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Risky Reform

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BOOK REVIEW

RISKY REFORM

There are no whole truths; all truths are half-truths. It is trying to treat them as whole truths that plays the devil.¹

BREAKING THE VICIOUS CIRCLE: TOWARD EFFECTIVE RISK REGULATION. By Stephen Breyer. Cambridge, Mass.: Harvard University Press, 1993. Pp. 127.

THE DEATH OF COMMON SENSE: HOW LAW IS SUFFOCATING AMERICA. By Philip K. Howard. New York: Random House, 1994. Pp. 202.

SCIENCE AND JUDGMENT IN RISK ASSESSMENT. By National Research Council. Washington, D.C.: National Academy Press, 1994. Pp. 651.

WORST THINGS FIRST? THE DEBATE OVER RISK-BASED NATIONAL ENVIRONMENTAL PRIORITIES. Edited by Adam M. Finkel and Dominic Golding. Washington, D.C.: Resources for the Future, 1994. Pp. 342.

Reviewed by David A. Wirth and Ellen K. Silbergeld***

I. INTRODUCTION

The Republicans' Contract With America catapulted the subject of these four books—theories of environmental, public health, and safety regulation, and specifically the art and science of quantitative risk assessment—to the center stage of American politics.² The Contract sets out the goals and rationale for regulatory reform as follows:

1. Dialogues of Alfred North Whitehead 16 (Lucien Price ed., 1953).

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2. As part of a proposed "Job Creation and Wage Enhancement Act," the Contract advocates a variety of policy changes, including small business incentives, a capital gains cut, unfunded mandate reform, and "risk assessment/cost benefit analysis," all intended to

Congress is never forced to ensure that the benefits of regulation, better health and productivity, outweigh the costs, lost jobs, and lower wages. Nor does Congress pursue integrated health and safety goals. Instead, Congress and federal regulators often attack whatever health risk has caught the public's attention, even if its regulatory solution exacerbates other health risks.

The Job Creation and Wage Enhancement Act [proposed in the Contract] requires each federal agency to assess the risks to human health and safety and the environment for each new regulation. Agencies must also provide the cost associated with the regulation and an analysis comparing the economic and compliance costs of the regulation to the public. Each agency must form an independent peer review panel to certify the assessment and incorporate the best available scientific data. The review panel members must either possess professional experience conducting risk assessment or in the given field of study.³

In this succinct passage, the Contract stokes a seething public policy debate: the role of the quasi-scientific discipline of risk assessment in improving regulation. Although an attempt to fit all health and safety regulation into the template of quantitative risk assessment,⁴ in the form of the Dole-Johnston Comprehensive Regulatory Reform Act of 1995, recently failed,⁵ the issue will very likely remain an active part of the Republican Congress's legislative agenda and the response of the Clinton Administration to those initiatives.

While all four of the books reviewed here appeared in print before the 104th Congress took office in January, 1995, each offers trenchant observations on the current legal and policy debate. Justice Breyer's *Breaking the Vicious Circle*, written before his elevation to the Supreme Court, memorializes the 1992 Oliver Wendell Holmes Lectures delivered at Harvard University. Of the lot, this book is the most self-consciously "legal," while simultaneously addressing the interdisciplinary interfaces between law and economics, science, and regulatory policy. Although the next book covers greater ground than just regulatory policy for the environment and public health, *The Death of Common Sense*, written by a lawyer, received a great deal of attention in the popular press, graced the *New York Times* best seller list for twenty-five consecutive weeks earlier this year, and in many respects is a populist analogue of the Breyer book. In *Science and Judgment in Risk Assessment*, the National Research Council of the National Academy of Sciences ostensibly responds to a statutory directive in the 1990 Clean Air Act Amendments. In a much more far-reach-

"create jobs and raise worker wages." Republican National Committee, *Contract With America* 11 (Ed Gillespie & Bob Schellhas eds., 1994).

3. *Id.* at 131-32.

4. Quantitative risk assessment involves assigning numerical values indicating the likelihood of adverse health effects including mortality.

5. S. 343, 104th Cong., 1st Sess. (1995). See Senate Risk Reform Bill in Limbo, But Talks Expected to Resume, *Risk Pol'y Rep.*, Aug. 18, 1995, at 3.

ing review that is, to a large extent, a successor to the Council's seminal "Red Book"⁶ of a decade earlier, which first delineated a consensus view on the role of quantitative risk assessment in regulatory policy, *Worst Things First?* is a group of essays collected by the nonprofit Resources for the Future that was designed "to initiate debate about the plans of the U.S. Environmental Protection Agency (EPA) to use risk assessment and expert judgment to help set national priorities in a 'rational,' rather than solely a political or a crisis-oriented, manner" (Finkel & Golding, eds. p. xiii).

Particularly when taken together, this clutch of four books is emblematic of the current policy controversy. Breyer's and Howard's works are express calls for regulatory reform, and all the books at least assume that regulatory reform, or at least more coherent regulatory choices, are both desirable and possible. Breyer and some of the contributors to *Worst Things First?* offer detailed remedies for the alleged disease of regulatory irrationality. As in the Contract With America, comparative risk assessment is a principal, although not the only,⁷ component of the prescribed cure. The current Congress in particular appears determined to arrange an exclusive union between quantitative risk assessment and regulatory reform. Certainly as an historical matter, the two have often led independent lives. Even now it is far from obvious that they were intended to be partners, and the anticipated marriage may be considerably less than satisfactory. In addition, Howard, and especially Breyer, advocate an even more drastic realignment of the relationships among the Congress, the Executive Branch, and the courts.

As a response to the Contract With America, the pending legislative proposals addressing quantitative risk assessment, these four books, and other similar strains of argument, this Essay explores the role of the art and science of risk assessment in the ongoing national dialogue concerning regulatory reform—a debate that engages complex themes of populism, democracy, technocracy, rationalism, and science. The Essay evaluates quantitative risk assessment as a public policy and regulatory instrument and describes the impetus for its increasing use. The Essay then analyzes the use of quantitative risk assessment as a methodology for comparing risks from different substances or activities in response to dissatisfaction with current approaches for establishing regulatory priorities. Howard's and Breyer's tracts provide a vehicle for examining calls for the reform of risk regulation. Finally, the Essay gathers these threads in or-

6. National Research Council, *Risk Assessment in the Federal Government: Managing the Process* (1983).

7. These books, the Contract With America, and the pending legislation contain a number of other recommendations for changes in environmental, public health, and safety regulation, such as a greater reliance on cost-benefit analysis. The principal purpose of this Essay is to analyze the utility of risk assessment as a vehicle for regulatory reform. Other issues, such as cost benefit analysis, are addressed only to the limited extent necessary in that context.

der to evaluate the larger systemic proposals for structural reform of the administrative process, as articulated by Breyer and Howard.

II. THE CURRENT SCIENTIFIC AND POLICY DEBATE OVER RISK ASSESSMENT

Prior to the late 1970s, regulation of toxic chemicals to reduce risks of diseases such as cancer was generally based on one of three philosophies:

- technology-based approaches, in which the stated goal of controlling releases or concentrations of a regulated substance are defined, and limited, by the technical capability of specified pollution control systems or production process changes;
- public health or environmental standards, in which the goal of regulation is to achieve a health-based risk reduction without specified technical or economic implications. One regulatory strategy for achieving such goals is the imposition of outright bans or prohibitions on specified substances or processes, such as the use of lead in gasoline or the land disposal of dioxins. Another is the specification of specific health- or environment-based regulatory targets, such as a 99.99% reduction of PCBs in waste treatment, protecting 99% of children from elevated blood lead levels, or staying below a maximum allowable increase in estimated cancer risk of 1 in 100,000; and
- risk-balanced goals, in which a stated health-based risk reduction is to be achieved conditionally—by also taking into account the costs of achieving the goal and the nature and extent of the risks—or through optimally cost-effective means.

The first option has readily identifiable limitations from a public health and environmental point of view. There is no necessary congruence between what may be judged technically achievable and what is desirable from a public policy perspective. Similarly, environmental standards framed in terms of the second approach, such as “zero discharge” policies, are only empirically zero; that is, they usually define as “zero” a level or concentration below detection, which is a changing value as analytic technology improves. If available technologies, or even strongly encouraged developments in technology through the creation of regulatory incentives, are inadequate to reduce risks to the extent considered desirable from other perspectives, then further actions, such as limits on production or specific use, should be available to policymakers.

The third approach, risk-balanced policy, which is the dominant theory in current legislation, seems rational in concept but has proven largely unworkable in practice. The Toxic Substances Control Act⁸ was

8. 15 U.S.C. §§ 2601—2629 (1988). Interestingly, relatively few statutory authorities expressly require risk assessments by name. See, e.g., Clean Air Act § 112, 42 U.S.C. § 7412 (1988) (hazardous air pollution); Comprehensive Environmental Response, Compensation, and Liability Act of 1980 § 104, 42 U.S.C. § 9604 (1988) (response authorities for hazardous waste disposal sites). Cf. Final Act Embodying the Results of the

the first statute to require a consideration of the nature and magnitude of risk as a condition precedent to regulation. The rigor required for the necessary finding of "unreasonable risk" prior to regulation, defined by reference to a risk-benefit balancing approach, has substantially compromised the statute's effectiveness as an instrument of public policy.⁹ Application of cost-benefit analysis to determine appropriateness of action, while widely urged,¹⁰ does not overcome the problems inherent in calculating benefits (defined as risks ameliorated or avoided) in valuing those benefits, or in accurately estimating costs of risk reduction. Moreover, there are significant methodological limitations in monetizing such environmental amenities as visibility, wilderness preservation, or endangered species. Other approaches, such as "the precautionary principle"¹¹ or "toxics use reduction,"¹² claim to avoid many of these analytic problems. However, the selection of substances in these approaches often implicitly incorporates a risk assessment, although it may not be explicitly quanti-

Uruguay Round of Multilateral Trade Negotiations, Agreement on the Application of Sanitary and Phytosanitary Measures, Dec. 3, 1993, G.A.T.T. Doc. MTN/FA II-A1A-4 (risk assessment expressly required under agreement); North American Free Trade Agreement, done Dec. 17, 1992, Can.-Mex.-U.S., ch. 7, § B, art. 715, 32 I.L.M. 289 at 378 (requiring risk assessments for food safety measures).

9. One court, for instance, has established a stringent test that appears to diverge from legislative history indicating that only the roughest of cost-benefit balancing is required under TSCA. See *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1214 (5th Cir. 1991). There, the court set aside EPA's final rule banning the manufacture, importation, processing, and distribution in commerce of most asbestos-containing products, promulgated under authority of Toxic Substances Control Act, despite ten years of agency work on regulation and hundreds of studies on the effects of asbestos. See *id.* at 1230.

10. See, e.g., R.B. Belzer, *The Use of Risk Assessment and Benefit-Cost Analysis in U.S. Risk-Management Decision Making*, 1 Proc. London Conf. on Risk Assessment 421-42 (1992). So, for example, while the phasedown of lead in gasoline was implemented under the authority of section 211(c)(1) of the Clean Air Act, 42 U.S.C. § 7545(c)(1) (Supp. 1993), which refers only to health considerations, that action was based largely on the results of a cost-benefit analysis conducted by the Environmental Protection Agency.

11. "Precautionary approaches" that have lately gained increasing acceptance on the international level express a preference for earlier, rather than later, governmental action with a lower, as opposed to higher, threshold of scientific proof:

In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.

The Rio Declaration on Environment and Development, June 14, 1992, Principle 15, U.N. Doc. A/CONF.151/5/Rev.1 (1992), reprinted in 31 I.L.M. 874 at 879; cf. *Ethyl Corp. v. EPA*, 541 F.2d 1, 28 (D.C. Cir.) (en banc) ("Where a statute is precautionary in nature, the evidence difficult to come by, uncertain, or conflicting because it is on the frontiers of scientific knowledge, the regulations designed to protect the public health, and the decision that of an expert administrator, we will not demand rigorous step-by-step proof of cause and effect. Such proof may be impossible to obtain if the precautionary purpose of the statute is to be served.") (footnote omitted), cert. denied, 426 U.S. 941 (1976).

12. See, e.g., Mary O'Brien, *A Proposal to Address, Rather Than Rank, Environmental Problems, in Worst Things First?* 87 (Adam M. Finkel & Dominic Golding eds., 1994).

fied. Indeed, some form of risk assessment, whether explicit or implicit, is almost inescapable whenever priorities are established. Consequently, the real issue for debate is the nature and form that risk assessment ought to take.

