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FORMED BY THALIDOMIDE: MASS TORTS AS A FALSE CURE FOR TOXIC EXPOSURE

Anita Bernstein*

Professor Bernstein considers a theme of Judge Weinstein's judicial and academic writings—that tort law works imperfectly to effect justice in mass disaster cases—through the vehicle of thalidomide, the paradigmatic toxic substance. Thirty-five years ago, thalidomide poisoned thousands of children, inflicting limb-reduction birth defects. Professor Bernstein argues that the drug has also had a malforming effect on mass tort law. Courts and scholars have used the precedent of thalidomide to build stringent legal standards of proof and causation, without enough attention to the functions and consistency of these standards. Thalidomide has also prompted commentators to celebrate American drug regulation and the American liability system; Professor Bernstein argues that these paeans are exaggerated. She concludes that the United States must confront its thalidomide history, as other nations in the world have done, and build social institutions—strong regulation and social insurance—to guard against toxic disasters of the future.

INTRODUCTION

Although an invitation to write about “one of Judge Weinstein’s interests” resembles an invitation to write about Life, anyone considering the innumerable possible topics will eventually reflect on the problem of causation in mass-exposure litigation, a subject illuminated in the writings of our honoree,¹ his fellow judges,² and scholars represented in this Tribute.³ This Essay addresses the venerable and familiar subject of cau-

* Professor of Law and Norman & Edna Freehling Scholar, Chicago-Kent College of Law; Law Clerk, Chief Judge Jack B. Weinstein, 1985–1986. The influence of Paul Fanning pervades this Essay, although Paul is blameless with respect to its shortcomings. Carolyn Raffensperger and Joel Tickner provided a wealth of ideas, particularly on the precautionary principle and other themes related to environmentalism. Jamie Schwartz delivered her research assistance sooner and more thoroughly than she promised. My colleagues at Chicago-Kent, especially Katharine Baker, Jacob Corré, and Hank Perritt, gave me the thoughtful comments on which I have come to depend. The Marshall Ewell Fund provided financial support. I salute Judge Weinstein on this celebration of his long, wise, and influential tenure on the federal bench.

1. See *In re “Agent Orange” Prod. Liab. Litig.*, 611 F. Supp. 1223, 1231 (E.D.N.Y. 1985), *aff’d*, 818 F.2d 187 (2d Cir. 1987); Jack B. Weinstein, *Individual Justice in Mass Tort Litigation* 151–52 (1994) [hereinafter Weinstein, *Individual Justice*]; Jack B. Weinstein, *The Role of the Court in Toxic Tort Litigation*, 73 *Geo. L.J.* 1389–90 (1985).

2. See *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579, 582–83 (1993) (Blackmun, J.) (reviewing disputed causation evidence), on remand, 43 F.3d 1311, 1313–14 (9th Cir. 1995) (Kozinski, J.) (analyzing statistical proof of causation); *In re “Agent Orange” Prod. Liab. Litig.*, 818 F.2d 145, 149 (2d Cir. 1987) (Winter, J.) (“Proving that the ailments of a particular individual were caused by Agent Orange is also extremely difficult.”).

3. See Margaret A. Berger, *Eliminating General Causation: Notes Towards a New Theory of Justice and Toxic Torts*, 97 *Colum. L. Rev.* 2117 *passim* (1997); John C.P.

sation through an unusual idiom. My vehicle is thalidomide, a drug that from 1957 to 1961 caused gruesome birth defects around the world, and would have wreaked disaster in the United States if the FDA had not refused to approve it.⁴ Though still manufactured and studied today,⁵ thalidomide lives on mostly in memory.

Exploring the memory of thalidomide, this Essay considers causation at different levels. Although some writers like to associate the substance with perfect certainty and perfect evil, thalidomide has become a source of ambiguity that now affects both litigated cases and public debate over environmentally induced illness. In particular, thalidomide is an important and underestimated causal antecedent in American liability law; "the aftermath" of thalidomide⁶ included substantive and procedural changes in mass tort law.⁷ My discussion of causation focuses on one of these changes, arguing that thalidomide has established an unrealistic standard of proof for claimants, both in the courts and in public debate about toxic exposure. Complacency accompanies this unrealistic ideal of causation: Americans have chosen to learn dubious lessons from their experience with thalidomide, using this memory to bolster their faith in mass

Goldberg, *Misconduct, Misfortune, and Just Compensation: Weinstein on Torts*, 97 *Colum. L. Rev.* 2034, 2039–42, 2053, 2058 (1997).

