Risk Assessment and the Interface Between Science and Law

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INTRODUCTION

In 1983 two events occurred which provided a major impetus to the use of risk assessment as a distinct tool in the regulation of hazardous chemical and physical agents. These events were not completely unrelated. The United States National Academy of Sciences released a document which detailed the risk assessment process and distinguished it from risk management.[1] Soon thereafter the Reagan Administration, under substantial fire for its environmental policies, replaced EPA Administrator Anne Gorsuch with William Ruckelshaus, who had been the original administrator of EPA when the Agency was created. The perception that EPA was using science for political ends had eroded public confidence in the Agency.[2] To restore this confidence it was necessary to focus on developing and sustaining a process capable of providing scientific and technical information free from the inference of bias. Therefore the Agency emphasized risk assessment as a process which was to be distinct from risk management.

Since that time the federal regulatory process has gained a great deal of experience with using risk assessment and many of

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1. NATIONAL ACADEMY OF SCIENCES, NATIONAL RESEARCH COUNCIL, COMMITTEE ON INSTITUTIONAL MEANS FOR ASSESSMENT OF RISKS TO PUBLIC HEALTH, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS (1983).

2. Among the reasons for the loss of EPA's credibility was the clear attempt by the incoming leadership in 1981 to dismantle its research and development program, and the impression given of a cavalier approach to the science underlying EPA decisionmaking. *See also Mandate for Leadership II: Continuing the Conservative Revolution*, The Heritage Foundation (1984). This think tank, which clearly represented the objectives of the Reagan administration, admitted "The Reagan Administration mistakenly reduced EPA's research efforts. Yet increased and improved research is essential for a rationalization of current regulations and for improved legislation." *Id.* at 87.

its advantages have become clear. The use of risk assessment has spilled over into state and local regulatory processes, the insurance industry, and in the area of toxic tort litigation. This has led to an even greater need for a clear understanding of the virtues and vices of risk assessment.

This paper will discuss a number of issues pertinent to an understanding of risk assessment, particularly as this process is designed to employ scientific information and its use by the legal community.

I. THE PURSUIT OF TRUTH: YOUR PURSUIT VS. MINE

One of the most fascinating interfaces in our society is that between science and law. The difference in the approaches of the two disciplines and resulting difficulty in communication between the two is highly significant as the two are based on very different values. At its base are completely different concepts and ethical values as to the appropriate manner to pursue truth. For instance, although it may be appropriate for a member of a law school faculty to present and discuss tactical approaches for including or disqualifying risk assessments as part of the adversarial "search for truth," such behavior from a faculty member in a science department would be quite inappropriate as it relates to the scientific "search for truth." The reason is simple. Lawyers are trained as advocates, and as such, present only one side of an issue in a civil or criminal suit. However, a scientist, to be credible, must present information that both supports and detracts from a hypothesis. Exclusion of negative evidence is unethical and a presentation which describes tactics to exclude pertinent negative information would be abhorrent to a scientist, although perfectly appropriate to attorneys.

This difference in approach, and the complications it causes, becomes particularly evident in considering how scientific expert opinion is used by a regulatory agency in establishing standards and guidelines. In order to simplify the analysis, let us assume there are two ways that we use experts to approximate the truth about the level of a compound that produces an adverse effect: the consensus approach and the confrontational approach. A scientist advising the Administrator of EPA on a basic risk assessment issue would attempt to use a consensus approach, as would

the National Academy of Sciences or a similar body.[3] To illustrate, let us start by assuming that there are 1000 scientists in the world with sufficient knowledge about chemical *X* to be considered experts, and that they are asked independently to come up with a number for the lowest adverse effect level of this chemical. A graph of the individual numbers would probably fit a bell-shaped curve. Some scientists will be at one end, some at the other, but most will fall in the middle. It is this middle which the consensus approach tries to determine, as it is the most likely estimation of truth as perceived by expert scientists.[4]

The scientific consensus approach does not attempt to individually request this number from 1000 scientists. Rather, the usual approach is to convene a panel of experts who are selected in an unbiased fashion from the pool of 1000 scientist experts. The consensus approach model assumes that the scientists on the panel will learn from each other as they listen to evidence, and weigh and discuss different viewpoints. Interestingly, at the end of this deliberative process, these scientists will usually end up with opinions closer to the center (mean) of this bell-shaped curve than they would have if they were simply asked for their individual opinions.[5] After discussing the subject, scientists

3. Actually, the National Academy of Sciences and similar organizations often attempt to balance their panels by including an equal representation from industry and public advocacy groups. The trick is to be sure that the individuals chosen will clearly understand that they are there as scientists, not as advocates. A strong chairperson who has a reputation for evenhandedness is crucial.

