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74. See figures 1 and 2 and table 14 in Anderson and Ursin (*7*).
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Risk and Responsibility

David L. Bazelon

Risk Regulation: A Problem for Democracy in the Technological Age

In 1906, Congress enacted the Pure Food and Drug Act, the first general food and drug safety law for the United States. Commenting on the provisions of the act, the House committee observed: "The question whether certain substances are poisonous or deleterious to health the bill does not undertake to determine, but leaves that to the determination of the Secretary . . . under the guidance of proper disinterested scientific authorities, after most careful study, examination, experiment and thorough research."

This statement reflected a deep faith in the ability of "disinterested" scientists to determine for society what substances posed an unacceptable risk. More than 70 years of regulation have called into question that naïve faith. We are no longer content to delegate the assessment of and response to risk to so-called disinterested scientists. Indeed, the very concept of objectivity embodied in the word disinterested is now discredited. The astounding explosion of scientific knowledge and the increasing sophistication of the public have radically transformed our attitude toward risk regulation. As governmental health and safety regulation has become pervasive, there is a pressing need to redefine the relation between science and law. This is one of the greatest challenges now facing government and, indeed, society as a whole.

Risk regulation poses a peculiar problem for government. Few favor risk for its own sake. But new risks are the inevitable price of the benefits of progress in an advanced industrial society. In order to have the energy necessary to run our homes and our factories, we incur risks of energy production, whether they be the risks of coal mining, nuclear reactor accidents, or the chance that a tree will fall on a man felling it to produce firewood. In order to have mobility, we risk auto accidents and illness from air pollution. In order to have variety and convenience in our food supply, we risk cancer or other toxic reactions to additives.

Ironically, scientific progress not only creates new risks but also uncovers previously unknown risks. As our understanding of the world grows exponentially, we are constantly learning that old activities, once thought safe, in fact pose substantial risks. The question then is not whether we will have risk at all, but how much risk, and from what source. Perhaps even more important, the question is who shall decide.

In our daily lives we do not confront the trade-off between dollars and lives very directly or self-consciously. But when we make societal policy decisions, such as how much to spend to eliminate disease-producing pollutants, we are painfully aware that we must make what Guido Calabresi has called "tragic choices."

In primitive societies these choices were often made by the tribal witch doctor. When the need to choose between cherished but conflicting values threatened to disrupt the society, the simplest path was decision by a shaman, or wizard, who claimed special and miraculous insight. In our time shamans carry the title doctor instead of wizard, and wear lab coats and black robes instead of religious garb.

But ours is an age of doubt and skepticism. The realist movement in law effectively stripped the judiciary of its Solomonic cloak. So, too, the public has come to realize the inherent limitations of scientific wisdom and knowledge. We have been cast from Eden, and must find ways to cope with our intellectual nakedness. To the basic question of how much risk is acceptable—a choice of values—we have learned that there is no one answer. To the problem of how much risk a given activity poses, we have learned that even our experts often lack the certain knowledge that would ease our decision-making tasks. Often the best we can say is that a product or an activity poses a "risk of risk."

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Who Decides? Scientists *v.* the Public

Under these circumstances, the questions of who decides and how that decision is made become all the more critical. Since we have no shaman we must have confidence in the decision-making process so that we may better tolerate the uncertainties of our decisions.

Courts are often thrust into the role of authoritative decision-makers. But in recent years there has been growing concern about the ability of the judiciary to cope with the complex scientific and technical issues that come before our courts. Critics note, quite correctly, that judges have little or no training to understand and resolve problems on the frontiers of nuclear physics, toxicology, hydrology, and a myriad of other specialties. And the problem is growing. Hardly a sitting in our court goes by without a case from the Environmental Protection Agency, the Food and Drug Administration, the Occupational Safety and Health Administration (OSHA), or the Nuclear Regulatory Commission (NRC). These cases often present questions that experts have grappled with for years, without coming to any consensus.

But the problem, of course, is not confined to the judicial branch. Legislators are daily faced with the same perplexing questions. They, too, lack the expertise to penetrate the deepest scientific mysteries at the core of important issues of public concern. This problem ultimately strikes at the very heart of democracy. The most important element of our government, the voter, simply cannot be expected to understand the scientific predicate of many issues he must face at the polls.

