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Science Courts, Evidentiary Procedures and Mixed Science-Policy Decisions

Carl F. Cranor*

Introduction

Mixed science and policy decisions are common. The scientific and policy questions that must be answered in order to make defensible decisions are difficult, do not admit of obvious answers, are frequently plagued by controversy, and are often second-guessed.

Specifically, such decisions and the institutions that make them are frequently criticized by the scientific community as irrational and not properly founded on good scientific evidence and theory. For example, tort litigation which serves to compensate victims injured by others' activities and products, as well as to deter similar conduct in the future, has been criticized as making decisions, at least sometimes, on the basis of "junk science," i. e., scientific theories that have no basis in scientific fact or theory.¹ Also, regulatory institutions that attempt to prevent harm from technological products or processes before they injure the public or employees in the workplace have been criticized — on the one hand for basing regulations, not on proper scientific risk assessments, but rather upon public sentiment and pressure, and on the other hand for being captured by industry's conception of the science.

As recounted elsewhere in this issue, Arthur Kantrowitz proposed a science court as an alternative or supplement to existing institutions. With advocates on both sides of a scientific debate and judges to evaluate their claims, a science court would evaluate only the scientific portion of mixed scientific-policy debates. His aim was to assure more

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¹ PETER HUBER, *GALILEOS REVENGE: JUNK SCIENCE IN THE COURTROOM* (1991).

accurate scientific information about technical issues, to limit the policy making powers of scientists (who are claimed to have too much policy influence), to prevent policy makers from hiding behind scientific conclusions for their policy decisions, and to identify and expose discredited scientific claims.²

Kantrowitz originally suggested that a science court might work best when addressing relatively specific, but “big” or “large scale” questions, such as whether the SST would harm the ozone layer or how rapidly to reduce automobile emissions. Since then, however, writers have suggested that any such procedure should be directed at quite specific scientific and technological issues that are addressed by regulatory agencies or even those that may arise in tort cases.

Exactly what role science courts should have or the aims they should serve is unclear. Should they address only very general scientific questions, and thus serve to modify the procedures of institutions such as the National Academy of Sciences? Should they replace technical sections in agencies such as the Environmental Protection Agency (EPA), the Occupational Safety and Health Administration (OSHA), or the Food and Drug Administration (FDA)? As the symposium introduction asks: Would they constrain or enhance the influence of scientists in public policy debates? Moreover, would they facilitate separation of scientific and policy issues, and is this desirable? These are only a few of the questions that might be raised about science courts, but they are more than enough for this paper.

Many of Kantrowitz’s concerns have merit. We should certainly resist scientists who propose their own projects and succeed because of special influence as may have happened with Star Wars. Also, even though scientists have technical expertise, that does not authorize them to make moral and political recommendations; their votes should count no more or less than others in a democracy. Neither is it desirable to have politicians avoid political responsibility for normative aspects of decisions nor for Washington science advisors to exercise inordinate

² See, e.g., Arthur Kantrowitz, *Controlling Technology Democratically*, 163 AM. SCIENTIST 505 (1975); see also, James A. Martin, *The Proposed “Science Court”*, 75 MICH. L.REV. 1058 (1977).

influence. Finally, most would agree that it is difficult to comprehend and control technological developments. Any institutional procedure which adequately addressed these concerns is to be commended.

In what follows, I do not focus directly on these issues. Instead, I consider the strengths and weaknesses of science courts to address but one aspect of our technological revolution — the identification and control of toxic substances. This group of mixed science-policy decisions may or may not be representative, but it serves to make issues specific, to illustrate some shortcomings of using science courts, and to illuminate some generic difficulties of relying upon scientific expertise to address sharply contested issues on the frontiers of knowledge.

With regard to control of toxic substances, it seems difficult, if not impossible, to separate socially useful scientific facts from normative judgments. It also appears that, because of different evidentiary requirements for scientific inquiry and public policy decisions, an attempt to separate the science from normative considerations and adhere to evidentiary standards typical of research science will poorly serve public debate on relevant issues. Thus, insofar as mixed science-policy problems raised by the identification, assessment and regulation of toxic substances are typical, science courts may not be the best way to address the scientific aspects of mixed science-policy issues. And if the problems raised here are atypical, this suggests limits to the applicability of science courts to technological problems.

