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Publication Date
1997-11-20

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"In our society (that is, advanced western society) we have lost even the pretense of a common culture. Persons educated with the greatest intensity we know can no longer communicate with each other on the plane of their major intellectual concern. This is serious for our creative, intellectual and, above all, our normal life. It is leading us to interpret the past wrongly, to misjudge the present, and to deny our hopes of the future. It is making it difficult or impossible for us to take good action."[1]

"It is dangerous to have two cultures which can't or don't communicate. In a time when science is determining much of our destiny, that is, whether we live or die, it is dangerous in the most practical terms. Scientists can give bad advice and decision-makers can't know whether it is good or bad."[2]

C. P.. Snow, The Two Cultures and a Second Look

REGULATING TOXIC SUBSTANCES THROUGH A GLASS DARKLY:

USING SCIENCE WITHOUT DISTORTING THE LAW[3]

Carl F. Cranor

Toxic substances have been of public concern at least since Rachel Carson's The Silent Spring.[4] Yet in many ways we are far short of coping adequately with problems posed by them. The research described below represents more than a decade's work directed at some of the philosophic, scientific, regulatory and legal problems encountered in trying to assess and ultimately control toxicants in our lives.

The vanishingly small size of toxicants makes them difficult to detect, identify, and understand whether they pose problems for humans. Each new substance often poses a different detective problem. In turn these difficulties are exacerbated by traditional scientific burdens of proof and the legal contexts in which they must considered. However, the legal regulation of toxic substances by the tort (or personal injury) or regulatory law can be addressed by sensitively designing scientific and legal burdens of proof for the legal and public health problem in question. In sections (V) and (VI) of this paper, I describe some approaches to ameliorating some of the proof and institutional design problems that currently preclude more expeditious prevention of public health problems from toxic substances. Some of this research has been incorporated into California legal procedures and aspects of it have been argued for in legal journals in an effort to modify how judges consider scientific evidence.

While aspects of this research engage some relatively technical aspects of philosophy, toxicology, and the law, it also involves several ideas that are of broad humanistic interest. First, the research seeks to address an aspect of the problem to which C. P. Snow called attention

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[1] C. P. Snow, The Two Cultures: and a Second Look: An Expanded Version of the Two Cultures and the Scientific Revolution (Cambridge: Cambridge University Press, 1964)., p. 64. This passage Snow describes as the "essence" of his Rede Lecture at Cambridge University.

[2] C. P. Snow, Two Cultures, p. 98. This is a second restatement of the essence of Snow's Rede Lecture. While he largely focuses on some of the potential bad consequences of scientific and humanistic cultures failure to communicate; he also draws attention to lost potential from failure to communicate. (*Id*.)

[3] This paper is taken in part from "Empirically and Institutionally Rich Legal and Moral Philosophy", Midwest Studies in Philosophy Vol. XXIII, pp. 286-311.

[4] Rachel Carson, Silent Spring (New York: Paul Books, 1962).

in his well-known Rede Lecture at Cambridge University in 1959, originally titled "Two Cultures and the Scientific Revolution."[5] Snow was concerned that because loss of "even the pretense of a common [intellectual] culture," was serious for our "creative, intellectual and . . .our normal life" and even "dangerous in the most practical terms," since, *inter alia*, we would not be confronting major social problems with the best knowledge we had for solving them. In particular, he noted that scientific advice alone might be insufficient to find the best solutions. Thirty years after he wrote, despite our recognition of the gap between scientific and humanistic cultures, it may be worse. Intellectual fields in contemporary universities, especially scientific and humanistic fields, may be even more isolated than when he wrote, although in some areas the gap has been recognized and partially addressed. The research described below tries to speak to some of Snow's concerns. In a small corner of our intellectual life--that concerning the effects of toxic substances on our lives--I have tried to bring aspects of scientific, legal and humanistic, i.e., philosophic, cultures together in order to assess some of the problems in the regulation of toxic substances and to improve human health protections.

Second, addressing Snow's problem meant that the research had to be both empirically and institutionally rich; in this respect the work resembled research in other humanistic and social science disciplines somewhat more than typical philosophic research does. More importantly, such detail was needed in order to contribute to the subject and to provide appropriate background for it. It was necessary to learn in some detail aspects of both the science and the law needed to regulate toxic substances. This is the nature of complex social problems embedded in institutions. Throughout this research I sought to learn "enough" of law and science in order to address with some care and sophistication the issues that arise at the interface of these fields and to speak with credibility to practitioners of those fields in their own terms about environmental health issues. However, there is a benefit from research based upon such detailed information. The scientific and institutional details helped to reveal philosophic issues that might not have been seen, except perhaps in their most abstract formulations and helped to suggest solutions to some of the problems in regulating toxic substances.

Third, Snow's problem requires that we re-organize how we think about social problems. Presented with complex and multi-faceted social problems, we need to change our "organization of knowledge,"[6] to address the problems with multidisciplinary or interdisciplinary approaches. This is particularly true of issues concerning the environment and environmental health, the subject of this presentation. There are at least two different strategies to organize the knowledge necessary to address the environmental health issues described below; I have followed both. One strategy is to work with teams of people to address a problem, bringing toxicologists, epidemiologists, biologists, and policy experts together, to ensure that there was appropriate expertise to speak to different technical issues in the relevant areas of law and science. The other is to rely upon one's own integration of the relevant knowledge to speak to the issues. Both approaches help to enrich the intellectual culture with which to address the problems: the first helps broaden the culture of all who participate in the project; the latter broadens the intellectual resources of the individual.

Fourth, a substantial theme of the work described below is what might be called "institutional morality." Philosophers and others interested in moral philosophic issues in most cases are typically concerned with individual moral relationships, e.g., in what circumstances promises might be binding, in what does fair treatment of persons consist, what are defensible principles of individual moral responsibility, etc. By contrast my research has focused on

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[5] C. P. Snow, Two Cultures.

[6] I borrow this term from Albert Carnesale, Chancellor, UCLA, who used it in remarks to the annual meeting of the University of California Deans of Letters and Sciences.

institutional design and institutional decisions that might be made about the use of science in the law and how that effects the welfare and lives of persons touched by the institutions and decisions within them. While this topic tends to be of lesser concern to many than issues of individual morality, it is of substantial moment in addressing issues of environmental health protection, because nearly all such protections are provided by the design of institutions and the decisions made within them by those charged with regulating toxic substances.

Fifth, the explicit topic of the research is quintessentially a philosophic (hence, humanistic) issue. Finding a defensible approach for utilizing science in the regulatory and tort law in order to protect humans from toxicants is not a scientific question and not a legal question, but one about the desirability and defensibility of the relationship between science and the law. It is a meta-scientific and meta-legal question. In this respect it involves matters of interpretation at both microscopic and macroscopic levels of law and science, an approach typical of the humanities. At the macro-level the main aim has been to provide an appropriate understanding for using scientific evidence in environmental health law and for using scientific evidence in toxic tort law. What is the appropriate use of scientific evidence in these areas of the law that have two quite different sets of aims, presuppositions, and rules that govern them? At what we might consider a more micro-level, what approaches should we take to interpreting actual scientific evidence when it is fraught with considerable uncertainty and laden with normative considerations? Finally, how do our answers to these different questions of interpretations interact with one another?

In what follows I outline aspects of a decade's research and sketch how it exemplifies some of these themes.

I

Molecules are submicroscopically small objects, unlike bullets, knives, or cars and they can harm humans in almost vanishingly small amounts. For example, in 1978 the Occupational Safety and Health Administration (OSHA) became concerned about workplace exposures to benzene and issued a regulation lowering the permissible exposure from 10 parts per million (ppm), a level which they thought was harmful, to 1 ppm, a level that was not necessarily not harmful, but the lowest level they could reliably detect in the workplace.[7] At 10 ppm the agency was concerned that employees exposed to benzene would contract leukemia or aplastic anemia, typically both life-threatening diseases. To put these concentrations of benzene in perspective, the ratio of 1 ppm is equivalent to the ratio of 1 inch to 16 miles (length), 1 cent to $10,000 (money), or 1 minute to 2 years (time). Thus, the tiniest concentrations of these substances can cause great harm to a person; they are quite potent on a unit basis.[8]

However, discovering the properties and effects of toxic substances is extremely difficult. Scientific, and in some cases molecular, detective work is required. We cannot rely on our built-in "intuitive toxicology" that may serve us well when it comes to the lethal effects of speeding cars or trains or of guns and knives.[9] However, because scientific investigation is labor-

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[7] And even this level might not be low enough; see Peter F. Infante, "Benzene and Leukemia: the 0.1 ppm ACGIH Proposed Threshold Limit Value for Benzene," Appl. Occup. Envirn. Hyg., Vol. 7, pp. 253-262 (1992).

[8] Subsequent analysis showed that 35% of leukemogenic diseases appeared to be caused by exposures below 6 ppm and that increased chromosomal breakage occurred at exposures at 1 ppm., so OSHA was hardly being too cautious in setting its exposure levels. (Infante, "Benzene and Leukemia.")

[9] Nancy Kraus, Torbjorn Malmfors, and Paul Slovic, "Intuitive Toxicology: Expert and Lay Judgments of Chemical Risks," Risk Analysis, Vol. 12, No. 2, pp. 215-232 (1992).

intensive, it takes time to identify and assess the toxicity of the substances involved. The detective work needed to tease out the effects of toxic substances is not different from other more mundane contexts, just more difficult.

Umberto Eco, in his medieval detective story, The Name of the Rose, reminds us of the difficulties of discerning the nature of the world around us in the comparatively ordinary and mundane world of a human murder mystery. However, his reminder captures some of the problems researchers face in trying to detect the effects of toxic substances in the much more esoteric world of scientific investigation:

> But, we see now through a glass darkly, and the truth, before it is revealed to all, face to face, we see in fragments (alas how illegible) in the error of the world, so we must spell out its faithful signals even when they seem obscure to us. . . [10]

The vanishingly small concentrations of substances that threaten us and the difficulty detecting them should not conceal that there are real human consequences from exposures to toxic substances. Such exposures, resulting from what has become an increasingly chemical society largely in the aftermath of World War II, can harm us just as much as the grosser forms of violence, theft and deception that have typically served as grist for philosophers' analytic mills. Indeed toxic molecules might cause more suffering than some of the things philosophers have traditionally considered to illustrate their principles or to challenge principles proposed by others. Carcinogens, for example, can kill us just as surely as, and often more agonizingly than can a gunshot or knife wound, but we might be unaware that an invasion of our interests has occurred, unaware when it occurred, and, because such substances typically have long latency periods between an initial invasion of the body and a clinically detectable effect, unaware of the source of harm.[11] Reproductive toxins may not kill us, but might maim our children, e.g., causing them to be born with stub arms or legs or worse[12], make it impossible for men to produce children because of low sperm counts[13], or in a kind of double whammy, give women cervical cancer and possibly give their offspring health problems as well, all because the women's mothers took the drug diethystilbestrol (DES).[14] Neurotoxins, such as lead, might lower a child's Intelligence Quotient or those of a whole generation. Thus, the effects caused by such substances might be as serious or more serious than the effects of the grosser forms of

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[10] Umberto Eco, *The Name of the Rose* (New York: Harcourt, Brace Jovanovich, Inc.: 1983), p. 3. Later the protagonist, the Medieval detective, Brother William, speaking to his apprentice, Adso, says "My good Adso. . . during our journey I have been teaching you to recognize the evidence through which the world speaks to us like a great book." (p. 18) The suggestion, insofar as it is correct, fits nicely with the research developed below, since as I argue in section III the evidence for carcinogenic effects on human beings is subject to a great deal of interpretation, and often sharply differing interpretations, before one can reach conclusions about a substance's toxic effects.