In response to these and other limitations in then-existing regulatory approaches, efforts in all three branches of the federal government contributed to the subsequent emergence of quantitative risk assessment as a public policy tool. In early 1979, an interagency committee of the Executive Branch proposed guidelines for identifying and assessing chemical carcinogens. This early proposal on risk assessment was premised on the following principles:

- chemical exposures are a significant contribution to the overall incidence of human cancer;
- chemical-induced cancers can be prevented or reduced by identifying potential human carcinogens before exposure has occurred on the large scale necessary before a cause-and-effect relationship between exposure and disease is apparent in human populations; and
- the evaluation of potential carcinogens should be not just qualitative, but should include a numerical quantification of risks.¹³

Congress also began to enact legislation, such as the Toxic Substances Control Act, that made greater demands on regulatory agencies in terms of defining quantitative risk. The Supreme Court's 1980 opinion setting aside the Occupational Safety and Health Administration's permissible exposure limit for benzene for want of a finding of "significant risk" by the agency¹⁴ increased the momentum for quantifying risks.

The quantification of risks received still further impetus from the National Research Council's "Red Book,"¹⁵ published in 1983. The Red Book endorsed a bifurcation of the regulatory process into two phases: "risk assessment," which in principle establishes the strictly scientific basis for regulatory action, and "risk management," which is the multidisciplinary process of choosing and implementing regulatory measures.¹⁶ In

13. Ellen K. Silbergeld, *Risk Assessment: The Perspective and Experience of U.S. Environmentalists*, 101 *Envtl. Health Persp.* 100, 100-01 (1993) (evaluating the contribution of risk assessment as policy-making tool).

14. *Industrial Union Dep't v. Am. Petroleum Inst.*, 448 U.S. 607 (1980). The Supreme Court did not expressly require a numerical, as opposed to qualitative, characterization of risk to precede regulatory action. The Court did, however, find that the agency's finding that a reduction in exposure to benzene, a demonstrated carcinogen, would decrease the risk of disease was insufficient to satisfy the statutory standard. See *id.* at 646-52.

15. See *supra* note 6.

16. 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

this two-stage methodology, scientific questions can supposedly be isolated and addressed in an objective manner through risk assessment methodologies at the beginning of the regulatory process. Pure policy choices are theoretically confined to the second phase: risk management. At this stage, science may be relevant for such tasks as evaluating technical options. Risk management decisions, however, also engage other considerations—most notably economics and social values.¹⁷

Although not free from controversy, a number of generally accepted principles have since circumscribed the public policy debate over quantitative risk assessment. First, consistent with a strategy of anticipation and prevention, risk assessment was to proceed in the absence of data on human response, relying when necessary on results from experimental research on animals. Reliance upon nonhuman data was considered unavoidable when considering new chemicals, or new uses, prior to the oc-

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.

William D. Ruckelshaus, *Risk, Science, and Democracy*, Issues In Sci. & Tech., Spring 1985, at 19, 28. The Red Book itself defines the dichotomy as follows:

We use *risk assessment* to mean the characterization of the potential adverse health effects of human exposures to environmental hazards. Risk assessments include several elements: description of the potential adverse health effects based on an evaluation of results of epidemiologic, clinical, toxicologic, and environmental research; extrapolation from those results to predict the type and estimate the extent of health effects in humans under given conditions of exposure; judgments as to the number and characteristics of persons exposed at various intensities and durations; and summary judgments on the existence and overall magnitude of the public-health problem. Risk assessment also includes characterization of the uncertainties inherent in the process of inferring risk.

The term *risk assessment* is often given narrower and broader meanings than we have adopted here. For some observers, the term is synonymous with *quantitative risk assessment* and emphasizes reliance on numerical results. Our broader definition includes quantification, but also includes qualitative expressions of risk. Quantitative estimates of risk are not always feasible, and they may be eschewed by agencies for policy reasons. Broader uses of the term than ours also embrace analysis of perceived risks, comparisons of risks associated with different regulatory strategies, and occasionally analysis of the economic and social implications of regulatory decisions—functions that we assign to risk management.

National Research Council, *supra* note 6, at 18.

17.

[R]isk management . . . describe[s] the process of evaluating alternative regulatory actions and selecting among them. Risk management, which is carried out by regulatory agencies under various legislative mandates, is an agency decision-making process that entails consideration of political, social, economic, and engineering information with risk-related information to develop, analyze, and compare regulatory options and to select the appropriate regulatory response to a potential chronic health hazard. The selection process necessarily requires the use of value judgments on such issues as the acceptability of risk and the reasonableness of the costs of control.

National Research Council, *supra* note 6, at 18–19.

currence of any human exposure. This rationale owed much to experience with the regulation of new pharmaceuticals and pesticides, in which "preclinical" or animal data could serve as a sufficient basis for decision-making. Second, agencies were to provide quantitative estimates of dose at a level of risk that was deemed to be politically acceptable. For instance, a one-in-a-million (10^{-6}) probability of developing a disease, typically cancer, over a lifetime of exposure is often taken as a consensus benchmark. Third, risk assessments were to be presumptively conservative, that is, protective of human health in the case of uncertainty. In the absence of empirical data, default assumptions were to be chosen so that the *actual* risk from the kind of long-term, low-level doses that characterize most human and environmental exposures was likely to be no greater than that calculated using a risk assessment methodology.

Despite several rounds of evaluation of quantitative risk assessment methodologies by the National Research Council (NRC) and other advisory bodies, Congress has continued to request further refinement in the scientific evaluation of the process, largely because of its dissatisfaction with the results of public policies based on risk assessment methodologies. In risk assessments, politicians have hoped to find magic answers to issues that the regulated sector considers most troubling: principles of extrapolation from animals to human doses; models for estimating low dose risk; and management of uncertain or incomplete data sets in assessments. During the 1980s, there were allegations that current practice at EPA and other agencies piled assumption upon assumption, resulting in assessments significantly biased toward conclusions of higher, rather than lower, risks. EPA was charged with ignoring important data that might modify such calculations and reduce estimated risks, and with presenting risk assessment results with inadequate attention to the uncertainties or range of equally probable estimates.

Science and Judgment in Risk Assessment is the most recent report on risk assessment, requested by Congress in the Clean Air Act Amendments of 1990 and published by the NRC in 1994. This massive volume largely reaffirms earlier statements on the subject, together with all their shortcomings, and gives little satisfaction to any side. To the critics of risk assessment-based policy, the NRC generally endorses the theory and practice at EPA, while calling upon the agency to continue its commitment to periodic review of its principles and practice. While *Science and Judgment* expresses dissatisfaction with current model-based approaches concerning the relationships between dose and risk at low levels of exposure, the book also acknowledges the absence of compelling information to change most of the assumptions first stated in 1979. To practitioners of risk assessment at EPA, the report gives less guidance than was expected in terms of handling uncertainties in risk estimates and incorporating new information.

The NRC's recommendations fell short of recognizing the major limitations in current risk assessment practice: the dearth of actual data,

animal or human, upon which to base risk assessments, and the lack of sophisticated methods to evaluate noncancer risks. The major problem with most risk assessments continues to be lack of data rather than inappropriate assumptions or models. No change in the repertoire of "defaults" or assumptions will overcome the need to use them as long as incentives continue to reward lack of information.¹⁸

The NRC's failure to address the need for methods to evaluate noncancer risks, as specifically requested by the statute, is even more serious. In an era when comparative risk assessments are increasingly used and form the major thesis for such approaches as those endorsed in *Worst Things First?*, there is little recognition of the fact that there are no formal methods to allow us to compare, for instance, risks of benzene with those of lead. The recent attempt by Adam Finkel, one of the editors of *Worst Things First?*, to compare the risks of alar with those of aflatoxin,¹⁹ while ingenious, sidesteps the major methodological and conceptual problems of comparing unlike outcomes. No rational system of risk comparison or prioritization, as called for by EPA in its reports on relative risk reduction, can function unless objective methods for risk calculation exist. In the present situation, because of the complexity and ability of cancer-focused methods to estimate low dose risks (whether or not this is done accurately is another question), cancer risks will tend to take precedence over other risks,²⁰ resulting in continued distortions in public policy.²¹

III. COMPARATIVE RISK ASSESSMENT IN REGULATORY POLICY

Quantitative risk assessment has been employed not only to evaluate risks from individual chemicals, but also to compare risks from different substances. In this context, the approach is often known as "comparative risk assessment." Breyer's work, *Worst Things First?*, and the National Research Council's publication all ascribe considerable importance to comparative risk assessment as an analytical methodology for scientifically ranking risks and for facilitating an ordering of regulatory priorities. When confronted with the title question of *Worst Things First?*, one's natural response is: "But of course. Why not?" Unfortunately, the methodological limitations of quantitative risk assessment are only compounded when applied to the comparisons inherent in this question.

18. See, e.g., Risk Assessment and Cost/Benefit Analysis: Hearings on Title III of H.R. 9 Before the House Comm. on Science, 104th Cong., 1st Sess. 2 (1995) (testimony of Ellen K. Silbergeld, Senior Toxicologist, Environmental Defense Fund).

19. See Adam M. Finkel, Toward Less Misleading Comparisons of Uncertain Risks: The Example of Aflatoxin and Alar, 103 *Envl. Health Persp.* 376 (1995).

20. See generally Joseph V. Rodricks, Calculated Risks: Understanding the Toxicity and Human Health Risks of Chemicals in Our Environment 227-28 (1992) (assessing risks of chemical and carcinogen exposure).

21. See Ellen K. Silbergeld & Kevin Tonat, Investing in Prevention: Opportunities to Prevent Disease and Reduce Health Care Costs by Identifying Environmental and Occupational Causes of Noncancer Disease, 10 *Toxicology & Indust. Health* 675, 675-77 (1994).

Risk assessment is a tool for analyzing empirical data in a manner useful for crafting regulatory policy. Those data under some circumstances may be produced by epidemiological studies that survey exposed human populations. However, as discussed above, in most cases toxicological tests on laboratory animals are the only source of relevant data. This empirical information, whatever its source, must then be extrapolated to actual environmental settings, which may be very different from those under which the data were collected. For instance, animal tests are ordinarily conducted at high doses and over a short period by comparison with the levels to which human beings typically experience long-term exposure to environmental toxins. As the editors of *Worst Things First?* acknowledge, these inferences, while necessary because of limitations on data gathering in both humans and animals, inevitably introduce uncertainty into any risk assessment: "Uncertainties in low-dose extrapolation and potency differences across species, within species, and across different routes of exposure complicate estimates of risk and make it difficult to know when enough risk research has been done" (Finkel & Golding, eds. p. 194). Additionally, this extrapolation necessarily requires inferences, choices, and assumptions that themselves reflect policy preferences, an area sometimes included in "science policy."²²

A. Approaches to Comparative Risk Assessment

Comparative risk assessment, more recently proposed as a vehicle for comparing risks from different substances and exposures,²³ has received a great deal of attention from a policy perspective both in and outside government. After William Ruckelshaus returned to EPA as Administrator in 1983, the agency made some systematic attempts to prioritize risks from a variety of sources. The subsequent EPA Administrator, Lee M. Thomas, initiated a process that led to an analysis by the agency's Science Advisory Board of the potential utility of comparative risk methodologies in *Unfinished Business: A Comparative Assessment of Environmental Problems*, published in 1987.²⁴ Under Thomas's successor, William K. Reilly, EPA's

22. See Carnegie Commission on Science, Technology, and Government, *Risk and the Environment: Improving Regulatory Decision Making* 78 (1993) (noting that "[r]isk assessment can be most useful when those who rely on it to inform the risk management process understand its nature and its limitations, and use it accordingly"); National Research Council, *supra* note 6, at 28-37 (analyzing scientific and policy judgments in risk assessment).

23. "Comparative risk assessment is simply the act of evaluating two or more risks simultaneously and juxtaposing the results for the purposes of examining whether the relative effort devoted to each risk should be changed." Adam M. Finkel, *Should We—and Can We—Reduce the Worst Risks First?*, in *Worst Things First?* 3, 7 (Adam M. Finkel & Domínez Golding eds., 1994).

