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Science and Values in the Regulatory Process

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Abstract. This article provides a framework for consideration of values in the use of science in the regulatory process. The science in question includes both the assessment of technologic risk and the assessment of technologic options to reduce those risks. The focus of the inquiry is on the role of the scientist and engineer as analyst or assessor. The difficulties in separating facts and values will be addressed by focusing on the central question: what level of evidence is sufficient to trigger a requirement for regulatory action? For the purposes of this article, the regulatory process includes notification of risks to interested parties, control of technologic hazards and compensation for harm caused by technology. The discussion will address the problems in achieving both a fair outcome and a fair process in the regulatory use of science.

Key words and phrases: Law and science policy, government regulation, environmental risks, scientific testimony, scientific and legal evidence, ethics and regulatory process.

"IF SCIENTISTS THINK LAWYERS CAN PRESENT ONE-SIDED CASES, THEY MAY WISH TO REDISCOVER THEMSELVES."
(NADER, 1974)

This article provides a framework for considering values in the use of science in the regulatory process. The science in question includes both the assessment of technologic risk—from chemicals, consumer products, energy sources, transportation technology, etc.—and the assessment of technologic options to reduce those risks, such as hazard control technology, product substitution and industrial process redesign.

The focus of this inquiry is on the role of the scientist-engineer as analyst-assessor and not as the designer of new products or processes, although the latter activity also presents serious ethical questions for scientists and engineers. Further, instead of analyzing the use of science by lawyers and other players in the legal system, this article adopts the premise that some criticisms of the adversary process in resolving science-based disputes can be better addressed by examining the role of scientists or engineers who participate in that process.

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For the purposes of this article, participation in the regulatory process includes a variety of activities from the undertaking of scientific and technologic inquiry relevant to regulation, to advocacy of particular actions within the regulatory process. The regulatory process is broadly defined to include the notification of interested parties of technologic risks and options, control of those risks and compensation for harm resulting from technology. Government at the federal or state level intervenes in all three sets of activities through regulatory agencies and the courts. But governmental decisions at each stage of the regulatory process critically depend on scientific and technologic information. The question is: what is the appropriate role of the scientist-engineer to ensure both a fair process and a fair outcome for science-based disputes in which he or she participates? What is the role of the science itself?

SCIENCE AND VALUES: CAN THEY BE SEPARATED?

Although scientific inquiry often claims to be value-neutral (i.e., non-normative), the same cannot be said for the uses of scientific information in decisions concerning the control of science and technology. It is therefore important to ask whether the conduct of policy-relevant scientific inquiry, such as risk assessment, can ever really be value neutral (Ashford, Ryan and Caldart, 1983; Hattis and Smith, 1986; Rushefsky, 1986). The practice of science has been described as

reductionist, that is, science teases out the most likely correct truth in an uncertain world by using simplifying assumptions and theories. The traditions and conventions adopted by science in order to establish "truth" are traditions and conventions to deal with uncertainties in both scientific theory and data. In the evolution of a scientific paradigm or methodology, for example, science often establishes clearly visible standards which must be achieved for something to be considered true. The things that are considered true according to these standards are called facts. When we are certain about scientific explanations, we call these explanations laws. When we are less certain, we call them theories. To change a scientific theory into a scientific law, we need both confirmation of the theory by existing data and acceptable explanations of data that appear to deviate from the predictions of the theory. Science recognizes that such confirmation or explanations cannot be 100% certain. Scientific tradition and conventions establish the minimum *scientifically* acceptable probability of being correct and the maximum *scientifically* acceptable probability of being wrong in reaching a conclusion.