Desiderata

The general issue raised by science courts is the desirability of having one institution or procedure rather than another to address mixed science-policy questions; there are several desiderata by which such procedures might be judged. The most obvious, and frequently claimed to be lacking, is scientific accuracy. A decision reached by an institution should be scientifically accurate or rest on accurate scientific judgments. On the one hand, if harm is alleged to be caused by a substance, and in fact it is not, but the government has acted because of public concerns, society will have wasted time, money and human resources in addressing a non-existent problem. On the other hand, if a substance is

misjudged not to cause harm, then people will be injured, and society will have wasted money by producing too much of a harmful product. Thus, the criterion of accuracy is critical and one to which Kantrowitz gives high priority. However, since no procedure is unerringly accurate, the evidentiary procedures that aim to secure accuracy are important. Also, the kinds and the costs of mistakes resulting from institutional procedures merit comment.

The *kinds of mistakes* likely to result from imperfect institutional procedures involves the *distribution* of institutional mistakes. Decisions about potential toxic substances which rest on imperfect scientific procedures may result in false positives, also called type I errors (a substance is wrongly thought to cause harm or risks of harm), or false negatives, also called type II errors (a substance or product is wrongly believed to be “safe”). Which kind of mistake should be of most concern raises questions of the social consequences of different kinds of mistakes in the context of different kinds of institutions. For example, criminal procedures strongly protect against wrongly punishing an innocent person, the juridical equivalent of a false positive, but public health agencies tend to be more concerned with missing possibly dangerous product or diseases, than the criminal law or pure scientific research.

The costs of making one kind of mistake rather than another are especially important in designing and deciding upon evidentiary procedures. In assessing possible toxic substances, false positives may misdirect investment and impose costs on manufacturers, shareholders, and consumers of their products. The very existence of firms or product lines or the welfare of the public may be threatened. False negatives impose costs on those put at risk of death, disease, or compromised quality of life — along with associated economic costs.

In science, peer review, demanding standards of evidence and research practices all protect against false positives to avoid mistakenly adding to the stock of scientific knowledge and misguiding future research.³ In contrast, when scientific research is used for public

³ False negatives are typically of lesser concern in science, perhaps on the theory that even if a scientific fact has not been detected, if it exists, it will eventually come

health purposes, such as designing procedures to screen for rubella antibodies, to detect the AIDS virus, or to identify toxic substances, the costs of false negatives become much more important. Thus, in addition to accuracy, simpliciter, in evaluating institutional decisions which have substantial social consequences, the *distribution* of the kinds of mistakes and the *magnitude of the costs* of those mistakes are of substantial moment. These two considerations are critical in evaluating the use of science in identifying and regulating carcinogens.⁴

Third, for institutions that must function within a democratic society, to what extent should they articulate with the democratic procedures and reflect the democratic will?⁵

Fourth, and related to the above point, institutions should be evaluated in terms of whom they politically empower. Kantrowitz seeks to limit the influence and power of scientists in institutions that must make mixed science-policy decisions and believes that science courts will achieve this goal. (Whether he is right on this is a further question to which we return.)

Fifth, in many cases the *rate* of decisions is also quite important; in others less so. In research science, the rate of scientific research is typically not a desiderata (except to the scientist concerned), unless the research has substantial social consequences. The rate of development of an atomic weapon was considered quite important during World War to light.

⁴ One should also take into account the costs of the procedures themselves in evaluating institutional mechanisms for making science-policy decisions, but I ignore these here. For example, it may be that the criminal law should provide even greater protections against wrongly convicting innocent people than it does at present, but if the costs of such protections become too great in monetary terms or infringe too much on other social values (e.g., permitting too many crimes to go unpunished), then the social costs of more extensive protections may be too great. The monetary and social costs of present procedures for identifying and regulating carcinogens are especially high. For a discussion, see Lester B. Lave et al., *Information Value of the Rodent Bioassay*, 336 NATURE 631 (1988), L.B. Lave & J.S. Omenn, *Cost Effectiveness or Short-Term Tests for Carcinogenicity*, 324 NATURE 29-34 (1986).

⁵ Kantrowitz claims that present institutions have insufficient democratic input and that there is insufficient democratic control over such decisions, because scientists tend to dominate even the non-scientific aspects of decisions.

II and the rate of research on AIDS is presently of great concern. However, when institutional decisions based on scientific research have social consequences, such as those with which we are concerned, the rate of decision making may be very important.