4. See S. Rep. No. 87-1744 (1962), reprinted in 1962 U.S.C.C.A.N. 2884, 2905–08 (summarizing thalidomide history). Famous among these defects is "phocomelia," a Greek term meaning "seal limbs." *Id.*, reprinted in 1962 U.S.C.C.A.N. 2884, 2905.

5. See Tina Adler, *The Return of Thalidomide*, 146 *Sci. News* 424 (1994) (noting that thalidomide has been used for decades outside the United States to treat leprosy); Tinker Ready, *Sullied Drug Endorsed: Thalidomide Found to Ease AIDS Sores*, *The News & Observer* (Raleigh, N.C.), May 22, 1997, at A1 (describing research on thalidomide as a treatment for ulcers, macular degeneration, leprosy, and AIDS-related diseases). Thalidomide recently received conditional FDA approval for the treatment of leprosy. See Sheryl Gay Stolberg, *37 Years Later, a Second Chance for Thalidomide*, *N.Y. Times*, Sept. 23, 1997, at A1.

6. Writers favor this locution, referring also to "the wake" of thalidomide. See Note, *FDA Reform and the European Medicines Evaluation Agency*, 108 *Harv. L. Rev.* 2009, 2012 (1995) [hereinafter Note, *FDA Reform*]; Curtis A. Kin, Note, *Coming Soon to the "Genetic Supermarket" Near You*, 48 *Stan. L. Rev.* 1573, 1581 n.44 (1996); Claire A. Milner, Comment, *Gulf War Guinea Pigs: Is Informed Consent Optional During War?*, 13 *J. Contemp. Health L. & Pol'y* 199, 212 n.85 (1996); John Schwartz, *Conservative Foes of Government Regulation Focus on the FDA*, *Wash. Post*, Jan. 21, 1995, at A7; *The Secret of Eternal Life*, *Economist*, May 24, 1997, at 60, 60.

7. Consistent with prevailing practice, I use "toxic torts," "mass torts," "mass exposure liability," "toxics liability," and similar terms more or less interchangeably. By "mass torts" I mean to exclude single-event, clear-cause disasters such as airplane crashes and the Bhopal explosion. This Essay focuses on claims of physical injury or disease resulting from "substances [encountered] by inhalation, ingestion, [or] dermal exposure," Gerald W. Boston & M. Stuart Madden, *Law of Environmental and Toxic Torts: Cases, Materials and Problems* 1 (1994), or other physical contact, where the substance reached numerous persons at about the same time. Common themes running through these cases include long latency periods, problems of proving causation, indeterminacies regarding the source of exposure, and the need for expert scientific testimony. See *id.* at 6–9.

torts as a cure for toxic exposure. A fairer reading of the thalidomide record supports a contrary inference.

This Essay follows a form related to its content. Part I offers an undisputed history of thalidomide-as-causal-agent. Social change and legal changes occurring soon after the thalidomide disaster are thought to be closely related to that experience. Some types of legal change—for example, settlements between thalidomide victims and national governments outside the United States⁸—are unquestionably tied to thalidomide; other changes, such as the creation of a European supranational drug regulatory agency, appear to be children of thalidomide as well.⁹ Part II, “Americans Celebrate Thalidomide,” and Part III, “Current Lessons from an Old Catastrophe,” move freely into an exploration of thalidomide as a signifier, considering this drug as a specter and a metaphor. My contention is that because thalidomide certainly caused some effects (i.e., birth defects), probably caused other effects, and might well have had something to do with even more effects, it is likely that thalidomide indicates a need for variation and flexibility on questions of toxic-tort causation; thalidomide does not mark a pole of causal confidence.

Causation in this flexible, variegated sense has entered public debate. Commentators have pointed out the divergence between two standards of proof, the legal and the scientific.¹⁰ But the thalidomide experience teaches that more than two standards are needed. Social and legal effects following thalidomide, some linked closely to the drug and some more distantly related, support an extension of causation beyond its forensic meaning.¹¹ Different evidence about the causation of harm justifies different responses.

Here thalidomide retains current vitality. In response to claims about new syndromes—Gulf War illness, silicone-related autoimmune disease, harms ascribed to “offgassing” and “sick buildings,” and others—some recent commentary has opposed the kind of flexibility about the standard of proof of causation that I advocate here.¹² This fashionable

8. See *infra* notes 30–36 and accompanying text.

9. See *infra* notes 47–55 and accompanying text.

10. See Sheila Jasanoff, *Science at the Bar: Law, Science, and Technology in America* 119–23 (1995) (examining the ways causation can be proved in court); Peter H. Schuck, *Multi-Culturalism Redux: Science, Law, and Politics*, 11 *Yale L. & Pol’y Rev.* 1, 14–29 (1993).

