

CAUSATION IN GOVERNMENT REGULATION AND TOXIC TORTS

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Over the past twenty years, courts, legislatures, agencies, and scholars have devoted thousands of pages to a single generic question: Does substance *A* cause injury *X*?¹ Of course, to be useful to any legal institution, the question must be restated as: Is there evidence that substance *A* causes injury *X* that is sufficient to justify taking some action with respect to substance *A* and those firms who are responsible for substance *A*?

The legal system uses different approaches to answer this question, depending on the purpose for which the question is asked. It is much more difficult to prove causation in a tort case than in a regulatory proceeding. This should not be surprising because the causal question relevant to a tort case differs significantly from the causal question relevant to a regulatory proceeding. Regulatory agencies are responsible for protecting the general public from the potential future adverse effects of toxic substances. The regulatory restrictions they can impose often include mandatory testing, mandatory labeling, emissions limits, exposure limits, and, in an extreme case, a ban on a substance. When deciding whether to impose a regulatory restriction, the agency asks whether there is sufficient evidence of a general causal relationship between substance *A* and injury *X* to justify imposition of a regulatory restriction.² By contrast, in a tort case, the court must decide whether a particular manufacturer of substance *A* is legally and financially responsible for a particular injury to a particular individual. For that purpose,

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1. See, e.g., Resource Conservation and Recovery Act, 42 U.S.C. §§ 6901-6992 (1994) (regulating hazardous waste); *General Elec. Co. v. Joiner*, 118 S. Ct. 512 (1997) (upholding decision that excluded evidence of toxicity in a tort case); *Industrial Union Dep't v. American Petroleum Inst.*, 448 U.S. 607 (1980) (rejecting as inadequate regulatory agency's findings with respect to toxicity of benzene); STEPHEN BREYER, *BREAKING THE VICIOUS CIRCLE: TOWARD EFFECTIVE RISK REGULATION* (1993); Troyen A. Brennan, *Helping Courts with Toxic Torts: Some Proposals Regarding Alternative Methods for Presenting and Assessing Scientific Evidence in Common Law Courts*, 51 U. PITT. L. REV. 1 (1989); Peter Huber, *Safety and the Second Best: The Hazards of Public Risk Management in the Courts*, 85 COLUM. L. REV. 277 (1985); Thomas O. McGarity, *Substantive and Procedural Discretion in Administrative Resolution of Science Policy Questions: Regulating Carcinogens in EPA and OSHA*, 67 GEO. L.J. 729 (1979); Albert Nichols & Richard Zeckhauser, *OSHA After a Decade: A Time for Reason*, in *CASE STUDIES IN REGULATION* 202 (Leonard W. Weiss & Michael W. Klass eds., 1981).

2. For an illustration of the causal reasoning typically used in the regulatory context, see *Troy Corp. v. Browner*, 120 F.3d 277 (D.C. Cir.), *reh'g denied*, 129 F.3d 1290 (D.C. Cir. 1997).

the court logically asks whether there is sufficient evidence to support a finding that substance *A* caused injury *X*.³

The two causal questions differ both with respect to their degree of particularity and with respect to the degree of confidence with which they must be answered. Thus, for instance, an agency often will justify imposition of a regulation by finding that substance *A* has some potential to cause some future harm to society, for example, ten premature deaths per year attributable to cancer. The agency does not have to support its causal finding with a high degree of confidence. Typically, the agency can predict with confidence only that substance *A* has the potential to produce a wide range of injuries, for example, between zero and one hundred premature deaths per year attributable to cancer.⁴ The probability that it will cause any particular level of injury, for example, ten deaths per year, is likely to be five percent or less. Similarly, the agency does not have to find a causal relationship between substance *A* and any particular case of cancer. By contrast, in a tort case, the court must find that it is more probable than not that substance *A* caused plaintiff *B*'s cancer to award damages to *B*.

This disparate approach to causation has shaped our present legal environment. There are only a handful of substances that trigger both a regulatory response and an award of tort damages. There are thousands of regulated substances that rarely, if ever, could be the subject of a successful tort action. The available evidence is sufficient to support a finding that they probably cause nontrivial injuries of some types, but it is insufficient to support a finding that they probably caused any particular injury. There are also 48,523 man-made chemicals used in commerce that are not subject to any regulation and that cannot possibly be the basis for a successful tort action.⁵ We have subjected twenty percent of those chemicals to some degree of toxicity testing and have found no causal relationship to injuries sufficient to justify either regulation or tort liability. We have conducted no tests of any type, however, to determine whether the remaining eighty percent of those chemicals cause injuries.⁶

This legal environment has provoked a great deal of controversy and has spawned scores of proposals to reform government regulation, tort law, or

3. See generally LINDA S. MULLENIX, *MASS TORT LITIGATION* 654-793 (1996).

4. See John F. Morrall III, *A Review of the Record*, *REGULATION*, Nov.-Dec. 1986, at 25.

5. See STEERING COMM. ON IDENTIFICATION OF TOXIC & POTENTIALLY TOXIC CHEMS. FOR CONSIDERATION BY THE NAT'L TOXICOLOGY PROGRAM, NATIONAL RESEARCH COUNCIL, *TOXICITY TESTING: STRATEGIES TO DETERMINE NEEDS AND PRIORITIES* 12 fig.2 (1984) [hereinafter *TOXICOLOGY TESTING*].

6. See *id.* at 11, 84 tbl.7, 94 tbl.10, 117 tbl.20.

both.⁷ Commentators who view the issues through the eyes of the victims of injuries criticize legislatures and agencies for excess timidity.⁸ They reserve their harshest criticisms for tort law, however, and particularly for the common-law requirement that a plaintiff must prove that an injury was more probably than not caused by a particular substance.⁹ Conversely, those who view the issues through the eyes of manufacturers of substances, or who favor pursuit of economic efficiency, support some variant of the common-law tort approach to causation and resist efforts to relax that approach. Many of them criticize the regulatory approach to causation on the basis that it often subjects too many substances to too much regulation.¹⁰

The debate about causation has produced numerous promising proposals for reform. In 1997, however, two new proposals surfaced that have the potential to turn a serious problem into an intractable problem. Two scholarly articles, one in *Columbia Law Review*¹¹ and the other in *Cornell Law Review*,¹² urged complete abolition of the requirement that a plaintiff prove causation in a toxic tort case. Moving in the other direction, the Third Circuit held the citizen suit provision of the Clean Water Act ("CWA") unconstitutional as applied, on the basis of the court's skepticism that a firm caused any injury when it committed 150 violations of its emissions permit.¹³ The goal of this Article is to persuade readers that we should summarily reject both of these new entrants into the great causation debate.

Part I describes and critiques the proposals to create no-cause legal regimes applicable to all toxic tort cases. Part I concludes that these proposals would impose intolerable costs on both the judiciary and society at large. Part II describes and critiques the Third Circuit's constitutional test for causation in the context of citizen suits brought to enforce the CWA. Part II concludes that the Third Circuit's approach impermissibly reallocates decision-making responsibility from Congress and agencies to courts. The Article argues that we should apply a new causation per se doctrine in cases in which a firm unlawfully exceeds the limits in its emissions permit. Ironically, while the no-cause proposals and the Third Circuit's approach obviously come from

7. See sources cited *supra* note 1.

8. See, e.g., Anita Bernstein, *Formed by Thalidomide: Mass Torts as a False Cure for Toxic Exposure*, 97 COLUM. L. REV. 2153 (1997); Wendy E. Wagner, *Choosing Ignorance in the Manufacture of Toxic Products*, 82 CORNELL L. REV. 773, 786-89, 809 (1997).

9. See, e.g., Margaret A. Berger, *Eliminating General Causation: Notes Towards a New Theory of Justice and Toxic Torts*, 97 COLUM. L. REV. 2117 (1997); Wagner, *supra* note 8.

10. See, e.g., BREYER, *supra* note 1; Morrall, *supra* note 4.

11. Berger, *supra* note 9.

12. Wagner, *supra* note 8.

13. See *Public Interest Research Group, Inc. v. Magnesium Elektron, Inc.*, 123 F.3d 111 (3d Cir. 1997).

opposite ends of the political and ideological spectrum, they share a common flaw. Both would assign to the judiciary tasks that it is not capable of performing.

I. THE PROPOSALS TO ELIMINATE THE NEED TO PROVE CAUSATION

In *Eliminating General Causation: Notes Towards a New Theory of Justice and Toxic Torts*,¹⁴ Margaret Berger argues that a plaintiff should no longer be required to prove that a toxic substance caused injury to recover from the firm that is responsible for exposing the plaintiff to the substance. Under Berger's proposal, a plaintiff could recover from a firm that exposes her to a toxic substance simply by proving that she suffered an injury of a type that might be attributable to such exposure and that the firm did not adequately test the substance to determine its toxic effects or did not adequately warn the public of those effects.¹⁵ Once a plaintiff proves exposure, injury, and negligent failure to test or warn, a defendant could avoid liability only by proving that the injury could not have been caused by exposure to the substance or that the injury was caused by exposure to another substance.¹⁶ As Berger recognizes, however, a defendant rarely could present evidence sufficient to prove either of those causal defenses¹⁷ for the same reasons that a plaintiff rarely can prove causation in a toxic tort case under the present legal regime.¹⁸ Thus, Berger proposes a pure no-cause negligence regime applicable to all toxic torts. Berger also proposes to eliminate limited corporate liability in toxic tort cases. She would subject managers, directors, and shareholders of firms to potential unlimited liability in her proposed no-cause system.¹⁹

Berger supports her proposal with the following reasoning. First, causation is the "central, decisive factor in mass tort litigation."²⁰ Second, potential plaintiffs rarely can prove causation because of the wide range of scientific uncertainty regarding the causal relationship between exposure to a substance and plaintiff's injury.²¹ Further, courts have applied demanding rules in deciding whether to admit evidence of causation and in deciding

14. Berger, *supra* note 9.

15. *See id.* at 2143-44.

16. *See id.* at 2144-45.

17. *See id.* at 2146-49.

18. *See supra* text accompanying note 9.

19. *See* Berger, *supra* note 9, at 2141-43. Berger argues that this unlimited liability will give corporate decision makers an incentive to obtain adequate information about their products. *See id.*

20. *Id.* at 2120 (citing JACK B. WEINSTEIN, *INDIVIDUAL JUSTICE IN MASS TORT LITIGATION* 148 (1995)).