Finally, it is important that the overall decision in mixed science-policy disputes be within the limits of acceptability to those affected by it. Presumably a science court would further this goal because at least the factual basis would be agreed to by the science court “judges” even if other aspects of the decision were subject to dispute. While science courts might preserve or enhance the standing of the scientific community, it is not clear that they will enhance the validity of overall mixed science-policy decisions.

Scientific Accuracy and Evidentiary Procedures

My first concerns with science courts cluster around the idea of scientific accuracy and attendant evidentiary procedures. Advocates of science courts claim that scientific facts can be separated from normative considerations. While there is much to this claim for many disputes, in carcinogen risk assessment it is difficult, in many cases impossible, to separate facts from normative or policy judgments so as to facilitate social decisions.⁶ My modest concern rests on the observation that in order to come to conclusions about the nature and extent of risks from carcinogens, risk assessors must rely upon numerous policy judgments, and if they do not, little socially useful information is available. Some of these are “science” policy judgments — scientific generalizations that are relied upon in particular cases which may or may not be accurate for the substance in question — and some are normative judgments, e.g., one should not take chances with human health.⁷ Moreover, risk assessors must also choose between several plausible policies in order

⁶ My view is not the one attributed to some sociological relativists that “scientific risk assessment — indeed science generally — is inevitably a product of, if not entirely constructed from — socio-cultural values.” Deborah G. Mayo, *Toward a More Objective Understanding of the Evidence of Carcinogenic Risk*, II PHIL. SCI. ASSN. 1988, 491 (A. Fine & J. Leplin eds.)

⁷ OFFICE OF TECHNOLOGY ASSESSMENT, *IDENTIFYING AND REGULATING CARCINOGENS*, 25 (1987).

to have socially useful information, and these choices have substantial normative consequences.

To establish that a substance, X, is a *human* carcinogen, several policy decisions must be made. For epidemiological studies a number of judgments, not straightforwardly scientific, are appropriate: What are the relative weights of positive and negative studies? What are the relative weights of prospective and case-control studies? What statistical significance is required for studies to be considered positive? What is the scientific or public health significance of positive findings when the route of exposure is different from a population at risk?⁸ And, finally, might these decisions be made differently for pure scientific research versus research for public health purposes?

Even the seemingly uncontroversial notion of statistical significance is infected with policy considerations. There is a *scientific convention* that a study must have a significance of .05 or lower to be scientifically valid, but this may not be decisive for either scientific or public health issues. One can show for an epidemiological study that *on the same facts* — same sample sizes, same background disease rates, and same reported disease or death rate — the choice of what constitutes a statistically significant result will affect whether the study is considered positive or negative.⁹ The raw data are not decisive; interpretation and the purposes for which the study will be used are equally critical. Similar statistical and policy problems plague the interpretation of animal studies. The point is not just that scientists in particular areas of research need convention to guide their interpretation of results or to determine what scientific evidence is valid or credible. This is expected simply because they are engaged in a human activity.¹⁰ Yet, the appropriate conventions may, and probably should, vary depending upon the purposes for which data will be used. I return to this in comparing burdens of proof in science and the law.

⁸ NATIONAL RESEARCH COUNCIL, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT, 29-30 (1983).

⁹ CARL F. CRANOR, REGULATING TOXIC SUBSTANCES: A PHILOSOPHY OF SCIENCE AND THE LAW (1993). Standard statistics textbooks also discuss the same point.

¹⁰ Allan Mazur suggested this point.

The first point is related to a second, equally basic issue. Even something as fundamental to scientific judgments as hypothesis acceptance and rejection tests have implicit social policy judgments in them. These tests were developed:¹¹

in a certain decision theoretic framework where there would be a clear basis for the test specifications... tests are formulated as mechanical rules or recipes for reaching one of two possible decisions: 'act as if H were true' or 'act as if H were false', according to whether H is accepted or rejected.... By considering such consequences the scientist is, presumably, able to specify the risks he can 'afford'.... However, this opens the door to the... relativist's concern. For such considerations of consequences — in our case social, ethical and economic — are clearly policy matters; so it appears that specifying a test is tantamount to making a policy decision....

