Health and Safety Risk Analyses: Information for Better Decisions

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Knowing the nature and magnitude of health and safety risks is helpful in setting priorities as well as in making decisions about pursuing recreational activities, foods, jobs, and other aspects of everyday living. "Risk-risk" situations require a choice among risky alternatives. "How safe" situations involve a more general choice as to how much of other desired activities to sacrifice for increased safety. "How safe" situations are inherently more difficult to manage, because they are subject to fuzzy thinking and rhetoric. The large uncertainties of current estimates must be conveyed explicitly to arrive at sensible decisions.

WHAT WOULD YOU DO IN THE FOLLOWING SITUATIONS: (i) You have a partially blocked coronary artery that can be treated by bypass surgery or medication. Although there is a chance of dying during surgery, if you survive you can expect less pain and a more active life than from medication. (ii) Your neighborhood school contains asbestos materials. School officials can ignore the problem or pay for the removal of the asbestos with funds from educational programs or a special property tax.

These two situations exemplify the types of health and safety hazards that all of us face (*1*). Intelligent decisions are needed on which potential hazards to ignore and how much risk reduction to seek. These decisions require information about the nature and probability of the hazard, how the risk is perceived, and safety goals.

The available data and tools to provide this information are replete with uncertainty, which complicates the decision process and occasionally negates the value of an analysis. The hard choices are clothed in uncertainty and conflicting goals. People feel deeply about health and safety issues but become uncomfortable when thinking about situations that involve danger to their children or to themselves.

The coronary heart disease situation has risks and benefits associated with both choices. With such "risk-risk" situations, a person must select the better alternative (*2*). For the asbestos situation, the probability of cancer can be lowered, but only by giving up other desired services or activities. In such "how safe is safe enough" situations, society must decide how much should be sacrificed to reduce risk. Each successive reduction in risk generally achieves a bit less and costs a little more, such as when reducing the levels of trace carcinogens in drinking water (*3*).

Despite the inevitable uncertainties, risk analysis has much to contribute to risk management. Risk analysis helps identify significant hazards, stimulates basic research, and spotlights the need to agree on health goals and priorities. In the past decade risk quantification has challenged much of the conventional wisdom about the safety of our technologies and the efficacy of particular interventions.

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Risk Analysis in Medical Decision-Making

Progress in science enhances understanding of the possible sources of harm and allows quantification of the probabilities, at least crudely. For example, one to two patients out of 100 die during bypass surgery (*4*). This datum simplifies the "risk-risk" situation for many people who would regard this probability as small in comparison with other dangers in this situation. But some individuals are at extraordinary risk. The tabulated frequency of deaths is the accumulated experience from many surgeons, hospitals, and patients of diverse characteristics. The chance of death during surgery would be much less for a 40-year-old in good physical condition with no other medical problems than for an 80-year-old with severe deterioration of the heart muscle and an inexperienced surgeon.

An individual's perception of the value of outcomes and desire for certainty are important determinants in the decision (*5*). A sports enthusiast might regard medical treatment of coronary heart disease as useless. Someone afraid of "dying on the table" might elect medical treatment instead of surgery. A patient without insurance would see the large costs associated with surgery. Even the way the outcomes are described, whether in terms of probability of dying or probability of survival, is likely to affect the choice of treatment (*6*). There is no single optimal decision for all people.

The key issues in medical decision-making are the extent and quality of information about the outcomes of alternative interventions, the incentives influencing the ill person and those treating him, and the preferences of those involved (*7*). Occasionally, decisions are as simple as treating a broken bone: information is good, treatment is beneficial and carries few complications, and there is a dominant decision. More generally, getting the right information is difficult or impossible. For example, a specialist in one mode of treatment finds it difficult to be neutral in offering advice because of his confidence in his skill and approach, his unfamiliarity with other approaches, and the financial incentive. Even the best available data bristle with snares. For example, cigarette smoking is the most important public health issue. Yet there is no confident answer to individuals who ask about their risk from smoking. Even a more-than-two-pack-a-day smoker has only a 15.6% chance of dying of a smoking-related disease before age 65 (36.4% before age 85); thus, some individuals, for genetic or other reasons, are more susceptible than others (*8*).

