

January 1994

Interaction between Regulatory Law and Tort Law in Controlling Toxic Chemical Exposure

John Endicott

Recommended Citation

John Endicott, *Interaction between Regulatory Law and Tort Law in Controlling Toxic Chemical Exposure*, 47 SMU L. REV. 501 (1994)
<https://scholar.smu.edu/smulr/vol47/iss3/3>

This Article is brought to you for free and open access by the Law Journals at SMU Scholar. It has been accepted for inclusion in SMU Law Review by an authorized administrator of SMU Scholar. For more information, please visit <http://digitalrepository.smu.edu>.

INTERACTION BETWEEN REGULATORY LAW AND TORT LAW IN CONTROLLING TOXIC CHEMICAL EXPOSURE

John Endicott*

I. INTRODUCTION

AS Chief Judge Stephen Breyer of the U.S. Court of Appeals for the First Circuit observes in the opening paragraph of a new book, "Regulators try to make our lives safer by eliminating or reducing our exposure to certain potentially risky substances."¹ In his book Breyer chooses to focus upon "the regulatory effort to reduce exposure to cancer-causing substances, both because of its illustrative power and because the public's fear of cancer currently drives the system."² For these same reasons, this Article likewise focuses primarily on chemicals known or suspected to cause cancer in humans. Exposures to these chemicals are controlled by regulators under federal environmental, occupational, food and drug, and consumer product safety laws. Furthermore, exposures may also lead to toxic tort litigation based on allegations that the exposures resulted in cancer, increased risk of cancer, or fear of cancer in individual plaintiffs.

Breyer states, "I do not believe the tort system can serve as a substitute for government regulation."³ This Article asserts that the converse of Breyer's proposition is also true, namely, that government regulation can, and increasingly will, serve as a substitute for the tort system, and that the actions of government regulators with respect to chemical exposures will in many instances control tort law activity. The Article discusses a trend toward increasing willingness of common law courts to draw upon regulatory conclusions in determining issues of policy and fact raised in tort litigation.⁴

* John Endicott, an attorney with the Dallas law firm of Gardere & Wynne, is a 1972 graduate of the University of Pennsylvania School of Law. Prior to joining Gardere & Wynne, Mr. Endicott spent nine years as a tort litigator with Maxus Energy Corporation in Dallas.

1. STEPHEN BREYER, *BREAKING THE VICIOUS CIRCLE: TOWARD EFFECTIVE RISK REGULATION* 3 (1993).

2. *Id.*

3. *Id.* at 59.

4. Another federal judge and prolific author, Judge Jack Weinstein of the U.S. District Court for the Eastern District of New York, has recently cited "the lack to date of an effective national administrative regulatory scheme capable of controlling undesirable conduct by manufacturers" as a factor that has "left the state and federal courts to their own devices" in dealing with toxic tort litigation. Jack B. Weinstein & Eileen B. Hershenov, *The Effect of Equity on Mass Tort Law*, 1991 U. ILL. L. REV. 269, 270. This Article takes the view that there are a growing number of exceptions to Judge Weinstein's blanket criticism of the regula-

The regulatory system for controlling carcinogenic and other chemical risks is relatively new, having received the lion's share of its authority and resources from federal legislation enacted in the 1970s and 1980s. As this regulatory system continues to develop and mature, it is beginning to offer answers to many of the same questions that concern courts in toxic tort litigation: (1) Does the chemical cause cancer in humans? (2) How certain can we be that it does? (3) If the chemical is a known or suspected carcinogen, should it be banned or can it be used with reasonable safety if an adequate warning is given? (4) If the latter, what exactly should the warning say?

When a government agency has offered answers to one or more of these questions, there are a number of overlapping rationales available for concluding that the agency's determination should control the court's subsequent determination of the same question: (a) rejection of expert testimony that does not conform to generally accepted scientific knowledge, (b) judicial deference to legislative fact-finding, (c) express or implied preemption, and (d) tort law adoption of standards of conduct established by statute or regulation.⁵ These points are developed in detail in Sections III-VI of this Article. First, however, it is helpful to provide a recapitulation of regulatory approaches to controlling chemical risks.

II. QUANTITATIVE RISK ASSESSMENT AND ITS LIMITATIONS

When issues of chemical safety are raised, it would seem that a government agency or a common law court has two basic options: control the exposure to a reasonably safe level, or, if it is determined there is no reasonably safe level of exposure, eliminate the exposure by banning the chemical outright. Chemical bans are infrequent and may be overturned when challenged. For example, the U.S. Court of Appeals for the Fifth Circuit recently overturned an Environmental Protection Agency (EPA) rule promulgated under the Toxic Substances Control Act (TSCA), banning the use of asbestos in almost all products.⁶ The court found that "Congress did not enact TSCA as a zero-risk statute"⁷ and that "the EPA [had] failed to show that there is not some intermediate state of regulation that would be superior to both the currently-regulated and the completely-banned world."⁸

The Occupational Safety and Health Act of 1970 likewise does not require risk-free regulation of carcinogenic chemicals, as the U.S. Supreme Court

tory system, and that the system has matured to an extent that common law courts are left considerably less "to their own devices" in dealing with toxic substances than they formerly were.

5. This last rationale is reflected in comment (a) to *Restatement (Second) of Torts* § 288C (1964). This comment provides that the court may, in its discretion, adopt a legislative or regulatory standard as the legal test of due care that is "sufficient for the occasion," at least "where there are no special circumstances." *Id.* § 288C cmt. a. This provision, which has almost never been used to bar liability, is particularly suited for use in toxic tort litigation involving chemicals subject to regulatory exposure and warning standards.

6. *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1207 (5th Cir. 1991).

7. *Id.* at 1215.

8. *Id.* at 1217.

held in 1980 when it overturned a benzene exposure standard issued by the Occupational Safety and Health Administration (OSHA), in a decision commonly referred to as *Benzene*.⁹ The Court noted that in the case of carcinogens such as benzene, both labor and "industry witnesses agreed that if the standard must ensure with absolute certainty that every single worker is protected from any risk of leukemia, only a zero exposure limit would suffice."¹⁰ The Court went on to hold that while the statute called for the agency to promulgate a standard reasonably necessary to provide a "safe" workplace, "'safe' is not the equivalent of 'risk-free.'"¹¹ Instead, the Court ruled that a workplace could not "be considered 'unsafe' unless it threatens the workers with a significant risk of harm."¹² The Court then offered the following illustration to give the agency some guidance in determining what might constitute significant risk:

Some risks are plainly acceptable and others are plainly unacceptable. If, for example, the odds are one in a billion that a person will die from cancer by taking a drink of chlorinated water, the risk clearly could not be considered significant. On the other hand, if the odds are one in a thousand that regular inhalation of gasoline vapors that are 2% benzene will be fatal, a reasonable person might well consider the risk significant and take appropriate steps to decrease or eliminate it.¹³

In suggesting that a one-in-a-thousand risk could be near the outer limit of a tolerable risk under OSHA's governing statute, *Benzene* impliedly endorsed the notion that *quantitative* risk assessment (QRA) for carcinogens is an enterprise that is not only feasible, but also incumbent upon OSHA to perform when setting standards for carcinogens. Since the Court decided *Benzene* in 1980, risk assessors at OSHA and other agencies have striven to provide QRAs for a variety of chemicals.¹⁴ For example, OSHA is currently considering whether to lower the permitted average daily exposure limit for the suspect carcinogen Methylene Chloride (MC) from the currently permitted level of 500 parts per million (ppm) to the proposed level of twenty-five ppm. In a November 1991 notice of proposed rulemaking, OSHA concluded its "Preliminary Quantitative Risk Assessment" for MC by estimating that "at the proposed level of twenty-five ppm, the [lifetime cancer] risk

9. *Industrial Union Dep't v. American Petroleum Inst.*, 448 U.S. 607, 659 (1980).

10. *Id.* at 636 n.41.

11. *Id.* at 642.

12. *Id.*

13. *Id.* at 655-56.