Legal actions seek to be fair and to encourage the correct outcome in societal activities, including the applications of science and technology. In prescribing or prohibiting a given activity, the law, like science, is sensitive to the probability that a certain view of the world might be right or might be wrong. What the law calls a fact—sometimes called a legal fact—is based on a set of data that is certain enough to justify a given directive or conclusion. But the law also seeks to encourage the correct result in the normative sense, that is, what John Rawls would call the just thing (Rawls, 1971). The law and the policy process recognize that something must be true enough to justify an action, but the same basis for truth is not required as a prerequisite to arriving at a just outcome in different situations. Law thus seemingly creates a paradox whereby things can be regarded as true for some purposes but not for others. Science, on the other hand, insists that things are either true or untrue, and by marshalling established scientific conventions as the tests, encourages us to believe that no value judgment ever attends the establishment of truth.

It is, however, clear that those who undertake scientific inquiry today, in fact, hold values concerning the use of their science. Within a given framework of scientific traditions and conventions, there are many ways to analyze and present data (Whittemore, 1983). There are also many ways to frame the scientific question and choose which data to collect. A scientist's choice among these possibilities is shaped by values. By either speaking out about those values or by remaining silent, scientists exercise a value judgment about the way science is used in regulation. Accordingly, as Professor Mark Rushefsky of Southwest Missouri State University has observed, "Ostensible disputes over the science are, in reality, over the values inherent in the assumptions" (Rushefsky, 1985, page 31).

If science is not value-free, then how can it best inform the public policy debate? Many would address that question by requiring agencies to establish a two-step process for dealing with risk: risk assessment and risk management. The former is expected to be a non-normative scientific determination, and the latter a value-laden political decision to control a given hazard. However, the key question for policy makers is this: at what level of proof does a showing of risk or danger trigger a requirement for regulatory action? What is considered sufficient proof is a *social* policy determination, requiring a judgment about the consequences of both regulating and not regulating a possibly hazardous activity. Science can inform, but should not necessarily dictate, the results of that analysis.

Such judgments can be in error because of uncertainties with regard to the nature and extent of the risk or the economic and technologic feasibility of regulatory controls. Type I errors are committed when society regulates an activity which turns out not to be harmful and resources are needlessly expended. Type II errors are committed when, because of insufficient evidence, society fails to regulate an activity which turns out to be harmful. Aversion to making Type I and Type II errors reflects differing value decisions about (1) the nature of the mistakes made and (2) the extent, prevalence or magnitude of the mistakes. An aversion to Type I errors underlies the often expressed pleas that we "move the regulatory process toward better science." In some cases this may simply be a request to be more permissive in controlling technologic activities.

The interplay of facts, or science, and values can be illuminated by three general scenarios concerning carcinogen regulation:

(1) If a causal relationship is shown which satisfies the accepted scientific conventions for establishing that a chemical causes cancer, then a *scientific determination* has been made which can inform the public policy process. (An example is the overwhelming evidence that asbestos exposure causes mesothelioma.) Then, the decision to notify, regulate, or compensate is essentially a social or public policy decision.

(2) If a sizable majority of the relevant and respected scientific community believes that a substance is probably carcinogenic (perhaps more likely than not), although causality has not been proven at the conventional (high) level of

statistical significance or with sufficient strength of association, then a *science policy determination* has been made that justifies treating the substance as if it were carcinogenic. The scientists who reach such a consensus have similar values regarding the use to which the scientific data will be put. Specifically, the decision to view the substance as a probable carcinogen in this scenario reflects an aversion to Type II errors, that is, erring on the side of caution. Their science policy decision can then inform the social policy decision taken by the regulatory agency.

(3) If the scientific community reaches no consensus about labeling a substance as carcinogenic (for regulatory purposes), then there is no scientific or science policy determination to inform regulatory decision making. However, it may still be sound *social policy* to control that substance. A decision to regulate under these circumstances would merely mean that the regulator's preference for making Type I versus Type II errors is different from that of the scientists who reviewed the evidence.