4. B.D. Goldstein, *The Scientific Basis for Policy Decision*, in ENVTL. & HEALTH RISK ASSESSMENT (1987); Goldstein, *Risk Assessment/Risk Management is a Three-Step Process: In Defense of EPA's Risk Assessment Guidelines*, 7 J. AM. C. TOXICOL. 543 (1988).

5. Note that the example given presumes that the question raised has a numerical answer; *e.g.*, the lowest observed effect level of a pollutant. More problematic is the situation in which the question has a discrete answer. This can be particularly important in the hazard identification step of the risk assessment process; *e.g.* is formaldehyde a human carcinogen? One can get a complete split in the scientific community on such a question. However, a question of this nature could be rephrased in terms of what is the probability that formaldehyde is a human carcinogen. If the latter approach were to be taken, one is likely to find a relatively narrow range of probabilities expressed by knowledgeable scientists, again fitting a bell-shaped curve. As discussed in footnote 4, *supra*, the hazard identification step for carcinogens is particularly prone to result in controversy. This is because as a society we have asked our regulators to protect us against not only the two dozen or so known human carcinogens, but also against chemicals which may be human carcinogens.

Also note that the assumption of a bell-shaped distribution of scientific inference is unlikely to be true for those pollutants for which there is a limited and controversial data base. For example, if scientific opinion is evenly split about the validity of one particularly crucial study, with very little other information available, then a bimodal distribution of numerical estimates would be expected.

would move toward a central consensus since most scientists intuitively huddle together on questions of this nature. This is because scientists do not want to be wrong, risking a loss of credibility. Scientists have more to lose by being the one person who turns out to be wrong, than they have to gain by being the one person who turns out to be right because credibility is the key to their success. Therefore, reputations are guarded by huddling together.

Consider now the approach to this same situation by ethical, well-trained lawyers. The opinion of as many as possible of these individual scientists is sampled and, quite appropriately, the lawyer selects scientists whose opinions are on one extreme of the bell-shaped curve, knowing full well there is a lawyer on the other side who is looking for scientists at the opposite extreme. There follows a confrontation among the scientific experts in a hearing or trial, in which the give and take of scientific discussion is neither possible, nor permitted.

The best way to summarize this point is to keep in mind that the scientists' basic credo is that there is absolute truth and that it will some day be known. This makes us very hesitant to say anything which differs from other scientists, inasmuch as the inevitable discovery of truth may show us to be the only one who is wrong, with devastating professional consequences. In contradiction, the attorney is basically an advocate, with a professional reputation that is dependent upon the efficacy of the advocacy, not the eventual finding of truth. The difference in these two profession's perception of truth is further illustrated by the fact that in most jurisprudence issues there is either no objective truth, or the truth consists of the determination of an individual's past act, rather than a repetitive and predictable law of nature.

For example, scientists have an innate belief that there is an objective truth underlying the question of whether or not formaldehyde is a human carcinogen, or the extent to which an individual is at risk of leukemia following exposure to a given level of benzene. Moreover, they have an optimistic faith that such truths will eventually be revealed. The legal profession, however, is more concerned with questions as to whether an event—such as whether exposure to a substance caused cancer—is more likely than not and need not concern itself with any outcome which becomes known after the litigation is complete.

