While the EPA may be correct in its conclusion that the alternate materials pose less risk than asbestos, we cannot say with any more assurance than that flowing from an educated guess that this conclusion is true.

Considering that many of the substitutes that the EPA itself concedes will be used in the place of asbestos have known carcinogenic effects, the EPA not only cannot assure this court that it has taken the least burdensome alternative, but cannot even prove that its regulations will increase workplace safety. Eager to douse the dangers of asbestos, the agency inadvertently actually may increase the risk of injury Americans face. The EPA's explicit failure to consider the toxicity of likely substitutes thus deprives its order of a reasonable basis. *Cf.* American Petroleum Inst. v. OSHA, 581 F.2d 493, 504 (5th Cir. 1978) (An agency is required to "regulate on the basis of knowledge rather than the unknown.").

Our opinion should not be construed to state that the EPA has an affirmative duty to seek out and test every workplace substitute for any product it seeks to regulate. TSCA does not place such a burden upon the agency. We do not think it unreasonable, however, once interested parties introduce credible studies and evidence showing the toxicity of workplace substitutes, or the decreased effectiveness of safety alternatives such as non-asbestos brakes, that the EPA then consider whether its regulations are even increasing workplace safety, and whether the increased risk occasioned by dangerous substitutes makes the proposed regulation no longer reasonable. In the words of the EPA's own release that initiated the asbestos rulemaking, we direct that the agency consider the adverse health effects of asbestos substitute "for comparison with the known hazards of asbestos," so that it can conduct, as it promised in 1979, a "balanced consideration of the environmental, economic, and social impact of any action taken by the agency." 44 Fed. Reg. at 60,065 (1979).

In short, a death is a death, whether occasioned by asbestos or by a toxic substitute product, and the EPA's decision not to evaluate the toxicity of known carcinogenic substitutes is not a reasonable action under TSCA. Once an interested party brings forth credible evidence suggesting the toxicity of the probable or only alternatives to a

substance, the EPA must consider the comparative toxic costs of each. Its failure to do so in this case thus deprived its regulation of a reasonable basis, at least in regard to those products as to which petitioners introduced credible evidence of the dangers of the likely substitutes.

4. Unreasonable Risk of Injury.

The final requirement the EPA must satisfy before engaging in any TSCA rulemaking is that it only take steps designed to prevent "unreasonable" risks. In evaluating what is "unreasonable," the EPA is required to consider the costs of any proposed actions and to "carry out this chapter in a reasonable and prudent manner [after considering] the environmental, economic, and social impact of any action." 15 U.S.C. § 2601(c).

As the District of Columbia Circuit stated when evaluating similar language governing the Federal Hazardous Substances Act, "[t]he requirement that the risk be 'unreasonable' necessarily involves a balancing test like that familiar in tort law: The regulation may issue if the severity of the injury that may result from the product, factored by the likelihood of the injury, offsets the harm the regulation itself imposes upon manufacturers and consumers." Forester v. CPSC, 559 F.2d 774, 789 (D.C. Cir. 1977). We have quoted this language approvingly when evaluating other statutes using similar language. *See, e.g., Aqua Slide*, 569 F.2d at 839.

That the EPA must balance the costs of its regulations against their benefits further is reinforced by the requirement that it seek the least burdensome regulation. While Congress did not dictate that the EPA engage in an exhaustive, full-scale cost-benefit analysis, it did require the EPA to consider both sides of the regulatory equation, and it rejected the notion that the EPA should pursue the reduction of workplace risk at any cost. *See American Textile Mfrs. Inst.*, 452 U.S. at 510 n. 30 ("unreasonable risk" statutes require "a generalized balancing of costs and benefits" (citing *Aqua Slide*, 569 F.2d at 839)). Thus, "Congress also plainly intended the EPA to consider the economic impact of *any* actions taken by it under . . . TSCA." *Chemical Mfrs. Ass'n*, 899 F.2d at 348.

Even taking all of the EPA's figures as true, and evaluating them in the light most favorable to the agency's decision (non-discounted benefits, discounted costs, analogous exposure estimates included), the agency's analysis results in figures as high as $74 million per life saved. For example, the EPA states that its ban of asbestos pipe will save three lives over the next thirteen years, at a cost of $128–227 million ($43–76 million per life saved), depending upon the price of substitutes; that its ban of asbestos shingles will cost $23–34 million to save 0.32 statistical lives ($72–106 million per life saved); that its ban of asbestos coatings will cost $46–181 million to save 3.33 lives ($14–54 million per life saved); and that its ban of asbestos paper products will save 0.60 lives at a cost of $4–5 million ($7–8 million per life saved). *See* 54 Fed. Reg. at 29,484–85. . . .

While we do not sit as a regulatory agency that must make the difficult decision as to what an appropriate expenditure is to prevent someone from incurring the risk of an asbestos-related death, we do

note that the EPA, in its zeal to ban any and all asbestos products, basically ignored the cost side of the TSCA equation. The EPA would have this court believe that Congress, when it enacted its requirement that the EPA consider the economic impacts of its regulations, thought that spending $200–300 million to save approximately seven lives (approximately $30–40 million per life) over thirteen years is reasonable.

As we stated in the OSHA context, until an agency "can provide substantial evidence that the benefits to be achieved by [a regulation] bear a reasonable relationship to the costs imposed by the reduction, it cannot show that the standard is reasonably necessary to provide safe or healthful workplaces." *American Petroleum Inst.*, 581 F.2d at 504. Although the OSHA statute differs in major respects from TSCA, the statute does require substantial evidence to support the EPA's contentions that its regulations both have a reasonable basis and are the least burdensome means to a reasonably safe workplace.

The EPA's willingness to argue that spending $23.7 million to save less than one-third of a life reveals that its economic review of its regulations, as required by TSCA, was meaningless. As the petitioners' brief and our review of EPA caselaw reveals, such high costs are rarely, if ever, used to support a safety regulation. If we were to allow such cavalier treatment of the EPA's duty to consider the economic effects of its decisions, we would have to excise entire sections and phrases from the language of TSCA. Because we are judges, not surgeons, we decline to do so. . . .

NOTES AND QUESTIONS

1. Applicable Risk Management Framework Under the TSCA. At what level does TSCA require that EPA regulate asbestos? How did EPA justify its regulation? More specifically, what comparison did EPA make in deciding that a total ban on asbestos complied with the requirements of the TSCA? On what basis did the court find this comparison to be insufficient?

The court interpreted TSCA as requiring that EPA use the least burdensome regulation to achieve its goal of minimum reasonable risk. Is this requirement explicit in the statute? How else could EPA's duties under the TSCA be framed? What is the applicable standard of review in this case? In light of this standard, could it be argued that the court overreached in this case?

2. Unquantified Benefits. The court identified a number of deficiencies in EPA's cost-benefit analysis, one of which was EPA's treatment of unquantified benefits. What category of benefits did EPA determine to be unquantifiable? On what basis did EPA make this determination? What role did EPA propose that unquantified benefits play in its cost-benefit analysis? How does the court describe the role of unquantifiable benefits in this case? Are there occasions when unquantifiable benefits may make the difference between two regulatory decisions? Is it desirable to push an agency to quantify all benefits of a proposed regulatory response?

3. Discounting Benefits to Present Value. The court also criticized EPA's failure to discount benefits to present value. What feature of the human health effects of asbestos led the court to require the discounting of the benefits of the proposed regulation to present value? Is it appropriate to

apply to human lives discounting techniques normally used for financial flows? What difficulties could you anticipate?

Interestingly, the appropriateness of discounting the value of human lives first received sustained attention in the regulatory proceeding that led to EPA's adoption of the ban on asbestos. The following account describes an attempt by OMB to discount to present value the cost of each cancer case avoided as a consequence of the adoption of a total ban, and the subsequent reaction within and outside of the agency:

> . . . In a March 1985 letter to A. James Barnes, EPA's acting Deputy Administrator, OMB raised questions about whether the benefits of the rule exceeded its costs. In performing a cost-benefit analysis, OMB used a value per cancer case avoided of $1 million and discounted this amount at a rate of 4% for the length of the latency period.
>
> In October 1985, a subcommittee of the U.S. House of Representatives chastised OMB for its insistence on discounting the value of human lives. It noted that discounting at OMB's 10% discount rate [OMB's preferred discount rate] over a forty year latency period would reduce the $1 million value per life saved to just over $22,000. Thus, on cost-benefit terms, one could not justify a current expenditure of over $22,000 to save a life forty years in the future. Even at a 4% discount rate, the $1 million value of life would be reduced to about $208,000.
>
> The subcommittee referred to the testimony of Don Clay, Director of EPA's Office of Toxic Substances, that EPA "never ha[d] used discounting over the latency period of a chronic hazard," and that, by reducing the value of benefits to such an extent, OMB's approach would prevent EPA from regulating any carcinogen with a long latency period. The subcommittee further reported that Clay "personally opposed the discounting of lives in the asbestos case on ethical grounds." It concluded that OMB's position with respect to the discounting of the value of life was "simply an outrage" and urged EPA to "reject the use of discounting over the latency period of diseases caused by chronic hazards."

Richard L. Revesz, *Environmental Regulation, Cost-Benefit Analysis, and the Discounting of Human Lives*, 99 COLUM. L. REV. 941, 950–51 (1999).

In determining whether it is appropriate to discount the value of human life to present value in performing cost-benefit analysis, consider whether a distinction should be drawn between environmental problems which result in harms with a latency period and those which result in harms that affect future generations. On what basis could it be argued that discounting is appropriate in the former scenario but not the latter? *See id.* at 999. *See also*, RICHARD L. REVESZ & MICHAEL A. LIVERMORE, RETAKING RATIONALITY 107–119 (2008).

4. Ethical Considerations.

> Consider an exceedingly simple economy with 100 units of resources. Two individuals, with identical utility functions, live in this economy: one from year 1 to year 50 and the other from year 51 to year 100. There is no possibility for productive activity; thus, the individuals will be able to derive utility only from the existing 100 units of resources.

> In the absence of discounting for time preference, each individual would be allocated 50 units of resources. In the face of a positive rate of time preference, however, even a relatively modest one, the first individual would get the bulk of the resources.

Revesz, *supra*, at 998. Is it ethically appropriate that the first individual be privileged in this manner, merely because she lived fifty years earlier than the second individual? What possible justifications exist for discounting for time preference at a positive rate? Do you find these justifications compelling? *See id.* at 999.

5. Marginal Consequences. EPA was also criticized for considering only the total consequences of its proposed ban—that is, the total benefits and total costs of its preferred policy response—in conducting its cost-benefit analysis. In circumstances where there are various policy responses open to the Agency, does this approach ensure the maximization of social welfare? Take, for example, a world in which there exist only three possible policy responses: no regulation, a partial ban (which would impose total costs of $400 million and result in total benefits of $500 million), and a total ban (which would impose costs of $800 million and result in benefits of $850 million). Which response would maximize social welfare? Which would EPA have adopted under its approach in *Corrosion Proof Fittings*?

6. Countervailing Risks. Finally, the court criticized EPA for its failure to consider the countervailing risks posed by the ban. What countervailing risks may arise in these circumstances? Consider, for instance, the application of asbestos as a fire-retardant. What factors influence the magnitude of these countervailing risks? According to the court, how should these risks be taken into account in the cost-benefit analysis?

7. Valuing Human Lives. The court faulted the agency for not weighing the costs of the regulation against its purported benefits—noting that the regulation would cost "$200–300 million to save approximately seven lives (approximately $30–40 million per life) over thirteen years." Does the court say what does constitute an appropriate value of life in these circumstances? On what basis then did the court find that this value was unreasonable? Why was the court unwilling to defer to the agency's actions in this instance?

8. *Corrosion Proof Fittings* and *EDF v. EPA*. What may account for the differences between the approaches of the D.C. Circuit in *Environmental Defense Fund v. EPA* and the Fifth Circuit in *Corrosion Proof Fittings*, decided some 15 years apart? To what extent might they demonstrate the rise of cost-benefit analysis as the predominant risk management framework in environmental decision making throughout this period?

9. Risk Management in the European Union: The Precautionary Principle. The precautionary principle is one of the core environmental principles recognized by the European Community Treaty. *See* Treaty Establishing the European Community art. 174, Nov. 10, 1997, 1997 O.J. (C340) 3. This principle has been accepted as a risk management strategy to deal with cases "where there are reasonable grounds for concern that potential hazards may affect the environment or human, animal or plant health, and when at the same time the available data preclude a detailed risk evaluation." *Communication from the Commission on the Precautionary Principle*, at 8 COM (2000) 1 final (Feb. 2, 2000). In those

circumstances, the precautionary principle "allows the competent public authority to take, on a provisional basis, preventive protective measures on what is as yet an incomplete scientific basis, pending the availability of additional scientific evidence." *Pfizer Animal Health SA v. Council of European Union*, Case t–13/99, 2002 E.C.R. II–03305, ¶ 387. What level of risk should be required to justify the enactment of regulation? Should every potential hazard be addressed? Consider the application of the precautionary to the use of nuclear energy. Nuclear power plants raise health and safety issues as well as the possibility that they could cause catastrophic harms. At the same time, the replacement of these plants with coal-fired power plants would create other risks such as air pollution and global warming. Which option should be chosen? Based on this and other examples, Professor Cass R. Sunstein argues:

> Taken in this strong form, the precautionary principle should be rejected, not because it leads in bad directions, but because it leads in no direction at all. The principle is literally paralyzing—forbidding inaction, stringent regulation, and everything in between. The reason is that in the relevant cases, every step, including inaction, creates a risk to health, the environment, or both.