24. As stated in the Agency's staff paper prepared for the Resources for the Future conference,

The publication of the report, *Unfinished Business: A Comparative Assessment of Environmental Problems*, was an important milestone in the development of risk-based priority setting. The seventy-five EPA professionals responsible for this

Science Advisory Board elaborated on its earlier evaluation of the policy implications of comparative risk assessment in *Reducing Risk: Setting Priorities and Strategies for Environmental Protection*, which appeared in 1990.²⁵

effort divided the universe of environmental problems into thirty-one areas, many of which were intentionally aligned with existing programs and statutes. For each problem area they considered four different types of risk: cancer risk, noncancer health risk, ecological effects, and welfare effects. The participants assembled and analyzed masses of existing data on pollutants, exposures, and effects, but ultimately had to fill substantial gaps in available data by using their collective judgement. They acknowledged that their conclusions represented as much expert opinion as objective and quantitative analysis. But despite the difficulties caused by lack of data and lack of accepted risk assessment methods in some areas, the participants were relatively confident in their final relative rankings.

This project team assumed that current controls would stay in place, and concentrated their attention on the remaining or "residual" risks that might require EPA involvement. The major results of the project were as follows:

- No problems rank relatively high in all four types of risk, or relatively low in all four. Whether an environmental problem appears large or not depends critically on the type of adverse effect with which one is concerned.
- Problems that rank relatively high in three of four risks types, or at least medium in all four, include: criteria air pollutants; stratospheric ozone depletion; pesticide residues on food; and other pesticide risks (runoff and air deposition of pesticides).
- Problems that rank relatively high in cancer and noncancer health risks but low in ecological and welfare risks include: hazardous air pollutants; indoor radon; indoor air pollution other than radon; pesticide application; exposure to consumer products; and worker exposures to chemicals.
- Problems that rank relatively high in ecological and welfare risks but low in both health risks include: global warming; point and nonpoint sources of surface water pollution; physical alteration of aquatic habitats (including estuaries and wetlands); and mining waste.
- Areas related to groundwater consistently rank medium or low.

The task force observed that EPA's budgetary and operational priorities did not track well with these estimates of remaining risk, but they did not make any recommendations about how priorities ought to be changed. Nevertheless, their efforts precipitated a great deal of internal and external debate as to the usefulness and appropriateness of using risk to set priorities in EPA, and they laid the groundwork for more systematic attempts in the years that followed.

Charles W. Kent & Frederick W. Allen, An Overview of Risk-Based Priority Setting at EPA, in *Worst Things First?* 47, 50-51 (Adam M. Finkel & Dominic Golding eds., 1994) (citations omitted).

25. According to the Agency's staff paper prepared for the Resources for the Future conference,

Soon after he arrived at EPA, Administrator William K. Reilly requested that the Science Advisory Board (SAB)—EPA's panel of outside scientists—review *Unfinished Business*, including its data, methodology, and conclusions, with the purpose of advising him whether this approach should be used for setting broad, long-term priorities for the agency.

The SAB worked intensively for over a year at this task. In its report, *Reducing Risk: Setting Priorities and Strategies for Environmental Protection*, published in September 1990, the SAB generally endorsed the approach taken in *Unfinished Business* with several strong caveats. It cautioned that much work remains to be done in developing data, refining the methodology, and applying comparative risk conclusions in a regulatory context. It also was careful to point out the

Comparative risk assessment is the exclusive focus of *Worst Things First?*, *Breaking the Vicious Circle* relies heavily on the technique in Justice Breyer's diagnosis of regulatory failure and his proposals for regulatory reform, and *Science and Judgment in Risk Assessment* necessarily addresses the topic as one of the current issues in the larger debate currently taking place over the utility of quantitative risk assessment. The last of these publications summarizes both the scientific and policy debate surrounding the use of comparative risk assessment as a normative vehicle for priority or agenda setting as follows:

Some analysts have pointed out that the failure to pay sufficient attention to the results of risk assessment has resulted in misplaced priorities and regulatory actions that are driven by social forces, not by science. They note that the fact that risk assessment is imperfect does not justify the use of decision-making approaches that suffer from even greater imperfections.

On the other hand, some commentators feel that risk assessment has been given too much weight, especially in light of its methodological limitations and inability to account for unquantifiable features of risk, such as voluntariness and fear. (National Research Council p. 42.)

Worst Things First? memorializes a three-day conference on comparative risk assessment sponsored by the Center for Risk Management of Resources for the Future (RFF), a nonprofit policy research institution, that was held on November 15–17, 1992 in Annapolis, Maryland. The editors, admitting some "trepidation" (Finkel & Golding, eds. p. 335), have succeeded in offering a reasonably broad array of perspectives on comparative risk assessment, including both criticisms and endorsements of the approach and a range of nuances in between. Given the timing of the conference, immediately after the election of President Clinton, the book was intended not only to assess EPA's application of the comparative risk

limitations inherent in estimating and comparing different kinds of risks. However, the SAB exhorted the agency to push forward with risk-based planning as a legitimate and useful priority-setting tool. In a series of ten general recommendations it urged that EPA:

- target its efforts on the basis of risk reduction opportunities;
- emphasize ecology as much as health;
- improve the data and methods used for comparative risk analysis;
- reflect risk-based priorities in its strategic plans;
- reflect risk-based priorities in its budget process;
- make greater use of all tools available to reduce risk;
- emphasize pollution prevention as the preferred option for addressing pollution problems;
- increase efforts to integrate environmental concerns into public policy throughout the government;
- work to improve public understanding of environmental risks and train the workforce; and
- develop improved analytical methods to value natural resources and to account for long-term environmental effects.

assessment methodology, but also to advise the incoming administration "as it weighed continuing, modifying, or rethinking the existing momentum toward risk-based environmental planning" (Finkel & Golding, eds. p. 12). The volume collects a keynote address by Alice Rivlin, currently Director of the President's Office of Management and Budget, sixteen commissioned papers, and additional editorial overviews resulting from the meeting.

Although not billed as such, the intellectual energy in the book is supplied by Richard B. Belzer, an economist with the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget (OMB), located in the Executive Office of the President. His contribution would be of interest if only because of the central institutional role of OMB from the Carter Administration onwards in promoting a "rational" ordering of priorities for environmental, public health, and safety regulation. But Belzer's essay is equally interesting for its unapologetic and aggressive deregulatory perspective:

The most democratic institution we have for setting priorities is the marketplace. Every day, millions of Americans make trillions of choices involving health risks and many other things. These decisions generally make sense, and government should not arrogate to itself the right to improve upon them. The moral basis for environmental policy vanishes if government itself abandons this fundamental American principle. The risk-based paradigm [based on a comparative risk assessment methodology] would become nothing more than benign despotism; its competing paradigms would offer us something considerably worse. (Finkel & Golding, eds. p. 180.)

One may well take issue with the assertion that "voting" by consumers through the expenditure of their dollars in the marketplace, when those dollars are distributed unequally throughout the population, is more "democratic" than collective public action undertaken through political institutions. Certainly Robert Bullard, who characterizes environmental justice for the poor and racial and ethnic minorities as a right in his essay which appears later in the book (Finkel & Golding p. 241), would disagree. And as has also often been noted, there are serious questions concerning fundamental limits on the incorporation of all externalities into the decisions of the marketplace.²⁶

Belzer's assertion is telling in that it plainly states that risk-based priority setting is the next best thing to outright deregulation.²⁷ Even Philip Howard's populist analysis in *The Death of Common Sense* does not go so far as Belzer, who, indeed, turns out to be the only outright advocate of de-

26. See, e.g., Kenneth Arrow et al., *Economic Growth, Carrying Capacity, and the Environment*, 268 *Science* 520, 520-21 (1995).

27. Certainly Justice Breyer, who is no less enthusiastic about comparative risk assessment, at least claims to disagree with such a conclusion. To the contrary, Breyer would likely argue, the purpose of agenda and priority setting is to assure the maximum efficacy of governmental regulation given the limited resources that might be devoted to it.

regulation in *Worst Things First?*. It is not difficult to see how this philosophy has led to such obvious distortions of risk assessment methodologies as the controversial "risk-risk" analysis suggested by the Contract With America's allusion to "regulatory solution[s that] exacerbate[] other health risks."²⁸

Belzer affirmatively articulates and succinctly defends the central components of what the editors of the book describe as a "hard" or quantitative version of the comparative risk assessment paradigm:

Although different observers' definitions of these two variants may not match precisely, the basic features of the hard version involve the use of expert panels to generate "best estimates" of the most probable magnitude of various risks, focusing on quantifiable dimensions such as the number of fatalities or the size of affected geographical areas. The experts then compare the sizes of the risks to either the current or potential costs of reducing each risk and recommend priorities designed to achieve the "biggest bang for the buck" in reducing risk, given resource constraints. . . .

In contrast, the soft version starts from the premise that risk is multidimensional and represents the confluence of a variety of public values and attitudes. A soft ranking of risks, therefore, would tend to be more impressionistic than formulaic; it might use the number of fatalities as a rough starting point, but would modify the ranking by folding in various factors, such as the qualities of dread, mistrust, and uncertainty associated with each risk, the equity (or lack thereof) in how each risk is borne by various individuals and subpopulations, and the perceived benefits the risk substance or activity confers. According to the proponents of the soft version, the only way to incorporate such factors, and enhance the legitimacy of the resulting priorities or risk rankings, is to give the public equal stature with the experts from early stages of the analysis. (Finkel & Golding, eds. pp. 7-8.)

28. See *supra* text accompanying note 3. For example, Justice Breyer provides an example of an asbestos abatement project in a tunnel, which was temporarily closed to joggers. Instead of retracing their steps, the joggers ran across a busy street, thereby increasing their exposure to risks (Breyer p. 28). However, the two sorts of risks are not comparable. One—crossing the busy street in an inappropriate place—is voluntary and the other—exposure to asbestos—is involuntary, or at least unknowing. An example of another influential article that engages in this sort of inappropriate reductionism, advocated most notably by OMB during previous administrations, is John F. Morrall III, A Review of the Record, Regulation, Nov.-Dec. 1986, at 25. See also Frank Swoboda, OMB's Logic: Less Protection Saves Lives: Letter Blocking Health Standards for 6 Million Workers Shocks Officials at Labor Dept., Wash. Post, Mar. 17, 1992, at A15 (discussing OMB decision to block new health standards because of potential wage and employment loss). Breyer relies on similar OMB analyses, which are largely unsubstantiated, in his discussion of tradeoffs in risks. (Breyer pp. 21-29) Howard, too, makes similar arguments. (Howard pp. 79-88)

F. Henry Habicht II, at the time of the conference the Deputy Administrator of EPA, articulates another vision of comparative risk assessment in his essay entitled "EPA's Vision for Setting National Environmental Priorities" (Finkel & Golding, eds. pp. 33-46). Habicht's description sounds somewhat "softer" than what Belzer advocates: "In fact, EPA's sense always was that a rigorous evaluation of relative risk is an important input for environmental policy, but that the people, through democratic institutions, are empowered, rightly, to decide what risks society should care most about and how to address them" (Finkel & Golding, eds. p. 38). Although this proposal has rhetorical appeal, the editors note that 95% of the Agency's budget is subject to Congressional mandates, leaving only 5% available for discretionary priorities established within the Executive Branch.

B. *The Scientific Basis for Comparative Risk Assessment*

The remainder of the pieces in *Worst Things First?* can be read as responses to the presentations by Belzer and Habicht. Not surprisingly, given the EPA's simultaneous use and evaluation of comparative risk assessment, some contributions are normative critiques; others are methodological. For instance, on the normative level Mary O'Brien describes proposals to rank environmental problems on the basis of relative risk as "essentially Sophie's choice writ large" (Finkel & Golding, eds. p. 89). Other authors reject comparative risk assessment as a model, with Barry Commoner offering instead the alternative of pollution prevention (Finkel & Golding, eds. pp. 203-228), Robert Bullard emphasizing the need for social justice for low-income and minority communities as an essential component of environmental decisionmaking (Finkel & Golding, eds. pp. 237-266), and Nicholas Ashford advocating technology-forcing as a philosophy of regulation (Finkel & Golding, eds. pp. 275-314). Still others, emphasizing application of the approach, offer more procedural solutions. Jonathan Lash perceives risk assessment as but one component of an integrated approach that also accounts for democracy and values (Finkel & Golding, eds. pp. 69-86). Donald Hornstein identifies procedural deficiencies in the "hard" model of comparative risk assessment, including overreliance on expert decisionmaking, overrepresentation of special interests, limited opportunities for public participation, and, ultimately, a lack of political legitimacy (Finkel & Golding, eds. pp. 147-65). Belzer's response to each of these critiques is unyielding: "*Are we really trying to reduce risks to human health and the environment, or is environmental protection merely an expedient vehicle for the achievement of other political objectives?*" (Finkel & Golding, eds. p. 168) (emphasis in original).