Risk analysis has enlightened decision-making in two ways. First it has allowed quantification of the chances of adverse outcomes

more precisely as well as of the quality of life and life expectancy implications of alternative modes of treatment. Second, it promotes the evaluation of treatment modes and individual performers. Many treatment modes have been found to be without efficacy, for example, routine removal of tonsils or radical mastectomies (*7*); some hospitals or surgeons have relatively poor outcomes, such as surgeons doing only a few coronary bypass operations each year (*4*).

Risk estimates are even more important in evaluating screening and preventive care, since individuals are counselled to seek these services (*9*). For this counsel to be ethical, not only must the action not be harmful, it must have a reasonable chance of benefiting the person. For example, on average 7.58% of U.S. women contract breast cancer. Early detection (through screening by physical examination plus x-ray) and treatment was found to decrease breast cancer mortality 40% (*10*). However, the screening is not an unalloyed benefit since a single mammogram in a 35-year-old woman involving a dose of 1 rad would increase the chance of cancer to between 7.59 and 7.61%. For annual examinations, the chance of cancer would rise to between 7.90 and 8.25%. Thus, mammography can have an appreciable risk. Screening at an earlier age or more examinations would increase the chance of radiogenic cancer, while offering diminishing incremental benefit in detecting disease. Although modern equipment has reduced the dose per plate about 50-fold, a screening protocol must balance the hazards of screening against those of undetected disease, considering the risk factors for each group.

Some modern equipment is designed to use more than twice as many x-rays per examination as in the clinical trial that showed efficacy. A Pittsburgh physician reports that in more than half the baseline examinations, radiologists recommend retesting because of some suspicious aspect of the film (*11*). The quest for greater certainty appears to have led some radiologists to increase the chance of inducing cancer, with presumably little improvement in detection. While the increased sensitivity of the equipment has lowered the dose per plate significantly, there is still a need to be concerned about inducing radiogenic cancer. Some radiologists appear to be making a decision about how much uncertainty to tolerate without calculating the benefits and risks of the extra plates and follow-up test. A risk-benefit calculation is needed and plates should be eliminated where they do not change treatment or are done only to avoid malpractice suits. A similar question occurs, although in less dramatic form, when physicians order additional tests that do not have health threats but do increase costs. How much should society be willing to pay to reduce risk?

Quantification of Risk

The dangers of being in a building with undamaged asbestos materials can be quantified for the "how safe" situation. The probability of children getting mesothelioma or lung cancer from such asbestos exposure in school is estimated to be about five per million lifetimes, less than 1/5000 the chance of death faced by these children from other current events in their lives (*12*). This analysis leads some to neglect asbestos in order to concentrate on reducing other risks, such as reducing time spent in the same room as cigarette smokers, wearing seat belts, or improving the quality of children's education and personal consumption. Others regard this additional risk from asbestos as nontrivial and want it removed. Careless removal of asbestos, however, can pose major risks to the workmen as well as to the children; many experts believe that asbestos in good repair ought to be left in place and removed only when there is a major renovation or a building is demolished (*13*).

At the current state of knowledge, quantifying risk is somewhat arbitrary. The estimated probabilities have large margins of uncertainty and are calculated from populations that may be quite unlike the individual having to make a decision. It is not a comfort to know that, on average, exposure to arsenic, chromium, or coke oven gases is not a major source of cancer in the United States if you live just downwind of a major emissions source (*14*).

