Volume 6, Spring Issue, 1993

BOOK NOTE

REGULATING TOXIC SUBSTANCES: A PHILOSOPHY OF SCIENCE AND THE LAW

By Carl F. Cranor.[1]
New York, New York: Oxford University Press. 1993.
Pp. 252. $45.00 (hard).

Toxic substances, such as carcinogens, pose a unique threat to human health and well-being (p. 3).[2] Carcinogens are invisible and often have long latency periods; moreover, significant exposure to them can be extremely harmful. In the United States alone, for example, more than 400,000 deaths per year result from cancer,[3] and conservative estimates suggest that between five and fifteen percent of these fatalities are due to workplace exposure to carcinogens.[4]

Determining whether the threats posed by carcinogens are substantial and deciding on how to respond to them are the major scientific and philosophical issues discussed by Dr. Carl Cranor in *Regulating Toxic Substances*. In particular, Cranor suggests re-orientating the scientific and risk assessment procedures used by the legal system, and argues that the procedures adopted by the courts and regulatory agencies need not correspond with those used in scientific research. Cranor argues that legal or regulatory bodies need not follow conservative determination techniques, as used in science research traditionally, when attempting to determine whether a substance is toxic or carcinogenic. Rather, he argues that in the legal and regulatory context the determination of these matters should be informed by policy considerations.[5]

The book begins with a thorough discussion of the traditional scientific approaches to determining whether a substance is carcinogenic. Chapter

---

1. Professor of Philosophy and Associate Dean of Humanities and Social Sciences at the University of California, Riverside.

2. In his discussion of toxic substances, the author focuses on carcinogens. This is in part because they have been the subject of substantial regulatory activity and because the data and scientific models relating to carcinogens are more comprehensive than they are for many other toxins.

3. U.S. CONGRESS, OFFICE OF TECH. ASSESSMENT, CANCER RISK: ASSESSING AND REDUCING THE DANGERS IN OUR SOCIETY 70-71 (1982).

4. *Id.* at 86- 91, 108.

5. Cranor focuses only on tort and administrative regulation of toxic substances, although toxic substances are regulated to some extent by criminal law and contract law as well.

One describes animal bioassays, which are used often by scientists to ascertain whether a substance causes cancer. In the typical animal bioassay, three or four experimental groups of rodents are fed high doses of a test substance and compared with groups not ingesting the substance. If higher rates of cancer are observed in the experimental groups, then this high-dose data is used to estimate the likelihood that humans exposed to the test substance, though at relatively low doses, will develop cancer (p. 15). If the estimations reveal a high probability of humans developing cancer, then the substance is characterized as carcinogenic. Of course, making such estimations on the basis of animal bioassays requires making certain assumptions and inferences. To minimize the number of incorrect positive conclusions regarding a substance's carcinogenicity, the National Academy of Sciences, for example, suggests conservative guidelines for scientists to follow when making the estimations (p. 22).

The second traditional scientific approach to determining carcinogenicity discussed by Cranor is the use of epidemiological studies. Cranor argues that the design and interpretation of such statistical studies often beg the normative concerns involved (p. 29). Just as they do with the bioassay estimations, scientists conduct these epidemiological studies in a way that minimizes the likelihood of characterizing a substance as carcinogenic when in actuality it is not. For example, only when the statistical evidence gathered from studies shows that it is more than ninety-five percent likely that a test substance causes cancer will the substance be characterized scientifically as carcinogenic.[6]

The conservative approach taken in analyzing the data from both the bioassays and the epidemiological studies reflects scientists' desire not to add invalid conclusions to the body of science. Maintaining the integrity of the knowledge base is crucial, because future research often builds on currently accepted scientific "truths" (p. 26). For this reason, conclusions regarding a substance's toxicity are reached by scientists only when the likelihood of making a false positive is slight.