14. Hard on the heels of *Benzene* came two official reports describing in some detail how QRA might be performed. See OFFICE OF TECHNOLOGY ASSESSMENT, CONGRESS OF THE UNITED STATES, *ASSESSMENT OF TECHNOLOGIES FOR DETERMINING CANCER RISKS FROM THE ENVIRONMENT* (1981); COMMITTEE ON THE INSTITUTIONAL MEANS FOR ASSESSMENT OF RISKS TO PUBLIC HEALTH, NATIONAL RESEARCH COUNCIL, *RISK ASSESSMENT IN THE FEDERAL GOVERNMENT; MANAGING THE PROCESS* (1983) [hereinafter NATIONAL RESEARCH COUNCIL]. In the decade since the National Research Council report was issued, there has been a vast outpouring of literature concerning QRA. Breyer's book contains some 40 pages of endnotes providing references to much of this literature. BREYER, *supra* note 1, at 85-124. The National Research Council itself has recently published a new study in this area. See NATIONAL RESEARCH COUNCIL, *ISSUES IN RISK ASSESSMENT* (1993).

is 1.67-2.32 per thousand."¹⁵ In other words, OSHA estimates that among a thousand individuals with average daily exposure to 25 ppm of MC for a working lifetime, there will be 1.67 to 2.32 cancer deaths in addition to the two to three hundred cancer deaths that would be expected in a non-exposed population of one thousand persons.¹⁶

OSHA's estimate of increased human cancer risk from MC exposure is based on a series of extrapolations from the results of high-dose testing of rodents. A good deal of controversy surrounds QRA derived from animal bioassays. In the case of Trichloroethylene (TCE), another chlorinated solvent, which, like MC, has been categorized as a suspect carcinogen on the basis of animal testing, estimates of cancer hazards have varied by a factor of many millions. Some commentators have observed that these "estimates provide a range of uncertainty equivalent to not knowing whether one has enough money to buy a cup of coffee or pay off the national debt."¹⁷

The lack of certainty involved in QRA based on animal testing stems from the number of default assumptions that must be made in the absence of scientific knowledge. The National Research Council, for example, offers a non-exhaustive list of fifty questions that might be asked when performing risk assessments.¹⁸ When scientific data are not available to answer these questions, as is often the case, certain assumptions must be made in order to progress to the next step in the risk analysis. Generally, risk assessors, in making such assumptions, consciously seek to err on the side of standards that will be more, not less, protective of human health. This is a laudable goal, but the net result can be a risk estimate that varies from the actual risk

15. Occupational Exposure to Methylene Chloride, 56 Fed. Reg. 57,036, 57,101 (1991).

16. *Id.*

17. Howard Latin, *Good Science, Bad Regulation, and Toxic Risk Assessment*, 5 YALE J. ON REG. 89, 92 (1988) (quoting Seth Cothorn et al., *Estimating Risk to Human Health*, 20 ENVTL. SCI. & TECH. 111, 115 (1986)). In a criticism directed at the false aura of certainty that QRA figures portray, at least one commentator has likened QRA to weighing hogs in the South: "Down there, they put the hog in one pan of a large set of scales, put rocks in the other pan, one by one, until they exactly balance the weight of the hog. Having done that very carefully, they guess how much the rocks weigh." BREYER, *supra* note 1, at 108 n.58.

18. NATIONAL RESEARCH COUNCIL, *supra* note 14, at 29-33. Some of the principal assumptions of QRA as practiced by regulatory agencies are that:

[C]ancer bioassay results in animals are valid predictors of human risk; the most susceptible animals must be used and challenged with maximum tolerated doses (MTDs); negative results are not indicative of safety; extrapolation of animal data to out-of-observed-range low-dose domains must proceed on the basis of policy-selected but scientifically unverified and highly conservative mathematical models; positive tests in animals preempt negative epidemiological evidence; estimates of exposure corresponding to the most exposed individual are to be utilized in risk assessment; no-effect thresholds for carcinogens do not exist.

Gio B. Gori & W. Gary Flamm, *How Sick a Patient? Report of a Workshop on Cancer Risk Assessment*, 14 REG. TOXICOLOGY & PHARMACOLOGY 215, 217 (1991). As these authors also point out, such default assumptions

are political and administrative conveniences that can be enforced only by authority and only so long as scientific knowledge is not available. In fact they have been violated over and over again when scientific information becomes available, as in the cases of d-limonene, melamine, and TCDD. As such, default assumptions are declarations of ignorance, not knowledge.

Id. at 219.

by many orders of magnitude. As the Office of Management and Budget has recently explained:

Suppose that there are ten independent steps in a risk assessment and prudence dictates assumptions that in each instance result in risk estimates two times the expected value. Such a process would yield a summary risk estimate that is more than 1,000 times higher than the most likely risk estimate. Because there are usually many more than ten steps, and many of them will incorporate conservative biases that exceed a [two times] order of magnitude, risk estimates based on such practices will often exceed the most likely value by a factor of one million or more.¹⁹

One such conservative assumption made by regulators involves estimating risk on the basis of the animal studies that find a carcinogenic effect and ignoring studies of other species that find no effect or a lesser effect. As a recent editorial in *Science* points out, the National Institute of Occupational Safety and Health has based its QRA for butadiene, used in the production of synthetic rubber, solely upon experiments performed on a particularly cancer-prone strain of mouse, disregarding results of rat, monkey, and human studies "showing major differences in uptake, retention and metabolism, and far less risk of cancer."²⁰ The editorial notes that a long-term study of butadiene workers showed "overall mortality from cancer was only 75% of that of the rate for the ordinary public."²¹

Even where human data demonstrate that there is indeed a carcinogenic effect in humans, the human data may likewise be ignored by regulatory risk assessment in favor of the animal data. In the case of vinyl chloride, a substance known to cause a rare form of cancer, angiosarcoma of the liver, the most recent default risk assessment model predicts (at historical doses) that up to 7500 workers out of 10,000 workers exposed would contract angiosarcomas of the liver as an upper bound. In the epidemiological study results, on the other hand, less than 10 out of 10,000 workers exposed at those levels during the 1940's, 50's and 60's have contracted the disease.²²

Lately, even regulators have begun to question the worth of high-dose animal testing as a basis for estimating human effects. According to a recent news report:

GAITHERSBURG, MD., March 20 [1993]

Dozens of caged rats and mice spend their days here in a laboratory chewing on Purina rodent chow laced with as much boric acid as they can tolerate without risk of death from [acute] poisoning.

.....

This project is just one of roughly 65 rodent studies underway at 15

19. BREYER, *supra* note 1, at 110 n.70 (quoting OFFICE OF MANAGEMENT AND BUDGET, REGULATORY PROGRAM OF THE UNITED STATES 26 (Apr. 1, 1990-Mar. 31, 1991)).

20. Philip H. Abelson, *Exaggerated Carcinogenicity of Chemicals*, 256 SCIENCE 1609, 1609 (1992).

21. *Id.*

22. Neil C. Hawkins, *Health Risk Assessment: The Right Tool for the Job?*, in HOW CLEAN IS CLEAN? 130, 134 (Air & Waste Management Ass'n ed., 1991).

laboratories across the country at an average cost of about \$2 million each. For much of the last two decades, these studies have been the Government's most important diagnostic tool for identifying environmental problems that are health hazards and setting priorities for Federal regulation.

BILLIONS DOWN THE DRAIN?

[E]ven Dr. Kenneth Olden, director of the National Institute of Environmental Health Sciences, the branch of the National Institutes of Health that directs the animal studies, asks whether the nation is wasting billions of dollars regulating substances that might pose little risk.

The findings from about 450 animal studies over the last several decades, Dr. Olden said, have led Federal and state governments to write thousands of regulations forcing government and industry to spend tens of billions of dollars a year regulating the use and disposal of several dozen chemicals, or finding alternatives for chemicals that have been restricted or banned. . . .

By the time Dr. Olden took over as director of the Health Sciences Institute in 1991, the animal studies were increasingly being called into question. Almost immediately, he empaneled a group of the nation's leading experts to study his agency's toxicology-research program to help him decide whether to look for a new approach.

Last summer, the group's report said many of the assumptions driving the rat and mouse research "do not appear to be valid." The experts particularly questioned the practice of feeding rodents the "maximum tolerated dose" of the chemical being tested

"The problem is we don't know what the findings really mean," Dr. Robert Maronpot, chief of the institute's experimental-pathology laboratory, said of the animal studies.²³

OSHA's proposed 25 ppm MC exposure limit is, as noted above, derived from QRA based on animal testing. Hearings were held in the fall of 1992, and Robert Maronpot, quoted in the above article, testified concerning the results of experiments in which rodents developed cancer when exposed to 2000 ppm of MC.²⁴ At the hearings, industry representatives argued that the limit should be 50 ppm or higher, while labor representatives argued for a limit of 10 ppm or lower. One reason for these divergent numbers lies in a dispute between industry and labor as to whether the proposed 25 ppm limit is economically "feasible," an issue that OSHA's governing statute requires OSHA to consider. OSHA has taken the entire matter under advisement and is expected to issue a final exposure limit in 1994.