Although remarkably different in process, both the consensus and confrontational approaches are appropriate for different situations. Both of these approaches are ethical when used in the proper context and both of them are a natural outgrowth of the basic philosophies of their respective disciplines. Nevertheless, there is an enormous amount of confusion among the public, as well as among the authors writing in this area, about which of these processes are being used to obtain scientific truth.[6]

At EPA, the consensus and confrontational approaches often occur simultaneously, usually organized by different constituency groups both in and out of the Agency. Until we understand which process is being used, we can not expect to be able to appropriately use the information, nor communicate the information accurately to the public.[7]

We must recognize that our society approaches environmental regulation with a unique blend of the scientific consensus and legal confrontational approaches to what are primarily matters of the laws of nature, *i.e.*, science. To a scientist, this interplay between approaches can be very frustrating, particularly when one is told by lawyers that a lack of agreement among scientific

6. I have been astounded at how often attorneys will choose to rebut this argument by pointing out that scientists have values and have often been known to misrepresent and cheat. This is both true and trivial. My point has to do with the inevitable consequences of the methods used to pursue truth, including the mechanisms that come into play to correct error. It is independent of whether some scientists are publicity hounds, have prostituted themselves to industry, or are wild-eyed environmentalist radicals out to destroy capitalism. There are both scientific and legal methods to inhibit and discredit such individuals. The point remains that there is an objective truth to the questions of risk. The culture of science drives us to manipulate symbols so as to devise formulae which will best approximate that objective truth, although knowing full well that if our formula is wrong the real world will eventually let our peers know of our error. Our suspicion and dislike of the legal/political sphere is that we too often observe its participants blatantly attempting to manipulate symbols so as to match their preconceived vision of what the real world ought to be.

7. The criticism that the legal process tends to exaggerate the extent of disagreement among scientists is also valid for describing the press. Like lawyers, few journalists have any expertise in science. The well-trained ethical journalist will consider him or herself to have presented a fair picture of the overall story by seeking balance. The usual tactic to achieve this balanced presentation is to approach both sides and ask them to provide the names of scientists who are expert in the area under discussion. Needless to say, this again results in presenting a picture of scientific disagreement which may not be justified. Unfortunately, journalists have neither the training nor the inclination to let readers know whether the balanced opposing viewpoints covered in the press represent two opposing scientific viewpoints with no one in between, or represent extreme views for which there is otherwise an overwhelming consensus of knowledgeable scientists somewhere between the two extremes.

experts is a major problem impeding regulatory approaches. Often what is impeding the regulation is not the fact that a lack of agreement exists, but the advocacy confrontational process of obtaining scientific information which tends to foster the disagreement within the scientific community.[8]

A frequent jest by regulators and legislators is to ask for a one-handed scientist, as they are tired of hearing scientists say "On the one hand . . ., but on the other hand . . . ." As a physician who has often been involved in major decisions in the face of significant uncertainty, I have much sympathy for the regulator. We would all like to deal with a world of absolutes so as to simplify our decisions. There is perhaps nothing more frustrating than to agonize over a decision concerning a possible risk when the options all have costs to society, or possible adverse consequences to the patient; yet we can not even be sure the risk is real. However, my experience at EPA suggests that the problem is not just one of scientists being unable to give a clear answer. It is just as often the failure of the regulator to ask a clear question. Much more interface between scientists and lawyers, of the type occurring at this symposium, is necessary to help frame questions appropriately in order to get the optimal response. Further, the time to frame the questions is very early, before the actual decision is made, in order to give the scientist the opportunity to obtain new information. Often regulators faced with the need to make a decision under a deadline will agonize over crucial uncertainties that could have been resolved, or narrowed, had the problem been faced in sufficient time to develop the necessary research.

It is far easier to point out this problem than to solve it. Western European countries tend to rely more on small panels of experts to make consensus decisions independent of a legal confrontational approach. However, such countries are smaller and have societies which are more homogeneous than the United States. For example, in Scandinavian countries, issues related to the setting of a numerical standard for a work place pollutant may often be decided at a single sitting by a total of three physicians representing labor, industry and government. These three physicians may well have graduated from the same medical school and have worked together for years. They will actually defer to each

8. Kantrowitz, *Proposal for an Institution for Scientific Judgment*, 156 SCIENCE 763 (1967).

other's expertise when interpreting the relevant scientific literature. In other words, one may be more knowledgeable about epidemiology, another may be an expert in toxicology and each scientist will take this into account in arriving at a consensus. This degree of cohesiveness and trust is simply not possible in our society; nor is it consistent with the basic checks and balances approach to decisionmaking that is inherent in our constitution and our traditions. Although as a scientist I might wish we could use this approach, it does not seem likely to me that our society will turn over the active regulatory process to consensus panels of experts.[9]

Much more can be done, however, to clearly delineate that part of governmental decisionmaking that depends upon scientific and technical expertise. EPA's focus on risk assessment must be understood as an approach to this delineation. It is a decision to leave risk assessment to the scientists and to emphasize the consensus approach. Failure to recognize the need to have risk assessment driven by scientific consensus rather than by confrontational approaches will inevitably doom the entire process. The risk assessment program at EPA, and at other federal or state agencies, needs to have a sign on its door saying "Regulatory Lawyers Keep Out."