These three scenarios, of course, represent points on what is really a continuum of scientific uncertainty. They merely illustrate the *varying* relationship of science and values encountered in the regulatory process. Under conditions of uncertainty, the nature of the scientific consensus or science policy determination, may depend on the use to which data and information will be put. Consensus on the minimum evidence required for action will, and probably should, differ according to whether the purpose is notification, regulation or compensation.

Thus, while a uniform intellectual *approach* to the question of risk assessment and risk management is theoretically desirable, *uniform* conventions, such as statistical significance or the rejection or acceptance of negative studies, are not advisable in deciding what level of proof is acceptable for policy purposes. Value judgments clearly attend decisions whether to lean in favor of Type I or Type II errors in specific cases. This is because the cost of being wrong in one instance may be vastly different from the cost of being wrong in another. For example, banning a chemical which is essential to a beneficial societal activity (such as the use of radionuclides in medicine) has potentially more drastic consequences than banning a nonessential chemical for which there is a close, cost-comparable substitute. It may be perfectly appropriate to rely on most likely estimates of risk in the first case and on worst case analysis in the second. This approach illustrates not only a preference for making Type I rather than Type II errors, but also illustrates the dependence of that preference on the size of the Type I error.

In each of the three scenarios described above, both a fair process and a fair outcome are desirable. A fair *process* has its origins in the legal tradition of due process, but more generally means that a procedure for the determinations of both science and policy has provided adequate opportunity for presentation and discussion of the data, their relevance for society and the underlying values and preferences of the participants regarding the use of the data or findings. Whether a process is fair or not, can usually be determined objectively by any observer without deciding questions of fact or policy one way or another. In contrast, a fair *outcome* has as its reference or basis a particular observer's view of the same issues. People who would make different decisions concerning a fact or policy might not call the outcome fair, although they might agree that the process leading to it was fair.

In Scenario 1, scientists can contribute their work product (or publish their findings) and hope that the facts will speak for themselves when considered by the decision makers. Of course, there may be vigorous dissent about the scientific studies themselves, and this may require open discussion of the science. But this process can usually be handled with fairness by the scientists themselves in an informal way through peer review and other avenues for open exchange and criticism. A more formal process targeted toward elucidating facts and values will then be required for the subsequent *policy* decision to ensure that the data are put to an appropriate use for regulatory purposes. It is within this scenario that a cost-benefit analysis, in which either net benefits of a proposed action, or a benefit-to-cost ratio, is sometimes the basis for a decision. Type I and Type II errors are small and hence play no part in the decision process. Instead, the decision maker's *values* regarding net benefits or a benefit-to-cost ratio is the basis.

In Scenario 2, a fair process is needed not only for the risk management decision, but also during risk assessment in order that the *science policy* determinations are properly arrived at. Such a process is required to illuminate the values that may be hidden behind science policy conclusions. In this scenario, uncertainty (and error avoidance) plays a larger role, and values enter in arriving at science policy conclusions. A cost-benefit basis for a decision appears to be, but is not the sole basis for the decision.

In Scenario 3 we are unsure about the correctness of the outcome, that is, Type I and/or Type II errors are large. The best we can do is to provide a fair process for the resolution of competing values, because the final social policy decision turns largely on value choices concerning Type I and Type II errors.

The remainder of the article deals with the ethical problems encountered by scientists participating in

the regulatory process and the problems of ensuring fairness in their contributions to policy decisions. Where the consideration of facts and values cannot be institutionally separated, as they arguably can be in Scenario 1, the trier of fact or decision maker must insist on a clarification of the values which influence the determinations of the scientist-participant. Only then can a decision maker fairly make the decision which society has mandated.

PARTICIPATION IN THE REGULATORY PROCESS AND ATTENDANT ETHICAL DILEMMAS

As noted earlier, the major components of the regulatory process are (1) notification of interested individuals or groups about technologic risks, (2) mandatory action for control of those risks and (3) compensation in the form of workers' compensation, insurance for the general public and tort (product liability) suits. Each type of regulatory action relies on scientific data and theories, but each seeks to fulfill a different societal purpose.