The rejoinder to Belzer's starkly phrased question depends in large part on the scientific integrity of comparative risk assessment. Belzer's question assumes that through the use of comparative risk assessment we can accurately identify those risks in need of action and, moreover, that we can appropriately calibrate interventions to adjust an otherwise per-

fect market in order to achieve greater or more equitable net benefits. The first of these propositions is far from free of scientific controversy, and scientific considerations counsel extreme caution in the application of comparative risk assessment.

Unfortunately, admonitions about the scientific limitations of comparative risk assessment have often been ignored rather than heeded by enthusiasts whose imagination has been captured by the apparent power of the approach.²⁹ Similarly, although they lie squarely at the core of the comparative risk methodology, purely scientific considerations receive curiously little attention in *Worst Things First?* and plainly constitute the weakest portion of the work. Few of the authors appear to have much first hand, day-to-day experience in performing risk assessments. Of the book's sixteen-plus essays, only two are presented as addressing "methodological concerns," and even those cover a relatively restricted range. Many of the contributors to *Worst Things First?* lament the limited input the public is likely to have in the technical business of risk assessment, but the book as a whole makes precious little attempt to bridge this gap.

From a scientific point of view, the most interesting exchange in *Worst Things First?* consists of an essay by Dale Hattis and Robert L. Goble which criticizes comparative risk assessment and another essay by M. Granger Morgan defending it. Hattis and Goble focus on the uncertainties inherent in comparative risk assessment, asserting that "it is clear from *Reducing Risk* that uncertainties will swamp any serious attempt to develop quantitative—as opposed to impressionistic—rankings on a top-down basis" (Finkel & Golding, eds. p. 126).³⁰ Hattis and Goble offer two additional incisive observations. First, they correctly distinguish between the largest risks as determined by a comparative risk assessment approach and the risks most amenable to cost-effective elimination or amelioration, whose identification requires a multi-factored policy judgment. The fallacy of equating the two, they note, flows from the artificial distinction between risk assessment and risk management, which is exacerbated under the conditions of scientific uncertainty that characterize most risk assessments.³¹

29. Justice Breyer, for example, appears to assume the legitimacy of the approach he relies on so heavily without necessarily examining its scientific limits. Breyer's analysis in *Breaking the Vicious Circle* is of the "hard" variety, at one point comparing the size of a variety of risks such as being struck by lightning by reference to a calculation of the risks presented by smoking a specified number of cigarettes over the course of a lifetime (Breyer p. 5). However, he makes no claim to scientific expertise (p. ix), and certainly no scientist would make the mistake of describing PAHs as "polynuclear" instead of "polycyclic" aromatic hydrocarbons (Breyer p. 17).

30. *Science and Judgment in Risk Assessment* reaffirms this observation in an important passage buried in a footnote in an appendix toward the end of the book: "[R]isk ranking under uncertainty is a complicated and error-prone process, regardless of whether conservative, average, or other point estimates are used to summarize each risk" (National Research Council p. 617 n.13).

31.

Second, Hattis and Goble observe that:

[r]isk analyses done in the context of a priority-setting question also will need to be somewhat different from risk analyses done in the context of full formal regulatory decision making. . . . One does not want the priority-setting enterprise to consume a major portion of the resources available to accomplish real change in the world. (Finkel & Golding, eds. p. 123.)

This critical point in the debate over risk-based priority setting is one that many commentators fail to appreciate. The integrity of any such process requires consideration of the largest possible universe of potential risks. To the extent that only the best understood risks are considered, the process loses its *raison d'être*. But, paradoxically, including risks as to which there are significant data gaps compromises the scientific validity of any conclusions.³² As Hattis and Goble appropriately caution, either setting the threshold of scientific certainty too high in a priority setting scheme or insisting on lengthy study of a potentially endless catalogue of poorly understood risks can divert resources from regulatory action. To paraphrase Belzer, are we really trying to reduce risks to human health, or are we erecting a risk-based priority setting structure as an impediment to action?

Morgan, ostensibly in defense of comparative risk assessment, begins by positing a dollar ratio of the cost of an optimally cost-effective risk management option to its quantified benefits. An array of the resulting values permits a ranking of those policy responses that have the greatest payoff per unit of investment. However, the author rapidly retreats from this rather simplistic, mechanistic approach. He acknowledges that his proposed calculus for risk ranking itself

is a normative choice. [That formula] chooses to set ranks so as to get the most risk reduction per mitigation dollar spent. But other considerations, such as equity, individual controllability, and so forth may also matter. . . . In principle, if one is careful in defining [the costs and benefits of regulation], all these other

The current trend toward distinguishing risk assessment from risk management has concealed . . . problems [of scientific uncertainty] and exacerbated them. Yet, how they are resolved may influence policy choices for the risk manager. If the manager fails to understand how these issues [involving scientific uncertainty] were resolved in a specific risk assessment, it limits his understanding of his options. At present, . . . there is no definitive scientific resolution for [certain] issues. Their treatment is properly at the interface of risk assessment and risk management, an interface which the artificial segregation of these activities makes increasingly difficult to define and analyze.

Ellen Silbergeld, *The Uses and Abuses of Scientific Uncertainty in Risk Assessment*, Nat. Resources & Env't, Fall 1986, at 17, 59.

32. *Reducing Risk* repeatedly and correctly identifies deficiencies in scientific information as a serious impediment to risk-based priority setting. See U.S. Environmental Protection Agency, *Reducing Risk: Setting Priorities and Strategies for Environmental Protection 8* (1987) [hereinafter *Reducing Risk*]. Nonetheless, the publication then goes on to carry out precisely that exercise. *Id.*

considerations will be captured. In practice, this is likely to be extremely difficult. The report *Reducing Risk* by the U.S. Environmental Protection Agency (EPA) recommends that EPA should set its priorities so as to take "advantage of the best opportunities for reducing the most serious remaining risks" . . . Clearly there is a long way to go between this imprecise statement and a workable definition of [a function that ranks regulatory priorities in quantitative terms]. (Finkel & Golding, eds. p. 135.)

Monetizing these components of the calculation, especially benefits, can present serious methodological difficulties. Moreover, admits Morgan, in all but the easiest cases scientific uncertainties make it difficult to rank risks in any meaningful way. Indeed, the NRC's *Science and Judgment* encourages regulatory authorities to attach quantitative ranges of uncertainty as a remedy for "artificially precise single estimates of risk" (National Research Council p. 166), a development that is likely only to exacerbate the difficulties of comparing risks. In lay terms, if our notions of what is "bigger" or "smaller" are foggy as opposed to precise, how much confidence can we have in a resulting ranking? Although billed as a kind of "point-counterpoint," the two pieces in *Worst Things First?* devoted to scientific considerations tend to collapse toward the center, with Morgan, the supposed proponent of comparative risk assessment, "endors[ing] Hattis and Goble's cautions about the limits of [quantitative] analysis and the need to use it as a vehicle for insight and guidance, not as a strategy for getting answers" (Finkel & Golding, eds. p. 143).

In reality, the scientific limitations of comparative risk assessment are rather more extensive. Risk estimates reduced to a single number, even one modulated by a quantified range of uncertainty, often cannot be compared. First, the metrics for comparison may diverge on such issues as whether risks are summed over a lifetime of exposure. For example, the frequently quoted risk of one in nine of developing breast cancer refers to the likelihood that a woman will contract the illness at some time over her entire lifespan, rather than the risks for any woman at a particular time. Second, as the editors of *Worst Things First?* acknowledge, "the synergistic effects of multiple insults to humans and ecosystems are largely unexplored" (Finkel & Golding, eds. p. 194). The nature of the risks from various substances themselves often cannot be equated. For instance, the likelihood of non-cancer neurological effects in children from low-level lead exposure are relatively certain, on a continuum with dose rather than dichotomous, and directly correlated to the level of exposure. By contrast, risk estimates of carcinogenicity embody much more of a probabilistic concept, addressed to the likelihood of effects in the relatively distant future and not to the severity of the illness. Significantly, neither *Unfinished Business* nor *Reducing Risk* identified lead poisoning as a serious hazard requiring additional attention from the Environmental Protection Agency. It is precisely this fixation with risk assessments for cancer-causing substances that produces a methodological

approach that may give incorrect answers, while simultaneously inviting critiques, such as Justice Breyer's allegation of overzealous regulation of small risks (Breyer pp. 11-19).

Serious data gaps for even the most highly suspect bad actors can significantly affect the confidence level of individual risk assessments and undermine their "comparability."³³ Just because we reduce an incomplete data set to a single number does not mean that we understand anything more about the substance involved. Indeed, such an approach may well mask significant underlying uncertainties. For precisely this reason, the committee that authored *Science and Judgment* urged EPA to discontinue the practice of precisely defining "point estimates" of risk. Instead, the committee suggests that the agency should offer a range of risks appropriate to the nature of the underlying data set.

In conducting risk assessments, as in other areas, the perfect should not be the enemy of the good. Unfortunately, however, in many risk assessments the underlying data is insufficient, and there are no widely accepted criteria for determining minimum adequacy. These difficulties are magnified in the case of comparative risk assessment which, by definition, involves multiple risk assessments.

C. *The Normative Choices Inherent in Comparative Risk Assessment*

Even if all these impediments could be addressed, risk assessments can never be expected to capture the following attributes of risk, all of which embody value judgments that should be considered in establishing public policy priorities:

- the involuntary or voluntary character of exposure to the risk;³⁴
- the extent to which the risk is concentrated in particular populations; and
- the potential for catastrophic harm even if the long-term, chronic risk is low.

Although artificially compartmentalized in the risk management phase of the regulatory process, the following attributes of public policy responses are relevant to the priority-setting process as well:

- the availability of technological options to reduce or eliminate the risk;
- the necessity for collective or governmental action as opposed to individual responses;
- the kind and degree of collective action required—e.g., labeling as opposed to an outright ban;

33. See generally Ellen K. Silbergeld, *The Risks of Comparing Risks*, 3 N.Y.U. Envtl. L. J. 405, 406 (1994) (arguing that comparative risk assessment proposals will not promote efficient government because of difficulty of meeting methodological and data requirements).

34. See, e.g., *supra* note 28 (Breyer's example of jogger).

- the extent to which the costs of regulation and the benefits may be unevenly distributed;
- the administrative resources likely to be required to reduce or eliminate risks; and
- the political acceptability of likely public policy responses.

Acknowledging these plainly relevant characteristics of a given risk does not compromise the rationality of a "hard" approach to risk-based priority setting. Rather, given the methodological limitations of comparative risk assessment, a preoccupation with quantitative reductionism while failing to consider the nature and kind of risks and the likely public policy responses to them is itself irrational. Some of these dimensions and complexities were recognized in the EPA analyses of prioritization in risk reduction.³⁵ Such considerations give greater value to acting, even under conditions of uncertainty, when doing so will prevent largely irreversible damage or when ancillary benefits may be achieved in the course of such actions.³⁶ To paraphrase Morgan, we can perform all the calculations we want, but the real question is: What do they mean? The editors of *Worst Things First?*, acknowledging these objective, but non-quantitative, contextual factors ask the crucial question: "Is risk ranking always—or ever—the same as priority setting?" (Finkel & Golding, eds. p. 332).

More generally, Belzer is wrong when he makes an exclusive disjunction between risk reduction and "other political objectives." Entirely apart from the scientific merits or deficiencies in quantitative risk assessment, the answer to Belzer is that of course we have multiple political and social goals of which environmental protection is one. In common with other actions of government, we attempt to achieve greater equity, economic advancement, social justice, and efficiency of process through government action.³⁷ We could substantially reduce the health costs of smoking through outright prohibition on the manufacture and sale of cigarettes, but the other costs of such action would be so detrimental to public order and governmental processes that such actions, at least since Prohibition, have not been seriously invoked by even the most extreme public health advocates. We could further reduce exposures to lead by banning most remaining uses of lead, but our explicit compromise to protect U.S. industry and job opportunities³⁸ directs us to use other approaches to lead risk reduction.