[11] Typically, however, people who suffer from the effects of exposure to toxic substances have not been intentionally or knowingly exposed as they might be intentionally or knowingly harmed by muggers or thieves.

[12] This resulted to children whose mothers took the drug thalidomide during pregnancy. For a general discussion, see Manson, J., "Teratogens," (Chapter 7) in Casarett and Doull's Toxicology, edited by C. Klaassen, M. Amdur, and J. Doull, (New York: Pergamon Press, 1996).

[13] 1,2-DIBROMO-3-CHLOROPROPANE (DBCP) causes such harms. For a general discussion, see Dixon, R. "Toxic Responses of the Reproductive System," (Chapter 16) in Casarett and Doull's Toxicology, edited by C. Klaassen, M. Amdur, and J. Doull, (New York: Pergamon Press, 1996).

[14] Diethystibestrol (DES) has been found to cause cervical cancer in the daughters of women who took DES during pregnancy with their daughters (*Sindell v. Abbott Laboratories*, 26 CAL. 3E 588, 607 P. 2D 924 (1980)). Some have suggested that DES might even cause third generation effects, but this effect is not well established.

violence, theft and deception in our lives. The effect of toxic substances on the life of one family is sketched in a letter from a woman whose husband contracted byssinosis (brown lung) from exposure to cotton dust.

> My husband worked in the cotton mill since (*sic)* 1937 to 1973. His breath was so short he couldn't walk from the parking lot to the gate the last two weeks he worked. . .
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> He was a big man, liked fishing, hunting, swimming, playing ball, and loved to camp. We liked to go to the mountains and watch the bears. He got so he could not breath (*sic*) and walk any distance, so we had to stop going anywhere. So we sold our camper, boat and his truck as his doctor, hospital and medicine bills were so high. We don't get to go anywhere now.
>
> The doctor said his lungs were as bad as they could get to still be alive. At first he used take oxygen about two or three times a week, then it got so he used more and more. So now he has an oxygen concentrator, he has to stay on it 24 hours a day. When he goes to the doctor or hospital he has a little portable tank.
>
> He is bedridden now. It's a shame the mill company doesn't want to pay compensation for brown lung. If they would just come and see him as he is now and only 61 years old. . .[15]

Despite the urgency that stories like Mrs. Talbert's give to addressing exposures to toxic substances, we are largely ignorant of the scope of the problems they pose. There are about 100,000 substances or their derivatives registered for use in commerce, but most have not been well-assessed for health effects. Moreover, for 75 percent of the 3,000 top-volume chemicals in commerce, the most basic toxicity results cannot be found in the public record; this finding is essentially unchanged from a 1984 study by the National Academy of Sciences.[16] It is difficult to get an accurate estimate of the carcinogens among them; rough estimates range from 10 percent up to 52 percent (using a relaxed criterion of carcinogenicity).[17] Finally, it is not clear how much environmental and workplace releases account for the cancer fatalities in the U.S. Estimates range from 3 percent up to 30 percent of about 500,000 cancer deaths per year. One author suggests that reasonable mainstream views estimate about 10,000-50,000 deaths per year,[18] but others argue that the workplace alone might result in 50,000-70,000 deaths per year.[19] Fifty thousand people is about the size of a medium-sized city in the U.S., a not inconsequential number.

However, even when regulatory agencies have been aware of toxic substances, they have done little by way of regulation. There are lists of carcinogens and other toxins on which there has been no or insufficient regulatory action, and often when agencies have clues about toxicity, they have not developed sufficient information about them to proceed with regulation. The U.S. Congress's Office of Technology Assessment found that of the carcinogens for which federal

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[15] Mrs. Steve Talbert, *Charlotte (N.C.) Observer*, February 10, 1980 (letter to the editor).

[16] In 1984 78% of chemicals in the U.S. with production volume greater than one million pounds per year lacked even "minimal toxicity information." (National Research Council, Toxicity Testing ((Washington, D.C.,: National Academy Press, 1984) p. 84). Little has changed in thirteen years; in 1997 75% of such substances lack minimal toxicity information. (Environmental Defense Fund, Toxic Ignorance (1997)).

[17] U. S. Congress, Office of Technological Assessment, Identifying and Regulating Carcinogens (Washington, D.C.: U.S. Government Printing Office, 1987), pp. 12, 130.

[18] Stephen Breyer, Breaking the Vicious Circle: The Oliver Wendell Holmes Lectures, 1992, (Cambridge, MA: Harvard University Press, 1993), p. 6.

[19] Phillip J. Landrigan, "Commentary: Environmental Disease--A Preventable Epidemic," Am. J. Public Health , Vol. 82, p. 941 (1992).

environmental health agencies had statutory authority, about one-half to two-thirds of the substances presumptively identified as carcinogens, had not been acted upon.[20] The research described herein has tried to address some of these problems.

II

Inherent properties of many toxic substances make acquiring the relevant scientific information about them difficult. Carcinogens, for example, have long-latency periods (the period from exposure to a substance until clinically detectable effects are manifested is from five to forty years),[21] typically operate by obscure causal mechanisms, result in diseases that are typically indistinguishable from naturally occurring illnesses, and, except in rare cases, lack unique causal "signatures."[22] Moreover, different toxic substances cause different kinds of harm by different mechanisms; there are few generalizations from one substance to another. Compare, for example, reproductive toxins, which cause damage to male or female reproductive tracts, to offspring, or to the developmental process itself, or neurotoxins such as lead, which affect the neurological system, with carcinogens (which sometimes cause harm by initiating the development of a tumor by causing damage to DNA and sometimes by promoting the development of tumors initiated by some other cause).

The above problems are exacerbated by the state of the science. Many of the scientific fields, in themselves or in application, on which we must rely for assessing the risks from toxic substances--epidemiological studies, animal studies, various short-term studies indicating toxicity, mechanisms, and so forth--are in their infancy. Some fields are not yet well-developed for identifying toxic substances and for assessing their potency (e.g., animal studies, various short term studies indicating toxicity and the biological mechanisms of action). Other fields, such as epidemiology, that have long and honorable histories must be applied anew to each example of exposure to a toxic substance to see whether there is a toxic effect compared with the occurrence of that effect in general population.

Those who develop substances for use in commerce tend to develop information about the benefits of their products and have more intimate information about their pollutants much earlier and in more detail than information about the typical health effects of those same substances. This favors permitting substances in commerce or keeping them in even though they may have as yet undiscovered adverse health effects. Consider, for example, DDT or asbestos as older examples or something as recent as the dietary drug combination phen-fen. In short, we might say that our information about the benefits from potentially toxic substances tends to be *asymmetrically* better than our information about potential health harms from them.[23]

Knowledge and informational asymmetries are exacerbated by political forces. Products using toxic substances, their toxic contaminants, or the toxic by-products of production have obvious constituencies, namely those who manufacture, use or dispose of them, whereas potential victims are much more diffuse and less organized, and may not even constitute a

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[20] Office of Technological Assessment, Identifying and Regulating Carcinogens, pp. 9-22. I am a co-author of that report for which the research was done during a Congressional Fellowship in 1985-86.

[21] D. Schottenfeld and J.F. Haas, "Carcinogens in the Workplace," CA-Cancer Journal for Clinicians, Vol. 144, pp. 156-159 (1979).

[22] Talbot Page, "A Generic View of Toxic Chemicals and Similar Risks," Ecology Law Quarterly, Vol. 7(2) (1978).

[23] I use the term "asymmetric information or knowledge" somewhat differently than lawyers and legal scholars tend to. They refer to asymmetric knowledge differences between two or more different individuals, while I am concerned that we tend to know asymmetrically less about some features of toxic substances (their adverse health effects) than others (their benefits).

constituency (because they may be unaware that a substance has caused their disease or that other persons are similarly adversely affected).[24] Politically, it is difficult to address and deter problems posed by toxic substances when political forces are arrayed asymmetrically.

In sum, many properties of toxic substances are inherently difficult to know, the tools for discovering their properties tend to be in their infancy or applied anew to each substance, and we tend to be asymmetrically better-informed about their benefits than we are about their adverse health effects.

Scientific responses to ignorance and uncertainties about toxic substances can exacerbate the above problems. In assessing the risks from toxic substances as a matter of doing good science, it is presumed that substances have no properties in particular until these have been established by appropriate studies. That is, if we were to hand a scientist an unknown substance and ask her whether it was toxic or not, she would remain agnostic, as a good scientist should, until she had done appropriate tests on it. If we ask more difficult questions, such as at what exposure levels it might be toxic to humans, it would take a much longer time for her to come to a scientifically respectable conclusion. Answering questions about the biological mechanism by which a substance causes harm would take even longer, if it were ever understood.[25] Moreover, before changing the hard-earned knowledge status quo ante, scientists seek more and better information about the substance and its properties, better understanding of the mechanisms of toxicity, and good theoretical models to guide their understanding, and require that all these aspects of their research be supported with considerable certainty.[26]

Thus, one issue is that the basic methodology, presumptions, the burdens of proof and the standards of proof typically followed in science inadvertently reinforce protections for potentially toxic substances. Typically, the burden of proof is on a scientist who would make a claim about a substance's toxicity to establish the claim by means of the appropriate methods. Moreover, these burdens of proof are typically reinforced by quite substantial standards of proof before such claims can be established.[27] It is not easy to establish the stringency of proof demanded in a systematic way, but several examples illustrate this point.