III. TOXIC TORT LITIGATION: *DAUBERT* AND THE "KNOWLEDGE" STANDARD

Meanwhile, in the summer of 1993, the U.S. Supreme Court issued its first

23. Joel Brinkley, *Many Say Lab-Animal Tests Fail to Measure Human Risk*, N.Y. TIMES, Mar. 23, 1993, at A1 (national edition). The reference to the experts' report questioning use of animal data is to National Toxicology Program (NTP), Final Report of the Advisory Review by the NTP Board of Scientific Counselors, 57 Fed. Reg. 31,721 (1992).

24. Author's review of hearing testimony at OSHA Docket Office in Washington, D.C.

decision concerning the standards of admissibility of scientific testimony in a toxic tort case. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*²⁵ involved a claim that birth defects suffered by the plaintiffs resulted from their mothers' ingestion of the anti-nausea drug Bendectin. The Court's narrow holding was that the *Frye*²⁶ "general acceptance" test of admissibility of expert testimony did not survive the adoption of the Federal Rules of Evidence.²⁷ In addition, the Court elaborated that under Federal Rule of Evidence 702, "[t]he subject of an expert's testimony must be 'scientific . . . knowledge.' The adjective 'scientific' implies a grounding in the methods and procedures of science. Similarly, the word 'knowledge' connotes more than subjective belief or unsupported speculation."²⁸

When QRA based on animal testing, as performed by government regulatory agencies and as described in the preceding section of this Article, is measured against the standards of scientific proof in tort litigation announced in *Daubert*, it would seem self-evident that QRA falls far short of the *Daubert* standards. To illustrate this point, one of the numerous conservative assumptions that regulatory agencies have used in performing QRA is "straight line extrapolation" from high-dose test results to low-dose expected health effects. This procedure assumes that at 1/100 and 1/1000 of the high dose tested, the risk of cancer is exactly 1/100 and 1/1000 of the risk detected at the high dose. As the U.S. Court of Appeals for the District of Columbia noted in approving this practice for *regulatory* purposes,

This method . . . will show some risk at every level because of the rules of arithmetic *rather than because of any knowledge*. In fact the risk at a certain point on the extrapolated line may have no relationship to reality; there is no particular reason to think that the actual line of the incidence of harm is represented by a straight line.²⁹

Even when using a more biologically plausible extrapolation procedure, the EPA itself has cautioned:

It should be emphasized that the linearized multistage procedure leads to a plausible upper limit to the risk that is consistent with some *proposed* mechanisms of carcinogenesis. Such an estimate, however, does not necessarily give a realistic prediction of the risk. *The true value of the risk is unknown, and may be as low as zero.*³⁰

As is clear from these passages, which both expressly disclaim that either procedure reflects "knowledge" as to the true risk, any estimate of risk that depends upon either extrapolation procedure will fail to meet the "knowledge" requirement announced in *Daubert*.

The Supreme Court in *Daubert* also observed that, ordinarily, a key question to be answered in determining whether a theory or technique is scien-

25. 113 S. Ct. 2786 (1993).

26. *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923).

27. *Daubert*, 113 S. Ct. at 2794.

28. *Id.* at 2795 (footnote omitted).

29. *Natural Resources Defense Council v. EPA*, 824 F.2d 1146, 1165 (D.C. Cir. 1987) (en banc) (emphasis added).

30. EPA Guidelines for Carcinogen Risk Assessment, 51 Fed. Reg. 33,992, 33,997-98 (1986) (emphasis added).

tific knowledge that will assist the trier of fact will be whether it can be (and has been) tested.³¹ The importance placed by *Daubert* on testability may derive from one of the amicus briefs filed with the Court:

One of the few briefs that proposes a method for screening scientific testimony was filed by the Carnegie Commission on Science, Technology, and Government. . . . [T]he brief urges the Court to apply a three-step test in which judges ask of a scientific claim: Is it testable? Has it been empirically tested? And has the testing been carried out according to a scientific methodology? A negative answer on any one of these points, Carnegie argues, should disqualify the evidence.³²

A persistent issue in toxic tort litigation, which the Court did not reach in *Daubert*, involves the admissibility of animal studies to prove that a chemical is a human carcinogen. The Carnegie Commission amicus brief indicates that when "a plaintiff relies solely on animal studies," it may be proper to allow the case to go to the jury "since a high correlation does in general exist with regard to human and animal reactions."³³ The brief also argues that the legal issue raised by animal studies relates to the sufficiency and not to the admissibility of the evidence, and is "ultimately a policy issue that an appellate court may have to resolve."³⁴

The "high correlation between human and animal reactions" cited in the Carnegie Commission brief is, however, misleading. It is true that, of the fewer than twenty chemicals that have been identified as carcinogenic to humans based upon epidemiological studies and that have also been tested on rodents, the predictive value from humans to rats of some carcinogenic response is seventy-five percent and is seventy-seven percent from humans to mice.³⁵ What one wants to know in public health and in toxic tort litigation, however, is the answer to a different question, namely:

[w]hether chemicals that have been shown to be carcinogenic in experimental animals are also carcinogenic in humans. This question cannot be answered by reversing the question (i.e., by asking whether chemicals that are human carcinogens are also carcinogenic in a rodent species) because even if most human carcinogens are rodent carcinogens [as they are], the converse does not necessarily follow, as can be demonstrated by a simple probabilistic argument.³⁶

Daubert's ruling that a scientific claim, such as that a human carcinogenic effect can be accurately predicted from the results of animal testing, is inad-

31. 113 S. Ct. at 2796-97 (citing KARL R. POPPER, CONJECTURES AND REFUTATIONS: THE GROWTH OF SCIENTIFIC KNOWLEDGE 37 (5th ed. 1989) (stating that "the criterion of the scientific status of a theory is its falsifiability, or refutability, or testability")).

32. Eliot Marshall, *Supreme Court to Weigh Science*, 259 SCIENCE 588, 590 (1993).

33. Brief of the Carnegie Commission on Science, Technology, and Government as Amicus Curiae in Support of Neither Party at 23-24, *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 113 S. Ct. 2786 (1993) (No. 92-102) [hereinafter Carnegie Commission Brief].

34. *Id.* at 24.

35. Lois S. Gold et al., *Target Organs in Chronic Bioassays of 533 Chemical Carcinogens*, 93 ENV'T'L HEALTH PERSP. 233, 245 (1991). Accurate prediction of cancer effects in specific target organs, for example the human lung to mouse lung, is much lower.

36. *Id.* (citing D.A. Freedman & H. Zeisel, *From Mouse to Man: The Quantitative Assessment of Cancer Risks*, 3 STAT. SCI. 3 (1988)).

missible if it is not testable is inconsistent with the Carnegie Commission's position that expert testimony based on animal data alone is admissible evidence and can only be challenged on grounds of evidentiary insufficiency. The latter position ignores that the entire purpose of the regulatory system is to attempt to identify potential human carcinogens by testing them on animals and thereafter controlling human exposure to chemicals thus identified as posing a possible human risk. This system is designed precisely to avoid the accumulation of cases of human cancer that would be necessary to "test" the hypotheses that the animal carcinogen in question also causes cancer in humans, or that most animal carcinogens are also human carcinogens.

As discussed above, the system is also conservatively designed so that it may identify as possible human carcinogens a certain number of substances that are in fact not carcinogenic to humans, or are insignificantly so, at ordinary human exposure levels. Such noncarcinogens will nevertheless be controlled in the same manner as the chemicals that are true carcinogens such that, if the system is working properly, it will never be possible to distinguish the actual human carcinogens from the noncarcinogens.³⁷ Although, as noted above, questions have been raised as to whether the system is excessively conservative, it does appear to be working reasonably well in terms of its primary purpose, which is to *avoid*, not confirm, identification of actual human carcinogens. The National Toxicology Program's 1991 Sixth Annual Report on Carcinogens, for example, is required by Section 301(b)(4)(A)(i) of the Public Health Service Act to separate substances into two categories: (1) substances "known" to be carcinogens because of sufficient evidence from human studies and (2) substances "reasonably anticipated" to be carcinogens based on animal studies and/or limited evidence from human studies.³⁸ The list contains only twenty-three known carcinogens, as opposed to 150 suspect carcinogens.³⁹ Only five of the twenty-three known carcinogens are in widespread use: arsenic, asbestos, benzene, chromium, and vinyl chloride, each of which has been identified as a human carcinogen for two de-

37. The rationale for the system is the same as for Pascal's famous wager. Blaise Pascal, a seventeenth century French philosopher and mathematician, made the following argument for belief in God:

Let us . . . say "God is, or He is not." But to which side shall we incline? Reason can decide nothing here. . . . A game is being played at the extremity of [an] infinite distance where heads or tails will turn up. What will you wager? According to reason, you can do neither the one thing nor the other; according to reason, you can defend neither of the propositions.