Public health objectives must be coherent with other social policies; if not, those aims will not be realized. Education and empowerment are the principal vehicles for achieving improvements in public health. Coer-

35. See *supra* notes 24 & 25 and accompanying text.

36. Cf. William D. Nordhaus, *Managing the Global Commons: The Economics of Climate Change* 174-76 (1994).

37. See, e.g., Steven Kelman, *Making Public Policy: A Hopeful View Of American Government* (1987).

38. The United States is the second largest primary lead producer in the world. See Anthony Cox et al., *The OECD Risk Reduction Strategy for Lead: An Economic Perspective* 19 (1994).

cive or prescriptive regulation, while useful or even necessary to achieve public health goals, is unlikely to be effective by itself. So, one cannot ask whether the goal (such as quarantine of disease outbreaks like Ebola) is to reduce risk or to achieve other social policy ends. Successful strategies for reducing risks necessarily engage broader social values. Prohibition is widely regarded as a failed effort to reduce the risks from alcohol consumption not because a ban on alcohol production and consumption was ineffective in achieving the public health goal, but because the public policy strategy employed diverged from underlying expectations and values in American society.

Similarly, risk assessment must respond to, and operate within the confines of, public preferences and priorities, a consideration that strongly argues in favor of the "soft" approach. This is yet another reason that Breyer's reduction of all risks to a single metric of cigarettes smoked,³⁹ and others like it, are not useful for public policy purposes. The American public appears to believe that it is acceptable for people voluntarily to expose themselves, and perhaps others as well, to the relatively high risk of cigarette smoke. Efforts further to reduce risks from this cause, as demonstrated by recent policy debates, are constrained by other social values, such as our collective notions of individual rights and freedoms. Other risks, such as workplace exposure to toxic chemicals and pollutants, may be characterized by different configurations of social values. While a "hard" version of risk assessment may produce what appear to be similarly scaled quantifications for comparing the two hazards, those numbers do not and cannot give an indication of the extent to which those risks are amenable to reduction in a broader public policy setting. As the editors of *Worst Things First?* state, "incommensurable" risks or programs *can* be compared, but only if they are compared with respect to the most important attributes that distinguish them" (Finkel & Golding, eds. p. 337, emphasis in original). This is hardly, as they claim, a "startling observation," (Finkel & Golding, eds. p. 337), but a fundamental and essential limitation on comparative risk assessment approaches.

Along similar lines, many of the contributors to *Worst Things First?* speak of allocating or prioritizing regulatory "resources." For instance, Belzer discusses "focussing government's energies on significant market failures" (Finkel & Golding, eds. p. 178). EPA's staff paper for the Annapolis conference describes budget allocations and research priorities, which are quite obviously not the same as risk reduction in the real world. It is not inconceivable that a supposedly rational ordering of priorities by reference to comparative risk approaches could produce a carefully crafted allocation of regulatory resources and research priorities without ever producing meaningful risk reduction in the real world. The distribution of bureaucratic and research resources are only relevant to the

39. See *supra* note 29 (Breyer's use of "hard" version of comparative risk assessment).

extent that that distribution bears some reasonable relationship to the actual reduction of risks. Unfortunately, a prioritization of outcomes instead of resources or "energies" receives all too little attention in *Worst Things First?* The public plainly expects action on environmental problems, not mere prioritization or ranking; the question is whether risk-based ranking is used as an energizing force for progress on environmental and public health challenges or as an excuse for inaction.

An example chosen by Justice Breyer is remarkably enlightening in just this respect. He invites his reader, presumably an American citizen, to compare how governmental resources devoted to an overly zealous toxic waste cleanup in New Hampshire⁴⁰ might be redirected to combat deforestation in Madagascar (Breyer p. 20). Although he suggests that the loss of forest cover on another continent is a compelling problem by comparison, there is no guarantee that the U.S. government's resources will have the slightest impact there. Our governmental officials may have little influence with a foreign state, which may, in turn, have its own priorities that do not include saving trees. Or, despite its best intentions, a foreign government may have little capacity to influence the behavior of those within its territory who are responsible for forest destruction. Under these circumstances, we might devote significant governmental resources to a problem judged by experts or the public or both as immensely important with little or nothing to show for the effort. In other words, it is crucial to tackle not only issues that are important, but problems that are amenable to solution,⁴¹ a criterion that at least the "hard" form of risk assessment does not accommodate. Even if none of that were the case, however, the health of children and forest cover at a fundamental level truly are, in Finkel's words, "incommensurable," in that it is exceedingly difficult if not impossible to reduce them to a common standard of value.

In the end, the use of comparative risk assessment is plainly driven by a diagnosis of regulatory failure and the perceived need for a remedy to that failure to a much greater extent than is supported by the scientific utility of the underlying methodology. As Habicht says in *Worst Things*

40. The reference is to the Ottati and Goss/Kingston Steel Drum Site in Kingston, New Hampshire. Before his elevation to the Supreme Court, Justice Breyer wrote the opinion in a Superfund case concerning this site. See *United States v. Ottati & Goss, Inc.*, 900 F.2d 429 (1st Cir. 1990). Justice Breyer criticizes EPA for requiring a \$9.3 million cleanup of the site so that it would be "clean enough for . . . children to eat small amounts [of soil] daily for 245 days per year without significant harm," instead of only 70 days associated with a less comprehensive cleanup (Breyer, p. 12). In response to the criticisms of Justice Breyer and others concerning this site, EPA has stated that the agency "based the cleanup on potential future land uses at the site," which could include residential uses. See Environmental Protection Agency, *Setting the Record Straight: A Rapid Response to Myths About Superfund* (1995).

41. For example, a recent study by the National Academy of Public Administration, subtitled "A New Direction for EPA," includes both strains in its name: *Setting Priorities, Getting Results*. See National Academy of Public Admin., *A New Direction for EPA, Setting Priorities, Getting Results* (1995).

First?, “risk assessment has become needed and important for integrating EPA’s loosely connected environmental programs” (Finkel & Golding, eds. p. 36). Despite their objective presentation of the constitutive contributions to the work, the editors of *Worst Things First?* nonetheless convey an unfortunate aura of inevitability about the very approach whose integrity they and the other authors claim to be analyzing. That comparative risk assessment is thought to have become “needed and important” does not imply that the technique is equal to all the myriad demands that have been put upon it.

IV. COMMON SENSE, THE VICIOUS CIRCLE, AND THE NEED FOR REGULATORY REFORM

More or less simultaneously with, and largely independently of, the rise in risk assessment as a regulatory policy tool, there have been repeated calls for reform in environmental, public health, and safety regulation. Both Justice Breyer’s and Philip Howard’s efforts are illustrative of the genre. They not only analyze the regulatory structure and propose reform, but they also illuminate current attitudes about risk regulation. The fact that *The Death of Common Sense* has been a best seller, and for the time that it has, suggests that the work has struck a responsive chord in the public psyche. These efforts and others like them can also be seen as laying the foundations for the current enthusiasm for regulatory reform in the Congress.

Although *The Death of Common Sense* is addressed to a popular audience and Justice Breyer’s volume has a much more erudite tone, their respective approach to characterizing the “problem” is remarkably similar. Both Breyer and Howard acknowledge that the goal of reform is not to eliminate governmentally established standards altogether, or even to lower expectations as to the level of protection the public may reasonably expect from governmental interventions. Instead, they agree that, in the words of the dictionary definition of “reform,” the task is “to put or change” statutory and administrative requirements “into an improved form or condition.”⁴² According to Howard, “[o]ur hatred of government is not caused mainly by government’s goals, whatever their wisdom, but by government’s techniques. How law works, not what it aims to do, is what is driving us crazy” (Howard p. 173). Similarly Breyer, disavowing deregulation, avers that “public demand for regulation is likely to continue, a demand that governments should not, and will not, ignore” (Breyer p. 56).

In this respect, the two works appear to be indicative of the current mood among the populace. These two books—and, in differing ways, the two others in this tetralogy—may reflect a conviction held in a variety of quarters that regulatory activity in the areas of environment and public health could be more cost-effective, more sensitive to the needs of the

42. Webster’s Tenth Collegiate Dictionary 983 (1994).

private sector, more responsive to a perceived need to establish reasonable priorities, and simply more rational. Nonetheless, governmental intervention is widely regarded as necessary to offset externalities that would otherwise result from an unregulated market. For example, a recent Harris poll found that "there is a massive majority against any reduction in regulatory strictness."⁴³

Despite the disclaimer that environmental, public health and safety regulation should be rationalized, not scrapped, both Howard and Breyer nonetheless recite a highly selective, one-sided litany of supposedly absurd regulatory requirements.⁴⁴ Despite its more scholarly tone, the Breyer work is scarcely more sophisticated in this regard than *The Death of Common Sense*. The current policy debate over regulatory reform has exposed some extreme cases in which advocates of regulatory reform have abused similar anecdotal accounts of purported regulatory improprieties.⁴⁵ Neither Breyer's nor Howard's examples appear to stray as far from the mark as the discredited accounts relied upon by some members of Congress. Even so, the legislative debate has demonstrated the serious weaknesses inherent in the selective use of carefully chosen cases as surrogates for the larger "problem." Notably lacking in any of these rosters of vignettes are situations, such as the removal of lead from gasoline and the ban on PCBs,⁴⁶ in which a retrospective analysis has demonstrated that the benefits of regulation have substantially *exceeded* those anticipated at the time regulatory requirements were put in place.

Howard's book reads like a populist manifesto. His explanation of the "causes" of the "problem" is imprecise, overgeneralized, and at times self-contradictory. A persistent theme is the regulator's asserted need for uniformity and predictability, which supposedly leads to requirements that are highly prescriptive in their level of detail. Of all regulatory fields, "[i]nanaging the pollution and poisons of modern society may be where detail gets in the way the most" (Howard p. 19). But regulatory detail is uncharacteristic of democracy; instead, the author repeatedly opines, "[i]n]odern regulatory law resembles central planning" (Howard p. 21) as practiced by some totalitarian states.

Howard recommends, predictably enough, greater flexibility on a case-by-case basis to accommodate particular circumstances. While that may well be in order, the author does not acknowledge the very real rela-

43. Humphrey Taylor, *The Environment Could Be a Tough Issue for Republican Candidates in 1996 Elections* at 2 Aug. 21, 1995 (Louis Harris & Associates), analysis based on nationwide poll conducted in August 1995.

44. See, e.g., *supra* note 28.

45. See, e.g., Tom Kenworthy, *Truth Is Victim in Rules Debate: Facts Don't Burden Some Hill Tales of Regulatory Abuse*, *Wash. Post*, Mar. 19, 1995, at A1 (relating these kinds of anecdotes that "have the ring of truth, but not the substance"); Jessica Mathews, *Horror in the House*, *Wash. Post*, Mar. 5, 1995, at C7 (describing prominent anecdotal evidence in regulatory reform as "horror stories").

46. See, e.g., *Risk Assessment and Cost/Benefit Analysis*, *supra* note 18 (testimony of Ellen K. Silbergeld, Senior Toxicologist, Environmental Defense Fund).

tionship between regulatory efficacy and administrative efficiency. Treating like cases in like fashion is often necessary to achieve regulatory goals and to create clear incentives and expectations of predictability among the regulated community. While requirements that are individually crafted for specific situations may under certain circumstances be responsive to considerations of equity, administrative resources are rarely sufficient for such an approach without compromising broader policy aims.⁴⁷ Howard never identifies those policy tools, such as emissions trading under the Clean Air Act Amendments of 1990 and elsewhere, that might further both ends simultaneously.

Another of Howard's key axioms is the remote character of government, which "acts like some extraterrestrial power, not an institution that exists to serve us. Its actions have an arbitrary quality: It almost never deals with real-life problems in a way that reflects an understanding of the situation" (Howard p. 9). At the same time, he evinces little but disdain for a remedy, already built into virtually all administrative schemes, to address precisely this problem: public participation in the regulatory process. It is too much process—"the velvet trap of process" (Howard p. 62)—not too little, that is suffocating our society. Moreover, Howard, like Breyer, gives little or no attention to a very important dynamic that has led to the layering of process upon process—at times vociferous, self-interested objections from regulated industries and other interests.

Howard gives insufficient attention to the crucial point that prescriptions for administrative process and the institution of judicial review have been entrenched in the law precisely to increase bureaucratic accountability to the regulated community and the public and to assure the substantive rationality of agency decisions. The author instead concludes that an intensified focus on process in the administrative state has produced less, rather than more, "common sense." A less than complete understanding of history may partially account for this aberrant conclusion. Howard paints a picture in which Congress, in the Administrative Procedure Act (APA), codified a highly deferential theory of judicial review, consistent with a New Deal model characterized by the predominance of technically expert bureaucratic agencies. The federal courts, he says, then chiseled away at that salutary model, purposefully reclaiming for themselves significant substantive power under the guise of legalistic, procedural supervision of agency decision making (Howard pp. 78–83).