21. *See id.* at 2120-29.

whether plaintiff's evidence of causation is sufficient to allow a jury to decide the case.²² Third, this requirement allows and encourages corporations to engage in irresponsible behavior. Corporations have refused to test adequately the substances they put on the market and refused to disclose the dangers posed by their products.²³ Fourth, because of the impossibility of proving causation in most cases, the tort system produces both underdeterrence of wrongful conduct and undercompensation of victims of toxic torts.²⁴

Wendy Wagner makes a generically similar but more complicated proposal in *Choosing Ignorance in the Manufacture of Toxic Products*.²⁵ Under Wagner's proposal, a plaintiff could establish "a prima facie case with proof of the following: (1) inadequate minimal testing on a product, (2) normal or foreseeable exposure to the product, and (3) serious harm that might be causally linked to exposure to the product."²⁶ Once the plaintiff establishes a prima facie case, the defendant could escape liability only by proving either that its product is "benign" or that it could not possibly have caused plaintiff's injury.²⁷ As Wagner recognizes, a defendant rarely would be able to prove either of those defenses for the same reasons that a potential plaintiff rarely can prove causation in a toxic tort case at present.²⁸ Wagner would allow the defendant the opportunity to avoid liability through one other mechanism, however. She would provide immunity from suit for manufacturers who have conducted a comprehensive battery of tests and found their product to be safe.²⁹

Wagner supports her proposed reform with a set of reasons similar to Berger's. She concludes that the current legal regime's requirement that a plaintiff prove causation in a toxic tort case produces severe adverse effects.

These adverse effects include an inadequate understanding of product safety, a lack of deterrence in the development of toxic products, undercompensation for victims who have been harmed by such products, and even the tendency of juries and some judges to nullify the causation rule when a defendant has been negligent in testing.³⁰

22. *See id.*

23. *See id.* at 2132-40.

24. *See id.* at 2133-37.

25. Wagner, *supra* note 8.

26. *Id.* at 834-35 (footnotes omitted).

27. *See id.* at 835-36.

28. *See id.*

29. *See id.* at 838-39.

30. *Id.* at 810.

A. Critique of the Proposed No-Cause Reforms

The reforms proposed by Berger and Wagner respond to real problems. Wagner does a particularly good job of documenting the ways in which the current liability rules deter manufacturers from testing their products.³¹ It is impossible to know the magnitude of the adverse effects on society caused by this unintended effect of tort law, but they could be substantial. Berger's and Wagner's no-cause proposals should be rejected, however. They would produce a series of adverse effects far worse than the adverse effects of the present legal regime. The direct adverse effects would include a massive increase in the use of scarce judicial resources to decide toxic tort cases, a massive increase in the cost of many socially beneficial products, and unavailability of many socially beneficial products.³² The indirect effects would include deterioration in the overall health of the population.³³

Berger and Wagner argue persuasively that courts are institutionally incapable of resolving in a satisfactory manner the vast majority of causation disputes that arise in toxic tort cases.³⁴ They therefore propose to shift the focus in all toxic tort cases from the causation question to the question of whether a manufacturer adequately tested its product. Both apparently believe that tort courts could answer that question more easily and more accurately than they can answer the causation question. That belief is mistaken.

Courts would experience extreme difficulty determining whether a manufacturer adequately tested a product. Courts would provide a large number of false positive answers to adequacy of testing questions, with severe adverse effects on society. Indeed, courts make that mistake with great frequency today. That flaw in the legal regime governing toxic torts is masked today by the dominance of causation disputes. In the present legal environment, an erroneous judicial determination that a manufacturer did not adequately test a product rarely has any adverse effect. As Berger and Wagner demonstrate, such a determination rarely renders a manufacturer

31. See *id.* at 774-96; see also Wendy E. Wagner, *The Science Charade in Toxic Risk Regulation*, 95 COLUM. L. REV. 1613 (1995).

32. See *infra* Part I.D.

33. See *infra* text accompanying notes 121-23.

34. See Berger, *supra* note 9, at 2120-29; Wagner, *supra* note 8, at 790-96. Proof of causation has become more difficult since Wagner and Berger wrote their articles. In *General Electric Co. v. Joiner*, 118 S. Ct. 512 (1997), the Court seemed to raise the hurdle for admission of evidence of causation by suggesting that animal studies should rarely, if ever, be admitted. See *id.* at 518. Further, the court held that a district court could exclude expert testimony on causation when only supported by insufficiently connected epidemiological studies. See *id.* at 519.

liable because a plaintiff rarely can prove causation.³⁵ In the no-cause regime proposed by Berger and Wagner, however, an erroneous judicial determination that a manufacturer failed to test a product adequately would determine the outcome in the vast majority of cases.

B. An Illustrative Application of the No-Cause Model

The fallacies that underlie the no-cause proposals can be illustrated by analyzing a hypothetical case under the proposed legal regime. Suppose that Tom Smith is diagnosed with cancer. Given the nature and stage of Tom's cancer, the prognosis is poor. His doctor tells him that he almost certainly will die of cancer within three years. Understandably, Tom begins to search for someone to blame for his illness and impending death. Tom wants the guilty party to compensate him and his surviving dependents.

Tom's search takes him to a toxicologically literate lawyer. Tom and his lawyer can quickly rule out the most obvious potential causes of his cancer. Tom has never smoked and has never been exposed to friable asbestos. In the new no-cause legal regime, however, Tom and his lawyer can identify many thousands of other promising defendants.

The toxicology literature identifies two particularly promising defendants—Starbuck's and Florida's Natural. For the past ten years, Tom drank a six ounce glass of Florida's Natural orange juice and a six ounce cup of Starbuck's coffee every morning. Both orange juice and coffee contain known animal carcinogens. Orange juice contains *d*-limonene,³⁶ while coffee contains nineteen known animal carcinogens, the most powerful of which is caffeic acid.³⁷ These are naturally occurring toxic substances, but it is hornbook law that a manufacturer can be held liable for exposing consumers to a naturally occurring toxic substance by including that substance in its product. Cigarette makers and asbestos manufacturers have both been held liable for billions of dollars under this theory.³⁸

Both Florida's Natural and Starbuck's would face formidable obstacles in any attempt to defend against Tom's tort action in a no-cause legal regime.

35. See Wagner, *supra* note 8, at 790-96; Berger, *supra* note 9, at 2120-29.

36. See Lois Swirsky Gold et al., *Rodent Carcinogens: Setting Priorities*, 258 SCIENCE 261, 263 (1992).

37. See *id.* at 262.

38. See, e.g., Milo Geyelin, *States Agree to \$206 Billion Tobacco Deal*, WALL ST. J., Nov. 23, 1998, at B9; *The Year in Review: Lawyer of the Year: Michael Moore, He Smoked Out Tobacco*, NAT'L L.J., Dec. 29, 1997-Jan. 5, 1998, at B7 (reporting multibillion dollar settlements by cigarette manufacturers); JUDICIAL CONFERENCE OF THE UNITED STATES, REPORT OF THE AD HOC COMMITTEE ON ASBESTOS LITIGATION (1991) (describing the many court cases in which manufacturers of products that contain asbestos have been held liable).

The natural ingredients of orange juice and coffee are certainly “plausible” causes of Tom’s cancer. Indeed, they are far more plausible than many of the substances that have attracted the attention of regulators. Toxicologists often use the HERP (human exposure/rodent potency) value of a substance as a measure of its relative carcinogenicity.³⁹ The HERP values of the *d*-limonene in orange juice and the caffeic acid in coffee are identical—0.04.⁴⁰ By contrast, the controversial pesticide Alar has a HERP value of 0.002⁴¹—more than an order of magnitude less than the HERP values of orange juice and coffee. Moreover, the natural ingredients in orange juice and coffee are more carcinogenic by six to eight orders of magnitude than three of the synthetic substances that the National Research Council (“NRC”) has identified as posing relatively high potential risks to humans.⁴²

Given the available scientific evidence, Florida’s Natural and Starbuck’s would have no chance of defending against Tom’s claim by arguing either that their products are “benign” or that Tom’s cancer was caused by exposure to some other substance. This would leave them with only one possible defense under the Berger and Wagner proposals. They must argue that they adequately tested the toxicity of their products and then adequately disclosed to the public the results of their testing program. The court would need to determine what constitutes adequate testing of a potentially toxic substance. This Article addresses that extraordinarily important and difficult question in detail in Part I.C. For now, a few numbers are sufficient to illustrate the potential range of answers to that question. The lowest cost test of any value—the Ames *Salmonella* microsome test (“Salmonella assay”)—costs less than \$10,000.⁴³ The tests required for a substance under the Toxic Substances Control Act (“TSCA”) may cost between \$300,000 and \$700,000.⁴⁴ The tests required to obtain Food and Drug Administration (“FDA”) approval of a proposed new drug can cost, on average, an estimated \$231 million.⁴⁵ Moreover, even compliance with the FDA’s testing protocols

39. See Gold et al., *supra* note 36, at 261.

40. See *id.* at 263 tbl.2.

41. See *id.*

42. See *id.* at 262-63.

43. See S. Stanley Young, *Do Short-Term Tests Predict Rodent Carcinogenicity?* 241 SCIENCE 1232, 1232 (1988).

44. See LYNDON B. JOHNSON SCHOOL OF PUBLIC AFFAIRS, POLICY RESEARCH PROJECT REP. NO. 50, THE TOXIC SUBSTANCES CONTROL ACT: OVERVIEW AND EVALUATION 121 (1982).

45. See Veronica Henry, *Problems with Pharmaceutical Regulation in the United States: Drug Lag and Orphan Drugs*, 14 J. LEGAL MED. 617, 617 (1993). I will use that estimate throughout this Article for lack of a better estimate. The \$231 million estimate may be unduly high for two reasons. First, it includes the cost of basic research and development, in addition to the cost of FDA-required testing. Second, it includes the cost of research, development, and testing of substances that are never approved by FDA. On the other hand, the estimate may be unduly low for another reason. The \$231

does not ensure that a firm has engaged in adequate testing. Both Wagner and Berger criticize, as inadequate, the amount of testing done on certain FDA-approved products.⁴⁶ Further, many courts have determined that compliance with the FDA's testing protocols does not satisfy a firm's common-law duty to engage in adequate testing.⁴⁷

Florida's Natural and Starbuck's would have little chance of prevailing by arguing that they adequately tested orange juice and coffee and adequately disclosed the known toxic risks posed by their products. The known animal carcinogens in orange juice and coffee have been subjected to some toxicity tests. But they have not been subjected to nearly as much testing as have many substances that have been, according to the judiciary, inadequately tested.⁴⁸ Moreover, many of the tests of orange juice and coffee have been positive.⁴⁹ Under the Berger and Wagner proposals, these positive findings would trigger a duty to engage in more extensive testing and a duty to disclose the positive results of the completed tests. Florida's Natural and Starbuck's would face a near certain decision that they failed to provide adequate warnings and that they did not adequately test their products. Therefore, in a no-cause legal regime, they would be required to compensate Tom and his survivors.