The problem with such tests is “automatically equating rejections of H (statistically significant differences) with finding substantively important discrepancies from H, and failures to reject H with finding... unimportant discrepancies.”¹²

Moreover, this raises the concern that different statistical cutoff points may be appropriate for different scientific and social purposes and concerns about what constitutes appropriate “facts”. If the conventional cutoff is met, scientific data are established as credible or valid, and if it is not, they are not. However, conventionally specified test cutoffs can be misleading for there may be perfectly good clues and evidence of harm even though a particular test of significance is not met.¹³ And, such conventions may beg some social policy issues (I return to this later).

More neutral ways have been suggested for presenting the results of statistical studies, ones that do not rely upon conventions of either statistical significance or hypothesis acceptance and rejection.¹⁴ These strategies avoid some of the problems of relying upon policy considerations, but they pose others. For one thing, the attempt to purge

¹¹ Mayo, *supra* note 6, at 496.

¹² *Id.*, at 496-7 (emphasis added).

¹³ Talbot Page, *The Significance of P-Values* (forthcoming).

¹⁴ Mayo, *supra* note 6, at 497-501.

carcinogen risk assessment of *all* policy considerations is likely to make the resulting document or report nearly unintelligible to all but a small class of experts — and of little use for the larger policy debates. This hardly serves social debate or understanding. For instance, in reporting the results from animal studies, should scientists report merely the number of tumors in the experimental and the control groups (which will not be terribly helpful to policy makers and can be controversial in contested cases) or go beyond this (relatively) raw data¹⁵ and judge whether this increase is *significant*? If the latter, they then encounter the problems just indicated. Of course, scientists might agree that there was a statistically significant increase in animal cancers but disagree whether that was evidence that a substance caused human cancer. But these further disagreements will also likely depend upon implicit policy considerations.¹⁶ Second, according to the science court model, science court judges would render a decision about which side is right. But this will pose other problems (discussed later). It seems, then, that advocates of science courts may be unduly optimistic about possible agreement in controversial cases.

Further, scientists and policy makers using animal studies as evidence for the claim that a carcinogen has a certain potency in humans face more problems. If scientists from opposing sides in a science court were to try to agree about what they knew, they might only agree on the experimental evidence, i. e., on the tumor counts in experimental and control groups of animals (and even that could be controversial). It is unlikely they would agree on the potency numbers at low doses for humans.¹⁷ In fact, if one insisted on unanimity for a science court in sharply contested cases, it would have to report that “there was not agreed-upon scientific evidence of the potency at low doses.”

¹⁵ Even for tumor reports there are disagreements about which tumors or unusual growths should count as evidence for carcinogenicity in animals and humans; IDENTIFYING AND REGULATING CARCINOGENS, *supra* note 7, at 49-50.

¹⁶ Cranor, *supra* note 9, at 13-28.

¹⁷ Philip H. Abelson, *Testing for Carcinogens With Rodents*, 249 SCIENCE 1357 (1990).

Thus, contrary to assumptions favoring science courts, it is, at a minimum, difficult to separate scientific fact from policy considerations in carcinogen risk assessments. Or, if there is success in achieving the separation, the results may be of little use in public debate. Thus, it is not clear how many facts might be scientifically uncontroversial to judges of such a court. And separately, it is unclear in sharply contested cases how much agreement could emerge between opposing scientists.¹⁸

Sufficiency of Evidence Generally

Underlying the above concerns is a view that scientific and other evidentiary procedures are not unerringly accurate. Thus, when doing research or making mixed science-policy decisions, we must rely upon the evidence available, but, *evidence* for a conclusion neither *guarantees* its *correctness* nor automatically reveals its *credibility* for a particular conclusion. How we use such evidence and the significance we attach to it bears on these issues. In research on carcinogens there are intra-scientific disagreements concerning the *sufficiency of the evidence* that a substance is a carcinogen and possible disagreements between the scientific and policy communities about appropriate standards of the sufficiency of evidence to support the claim that something is a human carcinogen.

For example, to have sufficient evidence that a substance is a carcinogen, some scientists have insisted not only on good epidemiological studies and good animal studies in several different species at exposure levels and routes of administration equivalent to that of humans, but also several positive short-term tests.¹⁹ Requiring such evidence as necessary and sufficient to treat something as a human carcinogen will lead to disagreement between scientists and to

¹⁸ To see this, consider recent court litigation revealing disagreements between the government and industry as to the correct assumptions regarding risk assessment: *ASCARCO v. OSHA*, 746 F.2d 483, 492-95 (9th Cir. 1986), *Public Citizen Health Research Group v. Tyson*, 796 F.2d 1479, 1495-98 (D.C. Cir. 1986), *Building and Construction Trades Dept. v. Brock*, 838 F.2d 1258, 1266-67 (D.C. Cir. 1988).