11. A determination of liability requires stronger proof of causation than a regulation, for instance, and a regulation requires stronger proof than a decision to investigate further. One standard of causation cannot fit a variety of policy options; many standards are needed. See *infra* Part II.B. Along similar lines, I mean to suggest that causation can be shown in ways other than a description of mechanistic displacement of particles. See *infra* note 87 and accompanying text. Cultural influences, for example, lead to new effects, and thus are “causal,” but cannot be shown to exist by Newtonian mechanistic evidence.

12. See *infra* note 116 and accompanying text.

posture obstructs good policymaking about toxic risks. The thalidomide experience indicates that new claims about risks will proliferate, and that they demand varying levels of respect. Never so stark and simple a poison as some observers like to think, thalidomide invites policymakers to use a variety of standards of proof when they assess claims of risk.

Above all, I conclude, thalidomide teaches that toxic risks call for stringent regulation and an expansion of social insurance. A legalistic approach to toxic exposure, with its strict and monolithic standards of proof, allows too much danger to flourish and neglects the calamities that invariably come after the creation of risk. Other wealthy nations, forced to confront their thalidomide heritage more directly than the United States, have drawn this inference. A causal antecedent whose influence is now (thankfully) discursive rather than physical, thalidomide may yet become a source for better law and policy.

I. THE SOCIAL AND LEGAL AFTERMATH OF THALIDOMIDE

A. *Thalidomide as a New Signifier*

Thalidomide spurred immeasurable political change, extending beyond law and regulation into the cultures of the world.¹³ In medicine and public health, teratology—the study of birth defects—bloomed from neglect and obscurity after thalidomide. A journal by that title began publishing in 1965;¹⁴ *Neurotoxicology and Teratology* followed later. Thalidomide prompted the adoption of developmental disability surveillance systems in the United States and around the world.¹⁵ Eight hundred studies by teratologists sought to understand how the substance caused phocomelia.¹⁶ Physicians became concerned with the ability of toxins to cross the placenta, and slowly became more cautious about prescribing drugs for pregnant patients.¹⁷ Public perceptions about the causes of harm to newborn infants shifted: before thalidomide, nature was blamed; after thalidomide, “human causes” emerged as a presumptive culprit.¹⁸

13. See Michael D. Green, *Bendectin and Birth Defects: The Challenges of Mass Toxic Substances Litigation* 82 (1996) (calling thalidomide the paradigmatic “dramatic event”); see also *id.* at 63 (noting that thalidomide “received more public attention than any other drug in history”).

14. See James G. Wilson, *Current Status of Teratology*, in *Handbook of Teratology* 47, 48 (James Wilson & F. Clarke Fraser eds., 1977) (listing the considerable literature on the subject).

15. See Godfrey B. Oakley, Jr., *Population and Case-Control Surveillance in the Search for Environmental Causes of Birth Defects*, *Pub. Health Rep.*, Sept.–Oct. 1984, at 465, available in LEXIS, GENMED Library, PHR File.

16. See Mark Dowie, *Teratology: The Loneliest Science*, *Am. Health*, June 1990, at 59, 61–62.

17. See Green, *supra* note 13, at 82.

18. Jean Reith Schroedel & Paul Peretz, *A Gender Analysis of Policy Formation: The Case of Fetal Abuse*, 19 *J. Health Pol. Pol’y & L.* 335, 351 (1994).

At an overtly political level, the story of Sherri Finkbine expanded support for abortion rights. A mother of several children who learned in 1961 that she was pregnant and knew that she had taken thalidomide at a crucial time, Finkbine sought an abortion in her home state of Arizona, a state that permitted abortion when sanctioned by a physician. A local hospital agreed to the procedure but withdrew its permission when publicity spread about Finkbine's reason, and Finkbine had to travel to Sweden for the abortion.¹⁹ Further publicity continued, linking thalidomide with reproductive freedom in particular and individual rights in general.²⁰ Horrific thalidomide damage seemed to many Americans a good justification to terminate pregnancy, and thus revealed the inadequacy of the "therapeutic" or "health-of-the-mother" criterion for abortion.²¹

Thalidomide quickly entered the lexicon as a metaphor for poison and evil. "For years I have heard the word 'Wait!'" wrote Martin Luther King, Jr. in his famous *Letter from Birmingham City Jail*. "It rings in the ear of every Negro with a piercing familiarity. This 'wait' has almost always meant 'Never.' It has been a tranquilizing thalidomide, relieving the emotional stress for a moment, only to give birth to an ill-formed infant of frustration."²² Conservative activists have compared day care to thalidomide,²³ and in congressional testimony thalidomide was mentioned by one witness who sought to denounce child abuse protection as "a new poison, posing as a cure."²⁴ Scholars in a variety of disciplines have explored thalidomide as a signifier—a chemical compound that has taken on a multifaceted cultural identity.²⁵

19. See Eva R. Rubin, *Abortion, Politics, and the Courts: Roe v. Wade and Its Aftermath* 20–21 (1982).

20. See James C. Mohr, *Abortion in America: The Origins and Evolution of National Policy, 1800–1900*, at 252–53 (1978); Laurence H. Tribe, *Abortion: The Clash of Absolutes* 37–38 (1990).