Some well-meaning scientists question the wisdom of leaving risk regulation to the scientifically untutored. They wonder, to themselves if not aloud, whether the public should be permitted to make decisions for society when it cannot understand the complex scientific questions that underlie the decisions. Some scientists point with relish to the contradictory and seemingly irrational response of the public to risk. They observe the public's alarm at the prospect of nuclear power and note that the same public tolerates 50,000 automobile deaths a year. They decry the Delaney clause, which singles out cancer among all serious risks and imposes a rigid ban, regardless of countervailing benefits.

Scientists are also concerned by the growing public involvement in decisions that, in the past, were left entirely to the scientific community. Many scientists believe that regulation has intruded too deeply into the sanctum sanctorum. The controversy ranges from the periphery of scientific pursuits, such as OSHA regulation of laboratory work conditions, to the heart of the scientific enterprise, such as the conflict over recombinant DNA research. Regulators are accused of stifling creativity and innovation in the name of the false god of safety. Science, once invoked as an ally to progressive government, more and more views the political process with hostility and disdain.

In reaction to the public's often emotional response to risk, scientists are tempted to disguise controversial value decisions in the cloak of scientific objectivity, obscuring those decisions from political accountability.

At its most extreme, I have heard scientists say that they would consider not disclosing risks which in their view are insignificant, but which might alarm the public if taken out of context. This problem is not mere speculation. Consider the recently released tapes of the NRC's deliberation over the accident at Three Mile Island. They illustrate dramatically how concern for minimizing public reaction can overwhelm scientific candor.

This attitude is doubly dangerous. First, it arrogates to the scientists the final say over which risks are important enough to merit public discussion. More important, it leads to the suppression of information that may be critical to developing new knowledge about risks or even to developing ways of avoiding those risks.

It is certainly true that the public's reaction to risk is not always in proportion to the seriousness of the threatened harm discounted by its probability. But the public's fears are real.

Scientists must resist the temptation to belittle these concerns, however irrational they may seem. The scientific community must not turn its back on the political processes to which we commit societal decisions. Scientists, like all citizens, must play an active role in the discussion of competing values. Their special expertise will inevitably and rightly give them a persuasive voice when issues are discussed in our assemblies and on our streets. But the choice must ultimately be made in a politically responsible fashion. To those who feel the public is incapable of comprehending the issues, and so unable to make informed value choices, I respond with the words of Thomas Jefferson:

> I know no safe depository of the ultimate powers of the society but the people themselves; and if we think them not enlightened enough to exercise their control with a wholesome discretion, the remedy is not to take it from them, but to inform their discretion.

Scientist, regulator, lawyer, and layman must work together to reconcile the sometimes conflicting values that underlie their respective interest, perspectives, and goals. This cooperation can be achieved only through a greater understanding of the proper roles of the scientific, political, and legal communities in addressing the public regulation of risk. Only then can we achieve a program of risk regulation that accommodates the best of scientific learning with the demands of democracy.

Sorting Out Scientific Facts, Inferences, and Values in Risk Regulation

The starting point is to identify the fact and value questions involved in a risk regulation decision. In determining questions of fact, such as the magnitude of risk from an activity, we as a society must rely on those with the appropriate expertise. Judges and politicians have no special insights in this area. Where questions of risk regulation involve value choices such as how much risk is acceptable, we must turn to the political process.

But even this formulation leaves many problems unanswered. There is no bright line between questions of value and of fact. Even where a problem is appropriately characterized as one of scientific fact, consensus and certainty may very often be impossible even in the scientific community. Many problems of scientific inference lie in the realm of "trans-science" and cannot be resolved by scientific method and experimentation.

The recent National Academy of Sciences (NAS) report on saccharin vividly illustrates the problem of separating fact from value in risk regulation. Although there is a reasonable scientific consensus on the effects of saccharin in rats, the important question of human risks and the appropriate response to those risks remain controversial. On the basis of uncontroverted animal experimental data, the NAS panel could not conclude whether saccharin should be considered a substance posing a "high" risk of cancer, or only a "moderate" risk. Yet this lack of consensus should not surprise us. As Philip Handler, president of the NAS, observed in his preface to the report, "the difference of opinion which led to this ambivalent statement is not a differing interpretation of scientific fact or observation; it reflects, rather, seriously differing value systems."

Handler's statement reveals a critical issue in risk regulation. When the debate over saccharin is couched in terms of the degree of risk, it sounds as though there is a scientific issue, appropriate for resolution by trained scientists. In fact, however, the terms moderate and high do not conform to any differences in experimental data, but rather correspond to the scientists' view of the appropriate regulatory response.