The best probability estimates would come from a "perfect" (controlling for confounding factors) epidemiology study on the population of interest at the range of doses or exposures of interest. There are no such studies, however, and, for most hazards, no human data at all. Epidemiology studies always have one or more of the following problems: too few subjects for confident conclusions, failure to control for important confounding factors, no data (or little data) on exposure, exposure levels many times greater than the standards being considered, inadequate diagnosis, subjects lost to follow-up, or subjects who are qualitatively different from the population to be protected. The Environmental Protection Agency (EPA) classifies epidemiology studies as sufficient, limited, or inadequate and then disregards the inadequate studies (*15*). Since experimental manipulation is not possible, a hard-nosed critic would regard every study as inadequate. Rather, scientists have to ask what can be learned from each study and the studies taken together, and how much confidence can be placed in the results (*16*).

Often, probabilities must be estimated from laboratory studies. Extrapolation of data from rodents or cultured cells to people is fraught with difficulties (*17, 18*). Since humans do not have zymbal glands, how should one interpret a study finding that a chemical causes cancer in the zymbal gland of rats? Until science is able to clarify the implications of such findings, regulators usually make the most conservative (that is, worst case), plausible assumption in each situation—for example, any chemical that increases the number of tumors (benign or malignant) in rodents (even in the zymbal gland) is assumed to be carcinogenic in people. The hope is that improvement in scientific understanding will obviate the need for arbitrary assumptions. Initial data on pharmacokinetics and DNA adducts are beginning to clarify critical issues (*19*). To date regulatory agencies seem reluctant to use these data when they imply lower estimated risks. But regulators must remember that current practice is based on assumptions rather than data; insisting that the current, somewhat arbitrary, assumptions cannot be changed until there is scientific consensus on a new approach is to choose assumptions based on little or no data over models validated by data.

In estimating probabilities from either human or rodent data, the standard assumption is that incidence is proportional to dose measured in milligrams per kilogram of body weight or body surface area (a linear, no threshold dose-response relation), a conservative assumption but still one that is plausible in some cases. Data from both epidemiology and rodent studies show that linearity is the best assumption over a wide range for carcinogens such as ionizing radiation (*20*). For some carcinogens, halving the dose reduces the number of tumors by less than half, whereas for most chemicals tested, halving a large dose more than halves the number of tumors. The extreme case occurs for carcinogens that are essential nutrients. Levels of chromium and nickel essential for nutrition are estimated to cause a small number of cancers (*21*).

Finally, current practice for EPA in carcinogen assessment is not to use the best (maximum likelihood or central tendency) estimate of the linear term coefficient in a multistage model. Rather, they construct a 95% confidence interval about that estimated coefficient and use the upper bound (*22*).

Although conservative assumptions are the rule, there are several places where the risk estimates might understate the true risk. First, people are not exposed to a single chemical, but rather to a number of chemicals. Even if they act independently, the risk will be the sum

of individual chemical risks. Second, the chemicals may interact and potentiate or dampen the effects of other chemicals. Third, some individuals may be particularly sensitive to some chemicals, more so than the rodents used in testing.

Nonetheless, agency risk assessors believe that, in general, their risk estimates overstate the true risks. In many cases there may be no risk to humans associated with current exposure levels. While there is still some chance that the risk estimates may understate true risks, agencies find that there is little threat associated with many environmental situations that cause popular concern, such as asbestos in good repair in buildings (*12, 14, 23, 24*). In contrast, the estimated risk associated with some hazards, such as radon in buildings, is extremely high for some homes (as high as 10,000 per million lifetimes), arsenic emissions from smelters (as high as 360,000 per million lifetimes), and some food contaminants (the tolerance level for aflatoxin in corn implies 700 cancers per million lifetimes) (*14*). Current levels of public concern are not closely aligned to the estimated risk level (*25*).

The value and even the interpretation of risk estimates are compromised by arbitrary assumptions, some conservative and some that would understate the true risk. Arbitrary assumptions inject scientists' personal goals or interpretations of public desires into the risk analysis. Rather, the risk analysis should reflect the best science, the range of plausible models, and judgments, based on the best science, of the appropriate confidence intervals about these estimates. The risk managers need unbiased information with the uncertainties displayed explicitly to help them arrive at good decisions. Regulatory agencies should arrive at similar risk estimates for a substance. The risk management decisions may differ across agencies, depending on the goals embodied in the statutes and the individual costs and benefits of control.