Cass R. Sunstein, *Beyond the Precautionary Principle*, 151 U. PA. L. REV. 1003, 1003 (2003). Do you find this opinion compelling?

10. Risk Management in the European Union: Other Principles. Besides the precautionary principle, risk management in the European Union is informed by the principles of proportionality, non-discrimination, consistency, examination of the benefits and costs of action or lack of action, and examination of scientific developments. *See Communication from the Commission on the Precautionary Principle*, at 17. The adoption of an approach based on the precautionary principle does not exclude the application of these other criteria. *See id.* Indeed, the principle of proportionality tempers the precautionary principle by requiring that measures adopted by Community institutions not exceed what is appropriate and necessary in order to attain the legitimate objective pursued by the legislation. *See Pfizer Animal Health SA v. Council of European Union*, Case t–13/99, 2002 E.C.R. II–03305, ¶ 411. Moreover, this principle also requires that where there is a choice among several appropriate measures, the least onerous must be chosen, and that the costs of the measure not be disproportionate to the aims pursued. *Id.* In *Pfizer Animal Health SA v. Council of European Union*, Pfizer argued that the contested regulation was adopted in breach of the principle of proportionality. *Id.* ¶ 441. The European Court of First Instance held:

> The Court observes that the importance of the objective pursued by the contested regulation, i.e. the protection of human health, may justify adverse consequences, and even substantial adverse consequences, for certain traders. . . . The protection of public health, which the contested regulation is intended to guarantee, must take precedence over economic considerations.

Pfizer Animal Health SA v. Council of European Union, ¶ 456. What does it mean that "public health . . . must take precedence over economic considerations"? Should public health always be put first? What if the risk were remote in time or space and the cost of reducing that risk were too high?

11. Cost-Benefit Analysis in the European Union. Article 174(3) of the European Community Treaty requires that Community institutions consider "the potential benefits and costs of action or lack of action" in preparing their environmental policy. Treaty Establishing the European Community art. 174(3). In applying this principle, community institutions must compare "the most likely positive or negative consequences of the envisaged action and those of inaction in terms of the overall cost to the Community, both in the long- and short-term." *Communication from the Commission on the Precautionary Principle*, at 18. Although this examination should include an economic cost-benefit analysis when this is appropriate and possible, it must also take non-economic considerations into account. *Id*. at 18–19. In this regard, the Commission has stated:

> Besides, other analysis methods, such as those concerning the efficacy of possible options and their acceptability to the public may also have to be taken into account. A society may be willing to pay a higher cost to protect an interest, such as the environment or health, to which it attaches priority.
>
> The Commission affirms . . . that requirements linked to the protection of public health should undoubtedly be given greater weight that economic considerations.

Id. at 19. Compare this approach with the one adopted by the United States. Which is more desirable?

12. Risk Management in the European Union and in the United States. Analyze the balance between the precautionary and proportionality principles. Do you think that the European approach would lead to the enactment of more stringent standards than those in the United States? Professor David Vogel argues:

> [The precautionary principle gives] more weight to risk avoidance over cost/risk-benefit analysis, and to public preferences over scientific risk assessments. By lowering the threshold of scientific proof that is required before regulators can determine that a particular substance, product or process poses an unacceptable threat to public health or the environment and by legitimating public participation in regulatory decision-making, the precautionary principle has created a normative basis for enacting a number of new and more stringent regulatory standards.

David Vogel, *The Politics of Risk Regulation in Europe and the United States*, 1 Y.B. EUR. ENVTL. L. 2 (2003). Compare the use of precaution in risk regulation in *Pfizer Animal Health SA v. Council of European Union*, Case t–13/99, 2002 E.C.R. II–03305 (discussed above) and in *Industrial Union Department, AFL-CIO v. American Petroleum Institute*, 448 U.S. 607, 655 (1980). Would you expect that, as a consequence of the application of the precautionary principle, the European Union would have enacted more risk adverse regulations than the United States? For an argument that the European Union recently adopted many more stringent or extensive regulations than the United States, see Vogel, *supra*. For an argument that the U.S. and E.U. approaches do not diverge as much as has been claimed, see Jonathan B. Wiener, *Whose Precaution After All? A Comment on the Comparison and Evolution of Risk Regulatory Systems*, DUKE J. COMP. & INT'L L., Summer 2003, at 207 (arguing that "[a]cross the

broad array of risks, neither Europe nor the United States can claim to be categorically more precautionary than the other across the board.").

3. DISTRIBUTION OF ENVIRONMENTAL RISKS

The preceding section described the rise of cost-benefit analysis as the prevailing risk management framework in contemporary environmental decisionmaking. Cost-benefit analysis is concerned with the aggregate net benefits of an environmental regulation. It is not concerned with the manner in which those benefits are distributed among the individuals affected by the regulation. A policy that maximizes net benefits across the whole population might nonetheless impose significant net costs on a subset of that population. The traditional economic perspective would not advocate modifying such a policy to reduce these inequities, preferring, instead, to deal with distributional questions through other policy instruments such as the tax system. For other perspectives, distributional issues are far more salient and would play an important role in the choice of the preferred policy.

The readings in this section address the central claims of the environmental justice movement—namely, that the poor and, primarily, persons of color are disproportionately affected by inadequate environmental quality. The focus is on the siting of locally undesirable land uses (LULUs), which has been one of the particular concerns of the environmental justice movement. The first part examines various theoretical perspectives. The second part examines the legal theories that have been invoked in an attempt to address the disproportionate allocation of risks.

A. THEORIES OF ENVIRONMENTAL JUSTICE

The first article excerpted by Robert Bullard asserts that "racism plays a key factor in environmental planning and decision-making," and that, as a result, communities of color in urban locations "face some of the worst environmental devastation in the nation." He claims that the problem manifests itself in a variety of contexts, including the siting of waste disposal sites, the exposure of children in inner cities to high levels of lead, and the risks faced by workers in the oil, chemical, and nuclear industries. Bullard argues that the disparities in access to environmental quality cannot be explained solely by reference to income differences and that race plays an independent role.

In the 1980s, two influential studies by the United States General Accounting Office (GAO) and the United Church of Christ's Committee for Racial Justice (CRJ) documented that hazardous waste facilities are disproportionately located in areas in which the surrounding communities have a high proportion of people of color and the poor. The next article, by Vicki Been, surveys those studies and questions whether the disparity is the product of disproportionate siting or of market dynamics. She notes that the GAO and CRJ studies both looked at the current demographic characteristics of the surrounding communities, rather than the characteristics at the time that the facilities were sited. It may be that the location of the LULU makes housing in the surrounding community less desirable and depresses

housing markets. A disproportionate number of those who can afford to leave the neighborhood will then do so and will be replaced by individuals searching for relatively inexpensive housing. Thus, it is possible that, even if there was no disparity in the racial and economic composition of the community at the time of the siting, market dynamics will subsequently make the community disproportionately composed of people of color and the poor.

An excerpt of another article by Vicki Been explores the meaning of fairness in connection with the siting of LULUs. She examines three different notions of fairness: fairness in the pattern of distribution, fairness as cost-internalization, and fairness as process. Fairness in the pattern of distribution could involve distributing the burdens of LULUs on a proportional basis over society as a whole by physically spreading the LULUs themselves among the different communities, by equalizing the probability that any community would be chosen as a location for the LULU, or by ensuring that any affected community is compensated. Alternatively, it could involve progressive siting, under which advantaged communities get more than their share of the burden. Fairness as cost-internalization requires that the generators of waste pay the full social cost that results from the disposal of this waste. Finally, fairness as process requires acceptable procedures for the distribution of burdens, but does not inquire about the substance of the allocations.

Robert Bullard, Anatomy of Environmental Racism and the Environmental Justice Movement

in CONFRONTING ENVIRONMENTAL RACISM, VOICES FROM THE GRASSROOTS 15 (Robert Bullard ed., 1993).*

Communities are not all created equal. In the United States, for example, some communities are routinely poisoned while the government looks the other way. Environmental regulations have not uniformly benefited all segments of society. People of color (African Americans, Latinos, Asians, Pacific Islanders, and Native Americans) are disproportionately harmed by industrial toxins on their jobs and in their neighborhoods. These groups must contend with dirty air and drinking water—the byproducts of municipal landfills, incinerators, polluting industries, and hazardous waste treatment, storage, and disposal facilities.

Why do some communities get "dumped on" while others escape? Why are environmental regulations vigorously enforced in some communities and not in others? Why are some workers protected from environmental threats to their health while others (such as migrant farmworkers) are still being poisoned? How can environmental justice be incorporated into the campaign for environmental protection? What institutional changes would enable the United States to become a just and sustainable society? What community organizing strategies are effective against environmental racism? . . .

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Environmental Racism

Racism plays a key factor in environmental planning and decisionmaking. Indeed, environmental racism is reinforced by government, legal, economic, political, and military institutions. It is a fact of life in the United States that the mainstream environmental movement is only beginning to wake up to. Yet, without a doubt, racism influences the likelihood of exposure to environmental and health risks and the accessibility to health care. Racism provides whites of all class levels with an "edge" in gaining access to a healthy physical environment. This has been documented again and again.

Whether by conscious design or institutional neglect, communities of color in urban ghettos, in rural "poverty pockets," or on economically impoverished Native-American reservations face some of the worst environmental devastation in the nation. Clearly, racial discrimination was not legislated out of existence in the 1960s. While some significant progress was made during this decade, people of color continue to struggle for equal treatment in many areas, including environmental justice. Agencies at all levels of government, including the federal EPA, have done a poor job protecting people of color from the ravages of pollution and industrial encroachment. It has thus been an up-hill battle convincing white judges, juries, government officials, and policymakers that racism exists in environmental protection, enforcement, and policy formulation.

The most polluted urban communities are those with crumbling infrastructure, ongoing economic disinvestment, deteriorating housing, inadequate schools, chronic unemployment, a high poverty rate, and an overloaded health-care system. Riot-torn South Central Los Angeles typifies this urban neglect. It is not surprising that the "dirtiest" zip code in California belongs to the mostly African-American and Latino neighborhood in that part of the city. In the Los Angeles basin, over 71 percent of the African Americans and 50 percent of the Latinos live in areas with the most polluted air, while only 34 percent of the white population does. This pattern exists nationally as well. As researchers Wernette and Nieves note:

> In 1990, 437 of the 3,109 counties and independent cities failed to meet at least one of the EPA ambient air quality standards . . . 57 percent of whites, 65 percent of African Americans, and 80 percent of Hispanics live in 437 counties with substandard air quality. Out of the whole population, a total of 33 percent of whites, 50 percent of African Americans, and 60 percent of Hispanics live in the 136 counties in which two or more air pollutants exceed standards. The percentage living in the 29 counties designated as nonattainment areas for three or more pollutants are 12 percent of whites, 20 percent of African Americans, and 31 percent of Hispanics.

[D.R. Wernette & L.A. Nieves, *Breaking Polluted Air*, EPA JOURNAL, March/ April 1992, at 16–17.]

Income alone does not account for these above-average percentages. Housing segregation and development patterns play a key role in determining where people live. Moreover, urban development and the "spatial configuration" of communities flow from the forces and

relationships of industrial production which, in turn, are influenced and subsidized by government policy. There is widespread agreement that vestiges of race-based decisionmaking still influence housing, education, employment, and criminal justice. The same is true for municipal services such as garbage pickup and disposal, neighborhood sanitation, fire and police protection, and library services. Institutional racism influences decisions on local land use, enforcement of environmental regulations, industrial facility siting, management of economic vulnerability, and the paths of freeways and highways.

People skeptical of the assertion that poor people and people of color are targeted for waste-disposal sites should consider the report the Cerrell Associates provided the California Waste Management Board. In their 1984 report, *Political Difficulties Facing Waste-to-Energy Conversion Plant Siting*, they offered a detailed profile of those neighborhoods most likely to organize effective resistance against incinerators. The policy conclusion based on this analysis is clear. As the report states:

> All socioeconomic groupings tend to resent the nearby siting of major facilities, but middle and upper socioeconomic strata possess better resources to effectuate their opposition. Middle and higher socioeconomic strata neighborhoods should not fall within the one-mile and five-mile radius of the proposed site.

[Id. at 43.]

Where then will incinerators or other polluting facilities be sited? For Cerrell Associates, the answer is low-income, disempowered neighborhoods with a high concentration of nonvoters. The ideal site, according to their report, has nothing to do with environmental soundness but everything to do with lack of social power. Communities of color in California are far more likely to fit this profile than are their white counterparts.