Tom could sue thousands of firms in addition to Florida's Natural and Starbuck's. If Tom chooses not to sue other firms, Florida's Natural and Starbuck's could implead them as codefendants. Tom, Florida's Natural, or Starbuck's could identify scores of other known animal carcinogens to which Tom has been exposed. Those carcinogens would include substances known to exist in all wine, beer, lettuce, root beer, apples, mushrooms, pears, plums,

million estimate was based on costs incurred between 1970 and 1982. Costs of drug research, development, and testing have increased significantly in recent years. See Nina Crimm, *A Tax Proposal to Promote Pharmacological Research, to Encourage Conventional Prescription Drug Innovation and Improvement, and to Reduce Product Liability Claims*, 29 WAKE FOREST L. REV. 1007, 1032-36 (1994). The Office of Technology Assessment estimated that the total cost of research, development, and testing required to bring a new drug to market was \$259 million to \$359 million in 1990 dollars, and that the after-tax cost of complying with FDA testing requirements was \$140 million to \$194 million per successful drug in 1990 dollars. OFFICE OF TECHNOLOGY ASSESSMENT, PHARMACEUTICAL R&D: COSTS, RISKS AND REWARDS 47-72 (1993).

46. See Wagner, *supra* note 8, at 828-30 (criticizing amount of testing of Bendectin as negligent and inadequate); Berger, *supra* note 9, at 2135 (same).

47. See *Oxendine v. Merrell Dow Pharm.*, 649 A.2d 825, 828 (D.C. 1994) (citing "numerous cases which have specifically held that the FDA prescription drug regulations and safety determinations are intended to be minimum standards which 'do not conflict with state law which sets higher standards for due care and safety in the manufacture of drugs.'" (quoting *Allen v. G.D. Searle & Co.*, 708 F. Supp. 1142, 1152 (D. Or. 1989))).

48. See *supra* note 47 and accompanying text.

49. See Gold et al., *supra* note 36, at 262-63.

peanut butter, tea, celery, carrots, bread, and chlorinated water.⁵⁰ Tom undoubtedly has been exposed to these carcinogens by thousands of firms that bake bread, operate swimming pools, and make hundreds of food products that include one of the many fruits and vegetables that contain animal carcinogens.

Additionally, there are 48,523 unregulated synthetic chemicals used in commerce.⁵¹ Eighty percent of those chemicals have not been subjected to any toxicity tests.⁵² Fifty percent of all substances that have been tested to date have been shown to be animal carcinogens.⁵³ A high percentage of all products available in the United States contain one or more of the 38,818 unregulated and untested synthetic chemicals.⁵⁴ Thus, with a little research, Tom, Florida's Natural, or Starbuck's could establish that virtually every firm from which Tom has purchased a product has exposed him to one or more potential carcinogens.

In attempting to avoid liability for Tom's cancer, each of these firms would confront obstacles similar to those confronted by Florida's Natural and Starbuck's. Under the Berger or Wagner proposals, the complete dearth of evidence suggesting any causal link between exposure to a substance and Tom's cancer would be totally irrelevant. Tom's injury "might be causally linked to exposure to the product."⁵⁵ This would be sufficient to establish a *prima facie* case for recovery from each firm. No firm in this category would have any chance of proving that its product is benign, that some other product caused Tom's injury, or that the firm adequately tested its product. Thus, each of these firms would be completely defenseless and would be held liable to Tom. That should come as no surprise, of course. Berger and Wagner intend to correct the alleged irresponsibility of these firms by exposing each firm to tort liability unless it tests all of the chemical constituents of its products.

Berger and Wagner appear not to recognize the staggering scope of their proposals. In addition to the 38,818 untested and unregulated synthetic chemicals used in commerce, there are thousands of untested, unregulated, naturally-occurring substances used in commerce.⁵⁶ The available

50. *See id.*

51. *See TOXICOLOGY TESTING, supra* note 5, at 12 fig.2.

52. *See id.* at 11, 84 tbl.7, 94 tbl.10, 117 tbl.20.

53. *See* Gold et al., *supra* note 36, at 261.

54. The United States made or imported 5.9 trillion pounds of chemicals in 1989. *See* Maurice Zeeman, *Our Fate Is Connected with the Animals*, 46 *BIOSCIENCE* 542, 544 (1996) (book review) (citing *INFORM, TOXICS WATCH* 1995 (1995)).

55. Wagner, *supra* note 8, at 835.

56. *See* Gold et al., *supra* note 36, at 261.

toxicological evidence provides no basis to distinguish between those two classes of untested, unregulated substances.⁵⁷ Nor do present legal doctrines support any such distinction.⁵⁸ Thus, in the no-cause legal environment proposed by Berger and Wagner, exposure to *any* substance would be the basis for liability in a toxic tort case unless the firm that is responsible for the exposure could prove that it engaged in adequate premarket testing. The root of this problem is the absence of any definition of "toxic substances" that can be used to discriminate among the tens of thousands of synthetic and naturally-occurring substances that have not been subjected to comprehensive testing.⁵⁹

Before I turn to the difficulties inherent in applying such a universal, outcome-determinative duty-to-test rule, it is useful to consider the enormous number of cases illustrated by Tom's case. Each year in the United States there are 1.3 million cases of cancer diagnosed⁶⁰ and over 500,000 deaths from cancer.⁶¹ Also, many other serious diseases might be causally linked to exposure to a toxic substance. For instance, in the United States, at least 117,000 children are born with birth defects each year.⁶² Teratology—the study of birth defects—was largely dormant until the 1960s.⁶³ The thalidomide tragedy greatly increased the incidence of testing of substances to determine their teratogenic potential.⁶⁴ Most substances have not been tested, of course, but the results of the limited teratological testing that has been completed roughly parallel the results of the carcinogenicity testing. A high proportion of all substances tested to date appear to have some teratogenic potential. There are nine hundred known animal teratogens.⁶⁵

57. See *id.* Naturally-occurring substances and synthetic substances have the same rate of positive test results. See *id.*

58. Manufacturers of cigarettes and asbestos have been held liable for including naturally-occurring toxic ingredients in their products. See *supra* note 38 and accompanying text.

59. See Sean D. Murphy, *Prospective Liability Regimes for the Transboundary Movement of Hazardous Wastes*, 88 AM. J. INT'L L. 24, 27-29 (1994) (reporting that there is no consistent definition of toxic substances either in international law or in domestic laws of any country).

60. See W. JOHN DIAMOND ET AL., AN ALTERNATIVE MEDICINE DEFINITIVE GUIDE TO CANCER 526 (1997).

61. See BREYER, *supra* note 1, at 6-7 (citation omitted).

62. There are 3.9 million babies born in the United States each year. See National Center for Health Statistics, Centers for Disease Control & Prevention, *Births, Marriages, Divorces, and Deaths for January 1997*, MONTHLY VITAL STATISTICS REP., Aug. 14, 1997, at 1, 1. Between three and seven percent of all babies are born with serious defects. See Patricia E. Levi, *Principles and Mechanisms of Teratogenesis*, in TERATOGENS: CHEMICALS WHICH CAUSE BIRTH DEFECTS 1, 8 (Vera M. Kolb ed., 2d ed. 1993).

63. See Levi, *supra* note 62, at 1-2.

64. See *id.* at 2.

65. See Doris K. Kolb, *Teratogenic Chemicals in Undergraduate Chemistry Laboratories*, in TERATOGENS: CHEMICALS WHICH CAUSE BIRTH DEFECTS, *supra* note 62, at 75, 79.

They include many antibiotics, soy beans, cottonseed oil, sugar, vitamin A, alcohol, and oxygen.⁶⁶

Thus, even if the universe of toxic tort cases were limited to cancer and birth defects, the courts could be required to resolve over a million toxic tort cases per year in the no-cause legal environment proposed by Berger and Wagner. Each case would look like Tom's case. Each would probably involve over one thousand defendants and many thousands of substances. With respect to each product, the central question would be whether the manufacturer of the product had adequately tested each of the substances contained in the product before it marketed the product. The answer to that question would be outcome-determinative in virtually all cases.

C. What Constitutes Adequate Testing?

The effects of the no-cause proposals depend entirely on the capability of judges and juries to determine how much testing a manufacturer must implement before it uses any substance in its products. If courts can perform that task with tolerable resource costs and accuracy, a no-cause legal environment would produce only the socially-beneficial results claimed by Berger and Wagner. If courts err in that process, however, the legal regime Berger and Wagner propose would have a wide range of serious adverse effects on society. To illustrate this potential, consider what would happen if courts held that a firm could satisfy the common-law duty to test by implementing the FDA testing protocol applicable to proposed new drugs. If courts applied this holding to the 38,878 untested, unregulated man-made chemicals now in commerce, it would impose immediate direct costs on the economy of almost nine trillion dollars.⁶⁷ That is equal to the annual U.S. domestic product. As I will explain in Part I.D, such a holding also would have devastating effects on the health of the U.S. population.

Berger and Wagner differ significantly with respect to the degree of confidence each has in the competence of courts to determine the optimal amount of testing of a potentially toxic substance. Berger expresses complete confidence in the ability of courts to make such determinations. She describes the task of determining the scope of the duty to test as "fact-finding that is well-suited to the jury's role as a representative of the community."⁶⁸ She contrasts that task with the present requirements that judges screen

66. *See id.* at 84; *Levi, supra* note 62, at 7-12.

67. 38,878 substances times \$231 million equals \$8.98 trillion.