Statistical procedures that are used to provide evidence for a departure from the current scientific knowledge status quo provide the first illustration. In such procedures, scientists are typically quite demanding in preventing false positives (FPs); that is, their procedures are designed to prevent showing that a substance has a toxic property that in fact it does not. They typically insist that there must be less than 5 percent (or sometimes less than 1 percent) odds by chance alone (as a result of sampling error) of their evidence showing that a substance is toxic when in fact it is not. There can also be mistakes in the other direction by chance alone, that is, procedures may fail to detect a toxic property of a substance when in fact it is toxic; this is a "false negative" (FN). However, scientists seem much less concerned about the possibility of false negatives, perhaps on the view that if they fail to detect a toxic property in a particular case, it will eventually come to scientific attention. Thus, in something as fundamental as statistical

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[24] For example, the reproductive toxicity of DBCP was discovered by employees at a DBCP plant discussing among one another at lunch the difficulties different families were having trying to conceive children.

[25] Scientists know, for example, that benzene causes leukemia, but as of this date they do not understand the full biological causal path by which the harm occurs.

[26] Carl F. Cranor, Regulating Toxic Substances: A Philosophy of Science and the Law (New York: Oxford University Press, 1993). pp. 25-28.

[27] The term "burden of proof" refers to who in an institution or practice such as the law has to make a showing or risk losing (in law) or being ignored (in science), while "standard of proof" refers to the degree of certainty with which a claim must be established.

support for conclusions, the foundation of most empirical research, scientists appear to devote greater attention to preventing false positives than to preventing false negatives.

Scientists' epistemic conservatism concerning the knowledge status quo ante is not confined to statistical tests. Consider what a well-known toxicologist would require to establish scientifically that something is a human carcinogen. He argues that since an epidemiological association does not establish a causal connection, one needs not only multiple epidemiological studies, but also multiple animal studies subjected to strict experimental conditions, so there is an animal model for the toxic effect, and multiple short-term studies that might indicate the activity of the substance, the biological mechanism by which it works, and other detailed features of the substance.[28] The problem with his criteria for regulatory purposes is that for few substances do we have such substantial information.[29]

Next, consider the views of one scientist who emphasizes the importance of ruling out alternative hypotheses before drawing a conclusion. Scientists, he claims, seek to establish causal connections with "proof . . . usually accepted in science" or possibly proof "beyond a reasonable doubt" because alternative explanations will slay "a beautiful [but mistaken] hypothesis."[30] This illustration is useful because he utilizes standard-of-proof terminology from the criminal law. We are familiar with it from other contexts and it serves as a comparison for discussing the standards of proof in science and the law. However, the "beyond a reasonable doubt" standard is one of the most demanding in the law. Accordingly, if one has "reasonable doubt" about the truth of the proposition under consideration, one should not accept it as true and presumably not act on it. If his views are representative of a significant number of scientists, as I believe they are, the standards they suggest make it difficult to establish the toxicity of substances.

Finally, James Huff and David Rall suggest a further explanation for why toxicologists in particular may be reluctant to conclude that substances are toxic to humans. I quote them at length.

> Many scientists who are expert in the care, feeding, and understanding of rodents and their response to carcinogens and noncarcinogens appear reluctant to apply their knowledge to predict what may happen when humans are exposed to these chemicals. This is, perhaps, understandable. Scientists are taught to follow the long-honored process from the initial idea, formulate and propose a hypothesis, then design and execute an experiment or series of experiments that can rigorously test that hypothesis. Only then does the scientist publicly explain to other scientists the nature of the hypothesis and the result of the experiments, usually at specialized meetings or in subject-oriented journals. In projecting the results of carcinogenicity studies from laboratory animals to predict what may logically happen to humans, the scientist might consider that the opportunity to test the "idea" or hypothesis has been denied. The idea or hypothesis, of course, the prediction that a chemical will or will not produce some estimated probability

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[28] Arthur Furst, "Yes, But is it a Human Carcinogen?" J. of the American College of Toxicology, Vol. 9, 1-18, 1990.

[29] Out of 736 substances that the World Health Organization has evaluated for carcinogenicity 74 substances are known human carcinogens (these might satisfy Furst's criteria), 56 are "probably" human carcinogens (which would not satisfy his criteria), and 225 "possibly" human carcinogens. IARC MONOGRAPHS vols. 1-71 (1972-1998), summarized at the International Agency for Research on Cancer website http://193.51.164.11 /monoeval/grlist.html (updated March 5, 1998).

[30] H. J.. Eysenck, "Were we really wrong?" American Journal of Public Health Vol. 133, No. 5, pp. 429-32 (1991).

> of adverse effects or cancers in humans given a certain level of exposure for a certain period of interval of time.
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> The laboratory scientist, accustomed to being able to close the circle from hypothesis, to test, to acceptance or rejection, to new hypothesis generation, is uncomfortable when lawyers, economists, journalists, and politicians take the hypothesis and use it in a system in which the circle cannot be closed and in which the answer often cannot be known with certainty. In fact in most basic research areas the "circle" is rarely closed; the usual course of events leads to other questions that need answering.[31]

Huff's and Ralls' view suggests that when scientists are asked to participate in the law concerning the regulation of toxic substances, they may feel quite uncomfortable testifying in these venues because they cannot complete to their satisfaction the kind of research they would ordinarily judge appropriate. In addition, if they insist on "completing the evidentiary circle" described they are likely to find that it is difficult or impossible to testify that a substance is a human carcinogen because they cannot support their conclusion as they would in normal research.

Scientific burdens of proof and the standards of proof with which they must be satisfied are reinforced by considerable skepticism and inferential caution because they play an important and legitimate role in the "institution" or "practice" of science. Scientists' responses to ignorance about toxic substances reflect important *epistemic* values and goals. They develop inferential caution to avoid mistakenly attributing properties to substances and changing the knowledge status quo. Healthy skepticism helps individual scientists by discouraging overly enthusiastic advocacy of their own ideas and by preventing them from wasting their own research efforts, and helps the profession self-regulate by discouraging it from chasing research chimeras and wasting collective efforts. More positively, scientists undergo critical training to develop virtues, skills, and techniques that lead to accurate outcomes, resist casually proposing views that overturn the hard-earned epistemic status quo, add carefully to the knowledge status quo, and improve their understanding of the mechanisms by which phenomena work.[32]

However, such skeptical attitudes, inferential caution, and epistemic virtues can have quite unintended and unexpected effects depending upon the context in which they are used. In research where scientists seek carefully to add to their knowledge, skepticism helps to protect against mistakenly overturning the hard-earned epistemic status quo and mistakenly adding to the stock of scientific knowledge; it helps to protect against making certain kinds of inferential mistakes. In this, it helps to protect the field and its knowledge base. In addition, for an individual scientist, it discourages overly enthusiastic advocacy of their own ideas and wasting of their own research efforts. By contrast, in the regulatory setting or in the tort law, such skeptical attitudes reinforce the knowledge and *legal* status quo.

Legal protection from toxic substances is largely provided by two different institutions: federal and state regulatory or administrative law and private personal injury or tort law. Administrative agencies work under laws that seek to protect our rights and interests by preventing harms from arising by specifying in advance how certain activities should be done.[33] Typical environmental health statutes authorize regulation to prevent "unreasonable risks of harm to health," to prevent human health risks "with an adequate (or ample) margin of safety" or

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[31] J. Huff and D. P.. Rall, Relevance *to Humans of Carcinogenesis Results from Laboratory Animal Toxicology Studies,* MAXCY-ROSENAU LAST PUBLIC HEALTH & PREVENTIVE MEDICINE, 13th Ed., J.M. Last and R.B. Wallace, (Eds.) (Norwalk, Conn.: Appleton & Lange, 1992), p. 433.

[32] Carl F. Cranor, "Discerning the Effects of Toxic Substances: Using Science without Distorting the Law," Jurimetrics: Journal of Law, Science and Technology, Vol. 38, pp. 445-452, (Spring, 1998).

[33] Cranor, Regulating Toxic Substances, pp. 49-82, 103-151.

to prevent exposure to substances which cause "cancer in humans or animals." In regulatory law, agencies use risk assessments to try to ascertain the risks from substances before they decide how to *manage* them. Risk assessment is the putatively factual and scientific part of the inquiry. The first step is to *identify* the hazard in question, for example, is it an acute toxin, a neurotoxin, a carcinogen? The second is to assess the *potency* of a substance, that is, what concentration of a substance does it take to cause a scientifically and legally worrisome effect in humans? Third, agencies need to assess the *routes and extent of exposure* to the substance, for example, via the air, water, food, and so forth, and finally to provide some overall *characterization* of the risk to humans. *Risk management* is concerned with managing the risks in question in accordance with the appropriate laws, taking into account the legal, political, economic, and moral considerations that bear on this issue.[34]

The tort or personal injury law seeks to secure the rightful borders of our possessions and ourselves by *making us whole* should we suffer damage by border crossings.[35] It sets *public* standards of conduct which must be *privately* enforced by the victim who receives compensation for injuries *caused* by a defendant acting in violation of the law. It aims to compensate wrongfully injured victims and to deter certain wrongful conduct. In the tort law the procedures for determining whether someone has been harmed or subjected to an unreasonable risk of harm are not as stylized as they are in regulatory settings, but the plaintiff, the person claiming injury from a toxic substance, must show that a particular defendant's substance more likely than not caused plaintiff's injuries. In this legal venue procedures similar to those used in risk assessment would be utilized to establish causal claims to the appropriate degree of certainty. However, as I discuss later, the standard of proof a plaintiff must satisfy in the tort law to establish such claims legally is not nearly as demanding as the standards of proof typically utilized in the science for research purposes, yet judicial insensitivity to the different contexts of research science and the tort law can distort the latter.

In environmental regulatory law, under a *postmarket* statute, that is, a statute according to which substances are permitted to remain in commerce until they are shown to pose a human health (or ecological) problem, where the burden of proof is on the government to show that a substance is harmful, skepticism and inferential caution about the toxicological properties of substances keep them in commerce until a human health problem is identified with sufficient certainty to overcome the skepticism. In torts similar problems arise because the plaintiff has the burden of proof. In such circumstances if the evidentiary requirements are very high as they are with the criminal law's "beyond a reasonable doubt" standard of proof, then it will be quite difficult to justify removing substances from commerce or reducing exposures to less harmful levels. The greater the proof barriers that must be satisfied, the harder it is to make the case for removing substances from commerce, and as in a legal trial, the more this protects one side in the regulatory or tort law debate about the proper course of action.[36] By contrast, under a premarket regulatory statute, where the burden of proof is typically on the manufacturer or registrant of a substance to show that it is safe, any skepticism and inferential caution about the extent of safety prevent a substance from commerce until the skepticism is overcome.[37]

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[34] National Research Council, Risk Assessment in the Federal Government (Washington, D.C.: National Academy Press, 1983), p. 3.

[35] Jeffrie G. Murphy and Jules L. Coleman, The Philosophy of Law: An Introduction (Boulder, CO: Westview Press), pp. 144-145.

[36] Vern R. Walker, "Preponderance, Probability and Warranted Fact-Finding," Brooklyn L.R., Vol. 62, pp., 1075, 1115, (1996).