It is helpful to expand these major types of regulatory activities into some subordinate activities that may create ethical dilemmas for the scientist-participant:

1. Alerting a regulatory agency or an industry to a problem or an opportunity to improve public health and safety. The institution thus alerted is then free to determine how serious the problem is and how it can be corrected. The regulatory agency or industry may, of course, control the hazard and/or notify people at risk.
2. Advising a regulatory agency or industry of the seriousness of a problem, that is, performing a risk assessment and/or identifying a substitute technology or industrial practice which might reduce the problem.
3. Participating in the regulatory standard-setting process.
4. Contesting a regulatory violation.
5. Participating in a proceeding wherein a victim seeks compensation for injury allegedly caused by exposure to a particular hazard.

As scientific data become available, a scientist may conclude that the results suggest action. Should the scientist alert a regulatory agency or an industry to his or her findings? Scientists work more or less independently on projects that interest them. Although they may have personal autonomy on a daily basis, they are constrained in their research by available resources, including external funding. Scientists may be asked to investigate the carcinogenicity of a chemical substance by a regulatory agency or by industry. Should they alert both if they discover a problem or only the body that funded the research? If the scientist alerts the agency or industry to the problem, is there a further duty to advise them both of the seriousness of the problem?

Another way scientists can participate is in the standard-setting process. Participation can take several forms, including serving on agency advisory committees, petitioning the agency to act, providing expert testimony in regulatory hearings, cross-examining other witnesses, commenting on another expert's testimony and participating in a challenge to the regulatory standard. Scientists operate with varying degrees of independence in these activities, participating to bring attention to their research, to critique a scientific principle or policy recommendation and on behalf of an interested party.

Scientists may run risks in being too outspoken in an advisory committee, because they may not be reappointed or asked to join others (Ashford, 1984). Agencies differ among themselves and over time as to how much critical comment they want to hear. Similarly, scientists may be reluctant to press for regulatory action because of the threat of loss of job, status or research funds. "The field is littered with the bones of scientists who spoke out bravely about controversial issues and were then forced to be at the mercy of a totally unresponsive and uncharitable society," claims Ralph Nader (Nader, 1974). Because of the effective grapevine that exists throughout industry and regulatory agencies, scientists who aggressively push agencies to act can be labeled troublemakers and find themselves jobless. Yet, Nader argues that, "Scientists should be the initiators, the interpreters, and the advocates in many public policy issues" (Nader, 1974).

How much information should scientists give when they testify? Should scientists volunteer facts unfavorable to the party for whom they are testifying? Should scientists assist in actively cross-examining other points of view? Should they only answer questions which are put to them? Is there a distinction between the duty of a scientist who testifies for an interested party and one that works as a special master for the court? These questions present ethical and professional dilemmas.

Once the regulatory hearing process is completed, the agency can use the data, testimony and recommendations from the various parties in setting a standard or taking other regulatory action. Here, too, dilemmas exist. Should scientists volunteer facts and interpretations unfavorable to their own argument? Scientists can assist industry, public interest groups or labor in challenging the agency's policy decision. Once a standard is in place, scientists can further involve themselves in enforcement

activities by helping to defend or challenge a citation for noncompliance.

Finally, scientific evidence is vital in adjudicating claims for compensation. What level of proof is sufficient to establish causation for purposes of compensation? Should a scientist's judgment be weighed heavily in this determination? The scientist, as much as any sworn witness, promises to tell the truth, the whole truth and nothing but the truth. If a scientist tells the whole truth, he should volunteer all the strengths and weaknesses of the scientific theory, data and reasoning relevant to the case at hand. The whole truth includes an exposition of the weaknesses of one's own testimony. Otherwise, the scientist is indeed no different from any other well-informed advocate who seeks to advance advantageous truth and to minimize or hide disadvantageous truth.