Food Additives

Food additives can introduce hazards and tend to elicit a great deal of emotional response (*26*). "Risk-risk" situations occur, as when sodium nitrite increases the chance of cancer but reduces the chance of botulism. More frequent are "how safe" situations, where food additives improve the flavor, appearance, or shelf life of food but also increase the chance of cancer. Is having brightly colored maraschino cherries worth even a minuscule threat (the risk of red food color is estimated to be 0.02 cancer per million lifetimes) (*14*)?

Consumers do not "need" nonnutritive sweeteners, color additives, or antioxidizers; food can be less sweet, can be sweetened with sugar, need not have vibrant colors, and can be susceptible to spoiling more quickly. To some people, these properties are of little value; when foods are properly labeled, they select food without additives. To others, these properties are important and worth a tiny increase in the chance of cancer. As long as people understand the hazards, they can make their own choices. For saccharin-sweetened foods, Congress has required that the label must indicate ingredients and that warning signs be posted informing people of the carcinogenic potential.

The mandate of the Food and Drug Administration (FDA) is to prevent food from becoming contaminated or adulterated; the FDA is to ensure that the food supply is healthy (and varied and not needlessly expensive) (*26*). That mandate requires that the FDA define standards for what is aesthetically acceptable and what is safe enough. The FDA has evolved a policy that if a food additive (or its metabolites or breakdown products) increases the chance by less than one cancers per million lifetimes, the threat is considered to be too small to be of concern (*27*). This policy is highly controversial and the subject of litigation. However, given the natural toxic substances in food, it is unclear what a sensible alternative would be (*28*). The FDA finds the upper bound cancer probabilities for some food constituents and contaminants to be much larger than the comparable figure for food additives (one cancer per million lifetimes or less). For example, the tolerance level of aflatoxin in corn is estimated to increase the incidence of cancer by as much as 700 per million lifetimes (*14*).

What is the meaning of an estimated probability such as one cancer per million lifetimes (*29*)? The actual chance might well be zero, since a rodent carcinogen might not be a human carcinogen, or it might be larger, because humans are more sensitive to this chemical than rodents. Applied to the United States, this estimate literally means 230 cancers over 70 years or 3 to 4 additional cancers each year, added to the 1 million "background" cancers. In particular, food colors, such as those used in coloring fruit cocktail, increase the risk about 0.4 cancer per million lifetimes, or about one cancer each year for the U.S. population.

As long as people are presumed to be reasonably well informed and to be capable of making their own judgments, those who like vibrant colored fruit cocktail can consume it while others can avoid it. However, if this food is consumed by someone ignorant of the risks, such as a child, society must decide whether the food colors should be banned. Apparently, the FDA considers a risk estimate of one cancer per million lifetimes to be small enough to let individuals make their own decisions, even if there are some people who take the risk without realizing it.

Traumatic Injuries and Death

Risk assessment has had a long history in analysis of "accidents." In 1985, 92,500 Americans were killed (about 5% of all deaths) and 9 million persons sustained disabling injuries from accidents (*30*). Almost half the deaths (45,600) were highway-related, 11,600 were work-related, 20,500 occurred at home, and 19,000 were other public accidents. Almost 60 million people were injured, resulting in 543 million restricted activity days. Safety analysts dislike the term "accident" since it has a connotation of being beyond human control. Instead, each trauma injury has a cause, and steps could have been taken to avoid it or at least mitigate the injury.

"Risk-risk" situations occur in designing safety equipment. If an energy-absorbing steering column in an automobile is designed to protect the driver during a low-speed crash, it offers less protection in a high-speed crash, and vice versa. One "how safe" situation is the controversy over whether air bags should be mandated in cars. There is no doubt that air bags would save lives, but the cost per life saved would be about $1 million (*31*).