II. Making Risk Assessment/Risk Management a Three Step Process: The Use of Risk Assessment Guidelines[10]

Several commentators in this symposium have noted that risk assessment is not really free of policy. Of course it is not. In fact, the whole process of risk assessment/risk management is really three steps, not two. Before assessment and management of risk can take place, first there must be a science policy process. It is this science policy approach that sets the general approach to the risk assessment, one example being an inherent conservatism. The policy basis for conservatism in risk assessment is similar to

9. Goldstein, *Risk Assessment/Risk Management is a Three-Step Process*, *supra* note 4.

10. Guidelines For Carcinogen Risk Assessment, 51 Fed. Reg. 33,992-34,003 (1986); Guidelines for Mutagenicity Risk Assessment, 51 Fed. Reg. 34,006-34,012 (1986); Guidelines for Exposure Assessment, 51 Fed. Reg. 34,042-34,054 (1986); Proposed Guidelines for Assessing Male Reproductive Risk, 53 Fed. Reg. 24,850-24,869 (1988); Proposed Guidelines for Assessing Female Reproductive Risk, 53 Fed. Reg. 24,834-24,847 (1988); Proposed Guidelines for Exposure-Related Measurements, 53 Fed. Reg. 48,830-48,853 (1988).

the prudence inherent in any public health approach; however, it must be built in a manner that is explicit, logical and consistently applied. The problem is that, until recently, there has been no road map to take one through risk assessment. It has been too easy for an advocate to pick whatever number was wanted: a low risk number if the advocate was opposed to regulation and a high risk if the advocate was in favor of regulation. Different risk numbers could be obtained by making different assumptions at different times.

In order to solve this problem, EPA has developed Risk Assessment Guidelines, which are, in essence, the science policy step preceding risk assessment and risk management. The aim is to provide an openly stated comprehensive road map showing how a scientific data base—such as animal bioassay or human epidemiologic data—is transformed into a quantitative or qualitative statement of risk. This is supplemented by a risk assessment forum[11] consisting of representatives from the scientific and regulatory offices at EPA. The forum provides an open means to consider scientific issues which might be pertinent to altering the Risk Assessment Guidelines, thus providing an avenue for new scientific discoveries relevant to generic issues of risk assessment. By establishing a risk assessment guideline process which states in advance how to do risk assessment, it is possible to avoid the sort of body English that can be given to a risk assessment by an advocacy process.

A. *Data Quality Objectives*

Quality assurance is one of the watchwords of the present EPA approach to any data base used by the Agency. Quality assurance concerns itself with all aspects of data, including the sampling process, the precision and reliability of the analytical technique, the description of the findings and the chain of custody linking the sample to the reported result. Although the need for EPA to assure the quality of its data would seem obvious, the Agency's recognition of this fact has been relatively long in coming. There

11. The types of issues considered by the risk assessment forum are evident from the following publications: E. RINDE, R. HILL, A. CHIU & B. HABERMAN, PROLIFERATIVE HEPATOCELLULAR LESIONS OF THE RAT: REVIEW AND FUTURE USE IN RISK ASSESSMENT, U.S. E.P.A. (Feb. 1986); J. BELLIN & D.G. BARNES, INTERIM PROCEDURES FOR ESTIMATING RISKS ASSOCIATED WITH EXPOSURES TO MIXTURES OF CHLORINATED DIBENZO-P-DIOXINS AND DIBENZOFURANS, U.S. E.P.A. (Mar. 1987).

is no doubt that quality assurance at EPA has been helped along by the legal profession who have appropriately shown that EPA will lose any litigation if its data does not meet quality assurance standards. The concepts of quality assurance are just as applicable to risk assessment as they are to measuring water quality.