Do not [say] . . . "The true course is not to wager at all." [Y]ou must wager. It is not optional. You are embarked. Which will you choose then? . . . Let us weigh the gain and loss in wagering that God is. Let us estimate the two chances. If you gain, you gain all; if you lose, you lose nothing. Wager, then, without hesitation that He is.

BLAISE PASCAL, *PENSEES* 233 (W.F. Trotter trans., 1952).

The regulatory system is likewise based on a wager that many or most animal carcinogens are also human carcinogens. The very last thing we want, however, is "knowledge" of the truth of this proposition, since true knowledge would result in many cases of human cancer, which we are hoping to avoid through regulatory control.

38. 42 U.S.C. § 241(b)(4)(A)(i) (1988).

39. PUBLIC HEALTH SERV., U.S. DEP'T OF HEALTH AND HUMAN SERVS., *SIXTH ANNUAL REPORT ON CARCINOGENS* iii-vii (1991).

acades or more, or from about the time that the current regulatory system began to take hold in the early 1970s.⁴⁰

Prior to *Daubert*, courts had divided over the issue of admissibility of animal studies to prove that a substance is toxic to humans. As a law review article devoted to this judicial controversy points out, the courts that had ruled the studies admissible in the past failed to distinguish between the differing policies of regulatory prudence and evidentiary reliability in tort litigation.⁴¹ From this point on, however, *Daubert's* new emphasis on testability as a criterion for admissibility of scientific testimony in a civil action, coupled with growing skepticism concerning the meaningfulness of the animal bioassay program even in the context of the regulatory scheme for which it was devised, may well lead the great majority of courts to accept the conclusion of the above-cited article that "animal studies have no place in the courtroom."⁴²

IV. DETERMINATION BY A REGULATORY AGENCY OF INADEQUATE EVIDENCE OF A CAUSAL RELATIONSHIP: A "LEGISLATIVE FACT?"

The preceding section of this Article asserted that common law courts should, because of the regulatory agencies' admissions concerning the multiple uncertainties involved in estimating human risk from animal studies, refuse to admit evidence of animal test results in tort litigation. Another situation in which judicial deference to agency conclusions seems appropriate occurs when the agency, after conducting a careful review to determine whether a specific health effect is associated with a specific chemical exposure, announces that it is unable to conclude that any cause-and-effect relation in fact exists. An example of such a review occurred recently when a panel of ten academic experts convened by the EPA met in April 1993 to discuss the weight of the evidence regarding the carcinogenicity of 2,4-Dichlorophenoxyacetic Acid (2,4-D) and its related compounds. After two days of deliberation and discussion, the consensus of the Joint Committee was expressed by its Chairman, Genevieve Matanoski, Professor of Epidemiology at Johns Hopkins University:

And I think I'm recapitulating pretty much what the committee has come down on. So that what we have is: some interesting human studies that are not confirming each other; an interesting single animal study that has never been confirmed in another study; and no basic mechanism from toxicological and genotoxicity data that would support a potential risk as a carcinogen. So we're left with a very

40. Vinyl Chloride, for example, was identified as a human carcinogen in early 1974, when a cluster of cases of angiosarcoma of the liver was identified among individuals with workplace exposure at a B.F. Goodrich plant in Kentucky. See Emergency Temporary Standard for Exposure to Vinyl Chloride, 39 Fed. Reg. 12,342, 12,342 (1974).

41. Jack L. Landau & W. Hugh O'Riordan, *Of Mice and Men: The Admissibility of Animal Studies to Prove Causation in Toxic Tort Litigation*, 25 IDAHO L. REV. 521, 560-65 (1988-89).

42. *Id.* at 565.

unsatisfactory weight of the evidence for carcinogenicity for the time I would believe.⁴³

Immediately following Dr. Matanoski's recapitulation, the other nine members of the panel expressed their agreement with her summary. Dr. Matanoski polled the committee members at the conclusion of the meeting concerning their preferred characterization of the weight of the evidence concerning 2,4-D carcinogenicity. The voting split between "weakly suggestive," "weakly possible," and "possible."⁴⁴

The EPA had previously categorized 2,4-D as a Group D carcinogen (not classifiable as to human carcinogenicity) following the recommendation of an earlier scientific review in 1988.⁴⁵ It is apparent that the April 1993 review will not lead the EPA to change this classification. A recent article indicates that the EPA may revisit the issue of 2,4-D carcinogenicity in 1995, once it has in hand the results of various studies concerning 2,4-D currently being conducted by the National Cancer Institute (NCI).⁴⁶ The NCI studies, when completed, may cast a different light on 2,4-D. As the Supreme Court noted in *Daubert*: "Scientific conclusions are subject to perpetual revision. Law, on the other hand, must resolve disputes finally and quickly."⁴⁷

Daubert also states that the *Frye* concept of "general acceptance," while no longer a prerequisite to the admissibility of expert testimony, "can yet have a bearing on the inquiry."⁴⁸ This led a trial court to comment that "*Daubert* kills *Frye* and then resurrects its ghost."⁴⁹ In the case of 2,4-D, the EPA's expert advisory panels are not the only consensus groups to have determined that the available evidence is insufficient to reach a conclusion concerning carcinogenicity. NTP, for example, has never listed 2,4-D in any of its annual reports on carcinogens, and the World Health Organization (WHO) has likewise concluded that "[a]vailable animal bioassays and epidemiological studies are inadequate for an assessment of the carcinogenic potential of 2,4-D or of its derivatives."⁵⁰

When regulatory agencies and other scientific consensus bodies, such as WHO, generally accept that a particular chemical does not cause a particular toxic effect, it would appear reasonable for a common law court, when the same issue of toxicity is raised in a tort action, to accept the consensus

43. Transcript of the Special Joint Committee of the Science Advisory Board and the FIFRA Scientific Advisory Panel on the Weight of Evidence of Carcinogenicity of 2,4-D, at 138 (Apr. 1-2, 1993) (on file with author).

44. *Id.* at 155.

45. See 2,4-D, 2,4-DB and 2,4-DP; Proposed Decision Not to Initiate a Special Review, 53 Fed. Reg. 9590, 9593 (1988).

46. 2,4-D Further Evaluation Likely: Fenner-Crisp, PESTICIDE & TOXIC CHEMICAL NEWS, July 21, 1993, at 15.

47. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 113 S. Ct. 2786, 2798 (1993).

48. *Id.* at 2797.

49. *In re Joint E. & S. Dist. Asbestos Litig.*, 827 F. Supp. 1014, 1033 (S.D.N.Y. 1993). This decision provides a useful review of the many federal and state decisions dealing with the issue of proving causation in toxic tort litigation.

50. WORLD HEALTH ORGANIZATION, ENVIRONMENTAL HEALTH CRITERIA 29, 2,4-DICHLOROPHOXYACETIC ACID 101 (1984).

view as binding on the issue. A recent pre-*Daubert* decision adopted this approach in dismissing a claim that DPT vaccine had caused a seizure suffered by plaintiff's daughter:

Within recent years numerous governmental and professional bodies have issued reports which have addressed the question of whether such vaccine causes permanent neurological damage. Among the authorities issuing such reports are the Institute of Medicine . . . , the Centers for Disease Control, the Child Neurology Society, the American Academy of Pediatrics, the American Academy of Neurology, the British Pediatric Association and the National Advisory Committee on Immunization of Canada. All of these groups have concluded that existing data and knowledge does not demonstrate that there is any causal connection between whole cell DPT vaccine and permanent neurological damage.⁵¹

The court in this case granted the defendant's motion for summary judgment on the ground that the product, as a matter of law, was not unreasonably dangerous, questioning: "how can Tri-Immunol be said to be '*unreasonably dangerous*' if there is a strong consensus among the majority of physicians and scientists who have studied the issue that whole cell DPT vaccine has not been shown to cause permanent neurological damage?"⁵²

The Bendectin litigation provides an apt illustration of the fact that case-by-case review of the same general causation issue offers a poor alternative to judicial deference to a determination of non-toxicity by the responsible agency, when such a determination is available. A comprehensive review of this litigation found that there were, as of early 1992, "a total of thirty-six appellate opinions concerning Bendectin,"⁵³ "[a]ll Bendectin cases pose the same general causation issue,"⁵⁴ and plaintiffs "have routinely met with defeat."⁵⁵

Bendectin was voluntarily withdrawn from the market in 1983,⁵⁶ before very many of the Bendectin lawsuits had reached trial, and as new scientific studies continued to be released. Since the Food and Drug Administration (FDA) had no occasion to reconsider its earlier approval of the marketing of Bendectin after the product was withdrawn in 1983, the manufacturer was not in a position to defend many cases on the basis of FDA approval,⁵⁷ which in any event has not generally been a successful defense for pharma-

51. *Pease v. American Cyanamid Co.*, 795 F. Supp. 755, 757 (D. Md. 1992).