Those still skeptical of the existence of environmental racism should also consider the fact that zoning boards and planning commissions are typically stacked with white developers. Generally, the decisions of these bodies reflect the special interests of the individuals who sit on these boards. People of color have been systematically excluded from these decisionmaking boards, commissions, and governmental agencies (or allowed only token representation). Grassroots leaders are now demanding a shared role in all the decisions that shape their communities. They are challenging the intended or unintended racist assumptions underlying environmental and industrial policies. . . .

Beyond the Race Versus Class Trap

Whether at home or abroad, the question of who pays and who *benefits* from current industrial and development policies is central to any analysis of environmental racism. In the United States, race interacts with class to create special environmental and health vulnerabilities. People of color, however, face elevated toxic exposure levels even when social class variables (income, education, and occupational status) are held constant. Race has been found to be an independent factor, not reducible to class, in predicting the distribution of (1) air pollution in our society; (2) contaminated fish consumption; (3)

the location of municipal landfills and incinerators; (4) the location of abandoned toxic waste dumps; and (5) lead poisoning in children.

Lead poisoning is a classic case in which race, not just class, determines exposure. It affects between three and four million children in the United States—most of whom are African Americans and Latinos living in urban areas. Among children five years old and younger, the percentage of African Americans who have excessive levels of lead in their blood far exceeds the percentage of whites at all income levels.

The federal Agency for Toxic Substances and Disease Registry found that for families earning less than $6,000 annually an estimated 68 percent of African-American children had lead poisoning, compared with 36 percent for white children. For families with incomes exceeding $15,000, more than 38 percent of African-American children have been poisoned, compared with 12 percent of white children. African-American children are two to three times more likely than their white counterparts to suffer from lead poisoning independent of class factors.

One reason for this is that African Americans and whites do not have the same opportunities to "vote with their feet" by leaving unhealthy physical environments. The ability of an individual to escape a health-threatening environment is usually correlated with income. However, racial barriers make it even harder for millions of African Americans, Latinos, Asians, Pacific Islanders, and Native Americans to relocate. Housing discrimination, redlining, and other market forces make it difficult for millions of households to buy their way out of polluted environments. For example, an affluent African-American family (with an income of $50,000 or more) is as segregated as an African-American family with an annual income of $5,000. Thus, lead poisoning of African-American children is not just a "poverty thing."

White racism helped create our current separate and unequal communities. It defines the boundaries of the urban ghetto, *barrio*, and reservation, and influences the provision of environmental protection and other public services. Apartheid-type housing and development policies reduce neighborhood options, limit mobility, diminish job opportunities, and decrease environmental choices for millions of Americans. It is unlikely that this nation will ever achieve lasting solutions to its environmental problems unless it also addresses the system of racial injustice that helps sustain the existence of powerless communities forced to bear disproportionate environmental costs.

NOTES AND QUESTIONS

1. Causes of Environmental Injustice. Consider three different explanations for Bullard's claim that persons of color are disproportionately affected by inadequate environmental quality. First, it might be that before 1970, when environmental quality first began to be regulated in a comprehensive manner, the disparities were even greater than they are now and that the process of equalizing access to environmental quality is still ongoing. Second, it might be that environmental regulation has unintentionally exacerbated the disparities (a disparate impact claim). Third, it might be that environmental regulation has intentionally discriminated against poor and minority communities (an intentional discrimination claim). To which of these views does Bullard subscribe?

Other representative works by environmental justice advocates include Luke W. Cole, *Empowerment as the Key to Environmental Protection: The Need for Environmental Poverty Law*, 19 ECOLOGY L.Q. 619 (1992); Paul Mohai & Bunyan Bryant, *Environmental Injustice: Weighing Race and Class as Factors in the Distribution of Environmental Hazards*, 63 U. COLO. L. REV. 921 (1992); KENNETH A. MANASTER, ENVIRONMENTAL PROTECTION AND JUSTICE (1995); THE LAW OF ENVIRONMENTAL JUSTICE: THEORIES AND PROCEDURES TO ADDRESS DISPROPORTIONATE RISKS (Michael Gerrard ed., 1999); and CLIFFORD RECHTSCHAFFEN & EILEEN GAUNA, ENVIRONMENTAL JUSTICE: LAW, POLICY & REGULATION (2002).

2. Political v. Economic Disempowerment. Is Bullard's claim that environmental injustice primarily reflects racial minorities' lack of political power or that it results from their lack of economic power? For discussion of the causes of environmental inequities, see Richard J. Lazarus, *Pursuing "Environmental Justice": The Distributional Effects of Environmental Protection*, 87 NW. U. L. REV. 787 (1993).

3. Lay v. Expert Perceptions of Risk. Are racial and economic disparities in communities surrounding environmentally undesirable facilities problematic only if the risk resulting from the environmental exposure is serious? If so, what should be more relevant: the objective estimates of risk or the perceptions of risk on the part of the surrounding community?

4. Environmental v. Non-Environmental LULUs. Does the siting of hazardous waste sites in poor or minority areas raise issues that are analytically different from the siting of highways or of homeless shelters? What are possible differences? Are these differences persuasive? Are the claims of the environmental justice movement simply a subset of claims about unfairness in the siting of any facility that a community might regard as undesirable, even if the effects of the facility are non-environmental?

5. LULUs v. Disparate Allocation of Public Amenities. Does the disparate siting of undesirable uses (environmental or non-environmental) raise issues that are analytically different from the disparate allocation of public amenities, such as higher quality schools or parks?

6. Cost and Siting Decisions. Is it appropriate for the price of land to be considered in decisions concerning the siting of LULUs? If so, is it inevitable that facilities will be disproportionately sited where land is cheapest? Are these areas likely to be disproportionately minority or poor?

7. Income Disparity and Access to Housing. It is inevitable that income disparities will result in access to different qualities of housing. The following factors contribute to such disparities:

(a) differences in the natural attractiveness of the location;

(b) differences in publicly provided amenities;

(c) differences in the allocation of non-environmentally undesirable uses; and

(d) differences in the allocation of environmentally undesirable uses.

Which of these differences in housing quality ought to be permissible?

8. Benefits and Environmental Justice. Some facilities may bring economic benefits in the form of jobs for the surrounding community. What is the argument for basing environmental justice claims solely on costs without considering possible benefits? To achieve environmental justice, should the siting of undesirable land uses take into account only the cost of the facility and not any of its benefits?

9. Compensation and Environmental Justice. Communities might also be compensated for accepting the siting of a LULU. Should they be prevented from striking a deal that they consider desirable? If so, why? Who should represent the interests of the affected community in the negotiations? By what means should one determine whether the community received fair compensation? *See* Vicki Been, *Compensated Siting Proposals: Is it Time to Pay Attention?*, 21 FORDHAM URB. L.J. 787 (1994).

10. Wages and Environmental Justice. Similarly, as was discussed previously in this chapter, workers generally get wage premiums for accepting more risky occupations. Does this form of compensation cure the environmental justice problem that would otherwise exist? Should environmental policy seek to reduce the disparities in exposure to risk even if the affected workers prefer the additional income? In a portion of his book that is not excerpted above, Bullard makes the following argument:

> Workers of color are especially vulnerable to job blackmail because of the greater threat of unemployment they face compared to whites and because of their concentration in low-paying, unskilled nonunionized occupations. . . . Fear of unemployment acts as a potent incentive for many African-American workers to accept and keep jobs they know are health threatening.

Robert D. Bullard, *Anatomy of Environmental Racism and the Environmental Justice Movement*, *in* CONFRONTING ENVIRONMENTAL RACISM, VOICES FROM THE GRASSROOTS 17, 23 (R. Bullard ed., 1993). How does this perspective affect the assessment of the adequacy of wage premiums or other forms of compensation?

11. Economic Perspective's Response to Disparities in Risk. As noted in the introduction to this section, the economic perspective should not be considered insensitive to the concerns of the environmental justice movement. However, rather than allowing distributional consequences to inhibit the efficient allocation of resources, advocates of the economic perspective would argue that discrepancies in risk should be addressed by way of wealth redistribution in the form of a progressive taxation regime. To what extent do you consider this response adequate? Why might environmental justice advocates argue that progressive taxation regimes may in fact not adequately compensate those communities facing disparate environmental risk?

Consider the following critique of the ability of centralized redistributive mechanisms to adequately account for the distributional consequences of aggregate policy:

> For [a] centralized redistributive mechanism [based on a tax and transfer system] to work properly, there must be an understanding of the net distributive consequences of the regulatory system, that is, how the cumulative costs and benefits

> of regulations are borne by the American public and its many subpopulations. Absent information about how the large set of federal regulations affects the distribution of wealth in society, it is impossible for a central redistributional mechanism like the tax-and-transfer system to adequately achieve distributional goals. Simply attending to straightforward measures of inequality—such as income and wealth disparities—will fail to take into account the large number of ways the regulatory system can create inequalities in well-being and quality of life enjoyed by different subpopulations within the United States. For example, measures of wealth and income don't capture important variables like life expectancy. Without specific information on how the regulatory state affects the distribution of wealth and welfare across the population, it is impossible for a redistributional program to make up for systematic regulatory bias, leading to serious questions about the fair distribution of social goods.

RICHARD L. REVESZ & MICHAEL A. LIVERMORE, RETAKING RATIONALITY 181 (2008). How difficult would it be for a government to obtain information pertaining to the "net distributive consequences of the regulatory system"?

12. Environmental Justice and Risk Assessment. The environmental justice movement contends that risk assessments systematically understate the risks that affect people of color and the poor. It makes two different types of claims: (1) that these individuals are more likely to be exposed to risk, principally as a result of multiple exposures and synergistic effects; and (2) that they are more susceptible to risk, in part as a result of genetic differences and social inequalities. For discussion, see Brian D. Israel, *An Environmental Justice Critique of Risk Assessment*, 3 N.Y.U. ENVTL L.J. 469 (1995). In what ways, if any, should the risk assessment process discussed in the first section of this chapter be modified to address these concerns?

Vicki Been, Locally Undesirable Land Uses in Minority Neighborhoods: Disproportionate Siting or Market Dynamics?

103 YALE L.J. 1383 (1994).*

The environmental justice movement contends that people of color and the poor are exposed to greater environmental risks than are whites and wealthier individuals. The movement charges that this disparity is due in part to racism and classism in the siting of environmental risks, the promulgation of environmental laws and regulations, the enforcement of environmental laws, and the attention given to the cleanup of polluted areas. To support the first charge—that the siting of waste dumps, polluting factories, and other locally undesirable land uses (LULUs) has been racist and classist—advocates for environmental justice have cited more than a dozen studies analyzing the relationship between neighborhoods' socioeconomic characteristics and the number of LULUs they host. The studies demonstrate that those neighborhoods in which LULUs are located

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have, on average, a higher percentage of racial minorities and are poorer than non-host communities.

That research does not, however, establish that the host communities were disproportionately minority or poor at the time the sites were selected. Most of the studies compare the *current* socioeconomic characteristics of communities that host various LULUs to those of communities that do not host such LULUs. This approach leaves open the possibility that the sites for LULUs were chosen fairly, but that subsequent events produced the current disproportion in the distribution of LULUs. In other words, the research fails to prove environmental justice advocates' claim that the disproportionate burden poor and minority communities now bear in hosting LULUs is the result of racism and classism in the *siting process* itself.

In addition, the research fails to explore an alternative or additional explanation for the proven correlation between the current demographics of communities and the likelihood that they host LULUs. Regardless of whether the LULUs originally were sited fairly, it could well be that neighborhoods surrounding LULUs became poorer and became home to a greater percentage of people of color over the years following the sitings. Such factors as poverty, housing discrimination, and the location of jobs, transportation, and other public services may have led the poor and racial minorities to "come to the nuisance"—to move to neighborhoods that host LULUs—because those neighborhoods offered the cheapest available housing. Despite the plausibility of that scenario, none of the existing research on environmental justice has examined how the siting of undesirable land uses has subsequently affected the socioeconomic characteristics of host communities. Because the research fails to prove that the siting process causes any of the disproportionate burden the poor and minorities now bear, and because the research has ignored the possibility that market dynamics may have played some role in the distribution of that burden, policymakers now have no way of knowing whether the siting process is "broke" and needs fixing. Nor can they know whether even an ideal siting system that ensured a perfectly fair initial distribution of LULUs would result in any long-term benefit to the poor or to people of color. . . .

Market Dynamics and the Distribution of LULUs

The residential housing market in the United States is extremely dynamic. Every year, approximately 17 percent to 20 percent of U.S. households move to a new home. Some of those people stay within the same neighborhood, but many move to different neighborhoods in the same city, or to different cities. Some people decide to move, at least in part, because they are dissatisfied with the quality of their current neighborhoods. Once a household decides to move, its choice of a new neighborhood usually depends somewhat on the cost of housing and the characteristics of the neighborhood. Those two factors are interrelated because the quality of the neighborhood affects the price of housing.

The siting of a LULU can influence the characteristics of the surrounding neighborhood in two ways. First, an undesirable land use may cause those who can afford to move to become dissatisfied and leave the neighborhood. Second, by making the neighborhood less desirable, the LULU may decrease the value of the neighborhood's property, making the housing more available to lower income

households and less attractive to higher income households. The end result of both influences is likely to be that the neighborhood becomes poorer than it was before the siting of the LULU.