The growing use of analytic tools such as cost-benefit analysis magnifies the chance that unrecognized value judgments will creep into apparently objective assessments. Even the most conscientious effort by experts not to exceed their sphere of competence may be inadequate to safeguard the validity of the decision-making process. Outside scrutiny may be imperative.

The Role of Courts

It is at this point that courts can make their contribution to sound decision-making. Courts cannot second-guess the decisions made by those who, by virtue of their expertise or their political accountability, have been entrusted with ultimate decisions. But courts can and have played a critical role in fostering the kind of dialogue and reflection that can improve the quality of those decisions.

Courts, standing outside both scientific and political debate, can help to make sure that decision-makers articulate the basis for their decisions. In the scientists' realm—the sphere of fact—courts can ask that the data be described, hypotheses articulated, and above all, in those areas where we lack knowledge, that ignorance be confessed. In the political realm—the sphere of values—courts can ask that decision-makers explain why they believe that a risk is too great to run, or why a particular trade-off is acceptable. Perhaps most important, at the interface of fact and value, courts can help ensure that the value component of decisions is explicitly acknowledged, not hidden in quasi-scientific jargon.

This role does not require, as some have suggested, that courts intrude excessively into an agency's processes. The demands of adequate process are not burdensome. Surely it is not unreasonable to suggest that agencies articulate the basis of their decisions or that they open their proceedings and deliberations to all interested participants and all relevant information.

These requirements are in everyone's best interest, including decision-makers themselves. If the decision-making process is open and candid it will inspire more confidence in those who are affected. Futher, by opening the process to public scrutiny and criticism, we reduce the risk that important information will be overlooked or ignored. Finally, openness will promote peer review of both factual determinations and value judgments.

Coping with Uncertainty

Risk regulation in itself carries risks. No problem of any significance is so well understood that we can predict with confidence what the outcome of any decision will be. But there are two different kinds of uncertainty that plague risk regulation. Some uncertainty is inherent in regulating activities on the frontiers of scientific progress. For example, we simply do not know enough about the containment potential of salt domes to know with confidence whether they are adequate for storing nuclear wastes for thousands of years. In the face of such uncertainty society must decide whether or not to take a chance—to wait for more information before going ahead with nuclear production, or to go forward and gamble that solutions will be found in the future.

The other kind of uncertainty that infects risk regulation comes from a refusal to face the hard questions created by lack of knowledge. It is uncertainty produced by scientists and regulators who assure the public that there are no risks, but know that the answers are not at hand. Perhaps more important, it is a false sense of security because the hard questions have never been asked in the first place.

In the early days of nuclear plant licensing, for example, the problem of long-term waste disposal was never even an issue. Only after extensive prodding by environmental and citizens' groups did the industry and regulators show any awareness of waste disposal as a problem at all. Judges like myself became troubled when those charged with ensuring nuclear safety refused even to recognize the seriousness of the waste disposal issue, much less to propose a solution.

I expressed these concerns in *Natural Resources Defense Council v. Nuclear Regulatory Commission* (*1*). In that case our court was asked to review the NRC's quantification of the environmental effects of the uranium fuel cycle, including the "back end" of the cycle, waste disposal and reprocessing.

The NRC concluded that those effects are "relatively insignificant." Yet the only evidence adduced in support of its assessment was the testimony of a single NRC expert. Most of the testimony was conclusory and the expert gave little or no explanation of the underlying basis for his optimism.

To my mind, that testimony, without more, provided an inadequate basis for making critical nuclear plant licensing decisions. My objection was not founded on any disagreement with the expert's conclusions. For all I knew then or know now, he may have been accurate in minimizing the risks from nuclear waste disposal. Nor do I criticize the NRC for failing to develop foolproof solutions to the problem of waste disposal. What I found unacceptable was the almost cavalier manner with which the NRC accepted the sanguine predictions and refused to come to grips with the limits of the agency's knowledge. I stated (*2*):

> To the extent that uncertainties necessarily underlie predictions of this importance on the frontiers of science and technology, there is a concomitant necessity to confront and explore fully the depth and consequences of such uncertainties. Not only were the generalities relied on in this case not subject to rigorous probing—in any form—but when apparently substantial criticisms were brought to the Commission's attention, it simply ignored them, or brushed them aside. Without a thorough exploration of the problems involved in waste disposal, including past mistakes, and a forthright assessment of the uncertainties and differences in expert opinion, this type of agency action cannot pass muster as reasoned decisionmaking.