When a scientist gives testimony on behalf of an interested party, his likely biases are recognized and accepted. His testimony is discredited only if it is clearly wrong. It is not discredited if he merely omits to disclose a fact or viewpoint upon which he was not asked to comment directly. Yet, if a scientist were to present a scientific paper with such omissions, it probably would not pass a review of his peers. He would not be allowed to ignore a contradictory theory or unfavorable data, or avoid answering an embarrassing question by a reviewer. Yet, some scientists who provide incomplete or partial testimony in regulatory proceedings maintain that they are complying with the standards of their profession (Ashford, 1983).

Even when a scientist is not formally affiliated with an interested party, influences exist that can bias his views. One important influence is industry's funding of academic research. Industry can "coopt the academic experts," and control the direction and content of academic research (Owen and Braeutigam, 1978). Industry funding for research at many universities has increased many times more than federal support and has raised questions about the independence of academic scientists.

Numerous motives can underlie an industry decision to fund a particular academic scientist. A manufacturer of a chemical that is already in production and whose safety is now questioned would prefer to fund a scientist whose research will not confirm the problem. It is not necessary to find a scientist who will lie, only one who customarily uses a relatively insensitive method of experimental or statistical analysis, or evaluates data by methods that fail to provide conclusive results. On the other hand, a firm may adopt the opposite strategy when it wants to determine whether a new compound is carcinogenic prior to marketing it and making a large capital investment in it. Here, all the incentives work in the direction of discovering carcinogenicity, if it exists. The firm wants to avoid a later and potentially more costly discovery of toxicity.

It is important to consider whether toxicologists asked by a regulatory agency to evaluate a chemical may not also be influenced by the sponsor. The difference, however, is that those performing government-funded research, whether through mission agencies or basic research institutes like the National Institutes of Health, have to maintain their long-term credibility and must contend with public oversight and advisory committees. Public funding comes under more public scrutiny. Decisions to fund certain types of research over others are made in a context sensitive to social demands, often directly by a peer group of scientists as well as indirectly by politicians who budget funds for projects viewed as important to society.

Scientists direct their research toward areas for which public or private funding is available (Ashford, 1983). But public interest or labor organizations that want scientific data to support their position are not likely to be able to fund such research even if they can find a scientist sympathetic to their cause. In a real sense, therefore, scientific expertise is likely to be biased against the interests of such organizations.

Regulation can confer considerable costs and benefits on the players. The anticipated consequences influence not only the political process, but also the conduct and use of science because, as we have argued, the practice of science is seldom interest-free. It is important to be sensitive to the allegiances or biases of the scientist-participant in order to uncover possible distortions of scientific data and conclusions.

SORTING OUT SUBJECTIVE VALUES FROM OBJECTIVE VIEWS

To achieve society's purposes, the use of science in the regulatory process should be objective, balanced and attended by a fair process. A fair process is valuable in itself, independent of the outcome it produces. What constitutes a fair process may be different for the different uses to which science is put and in the different components in the regulatory process.

It is important to distinguish balance from objectivity. If a sufficiently diverse group of scientists is brought together to address a problem or interpret a set of data, that group's determination may be called balanced. That determination may be or may not represent a consensus. The group may simply express a wide diversity of legitimate views. In either case, we should avoid the use of the term objective to describe the determination. It is quite another matter to call an individual scientist's testimony balanced. An individual's views are balanced only if they are objective.

As we have discussed, however, a variety of factors make it difficult for any individual scientist to achieve true objectivity. It is also difficult for the external observer to determine whether an individual has given balanced consideration to the facts before him. Because there are so many assumptions, tradition and conventions which he may use in the face of uncertainty, it is well nigh impossible to delve into the reasons for all of his choices. Sometimes the mechanism of cross-examination can be used to discredit a particularly biased or uninformed analysis. For a cross-examination to be effective, the examiner should demand disclosure of all those factors which could, at their worst, result in distortions of fact, omissions of data or failures to consider alternative views and theories.