Contrary to Howard's view, "[t]he erosion of the legitimating power of expertise theory, and the consequent reemergence of legalism and proceduralism, best explain the significance of the APA of 1946."⁴⁸ Moreover, the trend toward legalism and proceduralism, which Howard

47. See, e.g., *E.I. duPont de Nemours & Co. v. Train*, 430 U.S. 112, 132 (1977) (noting that case-by-case determination of pollution requirements for individual facilities "would place an impossible burden on [the E.P.A.]").

48. Morton J. Horwitz, *The Transformation of American Law 1870–1960: The Crisis of Legal Orthodoxy* 235 (1992).

deploras, was catalyzed not purely by activist judges, but purposefully and knowingly by vested interests distrustful of a highly professionalized cadre of regulators and bureaucrats.⁴⁹ In other words, the institution of judicial review as codified in the APA, and its attendant emphasis on procedural regularity, was specifically intended to circumscribe regulatory activity and to assure oversight by the judiciary, all with the intent of assuring rational decisions and reducing unnecessary regulatory burdens—precisely the goals that Howard advocates. Howard's conclusion, while counterintuitive, might be defensible if supported by a more sophisticated analysis. As it is, the reader suspects instead that the author's real quarrel lies with those courts that, applying the same neutral procedural principles, have spurred reluctant agencies to meet statutorily-mandated standards in the environmental area.⁵⁰

Justice Breyer's short tract, *Breaking the Vicious Circle*, as might be expected, presents a somewhat more nuanced and scholarly description of the "problem" than the Howard book, which is intended for a popular audience. The first symptom identified in Breyer's diagnosis is "tunnel vision," or a fixation on eliminating the last ten percent of risks. Agencies charged with the missions of protecting the environment, public health and safety, so the argument goes, irrationally focus on eliminating even the last bit of risk, typically the most expensive to abate, with gilt-edged regulations addressing virtually all hazards from known harmful substances (Breyer pp. 11–19). Instead, he asserts, it is preferable to skim the cream off the universe of risks by addressing the largest, cheapest, most cost-effective reductions in risk from a wider variety of substances. Second, Breyer argues that the current regulatory landscape is afflicted by random agenda selection or, worse, the "squeaky wheel" phenomenon in which regulatory agencies careen from one real-world problem to another as a result of unpredictable shifts in public concerns (Breyer pp. 19–20). As a result, smaller risks can receive priority attention to the exclusion of larger ones, with little sense to the choice of regulatory priorities. As described above, the book relies heavily on what amounts to a "hard" version of comparative risk assessment in reaching these conclusions. Breyer places much of the blame for this inconsistency on Congress, which adopts statutory standards that vary from one regulatory program to another, further exacerbating the overall incoherence of regulation in this area (Breyer pp. 21–28).

Unlike Howard, Breyer's tone is very elitist. The ultimate culprit is *vox populi*. According to *Breaking the Vicious Circle*, the public, acting through its elected representatives like those in the Congress, cannot be expected to acquire sufficient technical expertise to understand rationally the magnitude of environmental risks from such hazards as toxic waste dumps. Regulatory agencies, in turn, supposedly find themselves

49. See *id.*

50. See *id.* at 242.

unable to establish logical, scientifically-based priorities because of the unreasonable pressures from elected officials, or directly from members of the public, to address small or overstated risks. Once an environmental hazard is targeted for action, the same forces are said to drive public authorities to adopt gold-plated standards that rely on excessively conservative scientific assumptions. Regulatory agencies, it is argued, are then compelled to over regulate a small number of bad actors by reducing risks to irrationally low levels when compared with other risks on which public resources could be deployed.

The structure of this diagnosis is misleading and sophistic because by definition it can accommodate virtually any additional case. Instances of overregulation are loosely correlated with an excess of public anxiety and outcry, and underregulated risks with insufficient popular concern. So, for instance, EPA establishes maximum residue limits or "tolerances" for pesticides in food based on the diet of an adult male of average weight. It is now well recognized that the tolerance-setting process must protect especially sensitive populations like children, who are exposed to higher risks from environmental contaminants because they consume disproportionately large amounts of certain foods.⁵¹ Even if Breyer were to acknowledge that pesticide residues in food are generally too large to protect children's health, his theory of causation neatly explains this situation as one involving a low profile in the press and the Congress by comparison with cases of supposedly irrational public outrage and hysteria, such as toxic waste dumps. The problem is that the issue of pesticide tolerances and risks to children has received plenty of press, as well as expert,⁵² attention with still little to show by way of policy action.

The actual reasons for differential regulatory attention to these risks, as to which Breyer evinces little appreciation, are related to the structure of laws, resistance by regulated industry, and problems in analysis. Thus, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), one of the oldest environmentally-related statutes, contains an explicit risk balancing provision based upon a basic assumption of the value of chemical pest control similar to that in drug legislation, in which a therapeutic risk-benefit ratio is incorporated in the regulatory decision-making process.⁵³ It must also be acknowledged that the pesticide/agribusiness industry has successfully accommodated to a post-FIFRA world and that the industry largely controls the discussion of pesticide risks through the exertion of broad claims of confidential business information, which restricts public

51. See, e.g., National Research Council, *Pesticides in the Diets of Infants and Children* 4 (1993).

52. See, e.g., Committee on Scientific and Regulatory Issues Underlying Pesticide Use Patterns and Agricultural Innovation, National Research Council, *Regulating Pesticides in Food: The Delaney Paradox* (1987); cf. *supra* note 24 (*Unfinished Business* identified pesticide residues in food as relatively high priority for regulating action).

53. See Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. § 135, et seq. (1994).

access to the analysis of risk information. By contrast, the more recent hazardous waste statutes compel a more rigorous approach to risk reduction, based upon the assumption that a hazardous waste site has little present value that must be considered in determining remedial action. The Superfund statute requires cost-effectiveness as a criterion, not cost-benefit analysis.

Close attention to the book's characterization of these "problems" reveals another significant logical deficiency. As a judge, Breyer would have to acknowledge that any system that deals with particularized determinations with respect to specific substances will necessarily produce some variation. The "problem," he asserts, is actually much larger, as demonstrated by those regulatable, but unregulated, large risks that have been passed over in preference for small ones. Breyer criticizes regulatory authorities for narrowing the options for regulation without identifying meaningful alternatives to current priorities, but he assumes without proof that those resources could be more effectively allocated elsewhere. In common with many deregulatory polemics, *Breaking the Vicious Circle* focuses almost exclusively on cases of regulatory overkill. Examples of the opposite—regulatory "undershoot," so to speak, such as much of occupational health regulation—are not just desirable but necessary to demonstrate the author's thesis of gross disparities between real-world risks and the universe of regulatory responses. But situations that demand more aggressive or rigorous regulatory requirements, such as the continuing epidemics of occupational and environmental lead poisoning, receive scant attention in the Breyer analysis.⁵⁴ If one is going to criticize choices of administrative priorities, it is at the least disingenuous not to suggest concrete, specific alternatives for meaningful, cost-effective regulatory action, many of which are easy to identify.

V. PROPOSALS FOR REGULATORY REFORM

The Death of Common Sense, Breaking the Vicious Circle, Worst Things First? and similar works have played a role in laying the intellectual foun-

54. A similar analysis criticizes the allocation of resources by the Environmental Protection Agency and the Occupational Safety and Health Administration without regard to the structure of public health institutions. See Tommy O. Tengs et al., *Five-Hundred Life-Saving Interventions and Their Cost-Effectiveness*, 15 *Risk Analysis* 369, 371 (1994); see also John F. Morrall III, *supra* note 28, at 25 (criticizing cost-ineffectiveness of certain public health regulation without proposing alternative risks for reduction). By contrast, the Environmental Protection Agency's Science Advisory Board has examined both sides of this "regulatory coin" and concluded that indoor air pollution (including radon), stratospheric ozone depletion, global warming, accidental releases of toxics, consumer and worker exposures to chemicals, non-point sources of water pollution, and environmental effects of pesticides require considerably more regulatory resources than are currently devoted to them. U.S. Environmental Protection Agency, *Unfinished Business: A Comparative Assessment of Environmental Problems* 59-90 (1987); see also *Reducing Risk*, *supra* note 32. But see *supra* text accompanying note 37-38 (neither *Unfinished Business* nor *Reducing Risk* identified lead poisoning as priority for future policy action).

dations for current regulatory reform efforts, particularly with respect to the role of risk assessment. Previously, some cases in which regulations were based on risk assessments generated concern, particularly among those in regulated communities, that the underlying assumptions were excessively cautious. More recently, as expressly recognized by the Contract With America and thoroughly internalized by Belzer,⁵⁵ the potential for quantitative risk assessment to raise the threshold to regulation or to serve as a vehicle for outright deregulation has been more fully appreciated.

A. Legislative Proposals in the 104th Congress

Current legislative proposals fall uneasily between the prescriptions of Breyer, Howard, and the National Research Council (NRC) on the one hand and the more enthusiastic proponents of comparative risk assessment in *Worst Things First?* on the other hand. The first three sources, to a greater or lesser extent, exhort greater reliance upon *judgment*, be it common sense, as advocated by Howard, or informed expertise, as prescribed by the NRC and Breyer. Much of the problem in current policy, as analyzed by Howard and Breyer, is a foolish consistency, to paraphrase Emerson, which generates the hobgoblin of regulation run amok. *Worst Things First?*, in contrast, appears to endorse calls for greater reliance upon stipulated and transparent methodologies of risk assessment/risk analysis. John Graham of the Harvard Center for Risk Analysis has been the most outspoken advocate of this technically-based solution, which proceeds from the assumption that, if regulators only used explicit, science based principles of analysis, their decisions would be rational and effective.⁵⁶ Consistent with that approach, the proposed legislation rejected by the Congress this past summer would have established detailed requirements for conducting risk assessments across a broad reach of health and safety legislation as a condition precedent to regulatory action by the federal government, with seemingly little recognition that such methods have application only to health assessment, and even in that domain, as discussed above, largely to cancer risks.⁵⁷

Advocates for reform have also seized upon one of the more opaque recommendations of the NRC: a call for an "iterative" approach to risk assessment. To the extent that there are uncertainties or gaps in the empirical data sets on which a risk assessment is based—a very common occurrence—the NRC is correct that, from a scientific point of view, risk assessment must be seen as an iterative process. That is, as more and better information becomes available, risk assessments should be revised to reflect those new developments.

55. See *supra* text accompanying notes 26–28.

56. See e.g., John D. Graham, *The Risk Not Reduced*, 3 N.Y.U. Envtl. L. J. 382 (1994).

57. See *supra* note 5 and accompanying text (proposed Dole-Johnston Comprehensive Regulatory Reform Act of 1995).

But this scenario, which might be compared with an airplane circling an airport an indefinite number of times before landing, is precisely the opposite of what the regulatory process requires. Just like the passenger in the plane, public officials and the public demand certainty: "How many more times before we land?" To the extent that regulatory action comes early in this process and is subject to later reconsideration, in retrospect it may appear premature or excessively costly. On the other hand, if a governmental response is delayed pending the collection of additional data, the resulting inaction may subsequently appear imprudent and foolhardy, particularly in situations in which further evidence demonstrates that the problem was greater than originally appreciated. Whereas science is an ongoing search for knowledge against a constantly shifting and evolving background that by its very nature is always operating at new frontiers, the regulatory process requires closure, and generally sooner rather than later. That is the fundamental paradox of quantitative risk assessment, a situation that generates discomfort among both scientists and regulatory authorities, although for very different reasons. Yet equally, the paradox must be acknowledged, and the limitations of quantitative risk assessment accommodated, if the methodology is to be appropriately employed in the regulatory process.

In science, iteration is the primary mode of validation; in policymaking, iteration can be an endless loop of delay and indecision, as in the case of the protracted assessment and reassessment of dioxin, from 1981 to the present time.⁵⁸ Attempts to apply the principle of iteration in a literal manner will distort the essential relationship between risk assessment and the regulatory process by overemphasizing the open-ended scientific character of quantitative risk assessment with insufficient recognition of the need for finality and certainty in administrative decisionmaking.