A variety of approaches have been used to assess the frequencies and mitigation possibilities (*32*). The most important is statistical analysis to identify the frequency of events and conditions leading to injury or death. Others include crash investigation, injury epidemiology, behavioral feedback, economic approaches, human factors, and more recently, the use of fault and event trees (*32*). The last approach is embodied in probabilistic risk analysis, developed for nuclear reactors and now used in other areas (*33*).

Aside from an occasional enthusiastic speech, no one talks about eliminating trauma—that would require banning activity. Activities such as mountain climbing are chosen by adults who can be presumed to be reasonably informed of the risks. For all activities, society tries to decrease risk by encouraging safe behavior and safer products; enhancing safety stops when the cost and inconvenience of increased safety exceeds the benefit of the safety gains (a "how safe" decision). The social decision is complicated by human

reactions to the safer product that could increase risk (*34*); when people do not use safety features, their use can be mandated (*35*).

Injury rates have declined markedly over many decades, whether measured by the fatalities per passenger mile for automobiles and commercial aircraft or occupational injury rates (*30*). Most of this decline is not related to governmental standards and inspection, but rather seems to come from company and consumer decisions as influenced by legal liability (*36*).

Risk Management

Risk analysis is done to enlighten decisions about "how safe" and "risk-risk" situations (*37*). Since the risk estimates have major uncertainties, they may be useless to the risk manager. If a toxic chemical is inexpensive to control or replace, even a hint of toxicity might lead to control (*38*), such as occurred in the banning of cyclamate. If a chemical is difficult to replace, such as vinyl chloride monomer or saccharin in 1978, it is unlikely to be banned even if the number of deaths associated with its use is nontrivial (*39*).

Although the dose-response relation has received the most attention, for health risks, exposure assessment adds greater uncertainty. This is anomalous since improving exposure assessment is not difficult.

Providing warning labels and signs does not guarantee that people will read them or understand them (*40*). However, there is a basic social choice about the extent to which individuals should be allowed to make their own decisions and to be able to understand the information provided and the consequences of their choices. None of this means that the victim and others will not be terribly sorry when a chance is taken and it turns out badly. What range of hazardous choices will society allow to individuals (*41*)? What information should be available to inform these decisions? Society is not and cannot be expected to maintain consistency, since these are hard decisions. For example, society allows individuals to smoke cigarettes while forbidding them to eat swordfish containing levels of mercury that pose a far lower risk. In some states a person traveling by car to spend a day hang gliding must buckle his seat belt.

Some hazards, such as those associated with a nuclear reactor or a plant making pesticides, endanger people in the vicinity; the decision concerning where to locate them is inherently social in nature since the individuals living nearby will have to accept this risk. Some of these people will see the plant as offering a trivial increase in risk, but others will see it as life threatening. Because individuals can do little to adjust their risk level, these situations exasperate those who disagree with the social decision (*42*).

"Risk-risk" situations require a balancing. This structure precludes rhetoric about being willing to spend anything to prevent a premature death. The "how safe" situation invites fuzzy thinking and rhetoric. The issue is not how many pieces of green paper are worth preventing a premature death, but rather how much inconvenience and discomfort to bear and how much consumption of other goods and services to give up to lower the probability of disease or death a bit more (*43*).

A person may appear to engage in inconsistent behavior in smoking cigarettes while worrying about food additives or not testing for radon while worrying about asbestos that is in good repair. The apparent contradictions may result from a complicated cognitive structure for perceiving hazardous situations (*25*). People are concerned with aspects different from those that experts focus on. Since they are the consumers and the voters in our democracy, people are the final arbiters of how safe is safe enough.