The neighborhood also is likely to become home to more people of color. Racial discrimination in the sale and rental of housing relegates people of color (especially African-Americans) to the least desirable neighborhoods, regardless of their income level. Moreover, once a neighborhood becomes a community of color, racial discrimination in the promulgation and enforcement of zoning and environmental protection laws, the provision of municipal services, and the lending practices of banks may cause neighborhood quality to decline further. That additional decline, in turn, will induce those who can leave the neighborhood—the least poor and those least subject to discrimination—to do so.

The dynamics of the housing market therefore are likely to cause the poor and people of color to move to or remain in the neighborhoods in which LULUs are located, regardless of the demographics of the communities when the LULUs were first sited. As long as the market allows the existing distribution of wealth to allocate goods and services, it would be surprising indeed if, over the long run, LULUs did not impose a disproportionate burden upon the poor. And as long as the market discriminates on the basis of race, it would be remarkable if LULUs did not eventually impose a disproportionate burden upon people of color.

By failing to address how LULUs have affected the demographics of their host communities, the current research has ignored the possibility that the correlation between the location of LULUs and the socioeconomic characteristics of neighborhoods may be a function of aspects of our free market system other than, or in addition to, the siting process. It is crucial to examine that possibility. Both the justice of the distribution of LULUs and the remedy for any injustice may differ if market dynamics play a significant role in the distribution.

If the siting process is primarily responsible for the correlation between the location of LULUs and the demographics of host neighborhoods, the process may be unjust under current constitutional doctrine, at least as to people of color. Siting processes that result in the selection of host neighborhoods that are disproportionately poor (but not disproportionately composed of people of color) would not be unconstitutional because the Supreme Court has been reluctant to recognize poverty as a suspect classification. A siting process motivated by racial prejudice, however, would be unconstitutional. A process that disproportionately affects people of color also would be unfair under some statutory schemes and some constitutional theories of discrimination.

On the other hand, if the disproportionate distribution of LULUs results from market forces which drive the poor, regardless of their race, to live in neighborhoods that offer cheaper housing because they host LULUs, then the fairness of the distribution becomes a question about the fairness of our market economy. Some might argue that the disproportionate burden is part and parcel of a free market economy that is, overall, fairer than alternative schemes, and that the costs of regulating the market to reduce the disproportionate burden outweigh

the benefits of doing so. Others might argue that those moving to a host neighborhood are compensated through the market for the disproportionate burden they bear by lower housing costs, and therefore that the situation is just. Similarly, some might contend that while the poor suffer lower quality neighborhoods, they also suffer lower quality food, housing, and medical care, and that the systemic problem of poverty is better addressed through income redistribution programs than through changes in siting processes.

Even if decisionmakers were to agree that it is unfair to allow post-siting market dynamics to create disproportionate environmental risk for the poor or minorities, the remedy for that injustice would have to be much more fundamental than the remedy for unjust siting *decisions*. Indeed, if market forces are the primary cause of the correlation between the presence of LULUs and the current socioeconomic characteristics of a neighborhood, even a siting process radically revised to ensure that LULUs are distributed equally among all neighborhoods may have only a short-term effect. The areas surrounding LULUs distributed equitably will become less desirable neighborhoods, and thus may soon be left to people of color or the poor, recreating the pattern of inequitable siting. Accordingly, if a disproportionate burden results from or is exacerbated by market dynamics, an effective remedy might require such reforms as stricter enforcement of laws against housing discrimination, more serious efforts to achieve residential integration, changes in the processes of siting low and moderate income housing, changes in programs designed to aid the poor in securing decent housing, greater regulatory protection for those neighborhoods that are chosen to host LULUs, and changes in production and consumption processes to reduce the number of LULUs needed.

Information about the role market dynamics play in the distribution of LULUs would promote a better understanding of the nature of the problem of environmental injustice and help point the way to appropriate solutions for the problem. Nonetheless, market dynamics have been largely ignored by the current research on environmental justice.

The Evidence of Disproportionate Siting

Several recent studies have attempted to assess whether locally undesirable land uses are disproportionately located in neighborhoods that are populated by more people of color or are more poor than is normal. The most important of the studies was published in 1987 by the [CRJ]. The CRJ conducted a cross-sectional study of the racial and socioeconomic characteristics of residents of the zip code areas surrounding 415 commercial hazardous waste facilities and compared those characteristics to those of zip code areas which did not have such facilities. The study revealed a correlation between the number of commercial hazardous waste facilities in an area and the percentage of the "non white" population in the area. Areas that had one operating commercial hazardous waste facility, other than a landfill, had about twice as many people of color as a percentage of the population as those that had no such facility. Areas that had more than one operating facility, or had one of the five largest landfills, had more than three times the percentage of minority residents as areas that had no such facilities.

Several regional and local studies buttress the findings of the nationwide CRJ study. The most frequently cited of those studies, which is often credited for first giving the issue of environmental justice visibility, was conducted by the United States General Accounting Office (GAO). The GAO examined the racial and socioeconomic characteristics of the communities surrounding four hazardous waste landfills in the eight southeastern states that make up EPA's Region IV. The sites studied include some of the largest landfills in the United States.

The results of the study are summarized in Table II.1. In short, three of the four communities where such landfills were sited were majority African-American in 1980; African-Americans made up 52 percent, 66 percent, and 90 percent of the population in those three communities. In contrast, African-Americans made up between 22 percent and 30 percent of the host states' populations. The host communities were all disproportionately poor, with between 26 percent and 42 percent of the population living below the poverty level. In comparison, the host states' poverty rates ranged from 14 percent to 19 percent.

Table II.1. Summary of GAO's Findings

		Mean Family Income		
Landfill	Population, % African-American	All Races	African-Americans	Population Below Poverty Level, %
Chemical Waste	90	$11,198	$10,752	42
SCA Services	38	16,371	6,781	31
Ind. Chem.	52	18,996	12,941	26
Warren Cty. PCB	66	10,367	9,285	32

Another frequently cited local study was conducted by sociologist Robert Bullard and formed important parts of his books, *Invisible Houston* and *Dumping in Dixie.* Professor Bullard found that although African-Americans made up only 28 percent of the Houston population in 1980, six of Houston's eight incinerators and mini-incinerators and fifteen of seventeen landfills were located in predominantly African-American neighborhoods. . . .

[N]one of the . . . studies addressed the question of which came first—the people of color and the poor, or the LULU. As noted by the CRJ, the studies "were not designed to show cause and effect," but only to explore the relationship between the current distribution of LULUs and host communities' demographics. The evidence of disproportionate siting is thus incomplete: it does not establish that *the siting* process had a disproportionate effect upon minorities or the poor. . . .

Did the Siting Disparities Revealed by the GAO and Professor Bullard Result from Siting Practices, Market Dynamics or Both?

To begin to fill the gaps in the literature, this Part expands the GAO and Bullard studies described above. First, it adds to those studies data regarding the socioeconomic characteristics of the host communities at the time the siting decisions were made. Second, it traces changes in the demographics of the host communities since the sitings. . . .

The extensions of the GAO and Bullard studies, . . . show the effect of using demographic data from the census closest to the actual siting or capacity change decision (rather than the latest census data). Tracing changes in the demographics from this baseline reveals a significant difference in the evidence the studies provide regarding the burden LULUs impose on minorities and the poor. These studies suggest that the siting process bears some responsibility for the disproportionate burden waste facilities now impose upon the poor and people of color. The extension of the GAO study suggests that market dynamics play no role in the distribution of the burden. The extension of the Bullard study, on the other hand, suggests that market dynamics do play a significant role in that distribution.

The different results obtained by the two extensions may be attributable to the generally slower rate of residential mobility in rural areas, such as those hosting the GAO sites, versus urban areas, such as those hosting the Houston sites. The difference also may be attributable to the size and nature of the facilities studied in the two extensions. The sites studied in the GAO report are quite large, and provide a substantial number of jobs to residents of the host counties. Persons moving to the area to take those jobs may have displaced the African-Americans who previously lived in the community. The sites at issue in Professor Bullard's study, on the other hand, were unlikely to have created many new jobs, and those jobs that were created would have been much less likely than the jobs at the GAO sites to induce people to move nearby in order to take them.

Conclusion

Significant evidence suggests that LULUs are disproportionately located in neighborhoods that are now home to more of the nation's people of color and poor than other neighborhoods. Efforts to address that disparity are hampered, however, by the lack of data about which came first—the people of color and poor or the LULU. If the neighborhoods were disproportionately populated by people of color or the poor at the time the siting decisions were made, a reasonable inference can be drawn that the siting process had a disproportionate effect upon the poor and people of color. In that case, changes in the siting process may be required.

On the other hand, if, after the LULU was built, the neighborhoods in which LULUs were sited became increasingly poor, or became home to an increasing percentage of people of color, the cure for the problem of disproportionate siting is likely to be much more complicated and difficult. The distribution of LULUs would then look more like a confluence of the forces of housing discrimination, poverty, and free

market economics. Remedies would have to take those forces into account.

The preliminary evidence derived from this extension of two of the leading studies of environmental justice . . . shows that research examining the socioeconomic characteristics of host neighborhoods at the time they were selected, then tracing changes in those characteristics following the siting, would go a long way toward answering the question of which came first—the LULU or its minority or poor neighbors. Until that research is complete, proposed "solutions" to the problem of disproportionate siting run a substantial risk of missing the mark.

NOTES AND QUESTIONS

1. Market Dynamics Hypothesis. If the market dynamics hypothesis presented by Been were to explain an important part of the *current* disparities in the socioeconomic characteristics of host communities, what solutions are possible to reduce or eliminate these disparities? Would anything short of massive economic redistribution work?

2. Market Dynamics Hypothesis and Disparate Impact. Does the market dynamics hypothesis explain why communities surrounding hazardous waste sites are not only disproportionately poor but also, even after adjusting for income, disproportionately composed of people of color?

3. Race and Income: CRJ Studies. The first CRJ study found that race was more significant than income as a predictor of the location of hazardous waste sites. In 1994, the CRJ updated its study using the 1990 census data. The results of the 1994 study were consistent with the original study. It found that zip codes hosting one facility had more than twice the percentage of minorities as zip codes hosting no facilities. *See* BENJAMIN A. GOLDMAN ET AL., TOXIC WASTES AND RACE REVISITED: AN UPDATE OF THE 1987 REPORT ON THE RACIAL AND SOCIOECONOMIC CHARACTERISTICS OF COMMUNITIES WITH HAZARDOUS WASTE SITES 3 (1994). A 2007 update of the study reached similar conclusions. It found that the percentage of people of color was 1.9 times greater in neighborhoods hosting one facility than in neighborhoods hosting no facilities. *See* ROBERT D. BULLARD ET AL., TOXIC WASTES AND RACE AT TWENTY: 1987–2007, 52 (2007). What factors might explain this phenomenon? Consider the following explanations:

(a) differential political power;

(b) differential access to information;

(c) differential mobility; and

(d) discrimination in housing.

4. Race and Income: SADRI Study. A study conducted by the Social and Demographic Research Institute (SADRI) at the University of Massachusetts–Amherst reached quite different conclusions. Examining the siting of the same facilities as CRJ, it found no significant difference in the percentage of African-Americans in census tracts with commercial hazardous waste facilities, as compared to tracts without such facilities. There was, however, a marginally significant difference between the percentage of Latinos in host and non-host tracts. *See* Douglas L. Anderton, Andy B. Anderson, John Michael Oakes & Michael R. Fraser, *Environmental Equity: The Demographics of Dumping*, 31 DEMOGRAPHY

229 (1994). Whereas the 1994 CRJ study had used zip codes as its unit of analysis, the SADRI study used census tracts, reasoning that they are intended to have a relatively homogeneous population. The SADRI study found, however, that while the host census tracts and the immediately adjoining census tracts did not have important racial disparities, tracts further from the facility but within a two-and-a-half mile radius contained significantly higher percentages of people of color and the poor than the remainder of the metropolitan area. What are possible explanations for this pattern? For an overview of the evidence of disparate siting, see Vicki Been, *Environmental Justice and Equity Issues*, *in* PATRICK J. ROHAN, ZONING AND LAND USE CONTROLS, ch. 25D (1995). For analyses of how to define the affected neighborhood, see John J. Fahsbender, *An Analytical Approach to Defining the Affected Neighborhood in the Environmental Justice Context*, 5 N.Y.U. ENVTL. L.J. 120 (1996); Bradford C. Mank, *Proving an Environmental Justice Case: Determining an Appropriate Comparison Population*, 20 VA. ENVTL. L.J. 365 (2001).

5. Compensation Under the Market Dynamics Hypothesis. How does the market dynamics hypothesis affect the evaluation of compensation schemes? Who should get the compensation:

(a) current owners of housing?

(b) current renters of housing?

(c) future owners of housing?

(d) future renters of housing?

(e) community groups?