52. *Id.* at 758 (emphasis added).

53. Joseph Sanders, *The Bendectin Litigation: A Case Study in the Life Cycle of Mass Torts*, 43 HASTINGS L.J. 301, 375 (1992).

54. *Id.* at 377.

55. *Id.* at 385.

56. Louis Lasagna & Sheila R. Shulman, *Bendectin and the Language of Causation*, in PHANTOM RISK: SCIENTIFIC INFERENCE AND THE LAW 101 (Kenneth R. Foster et al. eds., 1993).

57. In December 1980, FDA proposed a package insert for Bendectin, that read in part: "It is not possible to prove that any drug . . . is totally free of risk, or absolutely safe, if taken during pregnancy. In 11 of 13 studies of women who took this drug during pregnancy, there was no evidence that it increased the risk of birth defects." Draft Guideline Patient Package Insert; Bendectin and Other Combination Drugs Containing Doxylamine and Vitamin B-6, 45 Fed. Reg. 80,740, 80,742 (1980). In June 1981, before a Congressional subcommittee, FDA

ceutical defendants.⁵⁸ The appellate courts, however, have with virtual unanimity reached the same conclusion of Bendectin safety that the FDA presumably would have adhered to if the drug were still on the market.

The Bendectin litigation, toward the end of its cycle, resulted in "legislative fact-finding" by the judiciary: "As a matter of law, Bendectin does not cause birth defects," as one commentator described the holding in one of the more recent Bendectin decisions.⁵⁹ Another study agrees that "the Bendectin causation cases may better be viewed as an instance of the courts making a finding of legislative fact that Bendectin does not cause birth defects."⁶⁰ This process of legislative fact-finding has apparently also taken place in mass tort litigation involving asbestos.⁶¹ Instructive in this regard is the opinion of Judge Becker of the U.S. Court of Appeals for the Third Circuit, concurring only that the New Jersey Supreme Court's decisions denying the state-of-the-art defense to asbestos manufacturers did not amount to an unconstitutional denial of equal protection of the law.⁶² The basis for Judge Becker's concurring opinion was his belief that the New Jersey Supreme Court, in singling out asbestos defendants, had "determined a legislative fact—that, at all relevant times, asbestosis harms were knowable to the industry. That being the case, the New Jersey Supreme Court has reasonably decided to preclude endless relitigation of what was 'knowable' to the asbestos industry."⁶³ Judge Becker went on to state that "[c]ommon law courts could not fashion rules grounded in reality if they were obliged to proceed

Commissioner Arthur Hayes "reiterated the FDA's determination that Bendectin did not cause birth defects." Lasagna & Shulman, *supra* note 56, at 109.

58. A recent decision collects cases that "have held that FDA certification and regulation of a product, or a party's compliance with FDA or other governmental regulations, does not automatically relieve a party of either liability or its duty to warn." *Hegna v. E.I. DuPont de Nemours & Co.*, 806 F. Supp. 822, 830 (D. Minn. 1992). *But see Hurley v. Lederle Labs.*, 863 F.2d 1173, 1179 (5th Cir. 1988) (holding that a decision by the FDA as to the proper wording of a drug warning label impliedly preempts a state law tort action challenging the adequacy of the warning, provided that the drug manufacturer can establish that it provided FDA with all of the necessary and available information on which to base the warning); *Collins v. Ortho Pharmaceutical Corp.*, 231 Cal. Rptr. 396, 404 (Ct. App. 1986) (opining that "[j]udicial interpretation of the effect of FDA approval by state courts which furthers [the] policy of interstate consistency is . . . preferable to interpretation which undermines this goal").

59. Sanders, *supra* note 53, at 384 (referring to *Ealy v. Richardson-Merrell*, 897 F.2d 1159 (D.C. Cir.), *cert. denied*, 498 U.S. 950 (1990)).

60. Michael D. Green, *Expert Witnesses and Sufficiency of Evidence in Toxic Substances Litigation: The Legacy of Agent Orange and Bendectin Litigation*, 86 NW. U. L. REV. 643, 679 (1992).

61. An example cited by Sanders is a 1990 order for a hearing on a proposed class certification which would allow the court to:

Declare and apply federal common law that establishes as a matter of law that asbestos-containing insulation products . . . are inherently dangerous in accordance with the governmental ban and the findings of all federal agencies that have addressed the question; and that such products were marketed without an adequate warning and were therefore, defective and unreasonably dangerous.

Sanders, *supra* note 53, at 386 (quoting *In re National Asbestos Litig.*, No. 1:90 CV, 11,000 (N.D. Ohio Aug. 10, 1990) (consolidation order), *quoted in* 5 Toxics L. Rep. (BNA) No. 11, at 360-61 (Aug. 15, 1990)).

62. *In re Asbestos Litig.*, 829 F.2d 1233, 1238-39 (3d Cir. 1987), *cert. denied*, 485 U.S. 1029 (1988).

63. *Id.* at 1245.

without aid of legislative facts."⁶⁴

Courts can determine "legislative facts," as Judge Becker indicates, and so can legislatures and their agents, such as regulatory agencies. As between courts and regulatory agencies, the latter would appear to have a clear advantage in determining legislative facts. As U.S. Supreme Court Justice Blackmun has noted, "all courts . . . face institutional limitations on our ability to gather information about 'legislative facts.'"⁶⁵

Medical questions as to whether a particular toxic effect can be caused by exposure to a particular chemical substance, such as birth defects by Bendectin, or cancer by 2,4-D, are essentially questions of legislative fact. This is true because of the nature of medicine, which cannot determine causation of chronic disease from the study of an individual case, but rather bases conclusions concerning causation on studies of large groups of similar cases: "Although causality operates at the individual level, it is impossible at present to study it at that level in systems as complex as a human body. All we can do is to study populations of similar systems."⁶⁶ Legislative facts are determined in the same way, by studying groups of cases, not merely a single case.⁶⁷

All toxic tort litigation involving the question of whether a particular product can cause cancer, or any other toxic effect commonly found in the general population, has the potential to become mass tort litigation similar to the Bendectin and asbestos litigation. It may also require determination of legislative facts concerning medical causation, the nature of a proper warning, and other such generic issues. Whenever regulatory agencies have determined such legislative facts after full review, it seems to make very little

64. *Id.* at 1248.

65. *United States v. Leon*, 468 U.S. 897, 927 (1984) (Blackmun, J., concurring). Judge David Bazelon, in a speech to the National Academy of Sciences, explaining why Congress had entrusted the task of controlling environmental risks to regulatory agencies rather than leaving the task to common law courts, agreed that "[c]ourts lack the technical competence to resolve scientific controversies; they lack the popular mandate and accountability to make the critical choices that regulation requires." David L. Bazelon, *The Judiciary: What Role in Health Improvement?*, 211 *SCIENCE* 792, 792 (1981).

66. Ronald N. Giere, *Knowledge, Values, and Technological Decisions*, in *ACCEPTABLE EVIDENCE: SCIENCE AND VALUES IN RISK MANAGEMENT* 193-94 (Deborah G. Mayo & Rachel D. Hollander eds., 1991). This same insight was expressed some millennia ago by Aristotle, who stated:

But none of these arts theorize about individual cases. Medicine, for instance, does not theorize about what will help to cure Socrates or Callias, but only about what will help to cure any or all of a given class of patients: this alone is its business: individual cases are so infinitely various that no systematic knowledge of them is possible.

ARISTOTLE, *RHETORIC* (W. Rhys Roberts trans.), *reprinted in GREAT BOOKS OF THE WESTERN WORLD* 593, 596 (Robert M. Hutchins ed., 1952).

67. As stated in the standard treatise on administrative law:

An industry-wide question calls for facts about the industry; facts about each company may be unhelpful and may even get in the way. If a court . . . is making law to govern an industry of 100 companies, the *useful* facts are about the 100 companies as a group, not about each company. The facts about the group are legislative, even though they are the sum of adjudicative facts about each company.

3 KENNETH C. DAVIS, *ADMINISTRATIVE LAW TREATISE* § 15:5, at 152-53 (2d ed. 1980).

sense—from the standpoint of judicial economy and legal consistency—for dozens or hundreds of courts to attempt to judicially redetermine such legislatively-determined facts. The following sections of this Article examine some rationales for declining to engage in such redetermination.