68. *Berger, supra* note 9, at 2151.

evidence through application of the difficult *Daubert*⁶⁹ test and that juries consider scientific evidence of causation that “they cannot properly appraise.”⁷⁰

Berger also applauds the judicial decisions that have imposed liability on Merrell Dow Pharmaceuticals, the manufacturer of Bendectin,⁷¹ even though she recognizes that the many extensive studies of Bendectin have failed to produce any credible evidence that Bendectin has the potential to cause the birth defects for which its manufacturer has been held liable.⁷² In Berger’s view, the manufacturer of Bendectin should be held liable for “thousands of cases” of birth defects Bendectin may not have caused because “Merrell gambled with people’s lives.”⁷³ This characterization of Merrell’s conduct provides a good insight into Berger’s views on how juries would, and should, apply the duty to test in a no-cause environment. The manufacturer of Bendectin complied with all of the FDA’s premarket testing protocols and then commissioned extensive postmarket studies when questions were raised about Bendectin’s potential teratogenic effects.⁷⁴ The FDA found the firm’s tests sufficient to demonstrate the safety of the drug.⁷⁵ Berger obviously believes that juries would, and should, define the duty to test to require more substantial tests than those required by FDA. It would be interesting to find out whether Berger also would conclude that Florida’s Natural and Starbuck’s should be held liable in thousands (or millions) of cases because they “gambled with people’s lives.” They have engaged in much less testing of their products than Merrell and there is much stronger evidence of the toxic potential of orange juice and coffee than of Bendectin. Furthermore, Florida’s Natural and Starbuck’s expose far more people to much higher concentrations of their “toxic products” than Merrell.

Wagner does not share Berger’s faith in courts’ ability to define and apply a duty to test in a no-cause environment. Her survey of the testing literature convinces her that: (1) there is no consensus with respect to types of tests that are appropriate in various circumstances;⁷⁶ (2) the range of potential testing protocols is extraordinarily wide;⁷⁷ (3) even the most comprehensive

69. *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993).

70. Berger, *supra* note 9, at 2151.

71. *See id.* at 2146-48.

72. *See id.* at 2146.

73. *Id.* at 2148.

74. *See Richardson v. Richardson-Merrell, Inc.*, 649 F. Supp. 799, 801-03 (D.D.C. 1986).

75. *See id.* at 803.

76. *See Wagner, supra* note 8, at 780-90, 836-52.

77. *See id.*

protocols will leave many important questions unanswered;⁷⁸ and (4) the protocols at the upper end of the range are “simply too expensive.”⁷⁹

Given this situation, Wagner recognizes that courts “will not be competent to implement”⁸⁰ her proposed reform without significant assistance from other institutions. She also recognizes, “Given the large penalties associated with a failure to conduct [adequate] testing, and the enormous transaction costs associated with an unclear rule, clarity of the testing requirements must be the first priority for a reform.”⁸¹ Wagner then looks in the right directions to find institutions that offer comparative advantages over courts as sources of a clear, rational set of rules with respect to the scope of the duty to test. She urges Congress to authorize one or more agencies with toxicological expertise to develop national checklists of the tests that would satisfy the duty to test in various circumstances.⁸²

To make the process of defining the duty to test manageable, Wagner urges initial issuance of only two sets of checklists: a minimal checklist and a state-of-the-art checklist.⁸³ Wagner suggests that the minimal testing list might consist only of the relatively inexpensive Salmonella assay.⁸⁴ Any firm responsible for exposing any individual to any substance that has not been subjected to minimal testing would be liable per se for any harm that befalls that individual.⁸⁵ Conversely, a firm would be immune from liability if it implements the state-of-the-art checklist.⁸⁶ Wagner recognizes that the task of devising an appropriate state-of-the-art checklist is daunting, “[I]t will be difficult (to put it modestly) to reach consensus on a single testing regime that would provide both a reliable and cost-effective decision-tree for adequate safety testing.”⁸⁷ Despite the extreme difficulty of the task, Wagner maintains that “a clear outline of testing requirements . . . is essential to avoid extended litigation over the nature and extent of the testing requirements.”⁸⁸

Wagner’s proposal looks in the right directions for answers to complicated issues of science, economics, and public policy. The legislatively-authorized, agency-developed minimal and state-of-the-art testing checklists she proposes provide a promising start for reform of the

78. *See id.*

79. *Id.* at 850.

80. *Id.* at 841.

81. *Id.* at 837 n.238 (citations omitted).

82. *See id.* at 841-43.

83. *See id.* at 842.

84. *See id.* at 843.

85. *See id.* at 833-36.

86. *See id.* at 838.

87. *Id.* at 843 n.253.

88. *Id.* at 844.

toxic torts legal regime. Wagner's proposal is inadequate, however, because it fails to address adequately a category of substances that includes about 20,000 chemicals, including chemicals that are contained in virtually all fruits and vegetables.⁸⁹

Under Wagner's proposal, every firm that exposes individuals to any substance would be required to conduct a Salmonella assay to avoid unlimited liability for every disease contracted by any individual who is exposed to the substance. Wagner asserts that this mandate passes a cost-benefit test, given the valuable information provided by the test and its low cost.⁹⁰ The claim seems defensible. If the Salmonella assay produces negative results, a firm presumably would have no duty to conduct additional tests absent some other reason for concern about the potential toxicity of the substance. Wagner recognizes that the Salmonella assay is far from a perfect predictor of toxicity. It has a fifty percent false negative rate with respect to carcinogenicity, and it has no ability to predict teratogenic or neurotoxic effects.⁹¹ Again, however, Wagner defends the proposed use of a negative result of a Salmonella assay as *prima facie* satisfaction of the minimum duty to test with reference to a cost-benefit analysis. There are no available inexpensive tests of neurotoxicity or teratogenicity, and the available tests that can increase the accuracy of a prediction of carcinogenicity are so expensive that they are not ordinarily cost-justified in the presence of a negative Salmonella assay result.⁹² Again, Wagner's judgement seems entirely defensible.

Under Wagner's proposal, when a firm satisfies the minimum testing requirement, whether or not the test is positive, "the burden of proving causation returns to the plaintiff and the traditional tort rules determine recovery."⁹³ The problem with Wagner's proposal is that a positive test may trigger a duty to engage in additional testing under the common-law rules.⁹⁴ But Wagner argues that, under the traditional judicial approach to causation, a positive Salmonella assay would not affect the outcome of many toxic tort

89. There are 38,818 untested, unregulated synthetic chemicals plus thousands of untested naturally-occurring chemicals used in commerce. See *supra* notes 51, 52 and accompanying text. Fifty percent of all substances that have been tested to date have been shown to be animal carcinogens. See *supra* note 53 and accompanying text. Thus, it is fair to infer that about 20,000 of the untested chemicals would be shown to be animal carcinogens if they were tested.

90. See Wagner, *supra* note 8, at 843 n.257. The Salmonella assay costs less than \$10,000. See Young, *supra* note 43.

91. See Wagner, *supra* note 8, at 844 n.257.

92. See *id.*

93. *Id.* at 836.

94. See *id.* at 836.

cases.⁹⁵ A plaintiff armed only with a positive result of a Salmonella assay is highly unlikely to prevail with respect to the causation issue. Given the difficulty the plaintiff would confront in proving causation, Wagner suggests that the open-ended nature of the duty to engage in further testing when a Salmonella assay is positive would have no practical effect on the legal environment.⁹⁶

I doubt that Wagner is right on this point for four reasons. First, as Wagner documents, the existence of a single positive or inconclusive epidemiological study of a substance can “lead to plaintiffs’ verdicts and increased filings.”⁹⁷ A single positive or inconclusive epidemiological study is a low price of admission for a plaintiff to pay to obtain jury application of an open-ended duty to engage in further testing. Second, as Wagner also documents, judges and juries often “nullify” the causation requirement when they are persuaded that a firm has not adequately tested a substance.⁹⁸ Judges and juries become so angry at what they perceive to be the irresponsible conduct of the firm that they award damages in cases in which the causal evidence is extremely weak. Third, it is easy to predict that judges and juries would become angry at a firm that does not follow up tests after receiving a positive result of a Salmonella assay. Wagner’s proposal would invite that reaction and the resulting exposure to liability in every case in which a firm obtains a positive result on the Salmonella assay. Fourth, if courts adopt the other elements of Wagner’s proposal, they are likely to extend the apparent logic of Wagner’s no-cause proposal and eliminate the requirement to prove causation in cases in which a substance has produced a positive result on a Salmonella assay. Wagner would subject to unlimited per se liability any firm that exposes people to a substance that the firm has absolutely no reason to believe has any potential harmful effects. Yet, Wagner would insulate from liability a firm that exposes the public to a substance that has tested positive for carcinogenicity on the only test the firm has implemented. From the perspective of a judge who lacks Wagner’s sophisticated understanding of the testing literature, the distinction Wagner urges would seem illogical. That distinction seems totally inconsistent with the definition of negligence.⁹⁹ The positive result of the Salmonella assay obviously increases the foreseeable risk of injury attributable to the substance.

Wagner is not clear about the scope of the duty to test she proposes when

95. *See id.* at 836-37.

96. *See id.*

97. *Id.* at 817-18.

98. *See id.* at 827-32.

99. *See, e.g.,* United States v. Carroll Towing Co., 159 F.2d 169, 173 (2d Cir. 1947).

a Salmonella assay yields a positive result. She notes that, in theory, a firm that obtains positive or inconclusive results from its initial testing should "conduct continuous epidemiological studies to monitor the chemical's effect on exposed populations."¹⁰⁰ She then abandons that approach as impractical, however.¹⁰¹ She apparently believes that it is unnecessary to address this issue in detail because she does not expect it to arise in many cases. Wagner emphasizes that the Salmonella assay has a false positive rate of less than twenty percent.¹⁰² She implies that the test is so accurate that a firm ordinarily should react to a positive result by declining to market the substance unless it is willing to devote a lot of resources to an elaborate premarket testing program.¹⁰³

Wagner's approach might be defensible if the Salmonella assay actually had a relevant false positive rate of less than twenty percent. It does not. The false positive rate logically relevant to the question of human carcinogenicity is calculated by dividing the number of cases in which the Salmonella assay produces a positive result by the number of cases in which a substance is shown to induce cancer in humans at the levels at which humans are likely to be exposed to the substance. Wagner uses the term "false positive rate" to refer to a very different calculation, however. In her words, "over eighty percent of the time, the positive Salmonella assay results accurately predict cancer *in rodents*."¹⁰⁴ Thus, the test has less than a twenty percent false positive rate only if we are interested in predicting rodent carcinogenicity.