Vicki Been, What's Fairness Got to Do with It? Environmental Justice and the Siting of Locally Undesirable Land Uses

78 CORNELL L. REV. 1001 (1993).*

Fairness in the Pattern of Distribution

Fairness Requires Equal Division—A Per Capita or Proportional Distribution of the Burdens of LULUs

A broad conception of fairness in siting would require that a LULU's burdens be spread on a per capita or proportional basis over society as a whole. This fairness concept is implicit in the contention that LULUs are inequitably sited if the percentage of LULUs in minority neighborhoods is disproportionate to the percentage of minorities in the nation's population. It is also inherent in the calls by the environmental justice movement demanding that people of color receive an "equitable distribution of 'healthy' physical environments" and that no neighborhood bear more than its proportionate share of LULUs. . . .

Several means of distribution are plausible under the proportional distribution of burden theory. One scheme would impose a physical proportional distribution: LULUs themselves would be distributed

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equally among neighborhoods. This distribution could be either equal *ex post* or equal *ex ante.* In an *ex post* scheme, the facilities and the harms that they pose would be distributed proportionately among neighborhoods. For example, if New York City requires facilities for 10,000 homeless individuals and has 100 neighborhoods, all holding some land suitable for a facility, each neighborhood would receive one facility housing 100 individuals. In an *ex ante* scheme, each neighborhood has an equal chance of being selected for the site through a lottery process. For example, if New York City requires a sewage sludge treatment plant, each of the 100 neighborhoods would have a 1/100 chance of being selected for the site. The *ex ante* physical distribution scheme is particularly well suited to situations in which there are economies of scale in building and operating fewer but larger LULUs. Some types of hazardous waste, for example, are stored most efficiently in large, centralized facilities. To accommodate such efficiency considerations, most neighborhoods should be spared the burden of having the facility nearby. A lottery procedure can ensure that although most neighborhoods will not have to host the site, all have an equal chance of being selected as the host site. The lottery accordingly achieves equality of opportunity before the actual distribution.

Instead of either *ex ante* or *ex post* physical equality, a distribution might seek "compensated" equality. In this distribution scheme, all individuals or communities that gain a net benefit from a particular LULU must compensate those who suffer a net loss. For example, if a sludge treatment plant imposed costs upon a neighborhood, each of the neighborhoods that benefitted from the plant, but did not suffer the detriment of close proximity, would have to pay a proportionate share of the costs. Compensated equality can operate either *ex ante* or *ex post.* In an *ex ante* scheme, the siting neighborhood would be compensated for the expected loss that the site might inflict, even though the loss might never occur. In an *ex post* scheme, the siting neighborhood would be compensated only as injuries occurred. Compensation could be in the form of cash, neighborhood amenities, insurance, or indemnification. Compensation also could include "risk substitution," involving commitments to reduce some other burden borne by the community, such as a landfill developer's promise to clean up existing waste dumps. The amount and nature of the compensation would be determined either by a government authority, such as an administrative agency, or by the affected neighborhood itself. . . .

Fairness Requires Progressive Siting

One could argue that a fair distribution of LULUs would require advantaged neighborhoods to bear more of the burden that LULUs impose than poor and minority neighborhoods. Such a distribution could involve either a physical siting scheme in which advantaged neighborhoods receive a disproportionately greater number of LULUs or a compensated siting scheme in which advantaged neighborhoods pay a greater share of the cost of LULUs. One rationale for such "progressive" siting would be compensatory justice: advantaged neighborhoods should bear more of the LULU burden in order to redress or remedy past discrimination against poor and minority neighborhoods.

Although the compensatory argument for progressive siting is backward-looking, at least four forward-looking justifications exist. First, progressive siting may be necessary to achieve equality of results, or equal impact of the burdens of LULUs. Because residents of poor and minority neighborhoods suffer from numerous disadvantages, such as poor health and barriers to mobility, a LULU in a disadvantaged neighborhood will have a greater impact than one in a more advantaged community. Thus, to achieve the same level of impact, advantaged communities must bear a greater share of the burden of LULUs. The environmental justice movement's focus on tailoring risk assessments and regulatory activities to account for the special health risks faced by low income or minority communities reflects this argument.

Second, if the marginal utility of environmental quality declines as neighborhoods receive more environmental amenities, LULUs would impose less disutility upon advantaged neighborhoods than upon poor and minority neighborhoods. Thus, progressive siting would induce equal sacrifice from all neighborhoods and impose the least damage to society as a whole. Third, progressive siting could maximize total utility if putting more LULUs in advantaged neighborhoods encouraged society to reduce the number of LULUs it requires.

Fourth, John Rawls' difference principle might justify progressive siting. Rawls' theory of justice does not directly apply to siting controversies because it addresses the design of fair institutional structures, not the fairness of individual distributional choices. Nevertheless, on a micro-level the difference principle requires the siting process to yield the greatest benefit, or the least burden, to the least advantaged. A progressive siting scheme is justified, in other words, if such siting would be more likely to improve the condition of the poorest members of society than one that either distributed the burden of LULUs equally or imposed the burden disproportionately upon the poor and minorities. . . .

Fairness Requires an Equal Initial Split and Competitive Bidding

A much different conception of fairness can be drawn from Ronald Dworkin's work on the meaning of equality. In exploring the ideal of equality of resources, Dworkin asks how resources should be distributed among shipwreck survivors washed up on a desert island. Dworkin's thought experiment is far removed from the problems of siting LULUs, but his analysis helps illuminate the notions of fairness inherent in several recent proposals that LULUs be "auctioned" among communities. Dworkin posits that equality of resources would result if each shipwreck survivor were assigned initially an equal share of clamshells that she could use to bid competitively for resources. He argues that a distribution is fair if no individual prefers the distribution that some other individual obtains. Competitive bidding among those with initially equal bidding currency will produce such a distribution.

Applied to the siting context, Dworkin's scheme requires that communities be given an equal number of bargaining chips with which to bid against LULUs. Society would decide which LULUs it would need for some period of time and put them on the auction block. Each community would then receive chips to buy its way out of particular LULUs essentially a currency of vetos.

For example, suppose there are five communities of equal population and land area and there are fifteen LULUs, ranging from a home for juvenile delinquents to a low-level radioactive waste dump. Each community would be allocated ten veto chips. The auctioneer would begin by announcing that a particular LULU would be randomly distributed among the communities, but the highest bidder could remove itself from the eligible pool. If community A bids two chips to avoid it, B bids three, and C bids four, C "wins" the veto, paying four of its chips to disqualify itself from the selection process. Communities A, B, D, and E are still eligible, unless one wants to bid again. Suppose that A and E each again bid two, and B bids three; B is then eliminated, and so on, until none of the eligible communities wishes to veto the LULU. It is then randomly distributed among them. The process repeats for the next LULU. Once a community spends its ten veto chips, it is eligible for all remaining LULUs. The auction ends once all LULUs have been distributed.

If communities change their minds about the LULUs they prefer, they may trade their LULUs with other willing communities. Suppose that through the auction community A receives a large oil refinery and a prison, while community B receives a low-level radioactive waste storage facility. If community B believes that its geographical characteristics and the qualifications of its work force would enable it to host the oil refinery and prison more efficiently than the radioactive waste facility, community B could seek to trade with community A.

Under this conception of fairness, an auction for LULUs involves an equitable distribution of veto power. Proposals to hold reverse auctions, in which the siting agency or developer offers to pay a specific sum of money to the first community that agrees to accept the LULU, then increases the amount until some community steps forward with an acceptable site, are not fair under this conception because they take advantage of any inequalities of wealth that existed prior to the auction. . . .

Fairness as Cost-Internalization

Many environmental justice advocates argue that fairness requires those who benefit from LULUs to bear the cost of the LULUs. Forcing the internalization of costs leads to greater fairness in two ways. First, it is fairer to hold individuals responsible for their actions than to let costs fall on innocent bystanders. Second, forcing the internalization of costs results in greater efficiency, and greater efficiency is likely to mean fewer LULUs. Purchasers of products that generate waste will reduce consumption once the prices of the products reflect the true cost of waste facilities. In turn, producers will develop more efficient means of production, given the cost of disposing the waste generated. The number of LULUs will thereby decrease to the socially optimal level—the level at which the marginal utility of the product necessitating the LULU equals its costs. . . .

The cost-internalization conception of fairness requires that those who consume a product or make an allocation decision bear the product's or decision's full costs. To attain that goal, the manufacturer whose product generates the need for a LULU could compensate the host neighborhood for the full damages that the LULU inflicts, and then pass that cost forward to the consumers of the product. However,

those who advocate cost-internalization as a means of combatting disproportionate siting generally oppose compensatory schemes. Instead, they either support programs to physically distribute LULUs more evenly across all neighborhoods or favor blocking all LULUs to encourage pollution prevention that would make LULUs unnecessary.

A physical distribution scheme would be less effective than compensation, however, at forcing the full internalization of the product's costs. It would be nonsensical to distribute one LULU to each consumer; therefore, a physical distribution of sites would always allow most consumers to avoid the full costs of their consumption decisions. Additionally, a physical distribution scheme would usually be both overinclusive and underinclusive: some residents of the host neighborhood might never consume the product in question, yet bear its burdens, while heavy users of the product outside the host neighborhood would bear no burden at all. . . .

Fairness as Process

Rather than focusing on the distribution of burdens to determine whether the siting process is equitable, the fairness as process theory focuses on the procedures by which the burden is distributed. The most obvious theory of fairness as process would assert that a distribution is fair as long as it results from a process that was agreed upon in advance by all those potentially affected. Although there are examples of interstate siting compacts and regional intrastate siting agreements, in which all participants voluntarily agree to a particular siting process, most LULUs are sited in communities that had no opportunity to remove themselves from the selection process. Therefore, this Section focuses on theories of fairness as process that do not rest upon voluntary agreement for their legitimacy.

Fairness Requires a Lack of Intentional Discrimination

A siting decision motivated by hostility toward people of a particular race is unfair under almost any theory of justice, and would not be considered fair under the Constitution. Under the intentional discrimination theory, fairness requires that a decision to site a LULU be made without any intent to disadvantage people of color. . . .

Fairness Requires Treatment as Equals

Even if discrimination is unintentional or based upon characteristics that do not trigger strict scrutiny under the Equal Protection Clause, disproportionate siting arguably would be inappropriate if it stemmed from a siting process that failed to treat people with "equal concern and respect," instead valuing certain people less than others. Under this theory, if a siting process is more attentive to the interests of wealthier or white neighborhoods than to the interests of poor or minority neighborhoods, that process illegitimately treats the poor and people of color as unequal.

Thus, if two potential sites were otherwise identical but one was in a poor neighborhood and one was in a wealthier neighborhood, society could not take note of the costs that the siting would impose on the wealthy, ignore the costs it would impose on the poor, and consequently site the LULU in the poor neighborhood. Nor could the siting decision consider the impact that the LULU would have on the poor, but

discount that impact on the ground that the value of being free from certain kinds of risks or harms is worth less to poor people. Instead, the siting decision would have to consider the interests of the poor just as fully and sympathetically as it considered the interests of the more wealthy. If the decision-maker then concluded that both neighborhoods faced equal risk or loss, the choice between the two neighborhoods would have to be made with the flip of a coin or some other lottery mechanism.

If the two potential sites were not identical, treatment as equals would require only that the harm that a site would cause to the poor be considered in exactly the same manner as the harm that a site would cause to the more affluent. Thus, if siting the LULU in the poor neighborhood would expose five neighbors to a particular risk while siting it in the wealthier area would expose twenty-five neighbors to risk, society would be justified under this theory in choosing the site in the poor neighborhood. . . .

NOTES AND QUESTIONS

1. Fairness and Economic Considerations. Been writes that, under the fairness as equal division theory, "if New York City requires facilities for 10,000 homeless individuals and has 100 neighborhoods, all holding some land suitable for a facility, each neighborhood would receive one facility housing 100 individuals." Consider the relevance of the following:

(a) land in certain communities is a great deal cheaper than in others;

(b) certain communities offer better social services for the homeless;

(c) the optimal size of each facility is 200 individuals; and

(d) the facilities impose less disutility in some communities than in others.

More generally, to what extent should fairness notions trump economic considerations?

2. Fairness as Auctions. How would one define what counts as a community for the purposes of an auction to allocate LULUs? How should a community's auction strategy be determined? Are the interests of all members of the community likely to be coextensive?

3. Fairness as Cost-Internalization. The internalization of the costs associated with waste disposal is achieved if the disposal charge reflects the expected harm of the waste. Is cost-internalization fair even if the community surrounding the site is not compensated for this harm? In contrast, if the community is compensated for this harm, does it matter if the funds are being disbursed by the disposer of the wastes? Should cost-internalization be seen as an independent notion of fairness?

4. Fairness as the Minimization of Property Depreciation. Evaluate the fairness of a process that allocates LULUs on the basis of where they will decrease property values the least and under which, on the basis of unimpeachable studies, the LULUs always get allocated to poor communities.

5. Disparate Impacts in Enforcement. So far the focus of the discussion has been on the siting of LULUs as the subject of environmental justice concerns. However, the disparities that have given rise to the environmental justice movement manifest themselves in a number of different contexts. For example, in addition to the siting of LULUs, the environmental justice movement has focused a great deal of attention on the disparate enforcement of environmental statutes and regulations and on the disparate remediation of contaminated sites. *See* David J. Galalis, Note, *Environmental Justice and Title VI in the Wake of* Alexander v. Sandoval*: Disparate-Impact Regulations Still Valid Under Chevron*, 31 B.C. ENVTL. AFF. L. REV. 61, 63 (2004).