[37] Note that in the above discussion it is important what question is asked in the context. In the postmarket context, the issue is "Is the substance harmful and, if so, how harmful is it?" whereas in the

Thus, the nature of the harms from toxic substances and the often obscure causal connections between exposures and harms force us to discern them by means of scientific procedures and inferences (contrasted with grosser kinds of harms). However, our very reliance on these procedures exacerbates existing asymmetries concerning our knowledge about potentially toxic substances. Yet because toxic substances pose threats, there is or should be a concern for discovering their effects sooner rather than later. This suggests that there may be a tension between the necessarily time-consuming, science-intensive procedures needed to discover and characterize harms and the moral and legal concerns for preventing them. As we see next, the unintended effects of scientific epistemic caution on the law are exacerbated because of the plasticity in some aspects of the science that supports regulation and tort law judgments.

III

A point less often noted is that the scientific procedures typically used in establishing risks of harm in regulatory law or the likelihood of harm in the tort law have some plasticity to them. By this I mean that two different scientists can use the same procedures and come to different conclusions depending upon how studies are designed, how the data from them are interpreted, and what science and other policy decisions guide the scientists.[38] For example, if one wanted the most accurate epidemiological studies, studies with both low chances of false positives and low chances of false negatives, that could detect relatively low relative risks for a disease, such as benzene-induced leukemia, one would have to use very large samples in a prospective cohort epidemiological study. For leukemia, one would have to conduct study of 135,000 people in the exposed group and an identical number in an unexposed group in order to detect a relative risk of 3 with false positive and false negative rates of .05 or less. However, such a study would likely be prohibitively expensive.[39] Thus, in order to save money, a researcher might be willing to sacrifice some of the accuracy of the study and risk higher rates of mistakes as a result of statistical chance. Smaller samples of the exposed and unexposed groups would facilitate this aim. However, once a sample smaller than the above described "ideal" is used, this forces researchers into critical trade offs between the chances of committing a false positive mistake, the chances of committing a false negative mistake, or having a study that is too small to detect the risk of concern. In short, in such circumstances one can show mathematically that it is impossible simultaneously to have low false positives, low false negatives, and studies of sufficient power to detect the low relative risks of initial concern, for example, a relative risk of three. Like the pucker in a wall-to-wall carpet that is too large for a room, removing a pucker problem in one area merely forces it to appear somewhere else.

The major point this raises is that once a less than ideal study forces researchers into these critical trade offs, which mistakes one risks in designing and interpreting the study are matters of substantial normative concern. Interpreting studies in such a way that scientists tolerate higher chances of false positives jeopardizes scientific respectability and acceptance of

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premarket context, the question by contrast is "Is the substance safe, or sufficiently so, that it can be permitted into commerce?" Thus, the questions are different in different contexts and the context together with the standard of proof that must be satisfied importantly affects the legal outcome.

[38] This is not merely the philosophy of science problem that the evidence underdetermines conclusions, but a more serious problem resulting from the kinds of evidence in question. Cranor, Regulating Toxic Substances, pp. 22-24.

[39] To put this in context, recently the New York Times reported that an epidemiological study of a drug thought to prevent breast cancer with a sample of 13,000 women cost $50 million. A linear extrapolation from these numbers, suggests that for a study to be fully accurate would cost at least as much as $500 million (and even this would not be adequate, if one needed that many subjects in both the experimental and control populations).

the results in the scientific community. Interpreting studies such that higher chances of false negatives are tolerated risks failing by chance alone to detect risks of concern. If one insists on both low false positive and low false negative rates, one may not even be able to detect a relative risk remotely close to the one that motivated the study initially. Thus, decisions about the size of the study and, once that is fixed decisions about which mistake to risk, raise important normative questions. Which mistake do we risk? Which is the morally defensible risk to take? These normative issues are embedded in the very design and interpretation of such scientific studies.[40]

The other scientific studies used to detect harms or risks of harm in regulatory law and to a lesser extent in torts are toxicity tests based upon animal studies. Statistical problems identical to those of epidemiology attend the use of animal studies, but there are additional ones as well. To keep costs under control relatively small groups of animals are studied. Animals (typically rats or mice) are fed several (two or three) relatively high doses of a suspected substance which do not damage the animals' ordinary health or lower its weight, but that are sufficient it is hoped to induce tumors in the animals over a lifetime (if the substance has that potential). The aim is to see whether such doses cause statistically significant increases in tumors in the experimental as opposed to the control groups of animals. A typical study might reveal two or three data points at such dose levels, but most human exposures tend to be much lower, so researchers must extrapolate from high dose data points to much lower dose levels to project what toxic response, if any, might occur at the low dose levels typical of human exposure. This, however, would only estimate the tumor response *in animals*; thus the next step is to extrapolate from low-dose responses in animals to low-dose responses in humans by means of an animal-to-human extrapolation model. In using animal studies, then, there are two significant extrapolations--from high-dose responses in animals to low-dose responses in animals and from low-dose responses in animals to low-dose responses in humans. Which extrapolation models are appropriate? Unfortunately, there is little scientific consensus on these matters, although there appears to be considerable *normative or policy* consensus on which are appropriate. The use of extrapolation models that are radically underdetermined by existing scientific evidence adds to the controversy about whether and the extent to which there are risks to humans from substances that cause cancers in animals.[41]

The larger point is that the use of animal studies for identifying carcinogens and assessing their potencies introduces some plasticity into the ultimate judgments about whether substances pose a carcinogenic risk to humans (for regulatory purposes) and about whether they more likely than not have caused someone's cancer (for toxic tort purposes). Again there can be reasonable disagreement about these matters because they are so unsettled. Someone interpreting such data must make judgments about whether to risk false positives or false negatives (or analogously overestimating or underestimating the risks from such substances) in interpreting the data and extrapolations from it, and different science and regulatory policies might guide those considering the data.

Given the plasticity in interpreting evidence, if scientists choose for regulatory or tort law purposes to follow the most cautious inference-drawing procedures of their field that systematically protect against false positives, they will inadvertently favor one side in the legal debate. That is, there are a number of presuppositions of scientific inquiry which make seemingly "neutral" scientific research function less than fully neutrally in other institutional venues such as regulatory and the tort law. Epistemic conservatism and inferential caution may

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[40] Carl F. Cranor, "Some Moral Issues in Risk Assessment," Ethics, Vol. 101 (October 1990) pp. 123-143.

[41] A National Academy of Sciences study has identified some fifty different "inferential gaps" in the chains of reasoning leading from empirically determined facts to conclusions about risks to humans. Risk Assessment in the Federal Government, pp. 28-40. I have merely indicated some of the leading "gaps."

contribute to delayed discovery of toxic properties. The plasticity of scientific evidence only exacerbates these problems. Automatic reversion to scientific caution in interpreting plastic evidence is likely to predispose legal disputes toward avoiding FPs and is likely to result in non-neutral effects between parties to a legal dispute (discussed below).

Scientists' typical approaches to the uncertainty and ignorance introduce other normative issues. When scientists are faced with uncertainty and ignorance they (a) acknowledge it in reporting results and (b) try to remove it with future research, but typically suspend judgment until it is removed. The *rate* at which knowledge is accumulated and uncertainty is removed is typically not critical in the scientific search for truth in research. However, for public health purposes and for purposes of justice between parties in the tort law, the rate at which substances are identified and assessed may be of considerable importance. Thus, even the approach to uncertainty and ignorance in research concerning toxic substances may raise substantial moral issues.

The previous discussion suggests the following generalizations: Difficulty in establishing information about, informational asymmetry about, and asymmetrical political constituencies favoring potentially toxic substances are all further reinforced scientifically by scientific burdens of proof, scientific standards of proof, and typical research scientific approaches to scientific ignorance and uncertainty. However, the plasticity in understanding and interpreting the evidence reveals normative issues in the utilization of science in assessing risks, and, in conjunction with certain scientific approaches to interpretation, may exacerbate some of the problems. However, the plasticity in interpreting evidence also provides opportunities for addressing some critical issues in risk assessment and the law; specifically, there are choices in how the data are utilized and inferences drawn. As I argue below, we should utilize those choices in different institutional settings to mitigate some of the effects of asymmetries in knowledge, to address uncertainties, and to ensure that the public health is protected in the different legal venues.

As I indicated at the outset, one larger theme of this research concerns interpretation of "pieces" of scientific evidence such as epidemiological studies and animal studies and interpretation of the appropriate use of scientific evidence in the law. The two are related as the previous paragraph suggests, but the main discussion to this point has focused on the interpretation of pieces of evidence. Much of what follows below describes interpretive issues concerning the appropriate use of scientific evidence in the law.

IV

The discussion above suggests several conclusions: (1) Because of ignorance, uncertainties, and the state of the science, carcinogen risk assessment differs markedly from settled areas of science, the science we tend to know from undergraduate classes and from textbooks. Simply put, it tends to be new, less well-developed, less well-settled and pervaded by more and greater uncertainties than many of the scientific areas with which we are likely familiar. (2) However, the problems just discussed are not merely a function of newness. There are more endemic problems as a result of the introduction of new substances: the identification and assessment of the toxicity properties of substances newly introduced into commerce may always be undeveloped. For example, there is a family of dyes based upon the chemical substance benzidine. If a manufacturer uses one of them and it turns out to be toxic, the firm may then turn to a different dye from the benzidine family. However, the manufacturer would argue, and a very demanding research scientist might agree, that the second dye is at least a

somewhat different substance whose toxicity should be assessed anew.[42] Under post-market regulatory statutes, a whole new assessment of a structurally similar substance leaves it in commerce until the analysis is complete. If the entire chemical family tends to be carcinogenic as it now appears, however, this is a problem.[43] When substitute products are not from the same chemical family, such problems are exacerbated. (3) Carcinogen risk assessment is in fact substantially influenced by normative judgments; both the idea of "a risk" (the chance of an untoward or undesirable outcome) and the extent of a risk (because of the plasticity of research design and interpretation) are normatively laden. (4) In addition, the concern about preventing false positives is inconsistent in many cases with the aims of public health protections (e.g., with the prevention of false negatives and prevention of disease) and with the aims of the tort law to serve justice between parties. In fact several scientific practices aimed at preventing false positives will paralyze risk assessment and regulatory activity: an insensitive demand for more and better science, for removing uncertainty, for multiple kinds of evidence, and for better understanding before regulation, including understanding of the mechanism of toxicity.

For environmental health protection we should find a better balance between false positives and false negatives, and we should better utilize the available scientific tools and understanding sensitively in order to achieve this. We need to recognize that our scientific and legal responses to ignorance and uncertainty may promote or frustrate the many institutional and social goals served by risk assessment and regulation. We should recognize the circumstances in which this is likely to occur and adopt policies in interpreting and utilizing scientific results in the different legal venues so that we promote and do not frustrate the legal goals of those venues.