Rodent carcinogenicity massively overpredicts human carcinogenicity for two reasons.¹⁰⁵ First, there is a problem of interspecies extrapolation. Many rodent carcinogens appear not to be human carcinogens at any dose level we can observe.¹⁰⁶ Second, there is a problem of extrapolation of the dose-response curve. We determine whether a substance is a rodent carcinogen by exposing rodents to doses of the substance far in excess of the level of exposure of any human.¹⁰⁷ Thus, for instance, the study that found that saccharin is a rodent carcinogen used a testing protocol in which rodents were exposed to quantities of saccharin equivalent to 800 cans of diet soda per day.¹⁰⁸ The vast majority of rodent carcinogens are not human

100. Wagner, *supra* note 8, at 842 n.253.

101. *See id.*

102. *See id.* at 843 n.257.

103. *See id.* at 837 n.237.

104. *Id.* (emphasis added).

105. *See* Gold et al., *supra* note 36, at 261, 264.

106. *See id.* at 261.

107. *See id.* at 264.

108. *See* JERRY L. MASHAW ET AL., ADMINISTRATIVE LAW: THE AMERICAN PUBLIC LAW

carcinogens at any level of exposure remotely relevant to humans.¹⁰⁹ Rodent carcinogenicity has a false positive rate that greatly exaggerates risk when applied to humans. Thus, the Salmonella assay also has a large false positive rate relevant to prediction of human carcinogenicity.¹¹⁰

The scope of the problem created by these high false positive rates can be illustrated with reference to two types of data. First, almost every fruit and vegetable contains at least one known rodent carcinogen.¹¹¹ It does not follow that we should stop eating fruits and vegetables unless we subject each to a massive testing program. To the contrary, increasing consumption of fruit and vegetables is second only to smoking cessation as a means of reducing a person's risk of contracting cancer.¹¹² The naturally-occurring rodent carcinogens in fruits and vegetables are more toxic than many of the synthetic chemicals we regulate. Nevertheless, they do not pose nearly enough danger to justify a product ban, a per se liability regime, or a legal mandate to engage in further testing. Second, half of all substances that have been tested to date have been shown to be rodent carcinogens.¹¹³ Thus, it is likely that about half of the 38,818 untested synthetic chemicals and of the thousands of untested naturally-occurring chemicals used in commerce will prove to be rodent carcinogens. Therefore, Wagner's proposal provides an inadequate alternative to the current regime because rodent carcinogenicity tests have such a high rate of false positives when applied to humans.

D. Costs of a No-Cause Rule

Adoption of a no-cause toxic tort regime would impose four types of costs on society. The most direct and obvious costs are the costs of the testing itself. Those direct costs produce two indirect costs: a reduction in the availability of socially-beneficial products and a reduction in the quality of health of the U.S. population. The Wagner proposal would impose costs approximately one-half as large as the costs imposed by the Berger proposal, because about one-half of the substances subjected to the Salmonella assay

SYSTEM 126 (3d ed. 1992).

109. See Gold et al., *supra* note 36, at 264. The same problems affect teratological determinations. There are 900 known rodent teratogens, but only 30 are believed to be human teratogens. See Kolb, *supra* note 65, at 79.

110. See Gold et al., *supra* note 36, at 261. Gold et al. attribute this exaggerated risk to testing at the maximum tolerated dose in rodents, which "frequently can cause chronic cell killing and consequent cell replacement (a risk factor for cancer that can be limited to high doses)." *Id.*

111. See Gold et al., *supra* note 36, at 261.

112. See *id.* at 264. See generally NATIONAL RESEARCH COUNCIL, DIET AND HEALTH: IMPLICATIONS FOR REDUCING CHRONIC DISEASE RISK (1989).

113. See Gold et al., *supra* note 36, at 261.

would test negative.

Both proposals would also impose direct costs in the form of commitment of scarce judicial resources to the task of applying the open-ended duty to test to tens of thousands of substances. Given the basic characteristics of our judicial system—heavy reliance on juries to resolve all issues of fact and decentralized allocation of lawmaking responsibility among fifty jurisdictions—each of the tens of thousands of substances would be the subject of multiple trials. If each substance were the subject of only a single trial in each jurisdiction, Berger's pure no-cause proposal would require approximately one million trials in which a judge and jury would have to decide whether a firm adequately tested a substance before including it in a product. The Wagner proposal would require about half as many proceedings of that type.

Estimating the testing costs of a no-cause rule requires prediction of the results of hundreds of thousands of jury trials with respect to the adequacy of testing of tens of thousands of substances. That is a daunting task. There are good reasons to predict, however, that juries would apply a duty to test at least as demanding as the FDA testing protocol for approval of new drugs. First, juries often have held that substances that had been subjected to the FDA protocol were inadequately tested.¹¹⁴ It would take only a few such decisions to convince manufacturers that the FDA protocol is the minimum legally safe level of testing. Second, there is no finite limit on the amount of testing that can enhance our understanding of the potential risks that are posed by a substance. We still lack a good understanding of the scope and magnitude of many of the risks posed by asbestos and thalidomide even after we have spent billions of dollars over a period of several decades and conducted hundreds of tests of both.¹¹⁵ Third, determining the optimal level of testing of a substance requires application of an extraordinarily complicated combination of scientific and economic expertise. Juries are not good at performing tasks of that type.¹¹⁶ Finally, each case would pit a sympathetic injured individual against a large institution. Juries have powerful systemic biases against defendants in that context.¹¹⁷

Indeed, we can use Berger's powerful visceral reaction to the adequacy of the testing programs conducted by numerous firms as a rough proxy for the jury verdicts we could expect in most cases. Berger characterizes as

114. See *supra* note 47.

115. See Bernstein, *supra* note 8, at 2156; Berger, *supra* note 9, at 2119 n.7.

116. See Huber, *supra* note 1, at 314-26.

117. See James K. Hammit et al., *Tort Standards and Jury Decisions*, 14 J. LEGAL STUD. 751, 754-56 (1985).

“irresponsible” testing programs that met, or surpassed, the FDA requirements for approval of a new drug.¹¹⁸ The estimated testing costs of the complete no-cause regime proposed by Berger is at least ten trillion dollars.¹¹⁹ That is a conservative estimate based on the assumption that no jury would find inadequate a testing program equivalent to the FDA protocol. Of course, that assumption is unsupportable. Just a few jury verdicts finding such a program inadequate would force firms to incur much higher testing costs, and it is easy to predict at least a few jury verdicts of that type.¹²⁰ On the same conservative basis, the Wagner proposal would cost about five trillion dollars.

Many firms would withdraw a substance from the market rather than spend the \$231 million required to test the substance to the extent necessary to minimize the risk of incurring liability for every case of cancer and every defective baby born in the United States. The number of substances withdrawn would increase, of course, if even a few juries found that conformance with FDA testing protocols is inadequate. Tens of thousands of socially-beneficial products containing those substances would therefore be withdrawn from the market.

Finally, the health of the U.S. population would deteriorate significantly for three reasons. First, many healthful products would be withdrawn from the market. We could still buy apples but probably not apple pie, spinach but probably not spinach quiche, etc. The reduced availability of products that contain fruits and vegetables would reduce the average intake of fruits and vegetables. That, in turn, would increase the incidence of cancer significantly.¹²¹ Second, some healthful products would remain on the market, but at the higher price necessary to reflect the cost of the judicially-mandated testing. Thus, for instance, orange juice probably would remain available because consumer demand for orange juice is so high that firms would spend the millions of dollars necessary to test it adequately. Products of that type would be more expensive, however, so their consumption would decline. That also would increase the incidence of cancer and many other diseases. Third, the rate of introduction of new synthetic substances on the market would decline dramatically. A firm would have to be confident of

118. Berger, *supra* note 9, at 2146-48.

119. Ten trillion dollars would cover the cost of subjecting 43,290 substances to the FDA testing protocol. There are 38,818 untested man-made chemicals plus several thousand untested naturally-occurring chemicals that are used in commerce. Moreover, the vast majority of the ten thousand plus substances that have been subjected to some testing have not been subjected to any testing program remotely comparable to the FDA protocol.

120. See *supra* note 47.

121. See NATIONAL RESEARCH COUNCIL, *supra* note 112, at 657-58.

obtaining an extraordinarily lucrative market to justify spending hundreds of millions of dollars for the right to begin selling a new substance. That also would have serious adverse health effects. On average, new substances pose lower health risks than older substances.¹²² The two most serious toxic substance problems we have encountered to date involve two ancient, naturally-occurring substances—*asbestos* and *tobacco*.¹²³

E. Summary of Evaluation of No-Cause Proposals

The no-cause toxic tort regimes proposed by Berger and Wagner should be summarily rejected. They share the same fatal defect—they would impose on the courts vast new decision-making responsibilities. Courts are inappropriate institutions to bear those responsibilities. Courts lack the competence to bear responsibilities of this type in three different senses of the word *competence*. They are technically incompetent, in the sense that they lack the sophisticated understanding of toxicology and economics necessary to define the scope of the duty to test substances to determine their toxic potential. They are procedurally incompetent, in the sense that the procedures they can use to gather and to evaluate the massive data relevant to decisions of this type are totally inadequate to the task. Finally, they are politically incompetent. A decision to adopt a no-cause toxic tort regime would have massive implications for human health and for the performance of the economy. Any decision of that type should be made by institutions that are more politically accountable than courts.

It would be neither fair nor accurate, however, simply to treat these two no-cause proposals as rough equivalents. The Berger and Wagner proposals differ significantly. Wagner recognizes the institutional limitations of the courts and strives to avoid burdening them with new responsibilities they cannot fulfill. I believe that her proposal is inadequate because it unintentionally assigns to courts daunting new responsibilities that Wagner recognizes to be beyond their institutional competence. Wagner is looking for solutions in the right direction, however. She is attempting to allocate responsibilities to the combination of institutions—legislatures and agencies—that are far more capable of fulfilling those responsibilities. She may be able to supplement her initial proposal with additional elements that would provide a promising means of addressing the problems she documents

122. See generally Peter Huber, *The Old-New Division in Risk Regulation*, 69 VA. L. REV. 1025 (1983).

123. *Asbestos*, a family of naturally occurring minerals, was used broadly by the ancient Greeks and Romans. See PAUL BRODEUR, *OUTRAGEOUS MISCONDUCT* 10-11 (1985).

without creating the unintended adverse collateral effects ascribed to her proposal.