For guidance on what risk levels to set, a variety of approaches has been used. One attempts to find what is a trivial or de minimis risk, so that the limited resources for improvement are not wasted to reduce risks beyond this level (*14, 44*). A second approach is to examine hazards that are readily accepted in everyday life and in regulations (*29*). A third is to seek public guidance through referendums or through the actions of elected representatives. Several state referendums on nuclear power have done little to clarify public preferences; each was voted down but each was phrased in such an extreme form that a moderate critic of nuclear power might have voted against the measure. Congress has not been much more informative, since legislation generally contains contradictory language. For example, the Occupational Safety and Health Act sets a goal" " . . . that no employee will suffer material impairment of health or functional capacity . . ."; however, the act also requires that the regulations " . . . assure insofar as practicable . . ." which is interpreted to mean both technical and economic feasibility. In one of the few cases where Congress was unequivocal about setting a stringent risk standard, the Delaney amendment to prohibit carcinogenic food additives, the FDA has permitted them, as long as they pose a tiny risk (*17, 27*). Congress, the agencies, and the courts are concerned that safety regulations not be so stringent as to halt the economy or even shut an industry. The result is that Occupational Safety and Health Act and EPA sometimes tolerate extremely large hazards because it is not technically or economically feasible to deal with them.

Just as a great advantage of risk assessment is bringing the calculations out into the open, uncertainties and all, so one of the great advantages of risk management has been bringing the decision process out into the open. Since the probabilities cannot be lowered to zero, there is good reason to inform the affected parties and the public of the basis for a decision. While it is time consuming and apparently wasteful to reach these decisions in a fishbowl, there is no other process likely to secure public confidence and consent.

Conclusion

Risk analysts should not attempt to overstate or understate threats, but rather to give a best estimate and the range of uncertainty. Decision-makers can choose the proper amount of conservatism in setting the standard. The various federal agencies ought to coordinate their risk assessment processes so that they will arrive at similar estimates for a particular hazard.

Current risk estimates are fraught with uncertainty. The process of conducting and defending risk analyses highlights these uncertainties and suggests a research agenda to resolve them. Rather than reify existing arbitrary assumptions, the process must be opened to new data and models, particularly since current assumptions often are based on little or no data.

It is inherently easier to manage "risk-risk" situations than "how safe" situations. The former are self-limiting and require an explicit balancing of the risks. The latter are subject to rhetoric about zero risk because there is no necessity to consider what is being sacrificed to lower the probability further. Risk management is inherently difficult not only because it requires setting specific goals, but because the situations involved often affect many people simultaneously, requiring a collective decision. Since people have different safety goals and are uncomfortable thinking about hazardous situations, collective decisions are difficult.

Progress in the field of risk analysis has been enormous—it hardly existed a decade ago. The intellectual ferment comes from the focus on helping to enlighten decisions, rather than on intellectual elegance. The constant interaction of those involved in risk analysis and in risk management is needed to stimulate analysts to make their greatest contribution.