21. See Kristin Luker, *Abortion and the Politics of Motherhood* 62–65 (1984).

22. Martin Luther King, Jr., *Letter from Birmingham City Jail* 5 (1963).

23. See Kenneth Labich, *Can Your Career Hurt Your Kids?*, *Fortune*, May 20, 1991, at 38, 44.

24. *Child Abuse Prevention and Treatment Act: Hearings Before the Subcomm. on Early Childhood, Youth, and Families of the House Comm. on Economic and Educational Opportunities*, 104th Cong. 39–49 (1995) (statement of Carol Lamb Hopkins, schoolteacher and school administrator).

25. For a survey of thalidomide-and-culture as seen within a variety of disciplines, see Konrad Bloch, *Blondes in Venetian Paintings, The Nine-Banded Armadillo, and Other Essays in Biochemistry* 225–26 (1994) (discussing thalidomide and comparative biochemistry); Roald Hoffmann, *The Same and Not the Same* 129–40 (1995) (exploring carbon compounds that are "the same and not the same" as thalidomide); David J. Skal, *The Monster Show: A Cultural History of Horror* 289–92 (1993) (linking thalidomide to a preoccupation of 1960s Hollywood films with the evils of sex and reproduction); (Rabbi) Immanuel Jacobovits, *Jewish Views on Abortion*, 22 *Hum. Life Rev.* 55, 57 (1996) (analyzing debate in Jewish law over the question of abortion when a pregnant woman knows she was exposed to thalidomide); Bob Lamm, *Television's Forgotten Gems: "The Nurses,"* 23 *J. Popular Film & Television* 72, 76 (1995) (discussing public effect of

B. *Legal Shifts Outside the United States*

In the United States, where thalidomide reached few victims,²⁶ national-level legal change emphasized regulatory protections but also took form in modifications to common-law doctrine. Elsewhere, where exposure was much greater, thalidomide had a more immediate impact on toxin litigation and national legislation.²⁷ At the international level, the European Union adopted a products liability reform statute²⁸ whose origins have been traced to the thalidomide experience in Western Europe.²⁹

Outside the United States, thalidomide exposure generated criminal and civil litigation that frequently resulted in state and private compensation of victims. In September 1965, German prosecutors charged nine industry executives with manslaughter and intent to commit bodily harm.³⁰ The manufacturer, Chemie Grünenthal, eventually agreed to establish a fund of DM 100 million to compensate the victims,³¹ a fund to which the West German government, recognizing its responsibility both as a social welfare state and as a government that had been remiss in writing and enforcing licensing laws, also agreed to contribute.³² Thalidomide victims in Japan brought class actions against two drug manufacturers and the Ministry of Health and Welfare, which concluded with both the drug manufacturers and the state admitting liability.³³ In

thalidomide drama episode aired in 1963); Valerie Grove, *Small Body, Big Voice, Big Heart*, *Times* (London), Feb. 2, 1996, at 14 (studying work of classical musician Thomas Quasthoff, a German singer disabled by thalidomide); Carl Mollins, *Echoes of the Past*, *Maclean's*, Dec. 25, 1995, at 54, 70-71 (reviewing coverage of thalidomide as news story by Canadian journalists); Roy Porter, *The Rise and Fall of the Age of Miracles*, *Hist. Today*, Nov. 1996, at 69, 73-74 (summarizing, from a historical perspective, the view that thalidomide augured a public perception of medicine as a cause rather than a cure of disease).

26. Seventeen cases of thalidomide-induced birth defects have been well documented, with another nine cases suspected of being caused by thalidomide. See Green, *supra* note 13, at 74. Thalidomide was never approved and thus never marketed in the United States, see *id.* at 66, but some Americans encountered the substance following foreign distribution. See *infra* note 110.

27. Thalidomide was marketed in 48 nations. See Lauran Neergaard, *FDA Eyes Thalidomide Return; New Use May Lessen Pain of AIDS*, *Chattanooga Times*, Nov. 13, 1996, at A1. Many but not all of these nations later strengthened their drug regulation and some established compensation plans for victims. See, e.g., Harvey Teff, *Drug Approval in England and the United States*, 33 *Am. J. Comp. L.* 567, 567 (1985).