II. THE THIRD CIRCUIT'S CONSTITUTIONAL TEST FOR CAUSATION

The other new entrant in the great causation debate is the Third Circuit's decision holding the citizen suit provision of the Clean Water Act ("CWA")¹²⁴ unconstitutional as applied because the plaintiffs could not prove that unlawful emissions caused them injury.¹²⁵ That entry in the debate obviously comes from the opposite end of the political and ideological spectrum from the no-cause proposal. Ironically, however, it is premised on the same basic misunderstanding of the relative competence of alternative legal institutions. Like the Berger no-cause proposal, the Third Circuit's approach burdens courts with responsibilities they cannot bear and fails to appreciate the major comparative advantages of legislatures and agencies in determining causal relationships in the context of toxic substances.

In *Public Interest Research Group, Inc. v. Magnesium Elektron, Inc.*,¹²⁶ the Third Circuit announced and applied a constitutional test for standing which requires courts to determine whether substance *A* causes injury *X*.¹²⁷ Under the Third Circuit's test, a plaintiff must establish the causal relationship between substance *A* and injury *X* to the satisfaction of a court even if an agency, acting under authority delegated by Congress, has already determined that substance *A* causes injury *X*. This new approach to causation has the same basic flaws as the proposed new no-cause legal regimes. It is based on a serious misunderstanding of the relative competence of courts, legislatures, and agencies.

The plaintiffs ("PIRG") in *Magnesium Elektron* filed an action under the citizen suit provision of the CWA. That provision authorizes "any citizen" to bring an action for civil penalties and injunctive relief against anyone who violates the CWA.¹²⁸ Congress used considerable care in drafting the citizen suit provision of CWA in a way that would keep courts from having to become enmeshed in difficult scientific or policy disputes. Three features of the CWA and the citizen suit provision illustrate the congressional pursuit of this goal. First, the CWA is drafted in a manner that equates violation of the CWA with violation of a National Pollutant Discharge Elimination System

124. See 33 U.S.C. § 1365 (1994).

125. See *Public Interest Research Group, Inc. v. Magnesium Elektron, Inc.*, 123 F.3d 111 (3d Cir. 1997).

126. 123 F.3d 111 (3d Cir. 1997).

127. See *id.* at 119-23.

128. 33 U.S.C. § 1365(a).

("NPDES") permit.¹²⁹ The judicially-enforceable provisions of those permits consist of precise numerical limits on the permissible levels of discharges of various substances, coupled with precise rules with respect to record-keeping, testing, and reporting.¹³⁰ The terms of the permit are determined by the Environmental Protection Agency ("EPA") and state environmental regulatory agencies. This feature of the CWA renders it unnecessary for a court to address any of the difficult scientific and policy issues concerning the appropriate level of emissions of a substance.

Second, a plaintiff cannot bring an action under the citizen suit provision of the CWA without first providing the EPA and the relevant state agency sixty days notice of his or her intent to do so.¹³¹ Third, a court cannot entertain an enforcement action brought by a citizen "if the [EPA] or State has commenced and is diligently prosecuting a[n] . . . action . . . to require compliance with the standard, limitation, or order."¹³² These two conditions on citizen suits provide additional means of insulating courts from the need to become enmeshed in scientific or policy disputes. If the EPA or a state agency decides that a planned citizen suit raises a scientific or policy issue of concern to the agency, it can block the citizen suit by stepping into the shoes of the citizen. In this legal environment, the courts are assigned a limited but important role well within the competence of courts. A court's sole responsibility is to enforce the congressionally-authorized, agency-created terms of an NPDES permit. The Third Circuit, however, decided to undertake a far more ambitious role in this legal regime.

PIRG sought civil penalties and injunctive relief against Magnesium Elektron on the basis of numerous alleged violations of its emissions permit.¹³³ Magnesium Elektron sought dismissal on the basis that PIRG lacked standing to bring the action.¹³⁴ The district court held that PIRG had

129. See 33 U.S.C. § 1365(f); see also 33 U.S.C. § 1342.

130. Many permits also contain a broadly worded prohibition on discharges that would violate water quality standards. Most courts have held that those provisions are not enforceable in a citizen suit, however. See, e.g., *Oregon Natural Resources Council v. U.S. Forest Serv.*, 834 F.2d 842, 848-50 (9th Cir. 1987). At least one court has held that they are enforceable. See *Northwest Env'tl. Advocates v. City of Portland*, 56 F.3d 979, 985-90 (9th Cir. 1995). That decision shares the same basic flaw as the Third Circuit's decision in *Magnesium Elektron*. It requires courts to perform tasks they are institutionally incapable of performing. See Bruce Allen Morris, *The Oregon Misstep and the Texas Two Step: Two Recent Appellate Cases Expand CWA Citizen Suits*, NATURAL RESOURCES & ENV'T, Fall 1996, at 50.

131. See 33 U.S.C. § 1365(b)(1)(A).

132. *Id.* § 1365(b)(1)(B).

133. See *Public Interest Research Group, Inc. v. Magnesium Elektron, Inc.*, 123 F.3d 111 (3d Cir. 1997).

134. See *id.* at 115.

standing.¹³⁵ The district court relied on affidavits submitted by several PIRG members to satisfy the “particularity” and “imminence” elements of standing.¹³⁶ Magnesium Elektron’s emissions flow into the Wickecheoke Creek, which flows into the Delaware River.¹³⁷ Each affiant stated that he or she regularly uses the Delaware River for a variety of recreational purposes and each described a variety of ways in which he or she is injured by the existence of pollutants in the River.¹³⁸ In finding that PIRG had standing, the district court relied in part on studies that demonstrated that the substances emitted by Magnesium Elektron have the potential to cause injuries to a river and to its aquatic biota. In an earlier decision, the Third Circuit upheld the district court’s decision on standing.¹³⁹

The district court then proceeded to the merits of the case. It found that Magnesium Elektron had committed 150 violations of its emissions permit.¹⁴⁰ It also issued an injunction prohibiting Magnesium Elektron from engaging in future violations and imposed civil penalties.¹⁴¹ The district court took one other action that proved to be important, however. In the penalty phase, it admitted the affidavit of a limnologist retained by Magnesium Elektron.¹⁴² That affidavit expressed the opinion that Magnesium Elektron’s illegal emissions caused no harm to the Wickecheoke Creek because of certain unusual characteristics of the water.¹⁴³ On the basis of that affidavit, the district court found that the unlawful emissions caused no harm to the

135. See *Public Interest Research Group, Inc. v. Magnesium Elektron, Inc.*, No. 89-3193 (JCL), 1992 WL 16314 (D.N.J. Jan. 23, 1992).

136. *Id.* In *Lujan v. Defenders of Wildlife*, 504 U.S. 555 (1992), the Supreme Court held that a membership organization lacked standing to obtain review of an agency decision because the members of the group had not established that agency action would cause them “particularized” and “imminent” injury. The decision in *Lujan* is both difficult to interpret and controversial. See Symposium, *Twenty-Fourth Annual Administrative Law Issue*, 42 DUKE L.J. 1141 (1993); Cass R. Sunstein, *What’s Standing After Lujan? Of Citizen Suits, Injuries, and Article III*, 91 MICH L. REV. 163 (1992). The fatal flaw in the affidavits of the individuals in *Lujan* was their failure to establish a sufficient connection to the situs of the injury. The injuries would take place in remote locations in other countries, and the affidavits did not include statements that the individuals planned to visit those locations at some time in the near future. In *Magnesium Elektron*, the Third Circuit recognized that the individuals’ affidavits did not share this flaw. In the majority’s words, “we have no doubt that PIRG’s members use the Delaware River.” 123 F.3d at 120.

137. See *Magnesium Elektron*, 123 F.3d at 115.

138. See *id.* at 116 (citing *Magnesium Elektron*, 1992 WL 16314, at *14-*15). On appeal, the Third Circuit affirmed. See *id.* (citing *Public Interest Research Group, Inc. v. Magnesium Elektron, Inc.*, 983 F.2d 1052 (3d Cir. 1992)).

139. See *Magnesium Elektron*, 983 F.2d 1052 (3d Cir. 1992).

140. See *Magnesium Elektron*, 123 F.3d at 115 (citing *Magnesium Elektron*, 1992 WL 16314).

141. See *id.* at 115-16 (citing *Magnesium Elektron*, 1992 WL 16314).

142. See *id.* at 116 (citing *Public Interest Research Group, Inc. v. Magnesium Elektron, Inc.*, No. 89-3193 (JCL), 1995 WL 461252 (D.N.J. Mar. 9, 1995)).

143. See *id.* at 116, 123 (citing *Magnesium Elektron*, 1995 WL 461252).

creek.¹⁴⁴ Neither the affidavit nor the district court opinion addressed the issue that formed the basis for the prior holding that PIRG had standing. The holding was based on the finding that Magnesium Elektron's emissions caused injury to the Delaware River, which in turn caused harm to PIRG's members.¹⁴⁵

Magnesium Elektron then appealed the district court's decision for a second time. It attempted to reargue the issue of PIRG's standing. A two-judge majority of a Third Circuit panel held that the standing issue was so important that it justified a departure from the law of the case doctrine.¹⁴⁶ The majority then held that the affidavit of the limnologist and the district court's finding of no harm to the creek rebutted PIRG's claim to standing.¹⁴⁷ The majority held that PIRG lacked standing, reasoning: (1) PIRG had the burden of proving that Magnesium Elektron's emissions caused harm to water quality at each stage of the proceeding, including the penalty stage,¹⁴⁸ (2) the affidavit and finding created doubt that Magnesium Elektron's illegal emissions caused harm either to Wickecheoke Creek or to the Delaware River;¹⁴⁹ (3) in that situation, PIRG had the burden to submit additional evidence sufficient to establish a specific causal relationship between the emissions and harm to either the creek or the river;¹⁵⁰ (4) PIRG failed to meet that burden;¹⁵¹ and, therefore, (5) the case must be dismissed for lack of

144. See *id.* at 116 (citing *Magnesium Elektron*, 1995 WL 461252).

145. See *Magnesium Elektron*, 1992 WL 16314.

146. See *Magnesium Elektron*, 123 F.3d at 116-19. The law of the case doctrine "directs courts to refrain from re-deciding issues that were resolved earlier in the litigation." *Id.* at 116.