A study by the National Law Journal (NLJ) conducted in 1992 found significant disparities in the enforcement of environmental laws. For example, with respect to cleanups of hazardous waste sites under the Superfund statute, it found that sites in minority neighborhoods took longer to be listed on the National Priorities List (NPL), which would make them eligible for the expenditure of federal funds for remedial action, and that the cleanups of these sites were less extensive. *See* Marianne Lavelle & Marcia Coyle, *Unequal Protection: The Racial Divide in Environmental Law*, NAT'L L.J., Sept. 21, 1992, at S2. In contrast, researchers at the University of Maryland found no statistically significant racial disparities in the choice of cleanup levels. Unlike the NLJ study, the University of Maryland study controlled for other variables, such as whether the site is located in an urban or rural area, that might influence the choice of cleanup remedy. Skreekant Gupta, George L. Van Houtven & Maureen L. Cropper, *Do Benefits and Costs Matter in Environmental Regulation? An Analysis of EPA Decisions Under Superfund*, *in* ANALYZING SUPERFUND: ECONOMICS, SCIENCE, AND LAW 83 (Richard L. Revesz & Richard B. Stewart, eds., 1995). What role should environmental justice concerns play in the setting of enforcement priorities?

6. Distributional Consequences Under the CAA and the Clean Water Act. Other studies have examined the distributional consequences of environmental policies in different contexts. One such study was conducted by Henry Peskin in 1978, examining the distributional impact of the CAA of 1970. Henry M. Peskin, *Environmental Policy and the Distribution of Benefits and Costs*, *in* CURRENT ISSUES IN ENVIRONMENTAL POLICY 144 (Paul R. Portney ed., 1978). The study allocated the national benefits of the legislation to regions. Within a region, the study assumed that each individual received an equal share of the benefit. Costs were initially allocated to industries, governments, or households. It was assumed that industrial costs were borne by families in proportion to their consumption of the product (the production of which generated the pollution regulated by the CAA); that government costs were allocated on the basis of each family's relative tax burden; and that household costs, which are primarily the costs of pollution controls for automobiles, were allocated proportionately to the number of vehicles owned by each family. The Peskin study showed the costs of pollution control to be spread out relatively evenly throughout the country, and critically, the benefits of the Act to be concentrated in highly polluted areas. Aggregating benefits and costs, Peskin found that people of color were the only net gainers from the legislation, as a result of their lower average vehicle ownership, larger average family size, and disproportionate concentration in urban locations. With respect to income, he concluded that the net benefits of the CAA,

which were negative for all groups, were neither progressively nor regressively distributed.

For a recent analysis in a similar vein (and with largely similar results), see Matthew E. Kahn, *The Beneficiaries of Clean Air Act Regulation*, REGULATION, Spring 2001, at 22. For a discussion of the distribution of costs in the context of federal water pollution control policies, see Leonard P. Gianessi & Henry M. Peskin, *The Distribution of the Costs of Federal Water Pollution Control Policy*, 56 LAND ECON. 85 (1978).

7. Retrospective v. Prospective Perspectives on Environmental Justice. The Peskin study showed that the greatest benefits of the CAA in its early years accrued to the dirtiest areas. It is likely, however, that despite the improvement, these areas continue to be dirtier than the norm. In evaluating the environmental laws from a justice perspective, should the focus be on the changes that have taken place since their adoption or on the inequities that remain?

8. Aggregation of Environmental Impacts. The Peskin study suggested that people of color are the greatest net beneficiaries of the CAA. They may, however, be disproportionately disadvantaged by other environmental programs. Is it appropriate to disaggregate the effects of the environmental laws and urge a massive restructuring of any program that has disproportionately negative effects on people of color or the poor? Why should the effects not be aggregated? Might it be appropriate to look even more broadly at the aggregate distributional consequences of all governmental programs, including taxes and transfer payments? For an argument that environmental impacts should be assessed in the aggregate, *see* Daveed Gartenstein-Ross, *An Analysis of the Rights-Based Justification for Federal Intervention in Environmental Regulation,* 14 DUKE ENVTL. L. & POL'Y F. 185 (2003).

9. Geographic Inequality. There is also geographic inequality in the distribution of environmental health impacts. Residential proximity to hazardous waste sites, industrial sites and cropland treated with pesticides have all been associated with an increased risk of adverse health outcomes. Jean D. Brender, Juliana A. Maantay, Jayajit Chakraborty, *Residential Proximity to Environmental Hazards and Health Outcomes*, 101 AM. J. PUB. HEALTH S37 (2011). The association between adverse health outcomes and geographic location has given rise to nicknames for areas perceived to have disproportionate environmental health impacts—Cancer Alley, in Louisiana, and Toxicana, in Texarkana, Texas. *See* Douglas A. McWilliams, *Environmental Justice and Industrial Redevelopment: Economics and Equality in Urban Revitalization*, 21 ECOLOGY L. Q. 705, 761 (1994). What are appropriate legal remedies to deal with geographic inequalities?

10. Disparate Impacts of Climate Change. A number of studies have shown that the detrimental effects of climate change are, and will continue to be, borne disproportionately by developing nations. *See, e.g.*, NICHOLAS STERN, THE ECONOMICS OF CLIMATE CHANGE (2006). For example, countries located in low-lying areas, as well as small-island states, will suffer disproportionately as a consequence of the projected rise in sea levels and the increased frequency and intensity of climate-related extreme weather events. More generally, the projected effects of climate change upon agricultural production will disproportionately affect developing nations, in which the agricultural sector comprises a relatively high component of

Gross Domestic Product. Furthermore, the inability of developing nations to adapt to the impacts of climate change—as a consequence of a lack of economic resources, technology, information, skills, infrastructure, and functioning institutional regimes—exacerbates their vulnerability to the impacts of climate change.

The disparate impacts of climate change are not isolated to the divide between developing and developed nations—a divide can also be drawn between current and future generations. The impacts of climate change that have already been experienced are only a portion of the total impacts that are expected to occur in the future. Even in the absence of any further emissions, greenhouse gases presently in the atmosphere will significantly affect the future climate, resulting in an estimated rise in temperature of between 0.4–0.6 degrees Celsius by the year 2100. *See* Gerald A. Meehl et al., *How Much More Global Warming and Sea Level Rise?*, 307 SCIENCE 1769 (2005). Moreover, at projected levels of emissions, the impacts upon future generations are expected to be severe. For example, it is estimated that by 2080, an additional 29–50 million people will be affected each year by floods attributable to climate change. Heat waves are projected to increase in intensity and duration, causing thousands of heat-related deaths. By 2100, the number of people exposed to malaria in Africa will increase by 16–28 percent, and the number of people exposed to dengue fever will increase by between 20–30 percent. *See* Richard L. Revesz & Matthew R. Shahabian, *Climate Change and Future Generations*, 84 S. CAL. L. REV. 1097 (2011).

In recent years, as a consequence of the increased recognition of these disparities, a rich vein of academic literature has emerged championing the justice movement in the context of climate change. Representative works include, EDWARD A. PAGE, CLIMATE CHANGE, JUSTICE AND FUTURE GENERATIONS (2006); and Neil Adger et al., *Towards Justice in Adaptation to Climate Change*, *in* FAIRNESS IN ADAPTATION TO CLIMATE CHANGE (2006). In what ways should the environmental justice movement in the international context be considered analytically different from the domestic environmental justice movement? How do each of the notions of fairness, discussed by Been above, apply in the international context? What should the international response to climate change learn from the domestic environmental justice movement?

B. LEGAL THEORIES FOR ADDRESSING DISPROPORTIONATE RISKS

This section chronicles the attempts by the environmental justice movement to establish environmental justice as an enforceable right in federal courts. It begins by examining the early environmental justice litigation under the Equal Protection Clause of the U.S. Constitution, before moving onto the more recent attempts to bring private actions under Title VI to the Civil Rights Act of 1964.

While a series of recent decisions have led many commentators to suggest that private actions challenging actions in federal court are all but foreclosed, regulations promulgated by EPA pursuant to § 602 of the Civil Rights Act do nevertheless provide an avenue for administrative relief. This section will conclude by examining this administrative mechanism, focusing upon the impact of Executive

Order 12,898 issued by President Clinton on February 11, 1994, which remained in effect throughout the Bush administration and remains in effect today.

i. EQUAL PROTECTION CLAUSE

Even before the movement gained prominence in the academic literature, attempts to defeat perceived governmental discrimination on environmental justice grounds had been made for a number of years under the Fourteenth Amendment. A 1979 Texas civil rights case is recognized as the first instance of environmental justice litigation. In *Bean v. Southwestern Waste Management Corp.*, 482 F. Supp. 673 (S.D. Tex. 1979), plaintiffs claimed that the siting of a proposed waste containment facility by the City of Houston was unconstitutional because it discriminated against the mostly African-American residents of Northwood Manor. While the action was ultimately dismissed for failure to establish that the siting of the facility had been motivated by purposeful racial discrimination, the case is nevertheless widely attributed with providing the "inspiration for the legal piece to the environmental justice movement." Luke W. Cole, *Environmental Justice Litigation: Another Stone in David's Sling*, 21 FORDHAM URB. L.J. 523, 523 (1994).

In order to succeed under the Equal Protection Clause, which provides that "no state shall . . . deny to any person within its jurisdiction the equal protection of the laws," a claimant must establish both that persons similarly situated are treated differently, and that defendants intended to discriminate. *Washington v. Davis*, 426 U.S. 229, 239 (1976). No environmental justice claim under the Fourteenth Amendment has ever prevailed. Invariably, just as in the *Bean* case, claims are defeated for failure to establish discriminatory intent. These difficulties are borne out in the following case.

East Bibb Twiggs Neighborhood Association v. Macon-Bibb County Planning & Zoning Commission

706 F. Supp. 880 (M.D. Ga. 1989).

■ OWENS, CHIEF JUDGE:

This case involves allegations that plaintiffs have been deprived of equal protection of the law by the Macon-Bibb County Planning & Zoning Commission (Commission). Specifically, plaintiffs allege that the Commission's decision to allow the creation of a private landfill in census tract No. 133.02 was motivated at least in part by considerations of race. Defendants vigorously contest that allegation. . . .

On or about May 14, 1986, defendants Mullis Tree Service, Inc. and Robert Mullis ("petitioners") applied to the Commission for a conditional use to operate a non-putrescible waste landfill at a site bounded at least in part by Davis and Donnan Davis Roads. The property in question is located in census tract No. 133.02, a tract containing five thousand five hundred twenty-seven (5,527) people, three thousand three hundred sixty-seven (3,367) of whom are black persons and two thousand one hundred forty-nine (2,149) of whom are

white persons. The only other private landfill approved by the Commission is situated in the adjacent census tract No. 133.01, a tract having a population of one thousand three hundred sixty-nine (1,369) people, one thousand forty-five (1,045) of whom are white persons and three hundred twenty (320) of whom are black persons. . . .

"To prove a claim of discrimination in violation of the Equal Protection Clause a plaintiff must show not only that the state action complained of had a disproportionate or discriminatory impact but also that the defendant acted with the intent to discriminate." *United States v. Yonkers Board of Education,* 837 F.2d 1181, 1216 (2d Cir. 1987), *cert. denied,* 486 U.S. 1055 (1988); *see Washington v. Davis,* 426 U.S. 229 (1976); *E & T Realty v. Strickland,* 830 F.2d 1107 (11th Cir. 1987), *cert. denied,* 485 U.S. 961 (1988). A plaintiff need not establish that "the challenged action rested solely on racially discriminatory purposes. Rarely can it be said that a legislature or administrative body operating under a broad mandate made a decision motivated solely by a single concern, or even that a particular purpose was the 'dominant' or 'primary' one." *Village of Arlington Heights v. Metropolitan Housing Development Corp.,* 429 U.S. 252, 265 (1977). "Determining whether invidious discriminatory purpose was a motivating factor demands a sensitive inquiry into such circumstantial and direct evidence of intent as may be available." *Id.* at 266. Considerations include the following: (1) the impact of the official action—whether it bears more heavily on one race than upon another; (2) the historical background of the decision; (3) the specific sequence of events leading up to the challenged decision; (4) any departures, substantive or procedural, from the normal decision-making process; and (5) the legislative or administrative history of the challenged decision. *Id.* at 266–68.

Having considered all of the evidence in light of the above-identified factors, this court is convinced that the Commission's decision to approve the conditional use in question was not motivated by the intent to discriminate against black persons. Regarding the discriminatory impact of the Commission's decision, the court observes the obvious—a decision to approve a landfill in any particular census tract impacts more heavily upon that census tract than upon any other. Since census tract No. 133.02 contains a majority black population equaling roughly sixty percent (60%) of the total population, the decision to approve the landfill in census tract No. 133.02 of necessity impacts greater upon that majority population.