28. See Council Directive 85/374, 1985 O.J. (L 210) 29.

29. See *infra* notes 48-51 and accompanying text.

30. "[T]he trial promised to rival Nuremberg." Phillip Knightley et al., *Insight Team of The Sunday Times of London, Suffer the Children: The Story of Thalidomide* 122 (1979).

31. See Patricia Howlett, *Compensation for Drug Induced Fetal Deformities in Common and Civil Law Systems*, 2 *Touro J. Transnat'l L.* 243, 252-55 (1991).

32. See John G. Fleming, *Drug Injury Compensation Plans*, 30 *Am. J. Comp. L.* 297, 314 (1982).

33. See Mark A. Behrens & Daniel H. Raddock, *Japan's New Product Liability Law: The Citadel of Strict Liability Falls, but Access to Recovery is Limited by Formidable*

Britain, a group of parents brought a lawsuit against Distillers, the British licensee, and won a settlement of about £54,000 per child, topped off with £5 million of government funds to offset the income tax due on the settlement awards.³⁴ A lawsuit against a Canadian distributor resulted in a settlement of about \$200,000 per child³⁵ and the establishment of a federal compensation fund of about \$8.5 million.³⁶

Legislatures were also active in addressing the thalidomide disaster. Germany adopted the Pharmaceutical Law of 1976,³⁷ which aimed at forestalling and repairing a thalidomide-scale tragedy in the future,³⁸ compensating drug-injured victims, and obliging pharmaceutical manufacturers to carry insurance.³⁹ In Sweden, under "the gun of alternative legislation by the Ministry of Justice,"⁴⁰ pharmaceutical manufacturers agreed to "voluntary" group insurance that would compensate drug-injured claimants beyond the levels of Swedish social security.⁴¹ Legislative responses to thalidomide in Japan included the Drug Side-Effect

Barriers, 16 U. Pa. J. Int'l Bus. L. 669, 686 & n.91 (1995). Awards averaged \$133,000 per child, \$13,000 per set of parents, and an additional \$13,000 for legal fees per claimant. See David Cohen & Karen Martin, *Western Ideology, Japanese Product Safety Regulation and International Trade*, 19 U.B.C. L. Rev. 315, 341 n.122 (1985). The famous litigation, a landmark of Japanese civil law, has been discussed widely in the law reviews as a specific instance of claims-consciousness in a society that generally condemns recourse to the courts. See Frank K. Upham, *Law and Social Change in Postwar Japan* 206-08 (1987); Akio Morishima & Malcolm Smith, *Accident Compensation Schemes in Japan: A Window on the Operation of Law in a Society*, 20 U. Brit. Colum. L. Rev. 491, 492 (1986).

34. See Knightley et al., *supra* note 30, at 146, 204-05.

35. See Elaine Carey, *Thalidomide 'Babies' at 25: Struggling to Live on a Pittance*, Toronto Star, Sept. 27, 1987, at A1. The figure is in Canadian dollars.

36. See *Thalidomide Victims Fight for Compensation: Government Demands 'Unreasonable,' They Say*, Edmonton J., Sept. 1, 1991, at A7. The figure is in Canadian dollars.

37. Gesetz zur Neuordnung des Arzneimittelrechts, v. 24.8.1976 (BGBl. I S.2445).

38. See Daniel F. O'Keefe, Jr. & Rainer G. Czeniek, *A Study of the Drug Laws of the Federal Republic of Germany*, 32 Food Drug Cosm. L.J. 488, 489 & n.4 (1977); John M. Geddes, *West German Drug Industry Besieged*, Wall St. J., May 31, 1984, at 35.

39. In order to be compensated, a drug claimant must be injured by a drug that is defective (defect being defined with reference to "damaging effects which exceed the bounds considered justifiable"), with strict liability, rather than fault or warranty, as the basis of responsibility. See Howlett, *supra* note 31, at 267-68.

40. Fleming, *supra* note 32, at 301.

41. Unlike the German scheme, the Swedish system does not require that the drug be defective and covers a variety of other injuries. See Carl Oldertz, *Security Insurance, Patient Insurance, and Pharmaceutical Insurance in Sweden*, 34 Am. J. Comp. L. 635, 640 (1986). The statute is *Produktansvar I, Ersättning for Rakemedelskada* (Compensation for Damage Caused to Persons and Property by Industrial Products), SOU 1976: 23, Stockholm, Ministry of Justice. See also Ferdinando Albanese & Louis F. Del Duca, *Developments in European Product Liability*, 5 Dick. J. Int'l L. 193, 203-04 (1987) (suggesting that a drug need not be defective, but that only injuries caused by medicines are covered).