147. See *id.* at 119-25.

148. See *id.* at 117.

149. See *id.* at 119.

150. See *id.*

151. See *id.* at 119-23. At one point in the opinion, the majority characterizes the fatal defect in the individuals' affidavits as a failure to establish an "injury," as opposed to a failure to establish a causal relationship between the illegal emissions and an injury. See *id.* at 121-22. The majority obviously felt compelled to engage in this characterization game to avoid recognizing that its holding is inconsistent with the holding in a prior circuit opinion. See *Public Interest Research Group, Inc. v. Powell Duffryn Terminals Inc.*, 913 F.2d 64 (3d Cir. 1990). *Powell Duffryn* held that an affidavit establishes a sufficient causal relationship if it states

that a defendant has (1) discharged some pollutant in concentrations greater than allowed by its permit (2) into a waterway in which the plaintiffs have an interest that is or may be adversely affected by the pollutant and that (3) this pollutant causes or contributes to the kinds of injuries alleged by the plaintiffs.

Id. at 72.

The majority's characterization does not work. The majority uses causal reasoning throughout its opinion. Thus, for instance, the majority says at one point in the opinion, "Here, we have no doubt that PIRG's members use the Delaware River. On the other hand, we are less confident that MEI's discharges have or will cause any injury to that waterway." *Magnesium Elektron*, 123 F.3d at 120 (emphasis added). In another passage, the majority says that "the only way PIRG could have met its injury requirement was to show that MEI's discharge violations posed a threat of injury to the

standing.¹⁵²

The dissenting judge criticized the majority on many grounds, including: (1) PIRG had no reason to believe that standing remained a live issue during the penalty phase of the proceeding; (2) PIRG had no notice that it had any burden to produce additional evidence that Magnesium Elektron's illegal emissions caused harm to water quality during the penalty phase; (3) the affidavit of the limnologist addressed only harm to water quality in the Creek and not harm to water quality in the Delaware River; (4) it is entirely plausible that Magnesium Elektron's illegal emissions caused harm to water quality in the Delaware River even if the court were to accept as accurate all of the opinions expressed in the affidavit of the limnologist; (5) it is entirely plausible that PIRG could prove that harm if it were given an opportunity to do so; and, (6) the court should have remanded the standing issue to the District Court to provide PIRG an opportunity to prove that Magnesium Elektron's illegal emissions caused harm to the water quality of the Delaware River.¹⁵³

A. Critique of the Third Circuit Test

The majority opinion in *Magnesium Elektron* is seriously flawed in many respects, some of which are described in the dissenting opinion.¹⁵⁴ To fully appreciate the misunderstandings that infect the opinion, however, it is necessary to understand the procedures through which the EPA and state agencies issue emissions permits. An emissions permit contains explicit numerical ceilings applicable to all pollutants a facility is authorized to emit. These numerical limits have one of two sources. Some are technology based, predicated on the agency's determination that the owner of the facility should use available technology that is capable of limiting its emissions of substance

members' recreational interests in the Delaware River and Raritan Canal." *Id.* at 122 (emphasis added).

In several passages, the majority suggests that the fatal defect in petitioner's case for standing was its failure to prove that the Delaware River is polluted. *See, e.g., id.* at 121. It is hard to take that assertion seriously. The longstanding water quality problems in the Delaware River are well known to anyone who reads or who has any contact with the river. *See generally* Richard C. Albert, *The Historical Context of Water Quality Management for the Delaware Estuary*, 11 *ESTUARIES* 99 (1988). This is the kind of fact that any court should notice. *See* 2 KENNETH CULP DAVIS & RICHARD J. PIERCE, JR., *ADMINISTRATIVE LAW TREATISE* §§ 10.5-.6 (3d ed. 1994); *see also* *Associated Gas Distribs. v. Federal Energy Regulatory Comm'n*, 824 F.2d 981, 1008 (D.C. Cir. 1987) (party does "not need to conduct experiments in order to rely on the prediction that an unsupported stone will fall").

152. *See Magnesium Elektron*, 123 F.3d at 125.

153. *See id.* at 125-26 (Lewis, J., dissenting).

154. *See id.*; *see also supra* note 151.

A to no more than X units.¹⁵⁵ Others are water quality-based limits.¹⁵⁶ Agencies establish those limits by determining whether there is a “reasonable potential” for emissions of substance A above level X “to cause or contribute to, an excursion above” the water quality standards applicable to the water bodies potentially affected by the emissions.¹⁵⁷

The district court found that Magnesium Elektron had violated four provisions of its emissions permit. It had repeatedly exceeded the numerical limits on thermal discharges, emissions of salt, and emissions of total organic carbon, and it had repeatedly violated the reporting conditions of its permit.¹⁵⁸ The emissions limit applicable to thermal discharges is technology based. The emissions limits applicable to salt and total organic carbon are water quality based. Specifically, the permitting agency determined that emissions of salt or total organic carbon above the limits set in the permit would harm the water quality of the Delaware River.¹⁵⁹ The majority opinion is seriously flawed even with respect to its treatment of the violations of the technology-based limit and of the reporting conditions.¹⁶⁰ The flaws in the opinion are easiest to understand, however, in the context of the violations of the water quality-based emissions limits.

The most obvious flaw is institutional. The court should not even have considered the affidavit of Magnesium Elektron’s limnologist on the issue of whether its illegal emissions caused harm to the creek and the river. In the case of the water quality-based emissions limits, the issue had already been resolved by the permitting agency.

An applicant for an emissions permit has access to an elaborate

155. See 33 U.S.C. §§ 1311(b), 1314(b), 1317(a) (1994). See generally *Morris*, *supra* note 130, at 50.

156. See 33 U.S.C. § 1313; see also 40 C.F.R. § 122.44(d) (1997) (describing manner in which permit writers must correlate emissions limits with water quality standards). See generally *Morris*, *supra* note 130, at 50.

157. *In re Broward County, Fla.*, NPDES Appeal No. 95-7, 1996 WL 514111, at *13 n.2 (E.P.A. Aug. 27, 1996) (citations omitted) (order denying review).

158. See *Magnesium Elektron*, 123 F.3d at 115, 123.

159. The limit applicable to salt was the product of negotiations with the Delaware River Basin Commission. See *Stipulation Between Magnesium Elektron, Department of Environmental Protection of the State of New Jersey, and Delaware River Basin Commission* (July 9, 1979). The limit on total organic carbon was determined through application of a computer model that predicts the level of dissolved oxygen in the river as a function of emissions of oxygen demanding substances. See generally *Albert*, *supra* note 151, at 103-04, 106.

160. The difference between technology-based limits and water quality-based limits is not as stark as the names imply. An applicant for a permit can apply for modifications of technology-based limits based in part on water quality. See 33 U.S.C. § 1311(g) (1994).

Violations of reporting requirements cause harm to all users of a water body, since the reported emissions data is used to monitor water quality and to determine the level of emissions that can be permitted without violating water quality standards.

multitiered set of procedures for determining whether its emissions cause harm to water bodies.¹⁶¹ That decision-making process is described in, and illustrated by, the multiple agency decisions with respect to the application of the Broward County Public Works Department.¹⁶² Broward applied for a permit that would authorize it to emit a large quantity of total residual chlorine ("TRC"). The EPA regional office published a draft permit that would have allowed Broward to emit a smaller quantity of TRC. The regional office also provided an explanation of the bases for the conditions in the draft permit. Broward submitted comments on the draft permit in which it maintained, among other things, that the TRC limit in the draft permit was based on an erroneous finding that Broward's emissions have the reasonable potential to cause a violation of Florida's water quality criteria for TRC. Broward further alleged that the test species of aquatic biota specified in the draft permit are not significant to the indigenous aquatic community. The regional office found those comments unpersuasive, rejected Broward's request for an evidentiary hearing, and issued a permit containing the same TRC limits as the draft permit.¹⁶³

Broward appealed to the EPA Environmental Appeals Board. The Board concluded that the regional office had not adequately supported its findings with respect to either the causal relationship between Broward's emissions and the water quality standards or with respect to the presence of the test species in the indigenous environment.¹⁶⁴ It remanded the proceeding to the regional office with instructions that it supplement the record and reconsider its findings with respect to those issues.¹⁶⁵ On remand, the regional office conducted further proceedings and supplemented the record on those issues. It reissued the permit with the same limit on TRC emissions. Broward then appealed again. This time, however, the Appeals Board upheld the findings of the regional office as adequately supported by the extensive evidence in the augmented record.¹⁶⁶ The Appeals Board also noted that Broward had the right to obtain reconsideration of the limits in its permit in the future if it believed that changes in circumstances or in the available evidence justified a

161. See Procedures for Decisionmaking, 40 C.F.R. § 124 (1997); see also Nancy B. Firestone & Elizabeth C. Brown, *Ensuring the Fairness of Agency Adjudications: The Environmental Appeals Board's First Four Years*, 2 ENVTL. LAW. 291, 321-25 (1996).

162. See *Broward County*, 1996 WL 514111; *In re Broward County, Florida, NPDES Appeal No. 92-11*, 1993 WL 208895 (E.P.A. June 7, 1993).

163. See *Broward County*, 1996 WL 514111, at *2-*3.

164. See *Broward County*, 1993 WL 208895, at *5, *7.

165. See *id.* at *10.

166. See *Broward County*, 1996 WL 514111, at *5-*8.

finding that it could emit more TRC without harming water quality.¹⁶⁷ Broward declined to avail itself of its right to obtain judicial review of the permitting agency's decision.

The *Broward* case illustrates four related points. First, the water quality-based limits on emissions contained in a permit are predicated on an agency's determination that emissions above that level cause harm to a potentially affected body of water and the aquatic biota it supports. Second, an applicant for a permit has ample opportunities to contest the agency's findings with respect to causation during the permitting process. Third, the applicant has the right to obtain judicial review of the agency's findings with respect to causation.¹⁶⁸ Fourth, the applicant has the right to petition to obtain an increase in its allowable emissions if it believes that it can emit more of a substance without causing harm to relevant water bodies.

In this situation, it is well established that a court is precluded from making a finding in an enforcement proceeding that differs from the agency's finding.¹⁶⁹ The only court that has any power to act in a manner contrary to the agency's finding is a court that receives a timely petition to review the agency's permitting decision.¹⁷⁰ Even then, the reviewing court's powers are limited. It must uphold the agency's action unless it is arbitrary and capricious.¹⁷¹ It cannot substitute its findings for those of the agency.¹⁷² Moreover, it cannot accept evidence that was not in the record before the agency, except in narrow circumstances that did not exist in *Magnesium Elektron*,¹⁷³ and it cannot consider arguments that were not made to the agency.¹⁷⁴ *Magnesium Elektron* submitted the affidavit of its limnologist to the wrong forum. If it wanted to try to establish that emissions above the level authorized by its permit do not harm water quality, it should have filed a petition to amend its permit with the issuing agency.