V. PREEMPTION, EXPRESS AND IMPLIED

In April 1991 the American Law Institute published a two-volume study entitled *Enterprise Responsibility for Personal Injury*.⁶⁸ One of the issues discussed in the 1991 study is the preemption doctrine as it applies to tort litigation. The study states: "The arguments for preemption are strongest when federal regulation is detailed and comprehensive: [E]xamples include cigarette labelling (where federal preemption has been upheld) and pharmaceuticals and pesticides (where courts have refused to recognize federal preemption)."⁶⁹ The statement that courts have refused to recognize preemption in the pesticide area is no longer true. As a result of the 1992 decision of the U.S. Supreme Court upholding preemption of tort actions based on allegations of inadequate cigarette labelling,⁷⁰ no fewer than five federal appellate courts quickly concluded within the following year that the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)⁷¹ likewise preempted common law failure to warn claims involving pesticides.⁷²

It appears that courts will also accept the preemption defense, post-*Cipollone*, under the Federal Hazardous Substances Act (FHSA),⁷³ which is administered by the Consumer Product Safety Commission. Noting that FHSA's preemption language is "almost identical" to the preemption language of FIFRA, the U.S. Court of Appeals for the Fourth Circuit recently became the first appellate court to find that FHSA preempted common law failure to warn claims involving chemicals and other products intended for household use.⁷⁴

68. THE AMERICAN LAW INSTITUTE, REPORTERS' STUDY: ENTERPRISE RESPONSIBILITY FOR PERSONAL INJURY (1991) [hereinafter ENTERPRISE RESPONSIBILITY STUDY].

69. *Id.* at 106.

70. *Cipollone v. Liggett Group, Inc.*, 112 S. Ct. 2608 (1992).

71. 7 U.S.C. §§ 136-136y (1988, Supp. II 1990, Supp. III 1991, & Supp. IV 1992). FIFRA's preemption language is very similar to the preemption language of the cigarette labeling statute.

72. See *King v. E.I. DuPont de Nemours & Co.*, 996 F.2d 1346, 1347 (1st Cir.), *cert. dismissed*, 114 S. Ct. 490 (1993); *Worm v. American Cyanamid Co.*, 5 F.3d 744, 747-48 (4th Cir. 1993); *Shaw v. Dow Brands, Inc.*, 994 F.2d 364, 377 (7th Cir. 1993); *Arkansas-Platte & Gulf Partnership v. Van Waters & Rogers, Inc.*, 981 F.2d 1177, 1179 (10th Cir.), *cert. denied*, 114 S. Ct. 60 (1993); *Papas v. Upjohn Co.*, 985 F.2d 516, 517 (11th Cir.), *cert. denied*, 114 S. Ct. 300 (1993). All federal courts of appeal that have considered the pesticide preemption issue post-*Cipollone* have concluded that preemption exists. As the defense attorney involved in defending the *Papas* case is quoted as saying following the U.S. Supreme Court's refusal to grant certiorari, the "handwriting is now on the wall for the plaintiffs' bar" which had "better get [inadequate labeling and failure-to-warn claims] out of their lexicon." *U.S. High Court Denies Review in Two Cases Involving Federal Pre-emption of Tort Suits*, 8 Toxics L. Rep. (BNA) No. 20, at 580 (Oct. 20, 1993) (quoting attorney Lawrence S. Ebner).

73. 15 U.S.C. §§ 1261-1277 (1988, Supp. II 1990, Supp. III 1991, & Supp. IV 1992).

74. *Moss v. Parks Corp.*, 985 F.2d 736, 740 n.3 (4th Cir.), *cert. denied*, 113 S. Ct. 2999 (U.S. 1993); *accord Lee v. Boyle-Midway Household Prods., Inc.*, 792 F. Supp. 1001, 1008 (W.D. Pa. 1992).

One such product, paint stripper containing MC, is the subject of a 1987 Consumer Product Safety Commission (CPSC) enforcement policy setting forth specific warning language, which the CPSC considers "suitable labeling for paint strippers containing relatively large amounts of methylene chloride."⁷⁵ The model labeling contains directions for safe use and also the following cancer warning: "Contains methylene chloride, which has been shown to cause cancer in certain laboratory animals. Risk to your health depends on level and duration of exposure."⁷⁶

A hundred different courts and juries might, if the task were entrusted to them, agree with a hundred different criticisms of the CPSC warning for paint strippers containing MC. If the FHSA preemption decisions cited above are accepted in multiple jurisdictions, however, as FIFRA preemption has been, there will no longer be room for lawsuits based upon claims that a different or more comprehensive cancer warning than that endorsed by CPSC should have been given.

VI. BEYOND PREEMPTION

OSHA, in its notice of proposed rulemaking, has suggested cancer hazard warning language for MC in the workplace.⁷⁷ The language would appear on material safety data sheets, which are the form of hazard communication used by manufacturers for products sold in bulk quantities (tank truck or rail car), rather than in labeled containers. In the mid-1980s, OSHA also promulgated a hazard communication standard imposing certain general rules governing the distribution and the content of material safety data sheets for hazardous chemicals.⁷⁸ The Occupational Health and Safety Act, unlike FIFRA and FHSA, however, does not contain language that expressly preempts state law labeling requirements.⁷⁹ As noted above, the

75. U.S. Consumer Product Safety Commission, Labeling of Certain Household Products Containing Methylene Chloride; Statement of Interpretation and Enforcement Policy, 52 Fed. Reg. 34,698, 34,702 (1987).

76. *Id.*

77. OSHA's proposed language is as follows:

II. Health Hazard Data

.....

2. Long-term (chronic) exposure: The evidence for the carcinogenic potential of MC is primarily based upon chronic studies in which MC was administered to three species of laboratory rodents (rats, mice, and hamsters). MC exposure produced lung and liver tumors in mice and mammary tumors in rats. No carcinogenic effects of MC were found in hamsters.

Occupational Exposure to Methylene Chloride, Proposed Rule, 56 Fed. Reg. 57,035, 57,134 (1991).

78. Hazard Communication, 29 C.F.R. § 1910.1200 (1992).

79. In 1991, the U.S. Court of Appeals for the First Circuit, reversing a lower court decision, held that the Occupational Safety and Health Act did not expressly or impliedly preempt a state law tort action based on a claim that the supplier of a hazardous product had failed to provide an adequate warning. *Pedraza v. Shell Oil Co.*, 942 F.2d 48, 52 (1st Cir. 1991), *cert. denied*, 112 S. Ct. 993 (1992). The particular substance involved in *Pedraza* was Epichlorohydrin, a chemical which is apparently regulated by OSHA in only two respects: OSHA has set a permissible exposure limit for this substance and requires employers to provide protective equipment for employees who work with any hazardous substance. *Id.* at 50.

As the *Pedraza* court recognized, even if preemption is not expressly provided for in the

courts, for the same reason, have not found that FDA approval of a pharmaceutical product preempts tort litigation relating to the product.⁸⁰

When the applicable statute does not contain express preemption language, an independent rationale may be available for arguing that regulatory action should control the outcome of toxic tort litigation. For example, one can argue that notwithstanding the fact that permissible exposure limits are not formally preemptive of state law tort actions under OSHA, a court should, as a matter of deference to agency expertise, dismiss a tort action whenever the alleged injurious exposure to chemicals has not been demonstrated to have exceeded the OSHA-allowed exposure limits. So far as the author is aware, this argument has never been made in a case involving an OSHA-regulated chemical.

A recent decision in the nuclear regulatory area, however, indicates that the argument for such judicial deference to OSHA expertise is plausible. In *O'Conner v. Commonwealth Edison Co.*⁸¹ a radiation worker sued an Illinois public utility, alleging that he had received a large dose of radiation that caused him to develop cataracts and other ailments. The plaintiff wore radiation measuring instruments whenever he entered any area of the plant that contained radiation. The measuring instrument apparently recorded exposures that fell, at all times, within the "permissible dose" set by the Nuclear

federal statute, "preemption will be inferred where the state law 'actually conflicts with federal law.'" *Id.* at 51 (quoting *English v. General Elec. Co.*, 496 U.S. 72, 79 (1990)). Where OSHA has prescribed express warning language for a particular substance, as it has not done for Epichlorohydrin but now proposes to do for MC, a state law tort claim that a manufacturer should have provided additional or different warnings might well be preempted under the "express conflict" branch of the preemption doctrine. Certain portions of the OSHA Hazard Communication Standard may also provide a basis for such an argument.

In the case of one substance, vinyl chloride, a very strong argument may be made in this regard. This standard specifies that the following mandatory warning language appear on containers of polyvinyl chloride:

POLYVINYL CHLORIDE (or TRADE NAME)

Contains

VINYL CHLORIDE

VINYL CHLORIDE IS A CANCER-SUSPECT AGENT

29 C.F.R. § 1910.1017(k)(7)(i)(4) (1992). OSHA's preamble to the adoption of this regulation makes clear that this is *the only* language that may appear on the label:

Coupled with the training requirement in the standard, we believe that the signs and labels required will adequately inform employees of the [cancer] hazard. . . .