The prescriptive requirements contained in some of the bills proposed in the current Congress are, quite simply, inconsistent with the fundamental character of risk assessment methodologies. To put it charitably, those proposals demonstrate a poor appreciation of the relationship, discussed above, between the scientific limitations of risk assessment and the regulatory process. Risk assessment can be a useful tool in the policy process when employed in a flexible manner that is responsive and appropriate to a particular regulatory context. But codifying procedurally rigorous requirements relating quantitative risk assessments on the one hand and regulatory decisionmaking on the other grossly extends the methodology beyond its scientific and policy justification. The numerous procedural and substantive hurdles that agencies would be required to clear, as set out in that proposed legislation, seem designed not to promote reform, but to induce regulatory lethargy. Far from harmless,

58. See Ellen K. Silbergeld & P. de Fur, *Risk Assessments of Dioxin-Like Compounds, in Dioxins, Related Chemicals and Health* 51-78 (A. Schechter ed., 1994).

this multiplicity of superfluous, prescriptive requirements may impede necessary regulation altogether.

Another major issue within the regulatory reform debate concerns judicial review. Subjecting quantitative risk assessment and the process by which it was prepared to judicial review will not resolve the scientific uncertainty in the process. While risk assessment is not a purely scientific undertaking, any third party adjudicatory mechanism designed to evaluate the integrity of a quantitative risk assessment would, of necessity, have to draw on significant scientific expertise in such disciplines as toxicology and statistics. In our legal system, courts composed of non-scientists are expected to defer to the informed judgment of technical experts precisely to avoid a situation in which a tribunal of lay persons might substitute its own judgment for that of scientific professionals.⁵⁹ Tellingly, even when the "judges" are scientists, there are considerable impediments to the adjudication of scientific questions and controversies. Proposals for "science courts"—tribunals composed of independent, objective scientists that would resolve questions of "scientific fact" isolated from the larger policy process⁶⁰—are now generally regarded as impracticable precisely because many scientific issues are not inherently "justiciable" in

59. See, e.g., *Baltimore Gas & Elec. Co. v. Natural Resources Defense Council*, 462 U.S. 87, 103 (1983) ("[A] reviewing court must remember that the [expert administrative agency] is making predictions, within its area of expertise, at the frontiers of science. When examining this kind of scientific determination, as opposed to simple findings of fact, a reviewing court must generally be at its most deferential."); *Limerick Ecology Action, Inc. v. Nuclear Regulatory Comm'n*, 869 F.2d 719, 743 (3d Cir. 1989); *Sierra Club v. Department of Transp.*, 753 F.2d 120, 129 (D.C. Cir. 1985) ("The agency is entrusted with the responsibility of considering the various modes of scientific evaluation and theory and choosing the one appropriate for the given circumstances. The court's responsibility lies in assuring that the agency had before it all the data to make an informed decision that adequately took account of the important environmental concerns."); Devra L. Davis, *The "Shotgun Wedding" of Science and Law: Risk Assessment and Judicial Review*, 10 *Colum. J. Envtl. L.* 67, 70-73 (1985); E. Donald Elliott, Jr., *The Dis-Integration of Administrative Law: A Comment on Shapiro*, 92 *Yale L.J.* 1523, 1527 (1983) ("Courts should be hesitant to second-guess agency risk assessments, not because a matter involves rulemaking rather than adjudication, but because the agency's exercise of discretion is based in part on technical evidence which judges rarely understand. The occasional court decision in the environmental area that has set aside an administrative decision for a 'clear error of judgment' in assessing technical evidence has usually been based on judicial ignorance of epidemiology, toxicology, or some other 'ology.'"); Howard Latin, *Good Science, Bad Regulation, and Toxic Risk Assessment*, 5 *Yale J. on Reg.* 89, 130-34 (1988); William H. Rodgers, Jr., *Judicial Review of Risk Assessments: The Role of Decision Theory in Unscrambling the Benzene Decision*, 11 *Envtl. L.* 301, 302 (1981) ("[T]he suspicion has arisen, certainly among practitioners who can say such things, that the grand synthesizing principle that tells us whether the court will dig deeply or bow cursorily depends exclusively on whether the judge agrees with the result of the administrative decision.").

60. See, e.g., Task Force of the Presidential Advisory Group on Anticipated Advances in Science and Technology, *The Science Court Experiment: An Interim Report*, 193 *Sci.* 653 (1976), reprinted in 4 *Risk: Issues in Health & Safety* 179 (1993) (proposing "science court" to resolve questions of scientific fact through adversary proceedings).

such an adjudicatory, adversarial setting.⁶¹ When the uncertainties, assumptions, and limitations which are inherent in the methodology and which may create unease or disagreement even among scientists are fully appreciated, the notion of judicial review of a quantitative risk assessment approaches absurdity.

B. *Structural Reform*

Science and Judgment and *Worst Things First?* both treat the issue of risk assessment and, by implication, regulatory reform within the reasonably well-defined parameters of the existing federal regulatory framework. By contrast, Howard and Breyer, consistent with their bird's eye—as opposed to worm's eye—approach to the issues they address, propose thoroughgoing, not to say radical, modifications to current institutional structures charged with regulatory decisionmaking. Both advocate greater administrative discretion, presumably with fewer statutory constraints and less judicial supervision than is currently the case. Quite tellingly, this is precisely the opposite of the approach currently proposed in the Congress, in which the principal statutory vehicle for reform would be a detailed prescription for the administrative process, including risk assessment methodologies, accompanied by an intensification of judicial review. These two works consequently inject a loud note of cognitive dissonance into the current debate.

Moreover, both the congressional and Breyer/Howard “solutions” could well exacerbate difficulties with existing regulatory mechanisms, although for different reasons. The Breyer/Howard model of unsupervised administrative discretion in particular has already been rejected as an historical matter, and for good reason. On the other hand, on a smaller scale and operating within existing regulatory parameters, their observations may well be useful admonitions for tempering some of the excessive constraints on regulatory authority proposed in the legislation to implement the Contract With America.

Regulatory reform efforts often advocate an artificial “consistency” achieved by across-the-board relaxation of regulatory constraints. For example, the Bush Administration's Council on Competitiveness, chaired by then-Vice President Quayle and later abolished by the Clinton Administration, was ostensibly created to assure regulatory consistency and ended up being widely regarded as a closed-door vehicle for pursuing an aggressively deregulatory agenda.⁶² Notwithstanding an anecdotal rather

61. For a sampling of the voluminous writing on science courts, much of it critical, see Jon R. Cavicchi, *The Science Court: A Bibliography*, 4 *Risk: Issues in Health & Safety* 171 (1993).

62. See, e.g., Jeffrey H. Birnbaum, *The Deregulator*, *Gov't Executive*, Sept. 1991, at 16, 16; Keith Schneider, *Washington at Work: Administration's Regulation Slayer Has Achieved a Perilous Prominence*, *N.Y. Times*, June 30, 1992, at A19; Michael Weisskopf, *Wetlands Protection and the Struggle Over Environmental Policy*, *Wash. Post*, Aug. 8, 1991, at A17. See generally Robert V. Percival, *Checks Without Balance: Executive Office*

than analytic methodology that considers only regulatory excesses instead of the larger universe of regulatory action, Breyer to his credit abjures such facile "solutions." In keeping with his argument that the "problem" is broad-gauge and systemic, as opposed to an affliction that affects the rationality of individual regulatory efforts in a context-specific manner, Breyer offers an overarching, institutional remedy. Like Howard, Breyer believes that deficiencies in environmental, public health and safety rules stem not just from poor judgment by governmental decisionmakers, but also from structural attributes and dynamics inherent in the regulatory process itself. According to Breyer, the vicious circle can be broken by creating an elite cadre of technical experts charged with rationalizing environmental, health, and safety regulation throughout the federal government and thoroughly insulated from the political process—a group that would appear to have considerably less accountability to the public than virtually any other entity in the political branches associated with crafting domestic regulatory policy. Although the role of the courts is vague, presumably judicial review of the decisions by this group would also be attenuated or abolished.

Breyer laments congressional micromanagement that he claims has led to inconsistencies among regulatory programs. But there is no reason to believe that the insular, unaccountable infrastructure proposed by Breyer will make necessary decisions on behalf of the public. Although Breyer focusses on regulatory excess, the 25-year history of modern environmental law has been characterized at least as much by a persistent pattern of bureaucratic inertia, for which the required remedy has been a dose of political energy supplied by the national legislature in the form of necessarily prescriptive regulatory deadlines, timetables, targets, and goals and implemented, in many cases, only after litigation initiated by private citizens' groups.⁶³ For example, the Toxic Substances Control Act (TSCA) gives the Environmental Protection Agency substantial discretion about whether and how to apply the statute to particular substances and situations. But compared with some of the more prescriptive environmental legislation, little has been accomplished under the authority of TSCA except in response to litigation initiated by nongovernmental environmental organizations with respect to such substances as dioxin and PCBs, largely because of the discretionary nature of the statutory mandate.⁶⁴

Oversight of the Environmental Protection Agency, 54 *L. & Contemp. Probs.* 127 (1991); Richard H. Pildes & Cass R. Sunstein, *Reinventing the Regulatory State*, 62 *U. Chi. L. Rev.* 1, 5 (1995).

63. See Silbergeld, *supra* note 13 at 100–01; see also, e.g., *Environmental Defense Fund, Inc. v. Thomas*, 657 F. Supp. 302 (D.D.C. 1987), *aff'd sub nom. Environmental Defense Fund, Inc. v. Reilly*, 909 F.2d 1497 (D.C. Cir. 1990) (dioxins and furans); *Environmental Defense Fund, Inc. v. EPA*, 636 F.2d 1267 (D.C. Cir. 1980) (PCBs).

64. Cf. *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1213–14 (5th Cir. 1991).

It is hardly an exaggeration to characterize Breyer's corps of technocrats as a Platonic oligarchy. Precisely this point provided one of the few moments of controversy during the hearings preceding then-Judge Breyer's confirmation as 108th Justice of the United States Supreme Court. Senator Biden, then Chair of the Senate Committee on the Judiciary, scolded the author for the volume's "presumptuous and elitist" tone. The Senator then observed, "I am delighted [that], as a judge, you are not going to be able to take your policy prescriptions into the Court."⁶⁵ *Breaking the Vicious Circle* is of great interest thanks to the light it sheds on how the institution and its newest member will address an area that appears to occupy an ever increasing share of the High Court's docket.⁶⁶ For that very reason the book is highly unusual for its skepticism, simultaneously both detailed and sweeping, on the part of a sitting Justice concerning the fundamental legitimacy of the activities of the political branches.

Experience with decisionmaking paradigms similar to that proposed by Justice Breyer suggests little cause for comfort. Although Breyer cites similar efforts by prior Presidents through the Office of Management and Budget to assure regulatory consistency, even he acknowledges that those undertakings have "undermined public confidence" (Breyer p. 69). France, touted as a model by the new Justice (Breyer pp. 70-71, 78), like most European countries is widely perceived as significantly less committed to the protection of public health from involuntary exposure to environmental contaminants than is the United States. The French Conseil d'Etat, which Breyer references approvingly, by American standards is highly centralized, largely inaccessible to the public, and unaccountable to either the legislature or the people.⁶⁷ A French technocratic elite remarkably similar to that proposed by Justice Breyer was largely responsi-

65. Supreme Court Confirmation of Judge Stephen G. Breyer: Hearings Before the Senate Comm. on the Judiciary, 103d Cong., 2d Sess. (statement of Sen. Biden, Chairman), available in Federal News Service, July 14, 1994.

66. In the term that concluded just before Justice Breyer joined the Supreme Court, that tribunal decided a record six major environmental cases: *C&A Carbone, Inc. v. Town of Clarkstown*, 114 S. Ct. 1677 (1994) (interstate transport of waste); *City of Chicago v. Environmental Defense Fund*, 114 S. Ct. 1588 (1994) (interpretation of hazardous waste laws); *Dolan v. City of Tigard*, 114 S. Ct. 2309 (1994) (land use regulation as constitutional "taking"); *Key Tronic Corp. v. United States*, 114 S. Ct. 1960 (1994) (recovery of attorney's fees in Superfund case); *Oregon Waste Sys., Inc. v. Department of Env't. Quality*, 114 S. Ct. 1345 (1994) (interstate transport of waste); *Jefferson County PUD No. 1 v. Washington Dep't of Ecology*, 114 S. Ct. 1900 (1994) (interpretation of Clean Water Act).