¹⁹ Arthur Furst, *Yes, But Is It a Human Carcinogen?* 9 J. AM. COLL. TOXICOL. 1 (1990).

disagreements between some scientists and the public and regulatory communities. Thus, adversarial scientists are unlikely to agree on such a point in sharply contested cases. Further, the use of such stringent standards of what counts as a human carcinogen would frustrate present regulatory policies even more than at present,²⁰ because for very few substances is all the required evidence available.²¹

Moreover, disagreements about the sufficiency of evidence that X is a carcinogen show how evidentiary standards serve different policy aims depending upon the context. In many circumstances, there can be an inconsistency between scientific and legal or social norms of good evidence — which is in turn a result of the consequences of different mistakes that are of concern in science and in protecting public health. Scientists primarily seek to prevent false positives, from falsely adding to scientific knowledge and mistakenly chasing research chimeras, while public health advocates are typically concerned to prevent false negatives, to avoid mistakenly treating a toxin as non-toxic. Even if both scientists and public health advocates were to agree as a matter of a decision principle on more general principles for addressing the costs of mistakes (as they might well)²², they are likely to disagree about the relative weight of mistakes to avoid: false positives or false negatives. Thus, they could and probably will endorse different evidentiary standards to avoid the mistake they regard as worse.²³

To see this point, consider analogous issues in the law. For various policy reasons, differing evidentiary standards and burdens of proof²⁴

²⁰ IDENTIFYING AND REGULATING CARCINOGENS, *supra* note 7, at 18-22.

²¹ Only about 30 substances are listed as known human carcinogens under California's Proposition 65, and some of these may not satisfy the stringent criteria discussed in this paragraph. *See, e.g.,* William S. Pease, *Identifying Chemical Hazards for Regulation: The Scientific Basis and Regulatory Scope of California's Proposition 65 List of Carcinogens and Reproductive Toxicants*, 3 RISK 127, 135 (1992).

²² Some economists, for instance, have suggested that the appropriate principle is one which minimizes the total costs of mistakes. *See* Lave et. al. and Lave & Omenn, *supra* note 4 for discussion of this point.

²³ Cranor, *supra* note 9, at 153-157, and Carl F. Cranor, *Scientific Research for Public Health Purposes*, in RESEARCH ETHICS (Kristin Shrader-Frechette ed. 1993).

²⁴ FLEMING JAMES, JR. & GEOFFREY C. HAZARD, CIVIL PROCEDURE, 249-260 (1977)

are assigned to one side in legal controversies. Those who fail to carry their burden to the satisfaction of fact finders such as juries lose, i. e. they fail to establish certain facts *for legal purposes*. Consider, for example, criminal insanity cases. If a defendant in a murder case wishes to argue that he is not guilty by reason of insanity, then the *defendant* must raise that issue. However, this does not dispose of the burden. As discussed in a legal treatise on evidence, there several possibilities.²⁵ First, the defendant might have to establish insanity by a *preponderance* of the evidence, i.e., insanity is more probable than not. Or he might have to establish it by “clear and convincing evidence” or the criminal law’s much more difficult “beyond a reasonable doubt” burden. Conversely, once a defendant raises the question of sanity, the prosecution might have to show “beyond a reasonable doubt” that the defendant is sane. Thus, whether an otherwise guilty defendant is adjudged not guilty by virtue of insanity is dependent upon which evidence is found credible in accordance with established burdens and levels of proof, i.e., upon who has the burden of proof, how *demanding* the burden is and whether the party with the burden has *carried it*. Thus, identical evidence can clearly lead to different legal outcomes in different jurisdictions.

Similarly, implicit burdens of proof in science and in policy areas that must use scientific evidence determine how much evidence is sufficient for such areas. I have argued elsewhere that the scientific .05 test of significance is roughly equivalent of the criminal law’s “beyond a reasonable doubt” burden of proof. If this standard is imposed in tort or regulatory proceedings that normally have less demanding burdens of proof, this will frustrate important social goals. Requiring proof beyond a reasonable doubt would be inappropriate when the “more likely than not standard” has been long established as sufficient.²⁶

Moreover, in carcinogen risk assessment and risk management, if there are disagreements about the sufficiency of evidence that a (discuss a number of policy reasons for allocating the burden of proof to one party or another in a legal forum).