The proper application of most protective measures requires an amount of training and indoctrination of employees that cannot easily be conveyed on a sign or label. Also, the variety of measures that could be prescribed *would result in an unwieldy or excessively detailed legend*. Consequently, the required message on signs and labels *will not* include information on precautions, relevant symptoms, etc. The addition of suitable information *by the employer* would be permitted, providing it does not detract in any way from the required statement.

Exposure to Vinyl Chloride, 39 Fed. Reg. 35,890, 35,895 (1974) (emphasis added).

80. With respect to FDA regulation of medical devices, express preemption language has been included in the 1976 Medical Devices Amendments (MDA) to the Federal Food, Drug and Cosmetic Act of 1938 (FDCA). 21 U.S.C. § 360k (1988); see *King v. Collagen Corp.*, 983 F.2d 1130, 1139 (1st Cir. 1993) (holding that regulations under the Medical Device Amendments of 1976 preempted plaintiff's failure to warn claims against manufacturer of cosmetic medical device); *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1421 (5th Cir. 1993) (holding the same).

81. 748 F. Supp. 672 (C.D. Ill. 1990), *aff'd*, 13 F.3d 1090 (7th Cir. 1994).

Regulatory Commission. The plaintiff argued that the instrument mis-recorded the exposure numbers at the time of the incident, and that the actual dose of radiation he received greatly exceeded the recorded numbers. The court did not resolve the question of measuring the actual exposure, but did resolve a preliminary question, on which it granted plaintiff's petition for an interlocutory appeal. The court answered the question of whether the regulation setting a permissible dose should be adopted as the standard of care in the affirmative.⁸²

The court in *O'Conner* thus accepted defendant's argument that "it is not proper to allow the jury to disregard the federal permissible dose limits and effectively set their own."⁸³ The court noted that the "federal permissible dose limits are based upon the national and international scientific consensus as to the hypothetical risk from exposure to low occupational levels of ionizing radiation."⁸⁴ It then concluded that "[i]n determining the likelihood of the injury from radiation, this Court believes that it should give deference to the administrative regulations which are the result of an agency's applied expertise."⁸⁵ As the attorney who represented the utility company defendant in *O'Conner* has written, "the *O'Conner* doctrine has a much broader application than just to radiation litigation. . . . [T]here are many other regulated toxic substances that may qualify for similar treatment."⁸⁶

In the case of FDA drug approval, a recent Pennsylvania concurring opinion adopts, without citing *O'Conner*, essentially the same rationale in support of its conclusion that strict product liability should not apply to prescription drugs.⁸⁷ Also, *O'Conner* finds support in administrative law de-

82. *Id.* at 678. Comment (a) to Section 288C of the *Restatement (Second) of Torts* states that a court may, in its discretion, adopt a legislative enactment or administrative regulation as the common law test of due care. See *supra* note 5. Although *O'Conner* does not mention this section of the *Restatement*, it appears to be the first reported decision in which comment (a) has, in effect, been applied in a case involving exposure to a toxic agent. The United States Court of Appeals for the Seventh Circuit subsequently denied the plaintiff's petition for interlocutory appeal. *O'Conner v. Commonwealth Edison Co.*, No. 90-8103 (7th Cir. Oct. 26, 1990); see *O'Conner v. Commonwealth Edison Co.*, 807 F. Supp. 1376, 1379 (C.D. Ill. 1992), *aff'd*, 13 F.3d 1090 (7th Cir. 1994).

83. *O'Conner*, 748 F. Supp. at 676.

84. *Id.* at 677.

85. *Id.*

86. Donald E. Jose, *Philadelphia Attorney Discusses 'Permissible' Toxics Levels*, Toxic Chemicals Litig. Rep. (Andrews) 14,596, 14,598 (Aug. 21, 1991). Of course, where industry itself agrees that the current regulatory exposure limit is obsolescent and too high, as is the case with the current limit for MC, it is not possible to argue that the *O'Conner* doctrine applies. The argument would also be difficult to make if, subsequent to the date the exposure limit was set (or, in the case of FDA, the drug was approved), evidence of a new toxic effect became available, and a plaintiff subsequently suffered from that effect before the agency had time to consider a new, lower limit or new warning language.

87. *Hahn v. Richter*, 628 A.2d 860, 870-71 (Pa. Super. Ct. 1993) (Cavanaugh, J., concurring). Because Judge Cavanaugh's opinion corresponds so closely to a central thesis of this Article, it is quoted from extensively below:

Two important, interrelated, public policy considerations exist for treating a prescription drug different [sic] than other manufactured products. First, prescription drugs are (potentially) inherently dangerous products whose costs are considered by society to be more beneficial than its [sic] potential harm. Second, the Food and Drug Administration ("FDA") has the institutional capacity and

cisions. For example, the Supreme Court of the United States has stated that when an agency "is making predictions, within its area of special expertise,

legislative mandate for weighing the costs and benefits for particular pharmaceutical

The first important policy consideration in this area is that prescription drugs are inherently dangerous products which are considered, *ex ante*, beneficial to society as a whole. Unlike most manufactured products, prescription drugs are considered dangerous. When not properly dispensed, prescription drugs can cause sickness or even death. Consequently, society has heavily regulated their use, such that they can be taken only when prescribed and monitored by a physician. Despite their inherently dangerous nature, we tolerate their use because the gain for society as a whole outweighs the risk that they may harm particular individuals. Unlike most other manufactured products, prescription drugs play a significant role in dissipating suffering and in prolonging human life

The second policy consideration in this area is that the FDA has a particular institutional capacity to determine whether a pharmaceutical's health benefits outweigh its risks. Congress has created a regulatory agency, the FDA, to "protect consumers from dangerous products." *United States v. Sullivan*, 332 U.S. 689, 696 (1948). In approving a new drug application, the FDA balances the "expected therapeutic gains" against the "risks entailed by its use." *United States v. Rutherford*, 442 U.S. 544, 555 (1979). Before a new drug is approved, federal law requires (1) preliminary evaluation of a pharmaceutical's chemical and therapeutic properties; (2) testing in animal models; (3) detailed protocols for testing in humans; (4) double-blind, placebo-controlled testing on several hundred persons; and (5) at least two long-term clinical trials including large groups of patients to assess safety, effectiveness and optimal dosage. *See* 47 Fed. Reg. 46,622, *et seq.* (Oct. 19, 1982); 48 Fed. Reg. 26,720, *et seq.* (June 9, 1983); 21 U.S.C. §§ 301, *et seq.* (1988).

This agency not only has the responsibility, but the resources, to fulfill its mission of balancing the risks against the benefits of particular pharmaceuticals. The application is reviewed by many types of health professionals who work within the FDA's National Center for Drugs and Biologics, including physicians, pharmacologists, chemists, and microbiologists. 47 Fed. Reg. 46,626 (Oct. 19, 1982). The recommendation of the health professionals is in turn reviewed by management personnel within the National Center for Drugs and Biologics before a final decision is made on the drug's application. *Id.* After the application is approved, the FDA has a process for monitoring adverse reactions to an approved pharmaceutical, as federal regulations mandate that all adverse reactions to a pharmaceutical be reported to the agency. 21 C.F.R. § 314.80(b). A drug manufacturer typically spends millions of dollars in developing or testing new drugs. *See Drug Price Competition and Patent Term Restoration Act: Hearing Before the Senate Comm. on Labor and Human Resources*, 98th Cong. 2d Sess. 106 (1984).

Based on the above, I would accordingly find that public policy is best served by not applying the doctrine of strict liability to prescription drugs. Prescription drugs are inherently dangerous products which benefit society. Moreover, a federal agency exists which is devoted to weighing the known benefits and costs of marketing a particular drug. . . . The FDA is in a unique position to make the decision whether a drug is efficacious, and to preserve the incentive for a company to produce a beneficial pharmaceutical. Juries and the judiciary do not have the requisite knowledge, resources, or societal mandate to make the decision as to a prescription drug's relative worth.

Id. at 870-71 (parallel citations omitted).

This Article's only criticism of Judge Cavanaugh's reasoning relates to his attempt to draw a distinction between prescription drugs and other products. If Judge Cavanaugh had not drawn such a distinction, however, the logic of his position would have compelled him to advocate the abandonment of the doctrine of strict liability as to all heavily regulated products. Judge Cavanaugh's statement that prescription drugs differ from most manufactured products in that they play a significant role in prolonging human life may be oversimplistic, in light of studies suggesting that economically productive activity, which requires the efficient use of

at the frontiers of science[.] . . . a reviewing court must generally be at its most deferential."⁸⁸ The reason courts accord such deference to the agency is that the courts themselves lack scientific expertise, a consideration that applies to all civil litigation, whether a case falls within the court's toxic tort jurisdiction or within its administrative review jurisdiction.