The first step in quality assurance, understanding the objective of the assay, is clearly the most important. Measuring a window for curtains does not require the same degree of precision or accuracy as measuring the O-Rings on the Challenger. Many in the field are asking for a data quality objective for risk assessment with a precision and accuracy well beyond what is needed.[12] An apt analogy is to the use of unemployment figures by the federal government. We know that the government's estimate of unemployment is useful in any debate about what to do about this problem. We believe that if actual unemployment goes up or down, it will be reflected in the published number. But I have never heard anyone accusing the Reagan Administration, or the Carter Administration, of distorting the numbers, or trying to do something with those numbers to make them other than what they are, some rough estimation of unemployment. The aim of risk assessment similarly should be merely to provide a number for guidance in the evaluation and implementation of regulatory approaches. With further scientific advances in understanding the mechanism of toxicity of environmental agents, and with further development of standardized approaches through Risk Assessment Guidelines, this goal is achievable.

The data quality objective for risk assessment was established by EPA for regulatory purposes, not for toxic tort suits. Therefore, the assessments are ill-suited for use in toxic tort litigation. To a physician, the crucial question in a toxic tort case is one of reasonable medical probability—basically is it more or less than a 50-50 chance that the unwanted outcome was due to the presumed causal agent? Many of the discussions at this symposium have been about hypothetical exposure situations added to a background risk of getting cancer of about 250,000 out of a million. Arguments about whether an exposure leads to an increase in cancer risk of one in a million or one in a hundred thousand can be translated numerically to overall risks of 250,001 or 250,010 in a million. This is simply not an issue of reasonable

12. *See e.g.*, Commoner, *The Hazards of Risk Assessment*, this volume.

medical probability. Although a debate between this ten-fold difference is still an important consideration for public health decisions, such as where to build a municipal incinerator, it is well out of the range of what is understood to be the province of toxic torts. It is therefore crucial that we understand the data quality objective for the performance of risk assessment and not complain about the failure of risk assessment to provide accuracy or precision at a level beyond its data quality objective.

B. *Conservatism in Risk Assessment*

One implication of the inherent conservatism in risk assessment is that the inevitable consequence of most scientific advances related to the assessment of risk for individual chemicals is to lower the calculated risk. There has been much discussion and public controversy surrounding the recent EPA proposal for lowering the unit risk number for dioxin.[13] Dioxin, of course, has a special emotional quality to it. So let us step back from the question of whether or not it was appropriate to lower the risk number for dioxin. Let us think about the foundations for developing risk numbers in general.

As a society we have put some conservatism into risk assessment. This conservative approach toward estimating risk has not been changed, even during the Reagan Era, and it is unlikely to ever change in the future. Following good public health precepts, in any risk calculation scientists lean over backwards to be prudent by using the plausible upper boundary, or ninety-five percent upper confidence level, rather than using the median "best" estimate.[14]

13. The controversy has even reached the front page of *The New York Times*, *see*, Shabecoff, *Estimate of Risk of Dioxin is Cut in Cancer Study*, N. Y. Times, Dec. 9, 1987 at A1, col. 1.

14. All measurements have some associated degree of precision which will be dependent upon a number of factors, including the inherent accuracy of measuring technique and of the measurer. This means that any measurement has some uncertainty and, under appropriate circumstances, the uncertainty can also be estimated. In some cases one aims at attaining a measurement which is not in the center of the range of uncertainty (*i.e.*, the mean) but is weighted to one or another side. For example, the standard measuring technique for a glazier is to use a six foot folding ruler, with 1/16 inch markings to measure a window that needs to be replaced. In the case of a large storefront window, this measurement might be made by one worker who will telephone the dimensions to the shop, who will then send out a truck with a replacement window and a crew of glaziers. The prudent foreman, knows that the glaziers working at the site can cut a larger window down to size (*i.e.*, can compensate for an overestimate), but that there is no way to stretch a too small

The obvious implication of using a conservative upper bound estimate is that the real risk number should be less. Accordingly, as scientists gather further information, they will tend to decrease the range of uncertainty about the real number. Therefore more often than not the ninety-five percent upper confidence limit, which is another way of saying plausible upper bound, will tend to become closer to the median level. Therefore, more scientific information in such cases means that the risk number will get lower.