Injury Relief Fund Act, passed by the Diet in 1979,⁴² and the Pharmaceutical Affairs Law, administered by the Ministry of Health and Welfare.⁴³ Under this legislation new drugs must be approved prior to introduction into the market, and must be overseen after introduction into the market, with attention to toxicity and efficacy.⁴⁴ Drug regulation in Canada, relatively elaborate before the thalidomide disaster,⁴⁵ was increased along the lines of the United States model.⁴⁶

In addition to spurring changes in the domestic law of many countries, the thalidomide experience contributed to a variety of legal changes at the international and supranational level. The European products liability statute of 1985, popularly called "the Directive," imposed comprehensive products liability reform on the European Union, generally in the direction of stricter liability than what had prevailed at the national level.⁴⁷ Thalidomide shaped the 1985 Directive in several ways, bringing to the fore a concern with nonprivity bystanders, unforeseeable risks, and personal injury (rather than economic loss, even though the jurisdictional basis of the European Union is commercial).⁴⁸ Scholars link both the Directive and its predecessors—including the 1977 Strasbourg Convention on Product Liability⁴⁹ and the 1978 Pearson Royal Commission recommendations⁵⁰—with a public sentiment for reform derived from the devastation of thalidomide in Europe.⁵¹

Perhaps influenced by the observation that Grünenthal had marketed thalidomide worldwide, the European Union promulgated numer-

42. See Fleming, *supra* note 32, at 303; see also *id.* at 303–04 (describing this fund as a device unlike the German model of strict liability and the Swedish group-insurance approach: it was rather "a special compensation fund with social security overtones").

43. See Rosemarie Kanusky, Comment, *Pharmaceutical Harmonization: Standardizing Regulations Among the United States, the European Economic Community, and Japan*, 16 *Hous. J. Int'l L.* 665, 683 (1994).

44. See *id.* at 685–87; see also Robert B. Leflar, *Informed Consent and Patients' Rights in Japan*, 33 *Hous. L. Rev.* 1, 75–76 (1996) (explaining Japan's motivation for "protection of human subjects" as caused by stricter western mandates for drug approval in their markets).

45. See Willem Wassenaar, *Drug Regulation in Canada*, 2 *Legal Med. Q.* 209 (1978).

46. See Joel Lexchin, *We Need a War on Legal Drugs: Useless and Unsafe Products Still Being Sold*, *Toronto Star*, June 13, 1994, at A15.

47. See 1985 O.J. (L 210) 29. The Directive announces its progressive purpose by referring to "liability without fault on the part of the producer," *id.* at Preamble, a term that moved ahead of fault and contract-based liability traditions. See Kathleen M. Nilles, Note, *Defining the Limits of Liability: A Legal and Political Analysis of the European Community Products Liability Directive*, 25 *Va. J. Int'l L.* 729, 735–36 (1985).

48. See Jane Stapleton, *Product Liability* 5, 42–43, 45 (1994).

49. *European Convention on Products Liability in Regard to Personal Injury and Death*, Jan. 27, 1977, 1977 *Europa T.S.* No. 91.

50. *Royal Commission on Civil Liability and Compensation for Personal Injury*, Report, 1978, Cmnd. 7054-I.

51. See Albanese & Del Duca, *supra* note 41, at 193–94; Jane Stapleton, *Products Liability Reform—Real or Illusory?*, 6 *Oxford J. Legal Stud.* 392, 392 (1986); Nilles, *supra* note 47, at 737–39.

ous directives pertaining to the regulation of pharmaceuticals and related products such as medical devices.⁵² These regulatory efforts receive additional support by frequent communication between the European Union and regulatory agencies in the United States and Japan as well as international agencies, including the World Health Organization and the Council of Europe.⁵³ The European Agency for the Evaluation of Medicinal Products, often described as the European counterpart to the FDA, now approves new drugs for marketing in the European Union, and monitors drug safety in the common market.⁵⁴ Historical links between this international regulatory scheme and thalidomide may be inferred.⁵⁵

II. AMERICANS CELEBRATE THALIDOMIDE

A. Unwarranted Confidence

1. *Agency Regulation.* — According to conventional wisdom, thalidomide had a strong effect on U.S. regulatory laws: the 1962 amendments to the Federal Food, Drug, and Cosmetic Act (FFDCA)⁵⁶ are said to have originated in the thalidomide disaster.⁵⁷ While the thalidomide experience has been given credit for building strong American drug regulations, strong American drug regulations have been given credit for the nation's unique experience with thalidomide.⁵⁸ The claim both that strong drug regulations caused the (fortunate) thalidomide experience and that the thalidomide experience caused strong drug regulations, though not entirely silly, betrays an eagerness to proclaim the power of

52. See Kanusky, *supra* note 43, at 676–83.

53. See Fernand Sauer, Harmonization of Biotechnological Regulations in the European Community, in *Drug Biotechnology Regulation: Scientific Basis and Practices* 455, 459 (Yuan-yuan H. Chiu & John L. Gueriguian eds., 1991).