²⁵ JOHN H. WIGMORE, WIGMORE ON EVIDENCE § 2501 (3d ed. 1940 & Supp. 1991).

²⁶ Cranor, *supra* note 9, at 71-78.

substance is a carcinogen and the more demanding standards of research science prevail,²⁷ this will tend to skew policy outcomes in favor of the status quo. In most cases, this will leave substances in commerce until they are found to pose risks of harm; in a few others, it may keep them out.²⁸ If scientists must have the same degree of confidence in results that they would if they were doing scientific research, this will result in several “no decision” or “not enough information for decision” judgments.²⁹ Such judgments, while appropriate for scientific research, in regulating toxic substances for public health purposes may not be appropriate where scientists may have some information in the form of clues of harm. Failure to act may leave people at risk from exposure to a toxic substance.

Furthermore, a report by a science court about what is and is not known about the substance in question, even if this leaves open the decision about appropriate action, may be misleading and inadvertently influence the public debate and decision. Kantrowitz indicates that such reports would have “presumptive validity.”³⁰ If “Does X cause cancer in humans?” is the question framed and answered by the court, the answer according to some will be negative on the evidence of a few positive animal studies *on scientific grounds alone*.³¹ Thus, the court might answer that there is some evidence of carcinogenic activity in animals and in short-term tests but, as a matter of the science, it cannot be concluded that X is a human carcinogen. Such a decision could easily be arrived at by scientists indicating what they did and did not know about a substance. Yet, it might be quite misleading and unduly persuasive in public debates if the public fails to understand the implications of the claim about human carcinogenicity. That scientists do

²⁷ This also raises the question of which kinds of scientists should make presentations to a science court.

²⁸ IDENTIFYING AND REGULATING CARCINOGENS, *supra* note 7, at 199-200.

²⁹ Kantrowitz, *supra* note 2, at 507, even indicates that science courts should have no hesitation in issuing negative judgments about the science when there is “inadequate evidence” for a view. I certainly agree, but one must be quite careful about when evidence is “inadequate” in the regulation of possibly toxic substances.

³⁰ Kantrowitz, *supra* note 2, at 509.

³¹ Furst, *supra* note 19.

not have the kind, amount and quality of evidence needed for certain purposes to conclude that X is a human carcinogen should not determine whether it should nevertheless be treated as such for other purposes.

Moreover, this concern about the contents of a report from a science court raises further issues about the implicit burdens of proof in science and its evidentiary conservatism.

Sufficiency of Evidence in Science

Some may believe that burdens of proof are not present in science, but they are mistaken. There is an appropriate background assumption in science that departures from the knowledge status quo ante must be justified by evidence and theories before scientists can add to the stock of scientific knowledge. If we have a substance, X, about which little is known, any additions to scientific knowledge must satisfy appropriate standards of evidence, research practices and peer review procedures before new information is accepted as scientifically sound. These evidentiary standards and concomitant procedures implementing them constitute implicit burdens of proof not dissimilar from those in the law. However, one important difference is that legal burdens of proof are designed (more or less deliberately) to serve the aims of the institution and vary with the area of law, being quite stringent in the criminal law and less stringent in tort and regulatory law because of different purposes the different areas of law serve.

Implicit burdens of proof in science have been designed or have evolved to serve the aims of scientific understanding and research, not necessarily to serve public policy purposes. It is not surprising, then, that scientific and public health burdens of proof, for example, may be different. However, we should not have institutional procedures that may conflate the two and substitute a less appropriate burden. Proposed science courts risk doing just that. Thus, a finding that there is not sufficient evidence that a substance is a *human* carcinogen may merely be the claim that the scientific burdens of proof required to show that it is a human carcinogen have not been met. It does not follow that the substance ought not to be treated as a human carcinogen or that it ought not to be the object of precautionary regulatory action. In fact there may

be sufficient evidence to take precautionary action, even if there is not sufficient evidence to establish on research scientific grounds that the substance is a *human* carcinogen.