Having said the above, however, there is an additional issue of which we need to be aware when considering scientific accuracy and institutional decisions--there will be mistakes from the scientific procedures used to assess risks and to judge issues of causation. There will also be mistakes from the legal procedures in which the scientific evidence is used. We are, thus, condemned to discovering the effects of toxic substances and taking action on them as "as through a glass darkly." Ideal scientific or legal procedures would result in no factual or legal mistakes- no false positives or false negatives of either kind. This is unrealistic now and into the foreseeable future, however.[44] Thus, in absence of perfect procedures for assessing and regulating toxic substances, whether in science or the law, I suggest that we should take into account the social costs of different kinds of mistakes as well as the social costs of utilizing particular procedures.[45]

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[42] Apparently the U.S. EPA is considering adopting just such an approach in which the toxicity of substances must be supported by good human evidence instead of other forms of evidence from which one might reasonably infer that substances would cause harm to humans. (Lauren Zeise, Ph.D., Member, the EPA's Science Advisory Board, personal communication, May, 1999.) Following such a course of action would seriously undermine the EPA's efforts to prevent harm to the public from toxic substances.

[43] The entire class of substances are, for example, listed as known carcinogens under California's Proposition 65 and the National Toxicology Program (Listed at the NTP website, http://ntpserver.niehs.nih.gov/NewHomeRoc/Known _list.html (visited June 7, 1999)) and as probably carcinogenic to humans by the International Agency for Research on Cancer (Listed at the IARC website, http://193.51.164.11/monoeval/crthgr01.html (visited June 7, 1999)).

[44] This concern is not just a function of ignorance in science or poorly designed institutions. Rather it would be difficult or impossible to design perfectly accurate scientific procedures and institutions that could guarantee perfect outcomes. Moreover, given the probabilistic nature of much of scientific inquiry, it is arguable that there could not be perfectly accurate scientific procedures.

[45] See John Rawls, A Theory of Justice (Cambridge, Mass: Harvard University Press, 1971), pp. 85-87, for a discussion of perfect and imperfect procedural justice.

We clearly do this at present in many of our institutions and activities; consider, for example, the criminal law. Over time courts and legislatures have designed search and seizure procedures, presumptions, burdens of proof, standards of proof, and other protections for the general citizenry and potential defendants in light of the general aims of the law to reduce violations of the criminal law and in light of the nature of criminal punishment (as well as the injustice of wrongly punishing innocent persons). In particular, pretrial and trial procedures have been developed in order to protect strongly against innocent people being wrongly punished; there is a somewhat lesser concern to protect against guilty parties going unpunished, even though that has social costs as well. The aphorism often cited in support of this view is that it is better that ten guilty people go free (the equivalent of a legal false negative) than that one innocent person be punished (the equivalent of the legal false positive). This is a clear example of a legal/social institution that has been tailored in accordance with important social values (including those against unjust punishment of innocent persons) even though the particular design will not always serve some of the deterrence aims of the criminal law. In short, the procedures have been designed for the context in question and for the significant social values at stake. Appellate justices and legislators have created institutional procedures to take into account the different costs of legal mistakes and the costs of the procedures themselves in designing and fine-tuning the institution. We could have greater deterrence and faster trials by removing some of the protections for defendants, but this would put in jeopardy some of our other values about justice, so we do not pursue such goals.

As an alternative example we might consider the design of breast cancer screening. In this activity there is a well-founded concern for avoiding falsely identifying benign tumors as malignant (a false positive) because at a minimum this will result in considerable psychological trauma and, if the mistake is not caught before an operation occurs, great costs, unnecessary operations, possible disfigurement, and additional psychological trauma. However, the greater concern is to avoid false negatives, failing to identify a malignant tumor. Positive results from screening can be followed up by additional and more sensitive tests to distinguish true from false positives, whereas false negatives are likely to result in tumors' going undetected or going undetected for so long that once they are identified it may not be possible to prevent the tumor from causing the death of the patient. Thus, breast cancer screening is designed quite differently from the criminal law with respect to the requisite institutional false positives and false negatives.

The above points can be generalized by considering the "designs" of several institutions or activities with which we are familiar which differ in their aims of preventing different kinds of mistakes. These are summarized in the following table with an schematic representation of social costs of false negatives ($SC_{FN)}$ and the social costs of false positives (SC_{FP}) or of legal FPs and legal FNs.

"Institution"/ Activity	False Positives	False Negatives	SC_{FP}-SC_{FN} Relation
Criminal Law	Greater concern to prevent	Lesser concern to prevent	$SC_{LFP} >> SC_{LFN}$
Research Science (field dependent)	Greater concern to prevent	Lesser concern to prevent	$SC_{FP} >> SC_{FN}$
Drug Approval Testing	Lesser concern to prevent	Greater concern to prevent	$SC_{LFN} > SC_{LFP}$

Breast Cancer Screening	Lesser concern to prevent	Greater concern to prevent	$SC_{FN}>>SC_{FP}$

Given the above examples, it is clear that we do not have a singular approach to institutional/activity design. This is not surprising, because of, among other things, the values inherent in the activities and the values that we seek to secure in case mistakes are made that guides such decisions. How such institutions should be designed is an institutional, social and philosophical question.

Thus, I have argued that we should adopt similar approaches toward the use of the science in the law. One common model for such purposes aims to minimize the total social costs of mistakes: the number and social costs of false positives, plus the number and social costs of false negatives, plus the costs of the evaluation, screening, trial, testing or regulatory procedures themselves. Put technically, we can express this as

> min $[(N_{FN} \times SC_{FN}) + (N_{FP} \times SC_{FP}) + SC_T]$, where SC_{FN} is the social cost of a false negative, SC_{FP} is the social cost of a false positive, and SC_T is the social cost of the procedure and using it.[46]

In regulating potentially toxic substances, false positives (and overregulation) will impose social and monetary costs on the manufacturers of the substances, on their shareholders, and on the consumers of their products. False negatives (and underregulation) will impose social and monetary costs on the victims or on those put at risk from the toxicity of the substances. Because of the uncertainties and normative presuppositions in risk assessment, the number and kinds of mistakes that will be made in regulating toxic substances depend upon how risk estimation tools are used for legal and public health protection purposes. Finally, there can be social costs to using institutional procedures as well. The law has an interest in relatively quick resolutions of disputes, so some legal procedures support this, whereas other procedures might favor greater time for preparation and more deliberate airing of the evidence. In regulatory procedures carcinogen risk assessment has been slow, even slower than animal studies, which are the foundation of regulation. But, if substances in commerce are harmful but unassessed, slow assessment prolongs the harm. At present it appears there has been great emphasis on being quite certain about the toxicity of substances before proceeding in regulation, but other values and social costs, e.g., health threats to those exposed, might well modify the seeming insistence on certainty.

The discussion of mistakes and their costs suggests that we face normative decisions in how we design and use risk assessment procedures in different legal venues, that is, in how demanding we make data, inference and procedural requirements for different legal purposes. A general concern is that scientific knowledge generation or knowledge accumulation activities that are subject to too many demands for science-intensive information can frustrate the public health and environmental protection goals of the regulatory law and the goals of justice between individuals in torts. How shall we err?

V

The above observations largely about risk assessment and its scientific foundations provide background for research on the use of such evidence in the law. One generic point is simple enough: much as in different areas of the law, we need different standards of evidentiary certainty and different kinds and amounts of evidence depending upon the context of inquiry or the activity in which we are engaged and the set of values at stake. Thus, I have argued that there is a difference between the need for certain kinds of evidentiary procedures and stringent

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[46] This formulation of a unified approach to mistakes is not uncontroversial, even from my point of view, since it bears such similarity to utilitarian approaches to social problems. I tend to favor a less utilitarian and less consequentialist approach to normative and distributive issues.

standards of certainty in science, on the one hand, and the need for evidence in the regulatory and tort law, on the other hand.

It is clear that presumptions, burdens of proof, and standards of proof of a particular institution or practice have important roles to play in decisions leading to action. Sometimes the burdens and standards of proof are explicit, as they are in the law, or more informal, as they tend to be in scientific inquiry; in either case insofar as they have determinative roles in decisions, what they are and how they are used will be important for decisions we make. Problems arise when we are not clear about consciously designing our institutions to recognize these issues.

In order to address some of the above problems, we should acknowledge that risk assessment is a mixed science-policy procedure (for the reasons indicated above) and that the kind and amount of evidence needed in a particular legal or social venue is a normative issue. **(**Or one might say that this is a matter of interpretation of the proper role of the use of science in different legal venues.) Both claims are relatively innocuous, but they can be liberating: freeing us from particular scientific paradigms about how scientific evidence should be used for risk assessment and regulatory and tort law activities, and freeing us to consider the possibility of other risk assessment designs and other approaches to acquiring knowledge and addressing uncertainty for the legal purposes in question. Moreover, we should be wary of an *insensitive* commitment to the epistemic values implicit in scientific inquiry (low false positive rates, demanding standards of proof, particular conceptions of rigor, and a desire not to add mistakenly to the stock of scientific knowledge) inadvertently trumping the values of the law, and the public health goals of carcinogen risk assessment and regulation. Our scientific epistemology can put these other values and goals at risk, if it is not well suited for the context. Thus, I suggest that we adopt a context-sensitive epistemology for using science and risk assessment in the law. In general we should design risk assessment, knowledge generation inquiries, and regulatory activities to serve aims of the institution in question with guidance from the norms of the institution and appropriate moral and philosophic principles.

In particular, as a generic strategy for regulation we should give greater attention to avoiding false negatives (appropriate to the legal context) than we have to date for two reasons: in order to protect the public health better and in order to mitigate some of the asymmetric knowledge we tend to have about toxic substances. Moreover, we should recognize that the rate of carcinogen identification and assessment is normatively important; slow knowledge accumulation *per force* may be harmful, especially given the large number of unassessed substances and the backlog of known animal carcinogens that may also be harmful to humans. Slow knowledge accumulation may frustrate action on a particular substance (e.g., dioxin has been under review and re-review by the U.S. Environmental Protection Agency for decades) and it diverts resources from acquiring information about the existing unassessed substances (in short, it has substantial opportunity costs). We should recognize the plasticity of interpretation and the mixed science-policy nature of these activities in order to address sensibly public health issues. We should consider utilizing approximations, presumptions, default assumptions, and policy choices to address uncertainties in risk assessment design, much as these devices are utilized in the law. Finally, in research we should find or design scientific procedures that address the need to expedite the identification and assessment of carcinogens and other toxic substances, but with sufficiently low false negative and low false positive error rates that they can be reasonably used for legal purposes; that is, we should find replacements for animal studies, the current basis of much toxicity information, that are faster and sufficiently accurate for the purposes in question.