However, the court notes that the only other Commission approved landfill is located within census tract No. 133.01, a census tract containing a majority white population of roughly seventy-six percent (76%) of the total population. This decision by the Commission and the existence of the landfill in a predominantly white census tract tend to undermine the development of a "clean pattern, unexplainable on grounds other than race. . . ." *Village of Arlington Heights*, 429 U.S. at 266.

Plaintiffs hasten to point out that both census tracts, Nos. 133.01 and 133.02, are located within County Commission District No. 1, a district whose black residents compose roughly seventy percent (70%) of the total population. Based upon the above facts, the court finds that while the Commission's decision to approve the landfill for location in

census tract No. 133.02 does of necessity impact to a somewhat larger degree upon the majority population therein, that decision fails to establish a clear pattern of racially motivated decisions.

Plaintiffs contend that the Commission's decision to locate the landfill in census tract No. 133.02 must be viewed against an historical background of locating undesirable land uses in black neighborhoods. First, the above discussion regarding the two Commission approved landfills rebuts any contention that such activities are always located in direct proximity to majority black areas. Further, the court notes that the Commission did not and indeed may not actively solicit this or any other landfill application. The Commission reacts to applications from private landowners for permission to use their property in a particular manner. The Commissioners observed during the course of these proceedings the necessity for a comprehensive scheme for the management of waste and for the location of landfills. In that such a scheme has yet to be introduced, the Commission is left to consider each request on its individual merits. In such a situation, this court finds it difficult to understand plaintiffs' contentions that this Commission's decision to approve a landowner's application for a private landfill is part of any pattern to place "undesirable uses" in black neighborhoods. Second, a considerable portion of plaintiffs' evidence focused upon governmental decisions made by agencies other than the planning and zoning commission, evidence which sheds little if any light upon the alleged discriminatory intent of the Commission.

Finally, regarding the historical background of the Commission's decision, plaintiffs have submitted numerous exhibits consisting of newspaper articles reflecting various zoning decisions made by the Commission. The court has read each article, and it is unable to discern a series of official actions taken by the Commission for invidious purposes. *See* *Village of Arlington Heights*, 429 U.S. at 267. Of the more recent articles, the court notes that in many instances matters under consideration by the Commission attracted widespread attention and vocal opposition. The Commission oft times was responsive to the opposition and refused to permit the particular development under consideration, while on other occasions the Commission permitted the development to proceed in the face of opposition. Neither the articles nor the evidence presented during trial provides factual support for a determination of the underlying motivations, if any, of the Commission in making the decisions. In short, plaintiffs' evidence does not establish a background of discrimination in the Commission's decisions.

"The specific sequence of events leading up to the challenged decision also may shed some light on the decisionmaker's purpose." *Village of Arlington Heights*, 429 U.S. at 267. Plaintiff identifies as the key piece of evidence in this regard a statement contained in "Action Plan for Housing," a study of the status of housing in the Macon area conducted by the Macon-Bibb County Planning and Zoning Commission. The study states that "[r]acial and low income discrimination still exist in the community." The study was issued in March of 1974, and it constitutes a recognition *by* the Commission that racial discrimination still existed in the Macon community in 1974. That recognition in no way implies that racial discrimination affected the decision-making process of the Commission itself. Rather, the

statement indicates the Commission's awareness that certain individuals and/or groups in society had yet to come to grips with the concept of equality before the law. The Commission's recognition of the situation does not constitute its adoption. Indeed, such recognition probably encourages that Commission to exercise vigilance in guarding against such unprincipled influence. The statements of the various Commissioners during their deliberations indicates a real concern about both the desires of the opposing citizens and the needs of the community in general.

In terms of other specific antecedant events, plaintiffs have not produced evidence of any such events nor has the court discerned any such events from its thorough review of the record. No sudden changes in the zoning classifications have been brought to the court's attention. Plaintiffs have not produced evidence showing a relaxation or other change in the standards applicable to the granting of a conditional use. Thus, this court finds no specific antecedant events which support a determination that race was a motivating factor in the Commission's decision.

Plaintiffs contend that the Commission deviated from its "normal procedures" in several ways. First, plaintiffs point to the Commission's efforts to encourage input from the County and the City. These efforts do not constitute evidence that "improper purposes are playing a role" in the Commission's decision. The statements of the Commissioners make clear that such efforts had their genesis in the Commission's concerns about accountability to the public for certain controversial governmental decisions and about centralized planning for the area's present and future waste disposal problems.

Plaintiffs' contentions regarding other alleged procedural irregularities, including the requirement that the Commission make certain findings of fact and that a rehearing was improperly granted, are without merit. The court has examined the Comprehensive Land Development Resolution in light of the actions taken and has been unable to identify any procedural flaws.

The final factor identified in *Village of Arlington Heights* involves the legislative or administrative history, particularly the contemporary statements made by members of the Commission. Plaintiffs focus on the reasons offered by the Commission for the initial denial of petitioners' application, *i.e.*, that the landfill was adjacent to a residential area and that the approval of the landfill in that area would result in increased traffic and noise, and they insist that those reasons are still valid. Thus, plaintiffs reason, some invidious racial purpose must have motivated the Commission to reconsider its decision and to approve that use which was at first denied. This court, having read the comments of the individual commissioners, cannot agree with plaintiffs' arguments.

NOTES AND QUESTIONS

1. Disparate Impact. The *East Bibb Twiggs* court found that the siting of the landfill in question did result in disparate environmental impacts. How did the court articulate these disparities? Do you agree with the court's analysis that the siting of any landfill facility would necessarily result in disparate impacts to the local neighborhood?

2. Discriminatory Intent. On what basis did the court find the Commission's decision to approve the landfill in question not to be motivated by the intent to discriminate against persons of color? What evidence did the plaintiffs provide to the contrary?

3. *Arlington Heights* Factors. As the *East Bibb Twiggs* case demonstrates, it is particularly difficult for a plaintiff to satisfy the *Arlington Heights* discriminatory intent test in an environmental justice context. Consider each of the five factors in turn. What evidence would be necessary to satisfy the test? In light of your response, how likely is it that a plaintiff will ever succeed in an environmental justice claim under the Fourteenth Amendment?

ii. TITLE VI OF THE CIVIL RIGHTS ACT

Section 601 of Title VI of the Civil Rights Act of 1964, which prohibits discrimination on the grounds of race, color, and national origin by "any program or activity receiving Federal financial assistance," offers an alternative avenue for legal challenge on environmental justice grounds. 42 U.S.C. § 2000d. The potential scope of Title VI is broad, given that virtually every state environmental agency receives some funding from EPA. Following the decision of the Supreme Court in *Guardians Association v. Civil Service Commission*, 463 U.S. 582 (1983), however, environmental justice actions under § 601 of the Civil Rights Act have been rendered largely impotent. Just as in the case of the Equal Protection Clause, the Supreme Court found that plaintiffs must establish proof of discriminatory intent on the part of government or industry in order to sustain a challenge under Title VI. For an account of the history of environmental justice actions brought under Title VI of the Civil Rights Act, see THE LAW OF ENVIRONMENTAL JUSTICE: THEORIES AND PROCEDURES TO ADDRESS DISPROPORTIONATE RISKS 23–68 (Michael Gerrard ed., 1999).

Section 602 of the Civil Rights Act requires that every federal agency promulgate regulations specifying how the agency will determine whether grant applications or recipients are engaging in racially discriminatory practices, and also provide a process for investigation and reviewing complaints of racial discrimination filed with the agency. 42 U.S.C. § 2001d–1. Pursuant to this authority, EPA promulgated "disparate-impact" regulations in 1973 prohibiting recipients of EPA funds from using "criteria or methods of administering its program or activity which have the effect of subjecting individuals to discrimination because of their race, color, national origin, or sex, or have the effect of defeating or substantially impairing accomplishment of the objectives of the program or activity with respect to individuals of a particular race, color, national origin, or sex." 40 C.F.R. § 7.35(b).

Initially, it had been thought that § 602 may give rise to a substantive cause of action pursuant to which environmental justice advocates could challenge the actions of federal agencies in the courts. This strategy was particularly attractive to environmental justice advocates, given that the "disparate-impact" regulations prohibited discrimination regardless of intent. Ultimately, however, this strategy was short lived. In 2001, the Supreme Court held that there was no implied private right of action to directly enforce an agency's "disparate-

impact" regulations. *Alexander v. Sandoval*, 532 U.S. 275 (2001). Instead, it held that regulations of this type provide only an avenue of administrative complaint. *Id*. As a result, the majority of direct environmental justice claims are now pursued in administrative forums. *See* Kyle W. La Londe, *Who Wants to Be an Environmental Justice Advocate?: Options for Bringing an Environmental Justice Complaint in the Wake of* Alexander v. Sandoval, 31 B.C. ENVTL. AFF. L. REV. 27 (2004).

In 1993, EPA established the Office of Civil Rights (OCR) within the Office of the Administrator. The OCR is responsible for administering EPA's "disparate-impact" regulations. These regulations contain a strict procedure for administrative complaints. First, a person alleging a violation of the regulations must file a complaint with OCR within 180 days of the alleged discriminatory event. 40 C.F.R. § 7.120(a). OCR is then required, within 20 days, to respond to the complaint; by either accepting, rejecting or forwarding the complaint to the appropriate federal agency. *Id*. In the event that the complaint is accepted for investigation, all relevant parties are then notified and given an opportunity to respond to the complaint in writing. 40 C.F.R. § 7.120(d)(2)(i). Next, the regulations provide for OCR to attempt to broker informal settlement. *Id*. Provided that resolution is not achieved, OCR must then make a preliminary determination after conducting an internal investigation into the matter. 40 C.F.R. § 7.115(c)(1)(i). If OCR makes a preliminary finding of noncompliance, it must advise the contravening party of how voluntary compliance may be achieved and of its right to engage in compliance negotiation. *Id*. The regulations make provision for the contravening party to request a hearing before EPA's Administrative Law Judge (ALJ), to challenge OCR's preliminary finding. 40 C.F.R. § 7.130(b). In the event that the preliminary finding is upheld by the ALJ, OCR is then entitled to bring a proceeding to terminate the contravening party's EPA funding under 40 C.F.R. § 7.130(a)–(b). If a complaint is denied, the complainant may challenge this denial under the Administrative Procedure Act. 5 U.S.C. § 706.

On February 11, 1994, President Clinton issued Executive Order No. 12,898, dealing with environmental justice. Exec. Order No. 12,898, 59 Fed. Reg. 7629 (1994). In broad terms, the Executive Order and its accompanying memorandum (which remain in effect) direct agencies to specifically address their responsibilities under Title VI and to formulate an environmental justice strategy. More specifically, the Order provides:

> [E]ach agency shall develop an agency-wide environmental strategy . . . that identifies and addresses disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority populations and low-income populations. The environmental justice strategy shall list programs, policies, planning and public participation processes, enforcement, and/or rulemaking related to human health or the environment that should be revised to, at a minimum: (1) promote enforcement of all health and environmental statutes in areas with minority populations and low-income populations; (2) ensure greater public participation; (3) improve research and data collection relating

> to the health of and environment of minority populations and low-income populations; and (4) identify differential patterns of consumption of natural resources among minority populations and low-income populations.

Id. The Executive Order was understandably perceived by the environmental justice movement as a renewed commitment on the part of the administration to act on its responsibilities under Title VI—responsibilities that EPA had largely avoided prior to 1993 for fear of disrupting state and local recipient agencies from pursuing pollution reduction initiatives. In the years following the issuance of the Executive Order, the OCR had difficulty responding to the number of complaints that were filed pursuant to the "disparate-impact" regulations. By 1998, despite having spent more than $50 million on investigations, the OCR had not resolved a single complaint. That year, EPA issued interim guidelines concerning the investigation of Title VI administrative complaints. EPA, INTERIM GUIDELINES FOR INVESTIGATING TITLE VI ADMINISTRATIVE COMPLAINTS CHALLENGING PERMITS (1998) (Interim Guidelines). The issuance of the Interim Guidelines, which was particularly controversial given its vague definition of "disparate impact," took place at the same time as the Shintech controversy (discussed in note 1 below)—which remains to this day the highest profile administrative challenge filed with the OCR pursuant to the "disparate-impact" regulations. In 2000, EPA revised its Interim Guidelines, in an attempt to provide greater certainty to recipients of federal funds of their obligations under Title VI. EPA, Draft Revised Guidance for Investigating Title VI Administrative Complaints Challenging Permits, 65 Fed. Reg. 39,650 (2000) (Revised Guidelines). Like the Interim Guidelines, the Revised Guidelines has been widely criticized. *See, e.g.*, Eileen Gauna, *EPA at 30: Fairness in Environmental Protection*, 31 ENVTL. L. REP. 10528, 10540–41 (2001); Tseming Yang, *The Form and Substance of Environmental Justice: The Challenge of Title VI of the Civil Rights Act of 1964 for Environmental Regulation*, 29 B.C. ENVTL. AFF. L. REV. 143, 156 (2002). The passage of the Revised Guidelines, which is yet to be formally adopted, did not result in any improvement in the rate at which complaints are processed by the OCR. As of August 2007, a total of 149 complaints had been lodged with the OCR pursuant to Title VI, of which 70 percent were dismissed or referred to other agencies, 6 percent were resolved informally, and 24 percent were pending. Much to the exasperation of the environmental justice movement, prior to 2011, the OCR did not find that a single recipient agency has acted in contravention of the "disparate-impact" regulations. For this reason, much contemporary environmental justice litigation attempts to defeat proposals on procedural grounds, rather than mounting a direct challenge against the disparate allocation of environmental risks.