Nevertheless, as Cranor suggests, reducing the likelihood of false positives raises simultaneously the likelihood that false negatives will appear, because it becomes more likely that a substance will be characterized as not being carcinogenic when in actuality it is. Cranor emphasizes

---

6. *See* Samuel D. Walter, *Determination of Significant Relevant Risks and Optimal Sampling Procedures in Prospective and Retrospective Comparative Studies of Various Sizes*, 105 AM. J. OF EPIDEMIOL. 387, 391 (1977).

that in the regulatory context it is desirable to keep the likelihood of false negatives low because it is undesirable to have carcinogens released on the market. At the same time, however, he notes that the regulatory system should not overly reduce the likelihood of false negatives since doing so would mean many substances that are in reality not carcinogenic might be characterized mistakenly as being carcinogenic. Where mistakes of this sort occur, useful substances might be kept from the market.

Thus, Cranor highlights a trade-off. Too liberal a standard for determining causality increases the likelihood that harmless substances would be deemed carcinogenic, yet at the same time reduces consumer risk. Too conservative a standard, on the other hand, results in more substances being released on the market, yet increases consumer risk. Cranor suggests that determinations of carcinogenicity should be informed by what optimizes this trade-off.[7] The practical result is that a substance may be deemed to be toxic, because doing so optimizes social welfare, even though under traditional scientific standards it would not be classed as toxic. Unfortunately, the regulatory agencies at present continue to rely on scientific conclusions when making determinations regarding a substance's toxicity.[8]

In Chapter Two, Cranor discusses the use of scientific evidence in tort litigation, and argues that we should preserve the current approach whereby courts determine legal causality more liberally than scientists determine scientific causality (p. 54).[9] At present, to determine legal

---

7. *See* Troyen Brennan, *Causal Chains and Statistical Links: The Role of Scientific Uncertainty in Hazardous Substance Litigation*, 73 CORN. L. REV. 469 (1988) (general discussion on the point of scientific versus legal causality, and why it might be preferable to determine each differently); Howard Latin, *Good Science, Bad Regulation and Toxic Risk Assessment*, 5 YALE J. ON REG. 89, 89-142 (1988) (arguing that social policy considerations must play as prominent a role in the choice of risk estimates as in the ultimate determination of which risks should be deemed unacceptable).

8. The NSF guidelines regarding whether a substance is carcinogenic, for example, also are used by regulatory agencies for the same considerations. *See* NATIONAL RESEARCH COUNCIL, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS 17-50 (1983).

9. One commentator on the subject, however, suggests that scientific standards should be met even in the legal and regulatory context. *See* Bert Black, *Evolving Legal Standards for the Admissibility of Scientific Evidence*, 239 SCI. 1511, 1512 (1987). Black argues "that especially in toxic tort cases a growing number of courts now delve into the reasoning behind an expert's conclusions and require that this reasoning reflect accepted scientific practice. As society grows more tied to science and technology and more enamored of litigation this development becomes increasingly necessary. The law should seek verdicts consistent with scientific reality and with each other and it can achieve this goal only by requiring scientific evidence to conform to the standards and criteria to which scientists themselves adhere." *Id.* at 1512. Black's argument seems to adhere to the scientific

causality, the plaintiff need only establish that the probability with which it is true that the substance in question causes cancer is at least fifty percent, rather than the ninety-five percent required to prove scientific causality (p. 56).[10] This rule makes it easier for plaintiffs to recover damages and, therefore, is consistent with the traditional compensatory and deterrence aims of the tort law, and it results in greater protection from potentially toxic substances (p. 79). Moreover, to the extent that manufacturers are more efficiently able to insure against such harms than are consumers, it might be preferable to make manufacturers bear the costs.

Joint causation in the contexts of both tort and administrative law is the subject of Chapter Three. After an interesting survey of the liability rules for causation and a discussion of the proof of causation in tort law, Cranor discusses why administrative law might be preferable to tort law in providing environmental health protections. One argument he notes is that it is much easier to establish causality in the administrative law context.[11] As an example, suppose that an individual's exposure to a carcinogen were sufficient to create a likelihood of 6/100,000 that leukemia would result. The natural occurrence of the disease, however, creates a probability of 10/100,000 that an individual would get leukemia.[12] There is, then, a total probability of 16/100,000 that an individual would acquire leukemia. If in a given case the source of the disease cannot be identified, the tort law standard of proof will not be met since there is only a thirty-eight percent likelihood that the leukemia would be attributable to exposure to carcinogens (p. 90-91).[13] Administrative law needs only this general statistical connection for *ex ante* regulation.

---

justification that false positives are undesirable, but, in the law, policy must be used to strike a balance between false positives and false negatives.