67. See Ronald Brickman et al., *Controlling Chemicals: The Politics of Regulation in Europe and the United States* 305-06 (1985). Justice Breyer acknowledges that "America is not France; nor are the substantive problems of risk regulation exactly the same as the problems of administrative regularity, legality, and efficacy that typically face the *Conseil d'Etat*" (Breyer p. 71). Even so, the Conseil d'Etat, whose powers have evolved over time, "has no parallel in another country" and efforts to transplant the model to other countries have generally not been successful. See Brickman, *supra*, at 102.

ble for, and contributed to the subsequent cover-up of, the HIV-tainted blood scandal in that country.⁶⁸

Howard eschews Breyer's ultra-rational approach, instead acknowledging what the editors of *Worst Things First?* describe as the "galvanizing energy that arises in response to perceived crises" (Finkel & Golding, eds. p. 14), such as the earthquake in Los Angeles and the Tylenol tampering. Howard, citing EPA's slow pace on pesticide re-registration (Howard pp. 58, 84), clearly acknowledges the need for affirmative governmental action in necessary situations. As he says, "[T]he role of government is to make . . . choices, not to avoid them under the illusion of searching for nonexistent truth" (Howard p. 88). Howard suggests that those priorities that have a strong motivating political imperative tend to get done more effectively than those that do not, an assertion that Breyer presumably would reject as insufficiently methodical and systematic.

In contrast to his elaborate depiction of supposed regulatory abuses, including inaction and delay, Howard's rather vague solution—whose lack of detail contrasts sharply with his numerous horror stories—is greater administrative discretion:

We should stop looking to law to provide the final answer. Law should articulate goals, award subsidies, allocate presumptions, and provide mechanisms for resolving disagreements, but law should almost never provide the final answer. Life is too complex. Our public goals are too complex. . . . Law can't think, and so law must be entrusted to humans and they must take responsibility for their interpretation of it. (Howard p. 186.)

Presumably, in light of the author's low regard for the institution of judicial review, this large discretion should be exercised free from the supervision of courts. Unfortunately, Howard gives little indication as to why there is reason to believe that bureaucrats with enhanced discretion "who would be willing to take responsibility for administrative decisions" (Howard p. 79) will necessarily be more reasonable or responsive to the needs of the public or of the regulated community. By reference to the author's own test, it is by no means common sense to assume that the cure will be preferable to the disease. There is good reason to believe the reverse, as the principal purpose of administrative process and judicial review is to assure accountability to the regulated community and the public by checking bureaucratic excess.⁶⁹ And how the law can "articu-

68. See, e.g., Michael Balter, AIDS Expert Charged in HIV-Blood Case, 268 *Sci.* 1563 (1995); Jane Kramer, Bad Blood, *New Yorker*, Oct. 11, 1993, at 74.

69. The Supreme Court's limited willingness to permit agencies to define their own mandates, see *Chevron U.S.A., Inc. v. Natural Resources Defense Council*, 467 U.S. 837 (1984), which is quite modest compared to Howard's suggestion, has drawn heated criticism on precisely this point. See, e.g., Panel Discussion, *Judicial Review of Administrative Action in a Conservative Era*, 39 *Admin. L. Rev.* 353, 368 (1987) (statement of Cass R. Sunstein) ("[T]hose who are limited in their authority by law should not be the judge of those limits. Administrative agencies are constrained by statute, that is, law, and the mere fact that the statute is ambiguous shouldn't give the agency, of all people, the

late goals" without "provid[ing] the final answer" (Howard p. 186) is not explained.

Although Breyer characterizes his "solution" as an innovation, the author of the *Death of Common Sense* recognizes his own very similar, although less detailed, prescription for the throwback that it is. As Howard says in describing the accretion of process since the enactment of the Administrative Procedure Act, "Jim Landis would be agape: The original point of bureaucracy was to have professional points of view" (Howard p. 82).⁷⁰ Contrary to Howard's opinion, however, the rise in legalism and the commensurate decline in the importance of "professional points of view" was not accidental. After World War II, "[a] declining faith in the ability of experts to produce scientific, neutral, and apolitical solutions to social and legal questions led in turn to a reemergence of proceduralism."⁷¹ Even Landis, Howard's herald of the New Deal technocracy, in his later years became somewhat disillusioned with that idealized model.⁷² Although Howard clearly disagrees with those developments, at least he, by comparison with Breyer, appreciates the systematic development away from highly technocratic models proposed during the New Deal precisely because of concerns about the potential concentration of power in, and consequent unresponsiveness of, unaccountable bureaucracies. But neither author offers any explanation as to why history, even if it were replayed, would come out any differently when there are good reasons why administrative law and practice evolved as they did. In short, we have been there already, and going back will very likely revive not only the useful, but also the less desirable, aspects of a model that has already been largely rejected.

Both authors' proposals for more technocracy and less democracy swim directly against the stream of much current thought in environmental, public health, and safety regulation. The Earth Summit, attended by over 100 heads of state in Brazil in June 1992, expressly linked popular participation in governmental decisionmaking and environmental quality.⁷³ The notion of affording EPA greater autonomy as an independent regulatory agency or commission, which was widely touted after the scan-

authority to decide on the meaning of the limitation. The cute way in which it's sometimes put is that foxes shouldn't guard henhouses. If *Chevron* is taken to mean that agencies judge the scope of their own authority, then one has precisely that problem.").

70. Cf. Barry Sullivan, *Democracy, Bureaucracy, and Science: Making the Trains Run on Time*, 89 *Nw. U. L. Rev.* 166, 187 (1994) (review of *Breaking the Vicious Circle* emphasizing "the real extent of the similarities between Judge Breyer's proposal and the thinking of New Deal theorists such as James M. Landis").

71. Horwitz, *supra* note 48, at 233; see also *id.* at 235 ("After 1946, political attacks on the regulatory state and intellectual challenges to social science claims of objectivity marched hand in hand. Every triumph of proceduralism occurred at the expense of professionalism"). Cf. *supra* text accompanying notes 37-38 (discussing judicial review under Administrative Procedure Act).

72. See Horwitz, *supra* note 48, at 241.

73. Principle 10 of The Rio Declaration on Environment and Development, one of the principal instruments that was to be adopted at the recent Earth Summit, specifies that

dals there during the early Reagan years, has been largely rejected in favor of the precise opposite: raising the Agency's political profile through its elevation to Cabinet status. More fundamentally, neither author appears to appreciate sufficiently that momentum generated by popular demands is an integral component of, if not a necessary precondition to, effective national environmental policies. It is more than just ironic that "reform" of a mission-oriented public policy agenda that exists almost solely by virtue of demand among the electorate requires virtually total insulation of the execution of that mission from the political process and the public.

Where Breyer and Howard advocate greater flexibility and discretion in regulatory decisionmaking, Congress threatens to go overboard in exactly the opposite direction, by expressing a strong preference for prescriptive micromanagement of the agency process through detailed statutory requirements for quantitative risk assessment, enforced by the courts through the institution of judicial review. For the reasons above, the marketplace of ideas rightly appears to have passed over the Breyer/Howard grand proposals for regulatory overhaul. But on a more modest scale, they add an important note of caution to the current debate.

The detailed, prescriptive nature of regulatory reform bills considered by the current Congress is precisely contrary to relaxing the role of law and assuring that "bureaucrats will make decisions," as suggested by Howard. For example, he is quite contemptuous of agency failure to make necessary decisions, such as those relating to pesticide re-registration (Howard p. 58). Further, the emphasis on judicial review in the pending legislation is likely to exacerbate rather than ameliorate the problem of over-emphasis on law and lack of opportunity for the exercise of professional discretion. Breyer would be likely to concur with the goal of this legislation, which is to assure, among other things, complete characterization of risk and comparisons among risks. However, it is not at all clear that he would agree with the vehicle of statutory mandates, which is quite the contrary of the solution that he advocates. Rather, Breyer would very likely say, much along the lines of Howard, that the best solution is to relax statutory constraints so that professionals can exercise their judgment unfettered by excessive oversight by the Congress or the courts.

Environmental issues are best handled with the participation of all concerned citizens, at the relevant level. At the national level, each individual shall have appropriate access to information concerning the environment that is held by public authorities, including information on hazardous materials and activities in their communities [sic], and the opportunity to participate in decision-making processes. States shall facilitate and encourage public awareness and participation by making information widely available. Effective access to judicial and administrative proceedings, including redress and remedy, shall be provided.

Rio Declaration on Environment and Development, June 14, 1992, U.N. Doc. A/CONF.151/5/Rev. 1 (1992), reprinted in 31 I.L.M. 876, 878 (1992).

As already discussed, quantitative risk assessment, correctly understood, is not fundamentally amenable to this sort of prescriptive approach. Although highly particularized mandates may be appropriate to spur agency action,⁷⁴ the bills currently pending in the Congress are intended to establish conditions that function as impediments to regulation. The net result is very likely to be considerably more process and many fewer decisions—in other words, regulatory stagation or inertia, not reform. This is *not* what Howard and Breyer at least purport to advocate. The bills considered earlier this year by the current Congress would not contribute anything to the rationality of regulation, but instead would raise the threshold before any regulation could be undertaken. The proposed legislation stalled in the Senate this past summer implies an excessively high degree of scientific rigor in the regulatory process, and particularly in priority setting. Although some of the bills do not purport to modify existing regulatory standards—many of which are purposely biased in favor of the protection of public health—as a practical matter they create significant impediments to regulation under conditions of scientific uncertainty. In context, these proposals for overlaying across-the-board requirements for risk assessments are designed not to facilitate regulatory reform but to assure regulatory gridlock and torpor by creating numerous conditions to future regulation. Even advocates of the “hard” or quantitatively rigorous form of comparative risk assessment by and large do not advocate that the methodology serve this stringent gatekeeping function.

VII. CONCLUSION

Despite its apparent acrimony and fever pitch, there are in fact large areas of agreement in the current debate over reform of risk regulation. There is plainly pressure for regulatory reform in the environmental, public health, and safety area that will likely lead to a public policy response. Further, science is inherent in the enterprise of environmental, public health and safety regulation, and better science is always preferable. There is, moreover, little disagreement that risk assessment is a useful tool as a component of a regulatory reform strategy. In particular, risk assessment may under some circumstances provide helpful guidance in establishing regulatory priorities. Indeed, the use of risk assessment in some areas ought to be expanded.

However, given the limitations of the methodology, its use must be clearly circumscribed. Risk assessment is not a substitute for democratically-determined social value choices and cannot capture many relevant objective and subjective distinctions among types of risks and public policy responses. The methodology should inform, but not constrain, regulatory choices. Most thoughtful proponents of comparative risk analysis appreciate its limitations, but seem to view a comparison of risks as better

74. See *supra* text accompanying notes 63–64.

than nothing. But even if one were to admit that there is a "problem," it is by no means apparent that it is of a magnitude that requires either the micromanagement of regulatory decisionmaking set out in this year's failed legislative initiatives or the radical structural surgery of the Breyer/Howard variety, which would toss the baby of democracy out with the bath water of a host of poorly documented allegations of regulatory transgressions.

In addition, there is evidence of considerable evolution within existing paradigms, with an increasing emphasis, even without structural reforms, on the use of more flexible economic instruments and performance-based standards instead of command-and-control and technology-based requirements. The "cures" proposed by the Congress on the one hand and by Breyer and Howard on the other hand—both of them "tyrannies of the rational"—are themselves risky and may very likely be worse than the "disease." Although it may not seem terribly exciting, the best solution may be for the public to demand more rational regulation through existing channels. The give-and-take among the branches of government and with the public may be a necessary, even desirable, characteristic of risk regulation. Democracy and cost-effective, rational regulation are not incompatible.⁷⁵ Indeed, all four of these books are themselves evidence of the contributions that can be made to the ongoing evolution of risk regulation, and the serious debate that can be stimulated, through familiar paradigms.

In any event, by reference to the Breyer/Howard diagnosis and recommendations, pending legislative proposals quite obviously would exacerbate the less desirable aspects of the current system rather than ameliorate them. In context, it is difficult to characterize the use of risk assessment in the legislative vehicles currently proposed as anything other than an abuse of that methodology, designed not to promote regulatory reform but to impede desirable or necessary regulatory activity. This debate demonstrates how an analytical technique appropriate in certain contexts can be twisted and distorted for instrumental purposes. If enacted, the legislation identified in the Contract With America truly would represent the death of common sense, a vehicle by which law might literally suffocate America.

75. See, e.g., Pildes & Sunstein, *supra* note 62, at 87 ("Justice Breyer's proposal places too much stress, we believe, on the technocratic side of risk regulation, and too little on the democratic side.").