54. See Eric M. Katz, Europe's Centralized New Drug Procedures: Is the United States Prepared to Keep Pace?, 48 *Food & Drug L.J.* 577, 577–78 (1993).

55. See W.J. Currie, The Evolving Horizon of Drug Registration—Europe and Beyond, 39 *Eur. J. Clinical Pharmacology* 453, 453 (1990) (connecting European Agency for the Evaluation of Medicinal Products with post-thalidomide national drug regulation); Kanusky, *supra* note 43, at 687–89 (surveying the history of “pharmaceutical harmonization” and finding early developments to have begun around 1970, when thalidomide-derived reforms had gotten underway).

56. Pub. L. No. 87-781, 76 Stat. 780 (1962).

57. See Steven R. Salbu, Regulation of Drug Treatments for HIV and AIDS: A Contractarian Model of Access, 11 *Yale J. on Reg.* 401, 408 (1994); Lewis A. Scheindlin, Note, New Drug Approval: *Lannett*, the Drug Lag, and the NDA System, 11 *Rut.-Cam. L.J.* 231, 233 (1980); Judith Havemann, Experimental Drugs, Power and the Limits of Deregulation, *Wash. Post*, July 15, 1987, at A21; Philip J. Hiltz, U.S. Cracks Down on Health Devices Made Before 1976, *N.Y. Times*, Feb. 24, 1992, at A1; Cody Holt, The Evolution of the OTC Drug Industry, *Am. Druggist*, Apr. 1996, at 51, 60.

58. See Knightley et al., *supra* note 30, at 245; Richard E. McFadyen, Thalidomide in America: A Brush with Tragedy, 11 *Clio Medica* 79, 80 (1976); Max Sherman & Steven Strauss, Thalidomide: A Twenty-Five Year Perspective, 41 *Food Drug Cosm. L.J.* 458, 458 (1986).

American regulation, facts or no facts.⁵⁹ Yet the relationship between thalidomide and drug regulation is far from direct. First, thalidomide certainly did not awaken President Kennedy and the United States Congress to the need for more rules; FFDCA amendments were well underway before the thalidomide story reached the United States, although the catastrophe undoubtedly helped Senator Kefauver and others interested in drug reform.⁶⁰ Second, it is not regulation as such but rather one regulator's intelligence and tenacity that stopped thalidomide from being marketed in the United States.⁶¹ Third, the 1962 FFDCA amendments focus on efficacy, not safety, and would thus be of little direct effect in preventing a future thalidomide-like disaster.⁶²

Despite these gaps between one phenomenon and another, the conventional wisdom linking thalidomide with regulation has proved expedient. Commentators who favor the expedited approval of new drug applications have complained that while patients die the FDA cannot move because it fears approving "the next thalidomide."⁶³ The FDA looks alert and vigilant if a bit gloomy. Industry looks well-monitored.

Yet if drug regulation was strengthened in Europe because of the disaster of thalidomide, as the record indicates, then it is plausible to surmise that drug regulation was not strengthened in the United States because of the triumph of thalidomide. Postapproval regulation, for example, has been and remains feeble.⁶⁴ The sensible proposal that the FDA handle clinical investigations of new drugs, with studies paid for by

59. See Julie De Falco, *The FDA and Its All-Purpose Response to Critics*, Wash. Times, March 30, 1995, at A25, available in LEXIS, New Library, PAPERS File.

60. See Mary T. Griffin, *AIDS Drugs & the Pharmaceutical Industry: A Need for Reform*, 17 Am. J.L. & Med. 363, 377 (1991); David Woodward, *The New Drug Marketing: A Consumer Protection Perspective*, 51 Food & Drug L.J. 637, 646-47 (1996).