10. In a courtroom the test for allowing a plaintiff to recover in a tort suit of this type is not scientific certainty but legal sufficiency: If reasonable jurors could conclude from the expert testimony that a toxin more likely than not caused the plaintiff's injury, the fact that another jury might reach the opposite conclusion or that science would require more evidence before conclusively considering the causation question resolved is irrelevant. *See* Ferebee v. Chevron Chemical Co., 736 F.2d 1529, 1536 (D.C. Cir. 1984).

11. *See* Steven Shavell, *Liability for Harm Versus Regulation of Safety*, 13 J. LEG. STUD. 355, 358 (1984) (discussing possible benefits of using *ex ante* regulatory law versus *ex post* tort liability as a means to regulate production and use of toxic substances).

12. Samuel D. Estep, *Radiation Injuries and Statistics: The Need for a New Approach to Injury Litigation*, 59 MICH. L. R. 259, 268 (1960).

13. Given that a person has acquired leukemia, then according to the statistical evidence there is a 6/16 chance (thirty-eight percent) that the leukemia resulted from exposure to carcinogens, and a 10/16 chance (sixty-two percent) that the leukemia resulted from other or natural causes.

Additionally, the costs of regulating potentially toxic substances can be placed on the least cost avoider, namely the firm that introduces the substances.

Indeed, from a justice standpoint, the party that benefits from imposing potentially hazardous risks on others should take precautions to see that the damage does not occur and should bear the risk of loss to those parties who have had the risk imposed on them. Cranor argues, however, that these arguments for preferring administrative law "should not blind us to some of the political shortcomings of relying on administrative law" (p. 102). He notes, therefore, that tort law should remain intact as a backup to the administrative agencies.

Chapter Four addresses the use of scientific procedures in regulatory agencies. Like Chapter Two, there is "a paradigm choice in how scientific evidentiary procedures are treated in the law" (p. 151). At present, regulatory agencies employ the same conservative determination techniques as are used traditionally in scientific research (p. 151). Nevertheless, Cranor argues that employing time-consuming scientific procedures in the regulatory context might be problematic, because there is not enough time to perform detailed scientific studies on each new substance produced, let alone on the many existing substances not already tested for toxicity.

Cranor, therefore, pushes for expedited approximation procedures such as tumorigenic dose ("TD_{50}") values (pp. 138-41) and the linearized multistage ("LMS") default dose-response mode (p. 141). He suggests that it might be preferable for the agencies to compromise the precision and accuracy obtained from the ordinary scientific research techniques in favor of the quicker results provided by the above approximation procedures.

Chapter Five is Cranor's most interesting. It is an essay on the epistemic and moral justifications for regulating toxic substances. Cranor argues that: (1) the standards of evidence ought to be appropriate to the institutional context, and (2) justice requires that priority be given to avoiding false negatives and underregulation (p. 152). Cranor does an excellent job of refuting utilitarianism with respect to regulating toxic substances, though it might have been preferable for him to have done so much earlier in the book.

Regulating Toxic Substances provides a thoughtful analysis of the scientific and philosophical issues arising in the context of toxic substance regulation. The material is thought-provoking and merits much consider-

ation. While the substantive coverage of the issues is excellent, the book's presentation is not always so. In particular, the sub-headings often seem incomplete, and consequently render some of the arguments difficult to follow. Moreover, the statistics in Chapter One are presented without sufficient explanation as to their source and meaning. This is problematic since the book appears to be directed to an audience that may well lack a strong statistics background. While not necessary to presenting the main arguments made, an appendix explaining the statistical analysis in more detail would have been helpful. Finally, Cranor should have provided more examples of other toxic substances rather than limiting most of the discussion to carcinogens. Nevertheless, none of these problems is terribly significant, especially since Cranor does provide a comprehensive notes section and bibliography. Thus, readers desiring greater understanding of the issues discussed will not be disappointed.

This book, particularly Chapters One and Five, should be read by all those interested in administrative law and tort law and who are involved in regulating toxic substances or in litigating toxic tort cases. Legislators, administrative agents, scientists performing bioassays and epidemiological studies, judges, and lawyers alike will find this book thought-provoking and persuasive.

Steven R. Weller