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Review of: Carl F. Cranor, *Regulating Toxic Substances*

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Book Reviews

Carl F. Cranor, *Regulating Toxic Substances* (Oxford University Press 1993). Acknowledgments, appendices, bibliography, figures, foreword by The Honorable George E. Brown, Jr., index, notes, tables. LC 91-47046; ISBN 0-19-507436-X. [272 pp. Cloth \$45.00. 200 Madison Avenue, New York NY 10016.]

The recent Supreme Court decision, *Daubert v. Merrell Dow Pharmaceuticals, Inc.*,¹ answered one question regarding court use of scientific evidence. It held that trial judges are to fulfill a gatekeeper role, admitting for consideration by the fact-finder only evidence that they find to be both relevant and reliable. Thus, the judge must assess the principles and methodology underlying the proffered evidence, and not the conclusions drawn therefrom.² A more difficult question that

¹ 113 S.Ct. 2786 (1993). The opinion is starting to influence lower courts, but it is unknown what the ramifications of *Daubert* will be. Compare *Datskow v. Teledyne Continental Motors Aircraft Pdts.*, 826 F. Supp. 677 (W.D. N.Y. 1993) (cites *Daubert* but does not apply criteria) and *Concerned Area Residents for the Environment v. Southview Farm*, 1993 U.S. Dist. LEXIS 14835 (W.D. N.Y. Oct. 19, 1993) (cites *Daubert* for proposition that weight of evidence is for jury) with *In re Joint Eastern and Southern District Asbestos Litigation*, 827 F. Supp. 1014 (S.D. N.Y. 1993) (does not exclude evidence, but upsets jury verdict for lack of support) and *Chikovskiy v. Ortho Pharmaceutical Corp.*, 1993 U.S. Dist. LEXIS 13342 (S.D. FL, Sept. 22 1993) (excludes testimony of causal link between topical Retin-A and birth defects). Arguably, *Daubert* gives litigants an additional tool to challenge proffers of scientific evidence, which may lead to more challenges and a greater load on judges to address the issues which many of them feel they are ill prepared to manage. The early disposition of these issues may lead to more rapid abandonment and settlement of cases, which may lead to greater efficiency in the system.

² *Daubert* definitely requires greater judicial scrutiny of the empirical basis underlying a witness' testimony, which may reduce the incidence of "junk science" in the courts. See Peter W. Huber, *Galileo's Revenge: Junk Science in the Courtroom* (1991); see also, *Phantom Risk: Scientific Inference and the Law* (Kenneth R. Foster, David E. Bernstein & Peter W. Huber eds. 1993).

In the more recent book, the editors pull together chapters describing the state of scientific knowledge in each of the following areas: electromagnetic fields and video display terminals, spermicides, Bendectin, asbestos, environmental pollutants (including dioxin, polychlorinated biphenyls, trichloroethylene, and radionuclides), trauma-induced cancer, and clinical ecology. For each substantive area, a legal critique of how the issues have fared in court is presented. Each subject is one in which litigation has occurred under circumstances where the science tending to establish or disprove a causal connection is (or was) uncertain. The editors draw on these examples to criticize the judicial fact-finding process for its deviation from the fact-finding

the Court did not reach is whether the standard of proof of science is relevant in judicial fact-finding. This issue is explored in detail by Cranor in his book.³

Cranor focuses on the different burdens of proof required in science versus those required in courts of law. Perhaps for simplicity, science and regulatory science (i.e., risk assessment) are treated as one. By comingling science, risk assessment and risk management concepts, he effectively undermines the reader's trust in the ability of science to protect us from unknown hazards because of the limitations of risk assessment. Cranor's arguments center on several major areas: (1) while science endeavors to minimize false positives (e.g., concluding a substance is carcinogenic when it in fact is *not*), science has been less concerned with minimizing false negatives (e.g., finding that a substance is not a concern when it in fact *should be*); (2) the slowness of risk assessments and rule-making tend to favor the status quo and may protect harmful chemicals better than public health; (3) science is not concerned with distributional justice issues; and (4) tort law serves as an important backup to administrative law in compensating victims and deterring the marketing of harmful products.