VI

The general strategic ideas just described suggest a number of more specific recommendations for the use of science in the law for environmental health protection purposes. In environmental health regulatory law agencies work under laws that seek to protect our rights

and interests by preventing harms from arising by specifying in advance how certain activities should be done. Typical statutes tend to be health-protective, suggesting to a greater or lesser degree a concern for preventing false negatives which vary by statute. Such laws tend to authorize regulation to prevent "unreasonable risks of harm to health," to prevent human health risks "with an adequate (or ample) margin of safety" or to prevent exposure to substances that cause "cancer in humans or animals."

One problem is that *potency assessments* of carcinogens, the second typical step in the risk assessment and regulatory process described above, whether done by the U.S. EPA or the California EPA, have been slow, taking, for example, from one-half to five person years per substance in the California EPA. One of the easier steps in risk assessment, this could and should be expedited, because potency assessments have not even kept pace with slow animal studies that take at least five years to complete. Thus, scientists at University of California, Berkeley, the California EPA, and I suggested that potency assessments should be expedited in order to process information about known carcinogens faster, to provide a more consistent regulatory process, and to provide a more health-protective regulatory outcome (because unassessed carcinogens will now be more nearly fully assessed). And these procedures appear to save considerable social and governmental resources because they are less science-intensive and fewer known carcinogens go unaddressed by agencies and unregulated (thus, they appear to reduce the number of regulatory false negatives).[47] The recommended risk assessment procedures and policy considerations aimed at mitigating social costs connected with science-intensive procedures (whose aim is to achieve a certain kind of accuracy and to minimize the number of false positives), so that the risk assessment process better served some of the health-protective aims of administrative health law. Our conclusion was that contrary to the current presumption, time-consuming, science-intensive assessments appear necessary only if there is low human exposure and the costs of regulating substances are quite high relative to the risks to human health.[48]

A second problem is that the *identification* of carcinogens and other toxic substances has also been slow. Tens of thousands of substances currently in commerce are unassessed. Some of these are of little or no import, but the most basic toxicity information is missing for 3,000 of the highest production volume substances according to two different reports thirteen years

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[47] Sara M. Hoover, Lauren Zeise, William S. Pease, Louise E. Lee, Mark P. Henning, Laura B. Weiss, and Carl Cranor, "Improving the Regulation of Carcinogens by Expediting Cancer Potency Estimation," Risk Analysis Vol. 15, No. 2, April, 1995, pp. 267-280, and Carl F. Cranor, "The Social Benefits of Expedited Risk Assessment," Risk Analysis Vol. 15, No. 4, June, 1995, pp. 353-358.

[48] The incompatibility between regulatory law and research science fields that might underlie it is expressed in the following relationships.

"Institution"/ Activity	False Positives	False Negatives	SC_{FP}-SC_{FN} Relation
Research Science (field dependent)	Greater concern to prevent	Lesser concern to prevent	$SC_{FP} >> SC_{FN}$
Env. Health Law	Lesser concern to prevent	Greater concern to prevent	$SC_{LFN} > SC_{LFP}$

For research there is a great concern to prevent false positives because of the social costs to science if scientists do not have this aim, while for environmental health law there is priority to prevent regulatory false negatives and overregulation because of Congressional mandates and the morality of protecting people from potential harms.

apart.[49] Thus, a research group at the University of California Berkeley, the California EPA, and I considered ways in which one might find quicker administrative procedures or scientific approximations to identify carcinogens (and similar things should be done for other toxic substances). We evaluated the use of comparatively quick and inexpensive short-term tests, such as mutagenicity tests, chemical structure-activity tests, and various in vitro tests, in order to assess them for their accuracy in comparison with animal studies for use in identifying carcinogens. The results in this area to date are not as promising as they were for expedited potency tests. However, even using less than fully accurate expedited identification procedures, the following results were suggested: if the percentage of carcinogens in the chemical universe is 10 percent or greater, and if in our considered social judgments on average the social costs of false negatives are greater than the social costs of false positives by a factor of 3.5 or greater (insofar as we can make such judgments), then there is a case for using expedited identification procedures compared with conventional science-intensive (e.g., animal) tests. Such identification procedures have relatively high false negative and false positive rates (both about .25). The high false negative rates in the context of trying to protect human health are probably so high they preclude adoption of the procedures, despite their having some plausibility from a modeling exercise. (Similar high false positive rates are more tolerable, since a manufacturer or registrant of the substance upon getting a positive test result has incentives to do further testing to see whether it is a true or a false positive.) If the false negative rate for identification procedures could be reduced to more tolerable levels, such short-term tests would provide for faster screening of potentially toxic substances coming into commerce and faster surveying of unassessed substances in commerce, thus addressing one of the major shortcomings of current identification and assessment procedures.[50]

Third, *susceptible subpopulations* have not been well protected by environmental regulations, for example, children, the elderly, the genetically susceptible, and those whose health is already compromised. Pursuant to a National Academy of Sciences Report,[51] several pieces of legislation,[52] an agency initiative, and a Presidential Order,[53] the U.S. EPA is beginning to address this shortcoming in its regulatory science and its regulations.[54] The legal and moral case for this seems clear. Several pieces of legislation seem to support this view and several moral principles as well. Consider only one such principle that has been deeply embedded in the tort law for more than a hundred years: it suggests that if others invade our legitimately protected interests, then even if someone is more susceptible to injury than others, that person is still entitled to protection, for example, even those with eggshell skulls or particular vulnerabilities to disease. Thus, if the healthy are entitled to preventive measures to protect them from invasion of their interests, others who might be more susceptible to disease have equal standing to be similarly protected. For risk assessment and regulation, it is only good

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[49] National Research Council, Toxicity Testing (1984), and the Environmental Defense Fund, Toxic Ignorance (1997).

[50] Carl F. Cranor, "The Normative Nature of Risk Assessment: Features and Possibilities," Risk: Health, Safety and Environment, Vol. 8, pp. 123-136 (Spring 1997).

[51] National Research Council, Pesticides in the Diets of Infants and Children (Washington, D.C.: National Academy Press, 1993).

[52] The 1992 Clean Air Act Amendment, the 1996 Food Quality Protection Act and the Safe Drinking Water Act amendments of 1996.

[53] Exec. Order No. 12,898, 3 C.F.R. 859 (1995), *reprinted in* 42 U.S.C.A. sec. 4321 (West 1994) ("Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations")

[54] Results of an EPA conference on this issue are reported in a special of Environmental Toxicology and Pharmacology Vol. 4 (1998).

descriptive science to recognize the presence of factors, which will make particular individuals or groups of people more at risk to disease. Moreover, pragmatically if we ignore special susceptibilities or sensitivities in risk assessment, they will surely be ignored in the management of the risks. Thus, it seems clear that susceptible subpopulations should be recognized for both risk assessment and risk management purposes.

Nonetheless, a strict research-science approach to this problem may frustrate some of the health-protective aims of protecting susceptible subpopulations. Good scientific research on the issue would identify all susceptible subpopulations potentially affected by exposure and identify the range of susceptibilities in order to set regulatory levels of exposure so that susceptible subpopulations had some appropriately low level of disease from exposures. Such an approach would involve considerable research into the particular susceptibilities, their causes and their range from most to least susceptible. This takes time and detailed information, even fundamental biological understanding of esoteric processes such as metabolic pathways and possibly the genetic bases of susceptibility. And it would have to be done on a chemical-by-chemical basis for each substance under consideration. While such research is being conducted, the regulation would be held up, protections for populations would be delayed, and, because resources were being spent for this purpose, they would not be available for addressing unassessed substances. In short there is the potential for considerable human and social costs, as well as great opportunity costs, from such an approach. By contrast, a context-sensitive approach to the problem would recognize such costs, and recognize that the policy basis for addressing susceptible subpopulations did not have to be supported by such detailed scientific studies in order to have a good health-protective social policy.

Thus, for example, agencies could shift some of the usual burdens of proof that exist in science and in postmarket regulatory processes to mitigate some of the these problems. Agencies should adopt, as some currently do, default safety factors or high upper confidence extrapolation models to serve as *placeholders* for variations in susceptible subpopulations until substantial, credible scientific evidence is provided to remove some of the uncertainty and change the default position.[55] Such an approach would, however, be a regulatory solution, not a scientific one. Just as in other areas of the law where certain *presumptions* are deemed appropriate for addressing a problem until there is evidence to the contrary, so similar presumptions in the form of default safety factors could be adopted in the risk assessment and regulatory contexts to address the range of susceptibilities in populations, given the legal and social policy aims in the contexts (and given the high costs of a science-intensive alternative).[56]

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[55] Current 10-fold default safety factors may not be large enough; perhaps they should be several hundred-fold. (D. Hattis and K. Barlow, "Human Interindividual Variability in Cancer Risks: Technical and Management Challenges," Health and Ecological Risk Assessment, Vol. 2, pp. 194-220 (1996); F. Perera, "Molecular Epidemiology: Insights into Cancer Susceptibility, Risk Assessment, and Prevention," J. Natl. Cancer Inst. Vol. 88, pp. 496-509 (1996); S. Venitt, "Mechanisms of Carcinogenesis and Individual Susceptibility to Cancer," Clin. Chem Vol. 40, pp. 1421-1425 (1994))

[56] For a conclusive or irrebuttable presumption "[i]f A is shown, then B is to be presumed without question and the court will not even receive evidence or entertain argument to show the nonexistence of B.. . [This]is a process of concealing by fiction a change in the substantive law. When the law presumes the presence of B from A, this means that the substantive law no longer requires the existence of B in cases where A is present, although it hesitates as yet to say so forthrightly. . . " e.g., presumption that the possessor of marijuana knows that it was illegally imported. (Fleming James, Jr., and Geoffrey C. Hazard, Jr. Civil Procedure (Boston: Little, Brown and Company, 1977), pp. 253-254.) For a rebuttable presumption B based on the establishment of fact A, "on a showing of A, B must be assumed by the trier [of fact] in the absence of evidence of non-B." (James and Hazard, p. 255) Both kinds of presumptions are devices for "allocating the production burden. . . if A is shown, then the party who asserts non-B has the production burden on the issue of B's existence or nonexistence." And, finally, a presumption has

A more sophisticated approach might create default positions for risk assessment and regulation based upon similar classes of compounds and similar biological predispositions of certain subpopulations in order to avoid some of the gross assumptions just described. How realistic this might be is a much more open question, however. In both approaches only if there is specific evidence about susceptible subpopulations inconsistent with the default should it be used instead. The overall approach, contrary to the typical procedure in science, is to presume that there will be a relatively wide range of biological responses as a result of susceptible subpopulations and to change this presumption only when specific scientific evidence to the contrary is developed.[57]