Obviously our knowledge is not perfect. There will be situations in which it will turn out that the real risk number is much higher. However, inherent in the rules of the game is that more scientific information for the same endpoint means, more often than not, that risk numbers will be decreasing. The worst thing that we can do is to set up a situation so that we cannot use this increased scientific information because of the political aspects of changing the numbers.[15]

III. Risk Characterization and Risk Communication: The Overlap Between Risk Assessment and Risk Management

Risk assessment and risk management clearly overlap in the risk characterization and risk communication processes. The endpoint of a risk assessment is the characterization of the risk. An important aspect of risk management is the communication of risks. The reason it is very difficult to separate risk assessment and risk management is simply because it is very hard to separate risk characterization from risk communication. One of the best examples of this problem is found in medicine. In our current era

glass window to the needed size. Similarly, public health agencies, such as the EPA, have decided as a matter of science policy to choose a risk number that is likely to overestimate rather than underestimate the risk: the rationale for this policy being based on prudence in dealing with human health. In the case of the glazier foreman, the extent to which the measured window size is overestimated will be a rule of thumb decision process depending in part upon the relative cost of sending out another truck, upon the cost of the excess glass which will be wasted, upon the past reliability of the measurer, etc. In the case of the risk assessment process, the overestimate is obtained by a formal mathematical process aimed at a number which 95 times out of 100 will be above the real measurement and only five times out of 100 will be below this estimation. *See* Anderson & The Carcinogen Assessment Group, *Quantitative Approaches in Use to Assess Cancer Risk*, 3 Risk Analysis 277 (1983).

15. Note that this does not mean scientific research will automatically result in decreasing the stringency of environmental regulation. The opposite will occur when research identifies previously unrecognized health effects, as has occurred with exposure to lead.

of holistic medicine, and obscene malpractice insurance rates, doctors teach medical students that they have to tell each patient all of the facts that they can possibly explain, and let the individual patient make the decision regarding treatment. However, you can come to a physician with a concern of yours, and a physician can say, yes, there is some reason to be concerned and there is a test, which is ninety-nine percent free of any risks, that will allow us to get more information about this problem. Or the physician can say, yes, you have a reason for concern and there is a test which will yield more information, but the test has a one percent likelihood of a severe side effect, including death.

The risk numbers are the same for the two physician statements, but which statement is chosen by the physician will often determine the patient's response. Much of this kind of selection goes on in the risk characterization—risk communication process, by all sides. Accordingly, the idea of an independent scientist who is just counting the unemployment figures is undermined most during the process of characterizing the risk.

IV. NON-TORT ENVIRONMENTAL RISKS: THE LIMITATIONS OF TOXIC TORTS IN SOLVING ENVIRONMENTAL PROBLEMS

We have many failures in the communication of risk to the public. In New Jersey, one of our biggest risks is radon, primarily in the northern part of the state. The risk far outweighs hazardous waste, or almost any one of the usual pollutants.[16] Yet, a disproportionate amount of judicial and legal time and resources is spent in deciding issues relating to the clean up of hazardous waste sites. It is very disturbing that we can not seem to get people to even check their homes for radon. This leads me to challenge the legal profession.

There is no question that the tort system is very valuable from a public health point of view. Clearly more people would get hip fractures after a snow in the northeast, were it not for the fact that we shovel our walks because we are afraid someone is going to sue us. In my judgment, "toxic torts" have definitely helped in cutting down on the amount of pollutants that we are exposed to. However, an issue like radon makes the limitations and distortions of the toxic tort system all too clear. It is hard for lawyers to

16. For a general discussion of the health risks associated with radon in New Jersey, *see* Klotz & Odasin, *Radon in New Jersey*, 85 N.J. MED. 940 (1988).

sue God, and even EPA has a tough time regulating Mother Nature. However, until practicing attorneys become concerned about "no fault" issues, the societal effort and dollars put into the toxic tort approach will inevitably produce a distorted approach to overall environmental health priorities.

V. Conclusion

It is not surprising that risk assessment is controversial. In a relatively short period of time it has become almost a routine procedure for considering the potential health impact of chemicals or physical agents. In view of its rapid growth in use, and the major political and economic consequences of its outcome, the risk assessment process and procedures have attracted the attention of a wide range of observers, in addition to the health scientists who are its practitioners. It is important that these practitioners carefully communicate the objectives, advantages and limitations of risk assessment to the entire interested community. It is important that those who approach risk assessment from an advocacy position also fully understand the derivation and role of risk assessment.