Cranor calls for greater attention to minimizing false negatives. He repeatedly states that the costs of under-regulation may be greater than those of over-regulation, but little empirical evidence is offered to support this assertion. As an additional justification for avoiding false negatives, he relies on philosophical considerations of distributional justice, in effect arguing for a rights-based approach to protecting individual health. More fundamentally, Cranor apparently attributes false negatives to science, rather than to risk management. Technically, as he acknowledges, science will not claim "negative" results, but only reveal no effect above a certain detection limit.

processes of science. The assessment of the quality of scientific reasoning and methodology obviously presents a challenge to the judiciary. *See also, generally*, The Carnegie Commission on Science, Technology and Government, *Science and Technology in Judicial Decision Making: Creating Opportunities and Meeting Challenges* (1993).

³ In doing so, Cranor generally criticizes commentary calling for judicial restraint in admitting scientific testimony. *See, e.g., Regulating Toxic Substances*, at 66.

With regard to risk assessment and regulation, we agree wholeheartedly with Cranor's recommendation that regulatory scientists carefully display the limitations of their data, models and conclusions. Scientists can provide a statement of knowledge of risks in timely manner and with caveats as to uncertainty ranges, assumptions and detection limits. Risk managers can then do the difficult job of balancing this information with other factors. The explicit characterization of uncertainty in data and models provides insights not only into the limitations of scientific evidence but also into setting research priorities which will bolster future risk management.

Cranor argues strenuously for the use of expedited approximation procedures for conducting risk assessments.⁴ He also suggests that uncertainties may be "reduced" through risk management decisions.⁵ In our view, uncertainty can be reduced only by developing better data and models. A wide range of uncertainty opens the door for other considerations (e.g., risk avoidance to protect public health, comparison to other risks, and economic, social and political effects) to have key roles in risk management. Such considerations should not enter into regulatory science itself, such as through the use of compound conservative assumptions.

Cranor asserts that the evidentiary standards of science should not apply to risk assessment for regulatory purposes, arguing instead for use of a "preponderance of evidence" standard of proof as applied in civil litigation. Nonetheless, even though he argues for consistency in risk assessment procedures, he appears less concerned with consistency of the standards of evidence employed therein. As Cranor recognizes, it is not clear how the choice of standards, on a necessarily ad hoc, case-by-case basis, should be guided.

We view Cranor's approach to be highly risk averse, and the full effect of his proposal on economic behavior is unknown. As a blanket rule for risk regulation, we fear his approach would lead to less

⁴ See, e.g., *id.* at 137.

⁵ See, e.g., *id.* at 136.

predictable regulations.⁶ He exacerbates this problem by calling for “universal” use of his proposed less comprehensive risk assessments, which could lead to false categorization of regulated products and, perhaps more dangerously, false reliance thereon.

Finally, with regard to civil litigation, Cranor’s thesis has a certain appeal: Actors who introduce risky goods into the market should do so at their own economic peril: they should bear the burden of analyzing their products and activities and ensuring that they are not too hazardous. To illustrate his arguments, Cranor relies heavily on one case, *Ferebee v. Chevron Chemical Co.*⁷ The *Ferebee* court distinguished the scientific uses of evidence from the uses of such evidence in the courts. *Ferebee* itself does not express a majority rule, and judicial events in the last two years have further undermined the precedential value of the case.⁸ Nonetheless, from Cranor’s discussion of this case and the role of the courts in regulating risky behavior, we

⁶ This problem may also be exacerbated by publication bias, or the tendency on the part of editors and authors to only publish positive results. This may lead to a biased sampling system under which only those studies that suggest toxic qualities of chemicals will initially make it into the literature. Since there is no good way to identify negative results, especially before any suggestion of toxic qualities are raised, then one suggestive study (even if statistically significant) may be quite inadequate, under any burden of proof, to establish the hazardous nature of a chemical. See, generally, Colin B. Begg & Jesse A. Berlin, *Publication Bias: A Problem in Interpreting Medical Data*, 151 *J. Royal Statist. Soc.* 419 (1988); Robert Rosenthal, *The “File Drawer Problem” and Tolerance for Null Results*, 86 *Psychol. Bull.* 638 (1979).

⁷ 736 F.2d 1529 (D.C. Cir. 1984).