The Federal Advisory Committee Act (FACA) requires that advisory committees be balanced among differing points of view. In formulating an operational definition of balance to meet the FACA requirements, three criteria should be considered: competence, discipline and bias or allegiance (Ashford, 1984). Ensuring balance in the effectiveness of technical argument surely requires equivalent competence among antagonists, but experts as a group may need to be tempered by nonexpert members in order to achieve a fully balanced perspective in other ways. Each discipline carries its own paradigmatic bias. To guard against this, both nonexperts and multiple disciplines should be represented, the mixture depending on the committee's particular agenda or purpose. Finally, political, institutional, ethnic or sexual bias or allegiance should be adequately balanced.

Voluntary disclosure of bias and identification of interests is imperative to a fair process for the resolution of science-informed disputes. If balance is to be achieved, whether in the context of a committee or in a hearing, the decision maker must be made aware of bias and interests. Within an advisory committee, disclosure of current professional affiliations and past or present consulting arrangements will let the public know what influences may be affecting the views of members. Disclosure is also important in the context of individual testimony. In a hearing, an expert can be cross-examined to test not only his competence, but the objectivity of his views and timely disclosure of bias or allegiance can influence the cross-examining process.

The decision maker, whether it is an administrative law judge, a regulatory official or a court, needs to be alerted to both bias and values of the participants in order to evaluate the evidence and put it to proper use. Science claims to be guided by the search for and the explication of truth. In regulation, however, the central question is not what is true but at what level of proof does the evidence trigger a requirement for action. This question creates a tension for scientists. It requires experts to balance the desire to follow scientific conventions for finding truth against the imperative of furthering a just social policy through the use of science. Scientists may be uncomfortable with and unaccustomed to making such judgments or trade-offs. It is safer for most experts to follow an accepted professional tradition rather than to argue over values. As we have noted, however, social policy determinations about risk are directly related to the aversion of the scientific observer or interpreter of evidence to commit Type I and Type II errors. Although scientists frequently make such value judgments, they are no more expert at making them than other informed decision makers.

What makes scientists important to the achievement of a fair process is that their intellectual contribution to regulation—science—is the starting point for the entire decision making process. Distortions of the scientific issues at the beginning can have serious consequences later on. Thus, one can argue that because of the powerful position that science and scientists occupy in the regulatory process, they have a special responsibility to guard against distortions or misuse of evidence.

TOWARD A SOLUTION

As experts in their field, scientists have tremendous power over the outcome of the process. Mistakes or tricks that misguide a decision maker lessen the chances for a fair process, let alone a fair outcome.

Many commentators on expert witnesses blame lawyers for failing to ask the right questions of experts. Scientists could help here. Lawyers are also blamed for using any available technique to win their case. But each side in a regulatory proceeding finds experts claiming different objective views of the data. "The obvious objective of the courts in respect to expert testimony is to optimize the search for the truth," says Paul Meier of the University of Chicago (Meier, 1986). Judges and lawyers may not have the expertise to extract truths from manipulated data, but experts do.

The misuse of science serves no one's ultimate purpose. A desired outcome may be obtained in a particular hearing or trial in spite of mistakes or an unfair process, but the credibility of both science and law will be damaged. Because of the uncertainties of science, it is critical for an attorney to marshall the opinions favoring the side he is representing, but neither dishonest interpretation nor omission of crucial facts allows for a fair process. Lawyers strive to explain scientific and technologic information to the decision maker using cross-examination to discredit

data that have been manipulated or conclusions that have no factual basis. Only experts can provide the remaining elements that ensure both a fair process *and* a fair outcome. These are best achieved when experts voluntarily clarify their values and make explicit their conventions, assumptions, reasons for their choices and rejection of alternatives, and especially the *limitations* of their own findings and conclusions.

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