O'Connor represents a departure from the traditional view that compliance with regulatory standards provides only some evidence, rather than conclusive evidence, of due care. This traditional view is based on "the general assumption of the law . . . that it is desirable to use two remedial systems [tort and regulatory] and require that the enterprise conform to whichever of the two standards is more stringent."⁸⁹ As argued in a recent law review note, however, while

[s]uch dual regulation may have been reasonable prior to the New Deal, when government regulation did little more than slightly modify existing judge-made law[.] . . . defendants operating within highly regulated fields may plead with conviction that compliance with strict, complex regulations should suffice to immunize them from tort liability.⁹⁰

This note cites specific examples of pervasively regulated fields, including nuclear power, pharmaceutical production, and aviation manufacture. The same considerations, however, apply today to known or possible carcinogens such as MC, 2,4-D, vinyl chloride, asbestos, benzene, and others that have likewise been subjected to extensive regulatory control and searching regulatory scrutiny.⁹¹

industrial chemicals, is itself essential to good public health. Wealthy nations, in other words, have always tended to be healthy nations. See BREYER, *supra* note 1, at 99-100 nn.118-22.

88. *Baltimore Gas & Elec. Co. v. Natural Resource Defense Council*, 462 U.S. 87, 103 (1983). The U.S. Court of Appeals for the District of Columbia, which reviews more challenges to agency rulemaking than does any other court, applied the same standard of deference in reviewing OSHA's estimate of health effects from asbestos exposure, stating: "When called upon to review technical determinations on matters to which the agency lays claim to special expertise, the courts are at their most deferential." *Building & Constr. Trades Dep't v. Brock*, 838 F.2d 1258, 1266 (D.C. Cir. 1988).

89. 1 ENTERPRISE RESPONSIBILITY STUDY, *supra* note 68, at 84-85.

90. Paul Dueffert, Note, *The Role of Regulatory Compliance in Tort Actions*, 26 HARV. J. ON LEGIS. 175, 177 (1989) (footnotes omitted).

91. The note also justifies the preemptive effect of the labelling act for cigarettes, in terms that equally apply to regulation of known or suspect industrial carcinogens:

As is the case with actions against nuclear power producers, courts are unwilling [with respect to issues of weighing health risks and economic benefits] to second-guess Congress, especially as they are limited in expertise, burdened by rules of evidence, constrained by busy dockets, and do not possess the fact-finding machinery of the legislature. Second, the federal statute is thought to impose needed uniformity in regulating tobacco, a uniformity that individual courts are not wont to disturb. Finally, the [statute] was the product of bitterly partisan infighting, and courts find it improper to intrude on this legislative debate. . . . Where governing regulation—federal or state, *formally preemptive or not*—is so much the product of intense political debate, courts should not devalue that debate by subjecting regulated conduct to additional tort liability.

Id. at 214 (footnote omitted) (emphasis added).

Politics likewise plays a role in the regulation of suspect carcinogens by OSHA. For example, in response to OSHA's proposal to greatly lower exposure limits for MC, owner-operators of small paint-stripping shops, of which there are several thousand in this country, have com-

Regulatory agencies are subject to criticism for the delays involved in rulemaking. OSHA's 1991 notice of proposed rulemaking for MC followed, by more than six years, a July 1985 petition for a new exposure limit submitted by the United Auto Workers.⁹² OSHA's final rule is not expected until 1994, at which time the rule may well be challenged in court. From its inception in 1971 through 1989, the year in which OSHA issued a set of new permissible exposure limits for 428 toxic substances, which was subsequently successfully challenged in court,⁹³ OSHA had conducted rulemaking proceedings and issued rules with respect to only twenty-four toxic substances.⁹⁴

Unless Congress amends OSHA's governing act, the best hope for accelerating the process of issuing revised standards that will reflect new knowledge concerning workplace hazards of chemicals may lie in "negotiated regulation"⁹⁵ between industry and labor. Negotiated rulemaking with respect to benzene was tried, but failed, in the early 1980s. One stumbling block was the "[i]ndustry's demand for a preamble [to the negotiated regulation] finding no significant risk at 1 ppm (designed to protect firms from tort litigation)."⁹⁶ Negotiated regulation in the chemical safety area might have a better chance of success if more courts follow the lead of the *O'Connor* court and find that, even in the absence of such a specifically-worded regulatory finding, compliance with regulatory exposure limits immunizes defendants from tort liability. For example, it is difficult to imagine that any manufacturer of a product suspected to cause cancer, on the basis of animal testing, would not agree, as part of negotiated regulation, to label language similar to that, quoted above, which OSHA and CPSC have devised for MC, if the manufacturer had assurance that its agreement would preclude a subsequent attack on the warning in tort litigation.

plained to their Congresspersons and submitted comments or testimony in strong opposition to the proposal. Such individuals, who themselves have MC exposure, have generally requested that the new limit be set at a higher level than the level suggested by the manufacturers of MC. Author's Inspection of Documents in OSHA Docket Office. Likewise, tighter controls on perchloroethylene, the chemical used in dry cleaning, are also politically sensitive because of the expense of installing new equipment to achieve lower emissions and the large number of dry cleaning shop owners in this country.

92. See Occupational Exposure to Methylene Chloride, 56 Fed. Reg. 57,035, 57,038 (1991).

93. *AFL-CIO v. OSHA*, 965 F.2d 962, 986-87 (11th Cir. 1992). OSHA claimed that its attempt to set new limits for the 428 additional substances represented "a much needed revision of the existing standards" originally set in 1971. *Id.* at 987. The reviewing court found, however, that OSHA's streamlined approach to this multi-substance rulemaking, which was challenged by both industry and labor, was "not consistent with the requirements of the OSH Act." *Id.*

94. CARNEGIE COMMISSION ON SCIENCE, TECHNOLOGY AND GOVERNMENT, *RISK AND THE ENVIRONMENT: IMPROVING REGULATORY DECISION MAKING* 57 (1993).

95. For a recent discussion of how such "reg-neg" operates, see Ellen Siegler, *Regulatory Negotiations: A Practical Perspective*, 22 *Env'tl. L. Rep. (Env'tl. L. Inst.)* 10,647 (Oct. 1992).

96. JOHN D. GRAHAM ET AL., *IN SEARCH OF SAFETY: CHEMICALS AND CANCER RISK* 90 (1988).

VII. CONCLUSION

Case-by-case litigation does not provide an efficient means of dealing with the problem of carcinogenic and other toxic exposures. Judge Breyer is justly critical of a system that "leaves the determination of 'too much risk' in the hands of tens of thousands of different juries."⁹⁷ The same criticism can be leveled at a system that leaves the design of warnings in the hands of tens of thousands of juries. Breyer rightly questions: "Who now reads the warnings on aspirin bottles, or the pharmaceutical drug warnings that run on, in tiny print, for several pages?"⁹⁸ The tort law case-by-case approach to designing warnings is inefficient, and perhaps dangerous.⁹⁹ This Article has discussed a number of recent decisions that suggest that the court system, in the face of the relatively recent onslaught of toxic tort litigation, is beginning both to come to grips with its own limitations and to recognize that judicial deference to well-considered regulatory findings and actions can promote the economic, fair, and predictable resolution of mass tort litigation involving toxic substances.

97. BREYER, *supra* note 1, at 59.

98. *Id.* at 28.

99. As a perceptive law review article explains, the case-by-case approach to designing warnings creates "legal incentive to eschew selective warnings [in favor of] extremely detailed comprehensive warnings. Courts that have preferred quantity of information over quality of communication not only allow, but also encourage, manufacturers to design legalistic warnings intended more to escape liability than to prevent accidents." Victor E. Schwartz & Russell W. Driver, *Warnings in the Workplace: The Need for a Synthesis of Law and Communication Theory*, 52 U. CIN. L. REV. 38, 60 (1983). The article continues:

The legal evaluation of product warnings generally occurs in the context of products liability litigation. Products liability cases tend to focus on the particular hazard that caused the plaintiff's injury, not the full array of possible hazards. When a person is injured by a very remote risk, the remoteness of the risk tends to be obscured by the reality of the plaintiff's injury. Courts generally do not ask how many other risks the manufacturer might also be required to warn about. Thus, the legal system's apparent preference for comprehensive warnings is less the result of a considered evaluation of the warnings problem than the net effect of hundreds of narrowly focused products liability cases.

Id. at 60 n.108.