VII

Finally, many of the generic concerns that led to recommendations about using science in regulatory law apply as well to the use of science in personal injury or the tort law. The tort law seeks to secure the rightful borders of our possessions and ourselves by *making us whole* should we suffer damage by "border crossings" resulting from the conduct of others. It sets public standards of conduct that must be privately enforced by the victim, who receives compensation for injuries caused by a defendant, acting in violation of the law. It aims to compensate wrongfully injured victims and to deter certain wrongful conduct. Injuries caused by toxic substances are one kind of legally compensable injury in torts. Establishing the cause of injury is just as much a scientific detective story in torts as it is in regulatory law.[58] Thus, similar issues arise concerning the use of scientific evidence in toxic tort cases. In particular, wholesale and insensitive adoption of scientists' burdens of proof, standards of proof, and pragmatic rules about the use of evidence in order to establish causation will distort the tort law, yet some courts and commentators urge this, suggesting that "science is science wherever you find it." Court requirements that scientific evidence satisfy the most stringent considerations take several forms. Some require expert testimony to be supported by multiple kinds of scientific evidence before a plaintiff can even have expert testimony admitted into court and before the plaintiff can present such testimony to a jury.[59] Some courts have instituted simple screening rules for admitting evidence into a trial, such as, requiring epidemiological evidence or requiring an "epidemiological threshold"[60] for evidence of human harm, placing special restrictions on epidemiological studies before even they can be admitted into evidence.[61] Many of these

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"an artificial procedural force and effect (at the point where proponent rests his case) over and above the logical probative effect of the evidence," because it predisposes the legal outcome if other party does not rebut the facts that have been raised. A presumption aids the party with the presumption, once certain facts are established whereas a burden of proof tends to handicap the party with the burden unless certain facts are established. (*Id*. at 255)

[57] Carl F. Cranor, "Eggshell Skulls and Loss of Hair from Fright: Some Moral and Legal Principles that Protect Susceptible Subpopulations," Environmental Toxicology and Pharmacology Vol. 4, pp. 239-245 (1997). These ideas have since been developed further in my "Risk Assessment, Susceptible Subpopulations and Environmental Equity," forthcoming in The Law of Environmental Justice, ed. Michael B. Gerrard, (The American Bar Association: 1999)

[58] There is a greater emphasis on screening scientific evidence and expert testimony based on it since the Supreme Court's decision in *Daubert v. Merrell-Dow, Inc.* 509 U.S. 579 (1993).

[59] This suggestion is analogous to the stringent scientific requirements that Professor Furst would place on judging that a substance is a human carcinogen (see text and footnotes at fn. 24).

[60] I owe this term to Michael D. Green, *Expert Witnesses and Sufficiency of Evidence*, 86 NW. U. L. REV. 643, 680-682 (1992).

[61] Requiring that studies be statistically significant at .05 level or below; requiring that studies exhibit a relative risk of at least two helps to provide evidence that plaintiff's injuries more likely than not resulted from exposure to defendant's substance; requiring Hill's factors or considerations, e.g., high relative risks, consistency with other studies, specificity, biological plausibility. Some courts and commentators appear

considerations are typical requirements for scientific accuracy, which aim largely at preventing false positives, but they may also increase the numbers of false negatives. Moreover, they will also distort tort law notions of accuracy,[62] which aims to achieve a much more balanced approach to preventing false positives and false negatives as the outcome of tort procedures and substantive law. In addition, such stringent scientific requirements for admitting evidence have important social and legal implications, because they, together with plaintiff's burden of proof, protect defendants at the expense of plaintiffs. Thus, failing to take into account the approximate balance of interests between plaintiffs and defendants in the tort law in designing the rules for admitting scientific evidence will over time distort the legal procedures of torts and the larger social aims they serve. Some courts have automatically excluded animal evidence, at least in the absence of epidemiological studies, for example, as was done in the Agent Orange litigation and some commentators recommend this course of action. However, this also is too strong a requirement. It is not something a good toxicologist would do.[63]

In contrast to the above recommendations, I have suggested that courts take somewhat different approaches to the admission of scientific evidence. First, they should develop a more sensitive understanding of the science involved, including both its strengths and weaknesses and its possible effects on the law, or return to more relaxed standards for admitting scientific evidence. Second, all evidence on which scientists rely when making judgments about causation should be admissible in tort cases involving toxic substances: clinical studies, epidemiological studies, case studies, animal studies, structure-activity relationships, and other short-term tests. At present some courts exclude as inadmissible evidence that scientists would normally take into account. Third, the rules for admitting expert testimony and the inferences on which experts rely should recognize the various patterns of evidence on which scientists themselves rely and further recognize that there may be considerable differences between experts on the kind and amount of evidence each judges sufficient for judging that a substance is likely harmful to humans. Fourth, the rules for admitting scientific evidence in tort law should preserve the traditional balance of interests between parties to a dispute and the traditional goals of tort law: to compensate victims for the harmful conduct of others that more likely than not harmed the victims, and to deter others from engaging in wrongful conduct that will probably harm others. Admissibility rules that explicitly or implicitly change the burdens of proof dramatically so that plaintiffs must establish a piece of scientific evidence to a very high level of certainty, approaching the criminal

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to require most of Hill's factors, but Hill himself did not; he regarded none of the nine "considerations" as a necessary condition, except one requiring that the cause precede the effect. Moreover, Hill himself points out that rigid adherence to Hill's factors would have led to delay in identifying the cause of meningitis (because it had a low relative risk), and to missing that occupational exposure to nickel causes cancer (because consistency did not obtain), that soot causes scrotum cancer (because at the time it was discovered it lacked biological plausibility since it was a new biological result), and that arsenic causes skin cancer (at the time it was discovered this result did not cohere with other scientific tests which were still inconclusive or negative). (Austin Bradford Hill, "The Environment and Disease: Association or Causation?," 58 Proceedings of the Royal Society of Medicine pp. 295, 299 (1965), *reprinted in* Evolution of Epidemiologic Ideas: Annotated Readings on Concepts and Methods , Sander Greenland ed., (Newton Lower Falls, MA: Epidemiology Resources, Inc., 1987), pp. 15-19.)

Such considerations strengthen the evidence and the study, but are not necessary conditions for a reliable study and should not be necessary conditions for evidence to be admitted into a legal case.

[62] Cranor, "Discerning the Effects of Toxic Substances," and Carl F. Cranor, John G. Fischer, and David A. Eastmond, "Judicial Boundary-Drawing and the Need for Context-Sensitive Science in Toxic Torts after *Daubert v. Merrell-Dow Pharmaceutical*", The Virginia Environmental Law Journal, Vol. 16, pp. 1-77 (1996)

[63] Well regarded scientific groups, such as the International Agency for Research on Cancer (IARC), always utilize animal studies, and there are substances classified as probable human carcinogens on the basis of animal and mechanistic evidence, in absence of clear epidemiological studies.

law's "beyond a reasonable doubt" burden of persuasion, will distort the tort law into a quite different institution. Finally, courts should adopt evidentiary standards that give due consideration to the notion of tort law accuracy in decisions; that is, tort law should provide roughly equal protection to avoiding both legal false positives and legal false negatives. [64]

Finally, courts need to develop sensitivity to the subtlety, complexity, strengths, and weaknesses of different kinds of scientific evidence, and not issue overly simple rules for admitting or barring available evidence. At the same time they must learn to follow pragmatic rules about the kind and amount of evidence needed for tort law purposes which will be somewhat different from those used by scientists. In particular, they need to develop on a case-by-case basis an idea of the minimal kinds and amounts of scientific evidence that are needed to satisfy admissibility, sufficiency and proof requirements for the tort law.[65]

The last point can be illustrated by reference to what is now an agreed human carcinogen. Ethylene oxide typically used as a sterilizing agent in hospitals was for some time a suspected, but not a known, carcinogen. Human epidemiological studies had mixed results, that is, some were positive, some negative, and in general the statistical evidence based upon human data was inconclusive. Nonetheless, an international scientific body, the International Agency for Research on Cancer, recently classified it as a *known* human carcinogen based upon the mixed human studies, animal studies and data about its mechanism of action.[66] Surprisingly, this was an evidentiary basis that would have been insufficient in some or many tort law jurisdictions for even having a court to consider a plaintiff's claim of injury meritorious enough to go to trial. Many jurisdictions would have precluded plaintiffs from trial simply because human epidemiological studies were inconclusive. Thus, if courts are going to seriously consider the science involved in deciding whether or not to admit evidence, they should at least utilize all the evidence on which scientists themselves would rely and preclude cases on the basis of overly simplified rules about the admissibility of evidence.[67]

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64 The distortion that might occur if scientific standards of appropriate evidence dominate tort law as an institution is indicated in the following relationships.

"Institution"/ Activity	False Positives	False Negatives	SC_{FP}-SC_{FN} Relation
Research science (field dependent)	Greater concern to prevent	Lesser concern to prevent	$SC_{FP} >> SC_{FN}$
Tort Law	Appx. equal concern to prevent		$SC_{LFN} = SC_{LFP}$

65 Cranor, "Discerning the Effects of Toxic Substances," and Cranor, et. al., "Judicial Boundary-Drawing and the Need for Context-Sensitive Science in Toxic Torts after *Daubert v. Merrell-Dow Pharmaceutical."*

66 IARC Monograph Series, Vol. 60 (1994) The overall evaluation of ethylene oxide was upgraded from a probable human carcinogen to a known human carcinogen with supporting evidence from other data relevant to the evaluation of carcinogenicity and its mechanisms.

67 In another interesting scientific case, investigators from the Centers for Disease Control, called in to investigate an unusual death that appeared to be murder, found that a disgruntled former lover of a woman tried to cause the slow death of her and her family by lacing lemonade in the refrigerator with a known carcinogen. The substance, dimethynitrosamine, was more potent than he anticipated with the result that he caused acute liver disease that killed several of them within a few days. The interesting thing about this is that all the scientific evidence that the substance was a liver toxin came, not from human studies, but from animal studies, a source of evidence that would not be permitted into many tort law cases, but which formed the basis of a criminal conviction for murder. (Renate D. Kimbrough, "Case Studies," Industrial Toxicology (P.L. Williams & J.L. Burson eds.), pp. 414, 417-20 (1985).

The work described above addresses by reference to issues in environmental science and policy a problem to which C. P. Snow called attention. Bringing scientific and philosophic fields together to help overcome some of the divisions present in our intellectual culture, I sought to speak to philosophic, scientific and policy issues that arise in the regulation of toxic substances. In order to accomplish these aims, the research has been empirically and institutionally rich and addressed micro-level interpretations of scientific evidence as well as more macro views of the proper use of scientific evidence in the regulatory and tort law. Finally, it required some reorganization of knowledge or different organization of knowledge in order to make progress on the issues.