REFERENCES AND NOTES

1. C. Starr, *Science* **165**, 1232 (1969); W. W. Lowrance, *Of Acceptable Risk* (Kaufmann, Los Altos, CA, 1976); W. D. Rowe, *An Anatomy of Risk* (Wiley, New York, 1977).
2. L. B. Lave, *The Strategy of Social Regulation* (Brookings Institution, Washington, DC, 1981).
3. National Research Council, *Drinking Water and Health* (National Academy Press, Washington, DC, 1986), vol. 6.
4. M. C. Weinstein and W. B. Stasson, *Annu. Rev. Public Health* **6**, 41 (1985).
5. B. J. McNeil and S. G. Pauker, *ibid.* **5**, 135 (1984).
6. _____, H. C. Sox, Jr., A. Tversky, *N. Engl. J. Med.* **306**, 1259 (1982).
7. J. P. Bunker, B. Barnes, F. Mosteller, Eds., *Costs, Risks, and Benefits of Surgery* (Oxford Univ. Press, New York, 1977); Institute of Medicine, *Assessing Medical Technologies* (National Academy Press, Washington, DC, 1985).
8. R. Doll and R. Peto, *Br. Med. J.* **2**, 1525 (1976); L. E. Kuller, E. Meilahn, M. Townsend, G. Weinberg, *Annu. Rev. Public Health* **3**, 153 (1982).
9. J. R. Lave *et al.*, in *Preventive Medicine, USA* (Prodist, New York, 1976), p. 675; J. R. Lave and L. B. Lave, *Health Soc.* **55**, 273 (1977); L. B. Russell, *Is Prevention Better than Cure?* (Brookings Institution, Washington, DC, 1986).
10. U.S. Department of Health and Human Services, *Determining Risks to Health: Federal Policy and Practice* (Auburn, Dover, MA, 1986), pp. 219–223; L. H. Baker, *CA Cancer J. Clin.* **32**, 194 (1982); J. K. Gohagen, W. P. Darby, E. L. Spitznagel, B. S. Monsees, A. E. Tome, *J. Natl. Cancer Inst.* 77, 71 (1986).
11. B. Block, personal communication.
12. R. Doll and J. Peto, *Asbestos: Effects on Health of Exposure to Asbestos* (Her Majesty's Stationery Office, London, 1985); H. Weill and J. M. Hughes, *Annu. Rev. Public Health* 7, 171 (1986).
13. D. C. Dewees, *Asbestos in Buildings: An Economic Investigation* (Resources for the Future, Washington, DC, 1986).
14. P. Milvy, *Risk Anal.* **6**, 69 (1986); C. C. Travis, S. A. Richter, E. A. C. Crouch, R. Wilson, *Environ. Sci. Technol.*, in press; D. Byrd and L. B. Lave, *De Minimis Risk*, C. Whipple, Ed. (Plenum, New York, 1987).
15. Environmental Protection Agency, *Fed. Regist.* **51**, 33992 (24 September 1986).
16. T. A. Louis, H. V. Fineberg, F. Mosteller, *Annu. Rev. Public Health* **5**, 433 (1984).
17. U.S. Office of Technology Assessment, *Assessment of Technologies of Determining Cancer Risks from the Environment* (U.S. Government Printing Office, Washington, DC, 1981); L. B. Lave, *Quantitative Risk Analysis in Regulation* (Brookings Institution, Washington, DC, 1982); U.S. Office of Science and Technology Policy, *Fed. Regist.* **50**, 10371 (1985).
18. L. B. Lave and G. S. Omenn, *Nature (London)* **324**, 29 (1986).
19. D. G. Hoel, R. A. Merrill, F. P. Perera, Eds., *Risk Quantification and Regulatory Policy* (Banbury Report 19, Cold Spring Harbor Laboratory, Cold Spring Harbor, NY, 1985); I. B. Weinstein, *Annu. Rev. Public Health* **4**, 409 (1983); D. B. Hattis, *Risk Anal.* **6**, 181 (1986); F. Perera, *ibid.*, p. 195.
20. National Research Council, *The Effects on Populations of Exposure to Low Levels of Ionizing Radiation* (National Academy Press, Washington, DC, 1980).
21. Cosmetic, Toiletry and Fragrance Association, "Comments on the decision to adopt a de minimis policy under the Delaney Clause" (Washington, DC, 1986).
22. E. L. Anderson *et al.*, *Risk Anal.* **3**, 277 (1983).
23. J. W. Grisham, *Health Aspects of the Disposal of Waste Chemicals* (Pergamon, New York, 1986); M. Russell, *Science* **236**, 286 (1987).