If a science court implicitly endorses the evidentiary standards of research science, it inadvertently reinforces what is typically one (the anti-regulatory position) side of the larger public debate about identifying and regulating carcinogens primarily because of the laws involved. Such an outcome may be inadvertent — resulting from the design of science courts and the explicit or implicit evidentiary procedures that scientists bring to it. We should not permit such accidental results, but design institutional procedures to address the problems directly. Perhaps a better approach (to which I return at the end) is to have public debates about the wisdom of one mixed science-policy course of action versus others, with all sides being as explicit as possible about both the scientific and the policy aspects of their view and then resolve those in some appropriate way.³² The science court proposal appears to predispose such debates in inappropriate ways.

The burdens of proof just described make scientific research an epistemically conservative institution; information is added cautiously and only after demanding scrutiny. In the regulation of toxic substances this can have substantial effects on public policy and the public health. There will be a tendency to evaluate each substance on a substance-by-substance basis, for otherwise one is not evaluating carefully each substance. Such analysis is slow, and several procedures for identifying carcinogens are insensitive (they may not detect a risk of harm even when it is present). This, combined with many laws that leave carcinogens in commerce until an agency has established that they pose risks of harm, indicates that few substances will be addressed. Both may leave human carcinogens unidentified and unaddressed as carcinogens for a considerable period of time. Science courts appear to reinforce this evidentiary conservatism, which raises questions about their appropriate use.

³² By way of democratic procedures or by means of negotiation as Sheila Jasanoff suggests, e.g., *infra* at 150.

Time Considerations

As mentioned above, science courts were originally conceived to address “big science” questions such as whether nuclear power is “safe enough” to use for producing electricity. When I first considered this, it seemed that despite several reservations expressed above, such procedures might provide for social decision making provided that the issues were general enough and sufficiently divorced from normal regulatory procedures that they would not become an impediment.

It seems clear that science courts should not become part of the ordinary regulatory procedures for evaluating toxic substances. Present procedures for identifying toxins, conducting potency and exposure assessments and coming to a regulatory decision are much too slow. Their slowness leaves a large universe of substances unassessed, and thus people at risk. We need faster, not slower and not more science-intensive procedures.³³ Science courts as part of ordinary regulatory processes at the EPA, OSHA or FDA seem likely to make regulatory processes even slower than they are at present. Proposed science court procedures seem roughly analogous to formal adjudicatory procedures within the agencies, the slowest and most cumbersome legal procedures that are most likely to frustrate more expeditious agency actions. Such considerations argue against incorporating science courts into ordinary agency procedures.

After reflecting upon some of the shortcomings of procedures aiming to separate scientific fact from policy and issues of “accuracy,” I am not sure science courts would serve well to address even large scale, more general scientific issues. For one thing, such questions frequently are not posed except in the more ordinary processes of regulatory agencies. Questions about nuclear safety usually are raised only when there are regulatory questions: Should a new reactor be licensed? Should an old one be decommissioned? However, it is possible that science courts could have a role in addressing large-scale issues provided that they do not frustrate the charge of the agency they aim to serve. On occasions when there might be special inquiries independent of

³³ IDENTIFYING AND REGULATING CARCINOGENS, *supra* note 7, at 19-22; Cranor, *supra* note 9, at 122-129 and 141-147; Carl F. Cranor, *The Social Benefits of Expedited Risk Assessment* (forthcoming).

regulatory proceedings, science courts might appropriately be used, provided they have no other serious shortcomings.

If more general, as well as specific, scientific debates are infected with policy considerations, incorporate possibly misleading standards for the sufficiency of scientific evidence and such, so as to make it difficult to separate scientific facts from values, then I have reservations about using the courts to address even more general issues. But this is more open, depending upon the area of science and the issues at stake. Not all technological and scientific issues on the frontiers of scientific knowledge may be as unsettled, uncertain, and infected with social policy issues as carcinogen risk assessment. If not, then science courts may be more appropriately used.

The Need for Public Scrutiny of Science

A claim that there is not agreed-upon scientific evidence for human carcinogenicity of a substance, or that it did not have harmful potency at levels of human exposure, can have substantial but misleading credibility in public debates. Because of the aura attached to scientific claims, the public and decision makers are likely to understand such claims as having a kind of unchallenged credibility. However, such claims may be quite misleading precisely because scientific theories and data in this area are so unsettled and controversial. Problems can arise because evidence of human carcinogenicity, in light of public health goals and some scientific generalizations, may justify precautionary action. A public policy decision must be made about what to do in light of sketchy evidence, underdetermined theories and substantial public interests. In some cases, authorizing further studies or doing nothing may be appropriate; in others, precautionary action may be. Yet, a report of a science court may unduly chill public discussion.