167. See *id.* at *9.

168. See 33 U.S.C. § 1369(b)(1) (1994).

169. Section 1369(b)(1) authorizes judicial review of any permitting decision within 120 days of the decision. Section 1369(b)(2) forbids judicial review of the agency's decision in any enforcement proceeding. Such limitations on judicial review are valid and must be respected by a court. See *Adamo Wrecking Co. v. United States*, 434 U.S. 275 (1978). See generally 2 DAVIS & PIERCE, *supra* note 151, § 15.2; 3 DAVIS & PIERCE, *supra* note 151, § 17.8.

170. The petition for review must be filed within 120 days of the issuance of the permit. See 33 U.S.C. § 1369(b)(1).

171. See generally 2 DAVIS & PIERCE, *supra* note 151, § 11.4.

172. For an overview of judicial review of agency adjudications, see *id.* at §§ 11.1-11.5.

173. See 33 U.S.C. § 1369(c); see also S. REP. NO. 92-414 (1971), reprinted in 1972 U.S.C.A.N. 3668, 3745 (courts should not reanalyze technological considerations in enforcement proceeding).

174. See 2 DAVIS & PIERCE, *supra* note 151, § 15.8.

B. The Third Circuit Test Violates Separation of Powers Principles

Separation of powers principles forbid a court from finding that a causal relationship does not exist after an agency has found that the causal relationship does exist. Congress assigned the task to an agency and not to the courts. Congress only authorized courts to engage in limited scope review of the agency decisions. Congress also instructed courts to enforce emissions permits at the behest of any citizen. A court cannot act in ways that are inconsistent with congressional commands unless it has a constitutional basis for doing so.

The Third Circuit relied on the Article III limitation on judicial power to justify its refusal to enforce the congressional command at issue in *Magnesium Elektron*.¹⁷⁵ It used a two-step reasoning process. First, a plaintiff must prove injury in fact caused by defendant's conduct as an Article III constitutional prerequisite to the exercise of judicial power.¹⁷⁶ Second, the plaintiff failed to prove one of the elements of causation, that is, the emissions injured the potentially affected bodies of water.¹⁷⁷ That reasoning process does not work in this context, however, because the permitting agency had already made the finding of causation pursuant to a congressional delegation of the power to do so. In this situation, a court called upon to enforce the permit cannot second-guess the agency's finding.¹⁷⁸

The irony in the Third Circuit's opinion is readily apparent. The court relied on separation of powers—the Article III limitation on judicial power—to justify an action that clearly violates separation of powers principles. Article III is designed to confine the role of the judiciary within boundaries appropriate to the characteristics of that institution.¹⁷⁹ Yet, the Third Circuit relied on Article III as a justification for a significant expansion of the judicial role that takes power away from the politically accountable branches of government. This is a classic illustration of institutional “aggrandizement”—a practice the Supreme Court has frequently condemned as a violation of separation of powers.¹⁸⁰

175. See *Public Interest Research Group, Inc. v. Magnesium Elektron, Inc.*, 123 F.3d 111, 118 (3d Cir. 1997).

176. See *id.* at 120-22.

177. See *id.* at 122-25.

178. See *supra* notes 169-74 and accompanying text.

179. See *Valley Forge Christian College v. Americans United for Separation of Church & State, Inc.*, 454 U.S. 464, 471-74 (1982); *Warth v. Seldin*, 422 U.S. 490, 498-500 (1975); see also Antonin Scalia, *The Doctrine of Standing as an Essential Element of the Separation of Powers*, 17 *SUFFOLK U. L. REV.* 881 (1983).

180. See, e.g., *Buckley v. Valeo*, 424 U.S. 1, 120-24 (1976). See generally 1 DAVIS & PIERCE, *supra* note 151, § 2.4.

C. Causation Per Se

The easiest way to understand the appropriate role of a court in a case like *Magnesium Elektron* is by analogy to the negligence per se doctrine.¹⁸¹ In a common-law negligence case, some combination of judge and jury must apply the familiar formula for determining negligence first announced by Learned Hand in *United States v. Carroll Towing Co.*¹⁸² In many cases, however, that is an extraordinarily difficult decision-making process.¹⁸³ It often requires access to, and analysis of, extensive, complicated data. It also often requires comparison of incommensurable values, such as, risks to life or health versus expenditures of scarce resources. In the absence of applicable statutes or regulations, judges and juries have no choice but to perform those tasks as well as they can—at high costs and with high rates of error. If a legislature or an agency has already performed the difficult tasks of gathering the relevant data, analyzing that data, and comparing the conflicting values at stake, however, no court believes that it has either the duty or the discretion to second-guess the results of that decision-making process.¹⁸⁴ Legislatures and agencies are vastly superior to courts for purposes of performing each of those functions. Courts acknowledge those comparative institutional advantages by routinely applying the negligence per se doctrine. By invoking that doctrine, the courts also further many other collateral goals. They increase the predictability of the legal system, they reduce the transaction costs of the legal system, and they increase the efficacy of the rules that legislatures and agencies issue.

A case like *Magnesium Elektron* provides a perfect context for announcing a new doctrine of causation per se. The analogy to negligence per se is perfect. The legislature has assigned to an agency the task of determining the level at which emissions of a substance causes harm to water bodies. The agency has performed that task and expressed the results in the form of a specific, easily enforced rule. A court should accord that decision the same respect it accords an agency decision that sets the speed limit in a particular location at thirty-five miles per hour or that requires a vessel to have a specified number of lifeboats.

In this situation, it makes no sense to require a plaintiff in an enforcement action to prove that particular violations of an emissions permit caused harm to particular water bodies. That would be an extraordinarily difficult and

181. See KENNETH S. ABRAHAM, *THE FORMS AND FUNCTIONS OF TORT LAW* 79 (1997).

182. 159 F.2d 169, 173 (2d Cir. 1947).

183. See ABRAHAM, *supra* note 181, at 61-67.

184. See *id.* at 79.

expensive undertaking. The facts of *Magnesium Elektron* illustrate the nature of the task. The Delaware River has myriad water quality problems that are attributable to a complicated combination of legal and illegal emissions from thousands of sources.¹⁸⁵ It would be virtually impossible for a party to an enforcement procedure to present evidence sufficient to isolate the causal effects of Magnesium Elektron's illegal emissions on water quality in the Delaware River. Moreover, it makes no sense for a court to attempt this daunting task when permitting agencies already set emissions limits through a decision-making process that is specifically designed to prohibit emissions that will cause harm to water bodies. Compared to agencies, judges are at an enormous disadvantage in this context. They know little about toxicology. They lack the massive database necessary to correlate emissions from thousands of sources with scores of potential water quality problems. They lack access to procedures that would enable them to obtain that data. They lack the analytical skills and computer software necessary to evaluate the relevant data if they could amass it. Finally, they lack the authority to make such decisions. Congress has wisely delegated that power to water pollution control agencies.

The judiciary is well aware of its severe institutional shortcomings in the toxic tort context. For decades, federal judges have pled with Congress to relieve the judiciary of tasks for which it is poorly suited. They requested the creation of administrative decision-making structures specifically tailored to confront the many challenges posed by the complicated world of toxic torts.¹⁸⁶ Thus, for instance, the Court began its 1997 opinion in *Amchem Products, Inc. v. Windsor*¹⁸⁷ by listing a string of terrible problems the courts have encountered, or inadvertently created, in the asbestos context. The Court then bemoaned the failure of Congress to create an agency-administered program that would relieve the courts of tasks they are incapable of performing well, as the Judicial Conference had urged in a 1991 report.¹⁸⁸

When Congress does create an agency-administered program to deal with an important and complicated subset of toxicity disputes, it ill behooves judges to refuse to enforce the program the legislature has created. Yet, that is exactly what the Third Circuit did in *Magnesium Elektron*. Congress relieved the courts of the extraordinarily difficult task of deciding what levels of emissions of various substances will, or will not, harm a water body by

185. See Albert, *supra* note 151.

186. See, e.g., JUDICIAL CONFERENCE OF THE UNITED STATES, *supra* note 38.

187. 117 S. Ct. 2231, 2237-38 (1997).

188. See *id.* at 2238.

assigning that task to agencies that are better suited to the task. Congress left courts with only one narrow, but crucial, responsibility: to enforce the emissions limits the agencies establish. The courts should fulfill that responsibility without attempting to perform tasks that agencies have already performed and that courts cannot perform in an acceptable manner.

III. CONCLUSION

The U.S. legal system is encountering extreme difficulties in its efforts to address the phenomenon of toxicity. Some combination of legal institutions must make a series of decisions with respect to tens of thousands of substances that are potentially toxic in some circumstances. Those decisions include: How much evidence now exists with respect to the relationship between various forms of exposure to a substance and various forms of harm? How much of society's scarce resources should we devote to the task of determining the existence and characteristics of such causal relationships? And what types of legal actions are justified by the available evidence with respect to these causal relationships?

These questions are extraordinarily difficult to answer because they require access to massive data, combined with application of sophisticated scientific and economic expertise. They are also paradigmatic public policy questions, the answers to which will have enormous implications for the health and welfare of the U.S. population. Any search for answers to those questions must begin at the institutional level. What institution, or combination of institutions, is best equipped to answer questions of this nature? The Supreme Court recognized the importance of that question and answered it correctly at the beginning of its opinion in *Amchem Products*.¹⁸⁹ For a host of reasons, agencies acting under authority delegated by Congress are far more capable of answering these questions than are judges and juries.

Both the Berger version of the no-cause proposal and the Third Circuit's decision in *Magnesium Elektron* are fatally flawed because they fail to recognize the importance of assigning tasks based on comparative institutional competence.¹⁹⁰ Both would assign to the judiciary tasks that are outside of its institutional competence. Wagner's no-cause proposal provides a promising start for a potentially beneficial reform, however. Unlike Berger and the authors of the Third Circuit opinion, Wagner recognizes the importance of the institutional decision and looks in the right direction for

189. *See id.* at 2237-38.

190. *See* NEIL K. KOMESAR, IMPERFECT ALTERNATIVES: CHOOSING INSTITUTIONS IN LAW, ECONOMICS, AND PUBLIC POLICY (1994).

reforms. Any meaningful progress in this difficult area of law is almost entirely dependent on actions taken by the politically accountable branches of government.