24. E. Whelan, *Toxic Terror* (Jameson, Ottawa, IL, 1985).
25. D. Kahneman, P. Slovic, A. Tversky, *Judgment Under Uncertainty: Heuristics and Biases* (Cambridge Univ. Press, New York, 1982); B. Fischhoff, S. Lichenstein, P. Slovic, R. Keeney, S. Derby, *Acceptable Risk* (Cambridge Univ. Press, New York, 1981); P. Slovic, *Science* **236**, 280 (1987).
26. P. B. Hutt, *Food-Drug-Cosmetic Law J.* **33**, 505 (1978); R. A. Merrill, *Mich. Law Rev.* 77, 171 (1978); S. A. Miller and M. G. Stephenson, *Am. J. Clin. Nutr.* **42**, 739 (1985).
27. Food and Drug Administration, *Fed. Regist.* **50**, 51551 (18 December 1985); M. Sun, *Science* **229**, 739 (1985).
28. B. N. Ames, *Science* **221**, 1256 (1983).
29. B. L. Cohen and I. S. Lee, *Health Phys.* **36**, 707 (1979); R. Wilson and E. Crouch, *Science* **236**, 267 (1987).
30. National Safety Council, *Accident Facts* (National Safety Council, Chicago, 1986); S. P. Baker, B. O'Neill, R. S. Karpf, *The Injury Fact Book* (Lexington, Lexington, MA, 1984); J. A. Waller, *Injury Control: A Guide to the Causes and Prevention of Trauma* (Lexington, Lexington, MA, 1985).
31. L. B. Lave, *Science* **212**, 893 (1981).
32. J. D. Graham and H. Piehler, unpublished observations.
33. W. E. Vesely, *Risk Anal.* **4**, 247 (1984).
34. L. Evans and R. C. Schwing, *Human Behavior and Traffic Safety* (Plenum, New York, 1985); W. K. Viscusi, *J. Law Econ.* **38**, 527 (1985).
35. E. A. Latimer and L. B. Lave, *Am. J. Public Health* 77, 183 (1987).
36. M. Baram, *Alternatives to Regulation* (Lexington, Lexington, MA, 1982).
37. National Research Council, *Risk Assessment in the Federal Government: Managing the Process* (National Academy Press, Washington, DC, 1983); W. Ruckleshaus, *Issues Sci. Technol.* **1**, 19 (1985); V. T. Covello and J. Mumpower, *Risk Anal.* **5**, 103 (1985).
38. National Research Council, *Toxicity Testing: Strategies to Determine Needs and Priorities* (National Academy Press, Washington, DC, 1984); L. B. Lave and A. C. Upton, *Toxic Substances, Health, and the Environment* (Johns Hopkins Univ. Press, Baltimore, 1987).
39. J. L. Badaracco, Jr., *Loading the Dice: A Five-Country Study of Vinyl Chloride Regulation* (Harvard Business School Press, Boston, MA, 1985); National Academy of Sciences, *Food Safety Policy: Scientific and Societal Considerations* (National Academy Press, Washington, DC, 1979).
40. A. Morris, M. B. Mazis, I. Barofsky, *Product Labeling and Health Risks* (Banbury Report 6, Cold Spring Harbor Laboratory, Cold Spring Harbor, NY, 1980); W. K. Viscusi, W. A. Magat, J. Huber, *Rand J. Econ.* 17, 351 (1986); W. K. Viscusi and W. A. Magat, *Learning About Risk: Consumer and Worker Responses to Hazard Information* (Harvard Univ. Press, Cambridge, MA, in press); S. G. Hadden, *Read the Label: Reducing Risk by Providing Information* (Westview, Boulder, CO, 1986).
41. D. MacLean, in *Risk Evaluation and Management*, V. T. Covello, J. Menkes, J. Mumpower, Eds. (Plenum, New York, 1986); R. L. Keeney, *Risk Anal.* **4**, 117 (1984); L. B. Lave, *Accident Anal. Prev.* **19**, 29 (1987).
42. L. B. Lave and T. Romer, *Risk Anal.* **3**, 217 (1983).
43. J. Linnerooth, *Inquiry* **17**, 52 (1979); W. K. Viscusi, *Risk by Choice: Regulating Health and Safety in the Workplace* (Harvard Univ. Press, Cambridge, MA, 1983).
44. Supreme Court, *Industrial Union Department, AFL-CIO* v. *American Petroleum Institute*, 448, US 607, 639 (1980).

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