The "thorough exploration" that I found lacking is particularly important in technically complex matters such as nuclear waste disposal. Since courts lack the expertise to assess the merits of the scientific controversy, "society must depend largely on oversight by the technically trained members of the agency and the scientific community at large to monitor technical decisions." There were a number of avenues open to the NRC for the kind of exploration that permits meaningful oversight—but the agency adopted none of them.

The Supreme Court unanimously reversed our decision (*3*). They felt that we had imposed extra procedures on the NRC beyond those required by law for so-called informal rule-making under the 1946 Administrative Procedure Act. They returned the case to our court, however, to determine whether the record supported the substantive conclusions of the NRC.

Whether the Supreme Court's decision represents a fair reading of what our opinion in fact required the agency to do,

I leave to the legal scholars. My own view is that the Supreme Court's decision will have little impact because many of the new laws governing risk regulation explicitly direct agencies to use decision-making procedures that supplement the minimal requirements of informal rule-making under the Administrative Procedure Act. Statutes such as the Clean Air Act Amendments of 1977, the Clean Water Act of 1977, and the Toxic Substances Control Act of 1976 include procedural and record-enhancing features that will contribute substantially to the quality and accountability of agency decisions.

A Structured Approach to Decision-Making Under Uncertainty

I have never believed that procedures per se are a cure-all for solving regulatory problems. Rather, procedural safeguards serve an instrumental role, and it is the fullness of the inquiry that is paramount. If the inquiry is comprehensive and conscientious without additional procedural safeguards, it provides the best record we can hope for in making the difficult choices we now face. Conversely, even when all the procedural niceties are observed, if there is no commitment to a candid exploration of the issues, the predicate for good decision-making will be lacking.

Agencies are now revising their procedures to increase the availability of expert advice without abdicating agency responsibility for value decisions. Agencies have begun to encourage and fund public intervenors. These steps have increased the range of the administrative process, and have forced the agencies to wrestle with the difficult questions which might otherwise escape public scrutiny. Restrictions on ex parte contacts have increased our confidence in agencies' impartiality and fairness. The visibility of decision-making processes and decisions themselves has been enhanced by Congress' and the courts' commitment to openness, through the Freedom of Information Act, the Advisory Committee Act, and the Sunshine Act. I am confident that the courts will continue vigorously to carry out Congress' mandate that decison-making be honest, open, thorough, rational, and fair.

The Problem of Delay

Considering all relevant data and viewpoints is essential to good decisions. This is why I am concerned by recent proposals to shorten the decision-making process for licensing nuclear reactors. I have no doubt that some of the current delay is unnecessary, and it may be that current proposals do not affect critical deliberative processes. I do not express any views on specific proposals. I only want to caution that in speeding up the process, we must take care not to sacrifice the valuable and productive safeguards that have come to be built into the decision-making process.

I do not favor delay caused by an unthinking rejection of progress. Delay from unjustified fear of the future can in the long run cause more harm than the risks it prevents. But delay that is necessary for calm reflection, full debate, and mature decision more than compensates for the additional costs it imposes. The Alaska Pipeline was embroiled in extensive controversy in our courts, primarily by environmental groups who questioned whether sufficient attention was given to safety issues. The litigation imposed substantial costs, both the rising expenses for building the pipeline and the cost of postponing a major source of domestic energy. But in the subsequent attorneys' fees proceedings the companies themselves conceded that the litigation produced substantial safety improvements in the pipeline that Congress ultimately approved. Sometimes the benefits of delay can be dramatic. The American experience in avoiding the tragedy of thalidomide is a poignant but not unique example.

By strengthening the administrative process we provide a constructive and creative response to the inherent uncertainties of risk regulation. Approaching the decision to take or to step back from risks such as nuclear power is like coming to a busy intersection with our view partially obscured. Our instincts tell us to proceed with caution, because intersections are dangerous. Ultimately, the importance of our journey and the desirability of our goal may lead us to brave the traffic and pull out into the highway. But even when we decide to proceed, we should not omit the moment of reflection to observe the passing cars, and look both ways.

References and Notes

1. *Natural Resources Defense Council v. Nuclear Regulatory Commission*, Fed. Rep. 2nd Ser., vol. 547, p. 633 (D.C. Circuit 1976), reversed *sub nom. Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council* (*3*). Nothing in these remarks should be taken to intimate any views of the merits of this case in its present posture, on remand from the Supreme Court.
2. *Ibid.*, p. 653.
3. *Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council*, U.S. Rep., vol. 435, p. 519 (1978).