While much of the research has been appropriately located in legal philosophy (because it concerns philosophic issues about regulatory and tort law and a defensible approach to using science therein), it is also part of moral philosophy. This feature deserves further comment. A partial map on which to locate the research within some of the major issues in moral philosophy is suggested by Normal Daniels:

> "Doing ethics" involves trying to solve very different kinds of problems answering to rather different interests we may have, some quite practical, others more theoretical. [i] Sometimes we want to know what to do in this case or in developing this policy or designing this institution. [ii] Sometimes our problem is in understanding the relationship between this case, policy or institution and others and making sure we adopt an approach consistent with what we are convinced we ought to do elsewhere. [iii] Sometimes our problem is to provide a systematic account of some salient element in our approach to thinking about cases, such as an account of the nature of rights or virtues or consequences. [iv] We can sometimes presume considerable agreement on some aspects of the problem but not others, so the practical problem may be how to leverage agreement we already have to reduce areas of disagreement. *There is no one thing we do that is always central to solving an ethical problem for there is no one paradigmatic ethical problem.* [68]

I agree with much of the above characterization; philosophers should recognize and embrace the multiplicity of activities that constitute ethics or moral philosophy. Within the above characterization, this research has tended to fall within [i] and [ii], with some present, but even more future research aimed at [iii]. That is, I have addressed philosophic issues in risk assessment and risk management ([i]), the use of risk assessment in the law ([i]), and issues of consistency between science and the law ([ii]). The aim has been to understand philosophically the relationships between these two institutions and to articulate appropriate principles to guide the regulation and control of environmental toxicants consistent with several different social goals.

This research has also largely been an instance of what we might call "institutional" morality. By that I mean the research addresses appropriate moral philosophic views for assessing the joint effect of two *institutions* or aspects of institutions on the lives of persons. Just as in criminal or constitutional legal philosophy where some of the issues are the proper role of and the effect of the state and its institutions on people, my concern has been with how the seemingly esoteric issue of the use of scientific evidence in the law should impact persons affected by these institutional designs and decisions. I have not discussed in detail the underlying moral principles guiding the inquiry directly, since I have yet to argue explicitly and

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[68] Norman Daniels, "Wide and Narrow Reflective Equilibrium in Practice," in Norman Daniels, ed., *Justice and Justification* (New York: Cambridge University Press, 1996), p. 339 (numbers added to the quotation).

fully for the moral view that should guide us on these matters (Daniels' [iii] above). Instead I have tended to identify and resolve incompatibilities between institutions and to articulate what their joint effect might be on persons, relying upon presuppositions of these institutions. However, implicit in these inquiries is a concern that certain normative moral philosophic approaches, e.g., utilitarian or consequentialist, to the issues are not the best way to address them. I have been guided *sub rosa* by a working moral philosophic hypothesis that tends to emphasize the protection of individual persons (in the Kantian tradition) more than is ordinarily recommended by utilitarian justifications and arguments. Developing this view more fully is on the agenda for future research.

Second, the research has been informed by detailed understanding of the kinds of scientific evidence relied upon to assess the human toxicity of carcinogens, detailed knowledge of the law and the nexus of the use of scientific evidence in regulatory and tort law proceedings. I sought to understand risk assessment in sufficient detail, so that I could reasonably assess it and its use in the law for regulating toxic substances. This understanding led to a diagnosis of some normative issues in (carcinogen) risk assessment and a diagnosis of some potential and actual problems between scientific approaches to evidence (as exemplified in debates about risk assessment) and evidentiary requirements of the law. As a consequence that background helped to reveal philosophic issues that might not have been seen, except perhaps in their most abstract formulations, and to suggest strategies for making progress on the some of the broader topics concerning the use of science in the law. The philosophic issues concerning the relationship between science and the law exist, but perhaps had not been clearly seen until they were put in relief by detailed descriptions of each. In addition, such research helped to uncover normative judgments concealed in risk assessment, the plasticity in assessing the risks from particular substances, and the strategy that these two ideas were a strength for using science in the law. Thus, in circumstances plagued by considerable ignorance and uncertainty and with limited resources to address problems, we need to ensure that risk assessment is done in ways that are appropriate for the context in which they will be used--consistent with health protections and with our legal and moral goals respectively. It is mistake to adopt the most cautious scientific principles for interpreting evidence. Thus, it is important to avoid having the epistemic standards of one institution or area of inquiry (science) hijacking, or to change the metaphor, trumping, those of another institution (the law).

Bridging science and the law also required detailed institutional understandings of administrative and tort law.[69] Philosophic analysis of the aims of the two areas was required: what are some of the aims or goals of regulatory law (and this, of course varies by statute), the relative balance of legal interests between parties, and the effect of different approaches to using scientific evidence in regulatory law? A similar philosophical analysis was needed for the tort law, its aims and goals, legal balance of interests between parties, and the effect of different pragmatic evidentiary rules concerning scientific evidence in torts.

Third, a significant but somewhat vague point is related to the above: the "organization of knowledge" to address social problems. As different disciplines and modern universities have struggled with addressing pressing social problems, it has become clear that the analysis of and solutions to problems tend not to come from single fields or areas of inquiry. Complex and multifaceted problems require the contributions of a number of different disciplines as traditionally conceived to address them. This is particularly true of issues concerning the environment and environmental health. Circumstances may force us to bring intellectual cultures together as Snow argued. This I have tried to do in the research described above.

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[69] Acquiring such knowledge is an extension of a long tradition in philosophy that has considered the philosophical presuppositions of different fields under the generic rubric of the philosophy of x, where x might be science, mathematics, mind, law, morality, etc.

One approach is for teams of researchers to address such complex problems. It may be difficult, however, to create the right team of people to identify and assess a problem, especially if they are not geographically proximate. There is also a problem translating between the languages and presuppositions of different disciplines (although this can be intellectually healthy for the participants). However, if these problems can be overcome, in some respects such an approach is the closest to realizing the ideal in addressing the problems to which Snow called attention. By having groups of people work together, learn the relevant aspects of science and the law, learn to translate between the fields, and acquire some understanding outside one's area of specialization, this helps to create, at least for that group, something of a common culture for addressing the problem in question. It also helps individual researchers develop an appreciation of the contributions that can be made from other fields. If enough scientists and humanists begin to acquire some common cultural understandings of the problems and the contributions different fields can make, this clearly helps to overcome in a broader way Snow's problem. Some of the research described above has followed this course, has been quite rewarding and has resulted in research products that have impacted the regulation of toxic substances.[70]

Much of the research has taken a somewhat different tack. I have explicitly sought to learn "enough" of other disciplines--appropriate aspects of science and the law--in order to address with some care and sophistication the philosophic issues that arise at the interface of these fields and to speak to practitioners of those fields in their own terms.[71] That is, it was necessary to acquire appropriate understanding of other disciplines in order to speak responsibly to the problems and to contribute to their solution. I sought in my own work to modify the organization of knowledge in order to speak to these issues. Such an approach has benefits for the individual who pursues it; his or her own intellectual resources for addressing the problems are enriched and improved. There are also benefits for one's discipline. In the instant case it seemed important not to be confined by traditional conceptions and boundaries of philosophy in order to try to resolve some of the issues which motivated the original research and in order to speak to some of the issues that emerged as it progressed. Such an approach permits philosophers to address new issues, to contribute to complex social problems where substantial philosophic issues are at stake and to have philosophic contributions taken seriously by those in other fields.[72] Such a strategy is not unprecedented--both current and historical philosophers have done it--but it may be increasingly important in the future in order to come to grips with urgent and complex social problems with substantial philosophical content.

Finally, a good bit of the research involved matters of interpretation, a research approach common to the humanities. I discussed in section III some of the micro-interpretations of scientific evidence which are so important for taking social action, the plasticity that attends this, and how easily conventional scientific approaches to interpretation of evidence may function non-neutrally in other contexts. Because of these possible effects, it has been necessary to discuss different approaches or interpretations at a macro (institutional)-level of how scientific

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[70] See, for example, Cranor, et. al., "Judicial Boundary-Drawing and the Need for Context-Sensitive Science in Toxic Torts after *Daubert v. Merrell-Dow Pharmaceutical"* and Hoover, et. al., "Improving the Regulation of Carcinogens by Expediting Cancer Potency Estimation" (The latter proposals have been become part of California law (*California Code of Regulations*, Title 22, Section 12705.).)

[71] See, for instance, my "Epidemiology and Procedural Protections for Workplace Health in the Aftermath of the *Benzene Case" Industrial Relations Law Journal* Vol. 5, 1984, pp. 372-401, 1984; "Some Moral Issues in Risk Assessment;" "The Social Benefits of Expedited Risk Assessment;" "Discerning the Effects of Toxic Substances;" "Eggshell Skulls and Loss of Hair from Fright;" "Risk Assessment, Susceptible Subpopulations and Environmental Equity."

[72] For more detail on these points, see my "A Philosophy of Risk Assessment and the Law: A Case Study of the Role of Philosophy in Public Policy," Philosophical Studies, Vol. 85, pp. 135-162 (1997).

evidence should be utilized in the law. One approach, which I have rejected, would be to wait until scientists had sufficient evidence for a *firm* conclusion about toxicity within the appropriate scientific field before regulatory action should be taken. Instead, as I discussed in sections IV--VII, there are a variety of strategies they could adopt to mitigate some of the non-neutral effects of scientific conventions on agency actions. These include such things as utilizing presumptions, scientific approximations, policy considerations, standards of proof, and regulatory procedures appropriate for the context as well as modifying burdens of proof in order to use better the available scientific evidence to provide human health protections. Agencies have adopted some of these strategies. I have suggested others and tried to provide good reasons for them. Similarly, in tort cases, judges should reject certain overly simple and overly cautious approaches to admitting evidence of human harm. Instead, they should recognize different patterns of evidence that might implicate substances as toxic and tolerate a comparatively wide range of expert testimony on toxicity.

The generic interpretive strategy has been to assess the institutional context and how scientific evidence might be used within that to address both the multiple goals of the law and the aims of human health protections. This contrasts with a more single-minded approach to the use of scientific evidence that may serve well the aims of scientific practice, but will function non-neutrally in the law.

The payoff from having detailed knowledge of the relevant parts of science and of the law, from reorganizing our knowledge, from bringing the sciences and the humanities together is to have a better base of knowledge and insights for understanding the issues and a broader perspective from which to address social problems. With respect to environmental health protections, I have sought to further C. P. Snow's hope of a common intellectual culture. Instead of arguing as many do that only the internal norms of science should dictate how scientific evidence should be interpreted and how science should be utilized in the law, I have tried to provide a more subtle, nuanced treatment of the issues so that we can use science in our legal institutions without distorting them. Even though we must discern the effects of toxic substances as through a glass darkly, we must do so and take appropriate legal action without distorting the law.