⁸ It is possible that the proffer of causation evidence in *Ferebee* would have been inadmissible under *Daubert*. Further, the liability basis of *Ferebee* has been substantially overturned by a line of cases following *Cipollone v. Liggett Group*, 112 S.Ct. 2608 (1992) and holding that various federal statutes preempt state failure-to-warn doctrine. See *Arkansas-Platte & Gulf Partnership v. Van Waters & Rogers Inc.*, 981 F.2d 1177 (10th Cir. 1993) (pesticide); *Shaw v. Dow Brands Inc.*, 61 U.S.L.W. 2727 (7th Cir. No. 92-2323, 1993) (bathroom cleaning products); *Moss v. Parks Corp.*, 985 F.2d 736 (4th Cir. 1993) (paint thinner); *Papas v. Upjohn Co.*, 985 F.2d 516 (4th Cir. 1993) (pesticides); *King v. E.I. DuPont de Nemours and Co.*, 996 F.2d 1346 (1st Cir. 1993) (herbicide).

Even in the D.C. Circuit, *Ferebee* has been limited to instances where the evidence “stands at the frontier of current medical and epidemiological inquiry” and thus not applied in cases where substantial scientific study, although inadequate to prove (or disprove) a particular risk, is extant. In re Joint Eastern and Southern District Asbestos Litigation, *supra* note 1.

came away with the distinct impression that he views the imposition of risk on any member of society as immoral.

Our system of tort law is not a system of absolute nor even “true” strict liability. The law requires a balancing of risks and benefits before holding a defendant liable for injuries caused to others.⁹ Unfortunately, we typically will be uncertain about the probability of bad outcomes and the causal link between exposures and injuries. To prevent paralysis, we must have some stopping rules enabling us to take action — such as the marketing of a new drug or chemical — before all risks are “known” and well characterized. If we adequately prioritize efforts to find the greatest risks and concentrate our resources on discovering and minimizing them, then the remaining risks should be reasonable. Given the unavoidable but reduceable uncertainty and constrained resources, what is the best way for society to manage risks?¹⁰

Our concern with the ability of the tort law to coherently manage risks is that the signals are blurred by varying fact patterns between cases, the workings of the trial courts are often obscured by lack of publication and post-trial settlements, and decisions are post-hoc and narrowly focused on injuries at hand.¹¹ Benefits are downplayed, and

⁹ See, e.g., Restatement (Second) of Torts § 520 (1977) (abnormally dangerous activities) and § 402A (abnormally dangerous condition of defective products). There are a few courts, like *Ferebee*, that impose strict liability under a guise of failure to warn of risks of which there was no reasonable obligation to discover. See *Ayers v. Johnson & Johnson Baby Products Co.*, 818 P.2d 1337 (Wash. 1991) (defendant liable for brain damage caused by inhalation of baby oil). Courts holding that foreseeability is not required ignore § 402A cmt. j, which requires a seller to give warning of latent dangers “if he has knowledge, or by the application of reasonable, developed human skill and foresight should have knowledge” of the risk.

¹⁰ See Richard Wilson, Edmund Crouch & Lauren Zeise, *Uncertainty in Risk Assessment* (1985).

¹¹ See also, Stephen Breyer, *Breaking the Vicious Circle: Toward Effective Risk Regulation* (1993). At 59, Breyer, who is Chief Judge of the U.S. Court of Appeals for the First Circuit, states:

Courts also administer a system of tort law which discourages the negligent production of risky substances by forcing producers... to compensate those whom they injure. That system, however, leaves the determination of “too much risk” in the hands of tens of thousands of different juries who are forced to answer the question not in terms of a statistical life, but in reference to a very real victim needing compensation in the courtroom before them. The result is a system much criticized for its random, lottery-like results and its high “transactions costs”.... Whatever its merits and problems, I do

the context in which society trades off quality of life with acceptance of some risks is hopelessly lost. The courts obviously have a role to play in controlling risky technology, but the specific competencies and limitations of administrative and judicial mechanisms need to be balanced in determining what their respective roles should be.

Regulating Toxic Substances challenges the reader to think about the potentially differing standards of evidence as used today in science, regulatory science, policy making and civil litigation. It is also useful for fleshing out the moral and legal issues involved in risk creation and management. We found Cranor's analysis stimulating and well worth reading.

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not believe the tort system can serve as a substitute for government regulation.

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