The last point raises a fundamental psychological or sociological point underlying the felt need for a science court. Kantrowitz and others argue for the importance of accuracy, worrying that science may become tainted if it is not accurate or becomes too contaminated by public policy disputes. This is a legitimate concern, but there is more than one side to

the issue. If science maintains its “purity,” this insures that, when scientists speak as scientists, they will have a certain automatic credibility. Their statements will be adjudged as beyond dispute, at least by lay persons. While it is easy to see the benefits for the scientific community, benefits for the general public are less clear. Scientific evidentiary standards preserve the knowledge status quo until evidence passes enough tests to overcome the implicit burdens of proof in the field, but this can frustrate good public health policy.

For the sake of public health protection, it is important that the public question both policies and their scientific bases. Thus, if the findings of a science court were to have a kind of automatic credibility which is epistemically conservative and which may beg policy questions, this is not necessarily desirable. It may be much better for the public to be skeptical toward both the scientific and policy judgments, so that experts in both areas are forced to defend their positions. Speaking as one who came to debates about carcinogen risk assessment from a non-biological background, it is clear that we should be skeptical of scientific claims for two major reasons. First, the “best science” conventionally conceived is epistemically and (typically) normatively conservative. Thus, it reinforces the regulatory status quo. Also, what counts as evidence in debates about carcinogens is so normatively laden that one’s larger philosophic views about health and larger social policies are critical. Thus, scientific claims should not be free from public scrutiny and skepticism. It is easy for putative “scientific facts” to disguise either implicit or explicit world views that should properly be open to debate. The remedy is not to separate science from policy — if this can even be done while providing useful information — but to increase scrutiny of both scientific experts and policy makers.

This raises a final point about the science court proposal. The suggestion appears to be that the scientific issues related to a particular policy question can be separated and decided independently of the particular policy, much as scientists might decide issues in their lab or at a conference. And the metaphor of a science “court” further suggests that “judges” might issue a judgment about which side has the correct scientific view, independent of the policy considerations.

Enough has been said to indicate what is problematic about both suggestions. There is an important interaction and substantial subtle understanding needed between the scientific data, evidentiary standards for judging it, and the policy decisions to be made. In assessing contested science-policy issues, one must judge which *composite* data-evidence-policy decision would be best in the circumstances, rather than have a scientific judgment endorsed by a science court independent of evidentiary standards appropriate to the policy and independent of the policy goals followed by contested policy debates of the scientific decision. At least in carcinogen risk assessment and risk management, it appears better, recognizing the complex data-evidence-policy relationship, to subject the composite product to careful scrutiny, including the science, than to try to address the scientific and policy issues completely separately.

Conclusions

Science courts may not be the best way to address mixed science-policy questions posed in identifying, assessing and regulating toxic substances. Scientific and policy issues are difficult if not impossible to separate so as to facilitate social decisions, and appropriate evidentiary procedures and burdens of proof are dependent on the policy goals of the activity in question. Also, science court procedures, if used in ordinary regulatory processes, would appear to make them even slower than at present, a decidedly bad consequence. Finally, while science courts might reduce scientific influence over policy decisions, it is at least as likely that they would inadvertently enhance the power of scientists over complex science-policy issues to the detriment of democratic decision making in the regulation of toxic substances. To achieve social validity for mixed science-policy decisions concerning toxic substances, it seems preferable to have critical discussion and evaluation of composite data-evidence-policy options with the science, the evidentiary standards, the policies and their subtle interactions subjected to healthy skepticism.

Throughout, I have used the assessment and regulation of toxic substances in examining mixed science-policy disputes. Problems in this area may or may not be representative of those in other areas. They appear representative, however, when the following features exist: Factual issues, plagued by considerable uncertainty and information gaps, are at the frontiers of scientific knowledge and infected by policy considerations; the kinds and costs of mistakes are quite different, in light of policy goals, from those posed in typical research science procedures; conservative evidentiary standards of science favor one of the obvious positions in the political debate; and the rate at which mixed science-policy decisions are made is important. In such cases, issue separation as proposed for science courts seems on balance undesirable. The extent to which this characterizes science-policy disputes elsewhere is for others to decide.