NOTES AND QUESTIONS

1. Shintech. In August 1996, Shintech, a Texas-based subsidiary of a Japanese chemical manufacturer, announced that it was considering construction of a $700 million polyvinyl chloride (PVC) plant on a sugar cane plantation along the Mississippi River in St. James Parish, Louisiana. St. James Parish is located in Louisiana's "Cancer Alley," the eighty-five-

mile stretch along the Mississippi River from Baton Rouge to New Orleans. While the average American was exposed to around ten pounds of toxic releases per year (and the average resident within Louisiana 21 pounds), residents within St. James Parish were subjected to approximately 360 pounds of toxic air pollutants per year. The proposal was particularly controversial, given that the Shintech proposal would have emitted over 600,000 pounds of air pollutants annually (including 143,000 pounds of vinyl chloride) and 3.6 million gallons of wastewater.

In May 1997, the Tulane Law Clinic, on behalf of several citizens' groups, filed an administrative complaint under EPA's Title VI regulations, challenging the Louisiana Department of Environmental Quality's (LDEQ) approval of the Shintech Plant. The complaint made specific reference to the fact that 95 percent of the 300 people living within one mile of the proposed plant were black and that 49 percent of the households had incomes of less than $15,000. *See* THE LAW OF ENVIRONMENTAL JUSTICE: THEORIES AND PROCEDURES TO ADDRESS DISPROPORTIONATE RISKS 46 (Michael Gerrard ed. 1999). In response, Shintech argued that the St. James Parish site had been selected on the basis that it offered the best access to raw materials and infrastructure. EPA, for its part, treated the Shintech complaint as a test case, to determine the manner in which it would apply the "disparate-impact" regulations in light of Executive Order 12,898. *See* Angela M. Baggetta, *Environmental Justice: Black Caucus, EPA to Meet on Shintech; Dispute May Be Test Case on Title VI Suits*, DAILY ENV'T REP., Jul. 21, 1998, at A1.

As the following account demonstrates, the complaint quickly gave rise to a political controversy of national significance:

> Environmental justice advocates strongly encouraged EPA to veto the proposed facility because of the cumulative burden of adding even one more plant to the already significant health risks in the area. Business interests and many Louisiana politicians, however, argued that rejection of the permit would cost jobs and make it much more difficult to build any industrial facilities in minority areas in the future.
>
> Unfortunately, the disagreements between environmentalists and business interests over Shintech often became heated. The Tulane environmental law clinic donated thousands of hours to assist the Shintech complainants, but the clinic's involvement led Governor Foster to denounce the law students involved with the clinic as "outlaws". . . .
>
> The minority community in St. James Parish and nationwide divided about whether the proposed facility's economic benefits outweighed the health risks. The Louisiana NAACP initially opposed the plant, but the St. James chapter supported its construction. The U.S. Chamber of Commerce and the Black Chamber of Commerce began working together for the first time to repeal the EPA's environmental justice program on the grounds that the agency's policies will prevent investment in minority communities. On the other hand, nearly all members of the Congressional Black Caucus, including Louisiana's only African American congressperson, William Jefferson, urged EPA to veto the Shintech permit.

Id. at 46–47. Against this political backdrop, in September 1997, EPA ordered the LDEQ to temporarily revoke the permits it had issued Shintech pursuant to the CAA on technical grounds. EPA deferred a decision on the environmental justice complaint, noting that these issues were the subject of ongoing investigations. However, before the OCR was able to reach a preliminary finding on this issue, Shintech finally bowed to the obstacles that impeded the development of the plant, and moved their proposed site to Plaqueminne (an area with a significantly lower percentage of minority population).

The Shintech saga was hailed as a triumph for the environmental justice movement, despite the fact that EPA failed to reach a decision on the Title VI complaint. What lessons can environmental justice advocates take from the Shintech experience in mounting future challenges under the Title VI regulations?

2. EPA's "Disparate-Impact" Regulations. What might explain the apparent hesitancy on the part of EPA to find that a recipient agency has acted in contravention of its Title VI regulations? Why may EPA be reluctant to revoke federal funding of state agencies?

3. Inclusion of Community Groups. In April of 2011, in response to a complaint filed in 1999, EPA found that the California Department of Pesticide Regulation (CDPR) violated the disparate impact regulations by renewing the registration of the pesticide methyl bromide. The OCR concluded that the application of methyl bromide between 1995 and 2001 resulted in disparate impacts on Latino schoolchildren. While CDPR disputed this finding, CDPR entered into an agreement with EPA to resolve the complaint. This agreement requires CDPR and the California Air Resources Board to monitor certain locations through the end of 2013 and to perform public outreach to the Latino community in five counties with high methyl bromide use. The agreement notes that CDPR has independently implemented several new regulatory measures for methyl bromide since 2001. Is this an effective resolution of the complaint?

The complainants expressed dissatisfaction with the process by which EPA reached an agreement with CDPR. They particularly pointed to EPA's lack of consultation with the complainants in reaching an agreement. Center of Race, Poverty & the Environment, PRESS RELEASE: EPA FAILS TO ENFORCE CIVIL RIGHTS ACT (2011), *available at* http://www.ejnet.org/ej/angelitac-crpe-pr.pdf. EPA has given complainants an opportunity to submit recommendations in a subsequent Title VI settlement agreement. *See* Daria E. Neal, *Recent Developments in Federal Implementation of Executive Order 12,898 and Title VI of the Civil Rights Act*, 57 HOW. L.J 941, 956 (2014).

The Department of Justice has incorporated environmental justice considerations into some enforcement settlement agreements. In May 2012, citizen groups helped shape a settlement with BP Products North America Inc. regarding its Whiting, Indiana refinery. The agreement required BP to pay a civil penalty, spend $400 million on pollution controls, make fenceline monitoring data available to the public, and spend $9.5 million on projects to reduce carbon emissions. In 2011, the Missouri Coalition for the Environment was included in settlement negotiations with the St. Louis Metropolitan Sewer District. The resulting settlement will require the sewer district to invest in projects to alleviate sewer overflows in low-income areas and provide online updates to help low-income residents

connect to the sewer. Jessica Coomes, *DOJ Says Government Has Incorporated Environmental Justice Into Settlements*, 43 ENV'T. REP. 261 (2012).

Does giving complainants an opportunity to contribute to settlement negotiations provide an adequate process for resolution of complaints? What are potential pitfalls?

4. Combating Agency Delay. In addition to bringing suit against a denial of a complaint, a complainant may also sue EPA for failing to respond to a complaint within the deadlines provided by the regulations under 5 U.S.C. § 706(1). *Rosemere Neighborhood Ass'n v. EPA*, 581 F.3d 1169, 1172 (9th Cir. 2009). Discovery in *Rosemere* revealed that EPA did not respond to a single complaint within the deadlines in 2006 or 2007. *Id.* at 1175. The Ninth Circuit allowed the Rosemere Neighborhood Association to proceed with a suit for injunctive relief compelling EPA to respond to future complaints by the appropriate deadlines. *Id.* at 1172–76. Is this likely to be a widely useful remedy? The complaint in question in *Rosemere* was first filed in 2003, and the Association sued EPA for delay in 2005. This first lawsuit was dismissed as moot after EPA accepted the complaint. However, EPA continued to delay and the Ninth Circuit ruling came from an appeal of a second lawsuit filed by the Association in 2007. *Id.* at 1171–72. Consider also that in 2012 EPA dismissed a Title VI complaint filed in 1994, following litigation by the complainants commenced in 2011. *See Padres Hacia Una Vida Mejor v. Jackson*, 922 F. Supp. 2d 1057, 1059 (E.D. Cal. 2013).

5. Administrative v. Judicial Enforcement. Consider the differences in bringing an action for administrative enforcement (under EPA's "disparate-impact" regulations) as opposed to an action for judicial enforcement (such as under the Equal Protection Clause or under § 601 of Title VI of the Civil Rights Act). What are the relative advantages of each avenue of enforcement? Which would prove less costly? Which would provide the greatest scope for public participation? What remedies are available under each avenue?

6. Executive Order 12,898. What is the effect of Executive Order 12,898? In what ways does it affect the actions of federal agencies?

7. Interagency Working Group and Memorandum of Understanding. Executive Order 12,898 also established the Federal Interagency Working Group on Environmental Justice. In August 2011, ten executive departments and EPA signed a memorandum of understanding (MOU) committing each agency to create or update an Environmental Justice Strategy, to allow public comment on the Strategy, and to issue annual progress reports on the implementation of the Strategy. The MOU instructs agencies to focus on the implementation of the National Environmental Policy Act and Title VI of the Civil Rights Act of 1964, as well as impacts from climate change and commercial transportation and supporting infrastructure (such as highways and railroads). The MOU also established a Charter for the Interagency Working Group. The Charter provides for monthly meetings and a number of avenues for public participation and interagency cooperation.

8. Plan EJ 2014. In 2011, EPA issued "Plan EJ 2014," a compilation of numerous strategies to better incorporate environmental justice into the decisionmaking of EPA and other agencies. The goals of the Plan are (1) to

protect health in communities over-burdened by pollution, (2) to empower communities to take action to improve their health and environment, and (3) to establish partnerships with local, state, tribal, and federal organizations to achieve healthy and sustainable communities. The Plan contains five "cross-agency focus areas," four "tools development areas," and programs initiatives within EPA offices. The Plan calls upon the Agency to incorporate environmental justice in rulemakings, permitting, and compliance and enforcement decisions. In 2014, EPA is due to make an assessment of its progress in achieving the plan's goals, and to produce a report on "accomplishments, lessons learned, challenges and next steps for continuing [EPA's] efforts to make environmental justice an integral part of every decision." EPA, Plan EJ 2014, http://www.epa.gov/environmentaljustice/plan-ej/index.html (last visited Sep. 24, 2014). What value do non-enforceable strategy documents have in this context? Will political actors be able to stop these agency initiatives? Or will they be perpetuated by other actors in the executive branch?

9. Solid Waste and Environmental Justice. In July 2011, EPA proposed a rule to alter the definition of solid waste under the Resource Recovery and Conservation Act for certain types of hazardous secondary materials. EPA, Proposed Rule on Definition of Solid Waste, 76 Fed. Reg. 44,094 (July 22, 2011). As a part of this proposed rule, EPA incorporated a new environmental justice analysis for solid waste. The analysis contains six steps:

1. Hazard characterization;
2. Identification of potentially affected communities;
3. Demographics of potentially affected communities;
4. Identify other factors that affect vulnerability in potentially affected communities;
5. Assessment of disproportionate impact; and
6. Identification of potential preventive and mitigation strategies.

Id. at 44,103–04. Step 4 included two sub-steps: ability to participate in the decisionmaking process, and multiple and cumulative effects. *Id*. at 44,106–07. EPA explains that the result of an environmental justice analysis "can affect how EPA uses its policy discretion under applicable authorities to pursue specific regulatory options or provide opportunities to involve the public in the implementation of regulations." *Id*. at 44,103. Overall, EPA proposed to alter the definition of solid waste "to address the potential for adverse impacts to human health and the environment from discarded material, including disproportionate impacts to minority and low income communities." *Id*. at 44,107. Should the definition of solid waste depend on which communities are affected?

10. State Environmental Justice Initiatives. A number of states have adopted programs designed to address environmental justice concerns. *See generally* Chuck D. Barlow, *State Environmental Justice Programs and Related Authorities, in* THE LAW OF ENVIRONMENTAL JUSTICE: THEORIES AND PROCEDURES TO ADDRESS DISPROPORTIONATE RISKS 140 (Michael Gerrard ed., 1999). Recognizing "the critical role that local land use procedures play in the distribution of undesirable land uses," state programs typically focus on planning and zoning processes, in addition to

state environmental impact review and facility permitting procedures. ROBERT C. ELLICKSON & VICKI BEEN, LAND USE CONTROLS 759 (3d ed. 2005). For example, the Department of Environmental Conservation in the state of New York has adopted regulations that "increase opportunities for public participation in permitting processes, require scrutiny to identify permit applications that may affect low-income or minority communities, and enhance the opportunities for considering environmental justice concerns in the environmental impact review process." *Id.* How successful do you think such measures will be in addressing environmental justice concerns?

In 2012, California approved legislation that assigned 25 percent of proceeds collected from the state's greenhouse gas emissions cap-and-trade program to benefit disadvantaged communities that are disproportionately affected by climate change. The legislation followed litigation by environmental justice groups arguing that the cap-and-trade program would adversely affect communities living near large emission sources. Disadvantaged communities are identified on the basis of geographic, socioeconomic, public health and environmental hazard criteria. *See* Vien Truong, *Addressing Poverty and Pollution: California's SB 535 Greenhouse GAS REDUCTION FUND*, 49 HARV. C.R.-C.L. L. REV. 493 (2014). Is this approach desirable?