61. See *infra* notes 66-68 and accompanying text.

62. See Pub. L. No. 87-781, 76 Stat. 781 (1962). The 1962 amendments made two basic changes in drug regulation: they required explicit FDA approval of new drugs, whereas before 1962 agency silence for a certain time after an application entitled an applicant to market the drug, and they required the FDA to investigate efficacy as well as safety. See Note, *FDA Reform*, *supra* note 6, at 2012. On the inability of the efficacy amendments to stop a thalidomide disaster, see Joseph G. Contrera, *The Food and Drug Administration and the International Conference on Harmonization: How Harmonious Will International Pharmaceutical Regulations Become?*, 8 Admin. L.J. Am. U. 927, 935-36 & n.35 (1995); Joseph Sanders, *The Bendectin Litigation: A Case Study in the Life Cycle of Mass Torts*, 43 Hastings L.J. 301, 314 n.57 (1992) (noting that teratogenic effects of thalidomide were not replicable in several species of animals, including rats, mice, and hamsters). Efficacy-related approval delays could, of course, have the incidental effect of allowing time for safety-related information to accrete.

63. See W. Kip Viscusi, *Fatal Trade-Offs* 273 (1992); accord C. Frederick Beckner III, *The FDA's War on Drugs*, 82 Geo. L.J. 529, 543 (1993). The complaint has achieved some success in hastening the approval process. See Salbu, *supra* note 57, at 410 (emphasizing how AIDS has increased the demand for expediting the approval process).

64. See Knightley et al., *supra* note 30, at 246-50.

the pharmaceutical-company sponsors, has languished for twenty years.⁶⁵ Few new ideas related to drug regulation, other than exhortation either to speed up approvals or slow them down, have been tried or even heard. By fixing attention on a regulatory "victory," thalidomide has built complacency about American drug regulation.

2. *The Isolation of Individuals.* — In addition to instilling a sense of unwarranted triumph about American regulatory law, the thalidomide experience in the United States helped to ground the development of mass exposure law in notions of individualism. Thalidomide emphasized the lone hero-regulator rather than the regulatory system, deepened a boundary line separating the United States from other industrialized countries, disconnected injured persons from one another with procedural barriers, and helped to build a destructive myth of the deserving plaintiff.

The American individual who gained the most fame from thalidomide, Frances Kelsey,⁶⁶ contributed unintentionally to a perception of toxic exposure as a threat to be countered with a strong personality. Emerging in sharp relief from her gray bureau, the Kelsey persona celebrates many illusory triumphs: the acumen of one mind, even though Kelsey partially misperceived the danger of thalidomide;⁶⁷ the ability of individual drug-industry regulators to resist external pressure, a notion belied most recently by the successes of an AIDS activists/industry coalition in changing FDA criteria for new-drug approval;⁶⁸ and the victory of a junior official over an industry Goliath, an improbable episode that has not recurred. Unquestionably heroic, and perhaps deserving of even more credit for her efforts against thalidomide, Frances Kelsey nonetheless cannot, by herself, stop or cure toxic exposure.

Just as Kelsey-the-individual grew to proportions beyond American regulation, an emphasis on individuals came to overwhelm the collective nature of American mass tort law. By now the claim that American law is "individualistic" has become a truism in need of no additional elabora-

65. The proposal is tentatively endorsed in Green, *supra* note 13, at 335. Suggestions along these lines are described in Sidney A. Shapiro, *Divorcing Profit Motivation from New Drug Research: A Consideration of Proposals to Provide the FDA with Reliable Test Data*, 1978 Duke L.J. 155, 177-81.

66. Frances Oldham Kelsey, who had both an M.D. and a Ph.D. in pharmacology, was the FDA official assigned to review the application for thalidomide; this application was the first she reviewed. Her refusal to approve the drug enraged the American manufacturer, Merrell (later known as Richardson-Merrell and Merrell Dow). The company pressured Kelsey relentlessly, even accusing her of libel. When news from Europe came in to support her judgment, Kelsey worked to stop the U.S. clinical trials, while a reluctant Merrell barely cooperated. In August 1962 Kelsey was awarded the President's Award for Distinguished Federal Civilian Service. See Cindy Pearson, *Doctor Who Stopped Thalidomide Celebrates 80th Birthday*, Nat'l Women's Health Network News, Sept. 1994, at 1.

67. Kelsey had worried about adult nerve damage rather than thalidomide's much more dangerous threat, phocomelia. See Knightley et al., *supra* note 30, at 78-79.

68. See Salbu, *supra* note 57, at 410-18.

tion.⁶⁹ Mass tort law, following thalidomide, was distorted by this predilection for individualism: the sine qua non of mass torts is aggregation,⁷⁰ but the thalidomide experience emphasized opposite circumstances.

Courts picked up the theme of isolation when plaintiffs brought thalidomide-related lawsuits in the United States. Although thalidomide crossed national borders, American courts interpreted the law of personal jurisdiction to refuse some claims of thalidomide-injured persons born in the United States,⁷¹ as well as claims of foreigners who were injured by thalidomide manufactured in the United States, but purchased abroad.⁷² One commentator identifies thalidomide litigation on the question of jurisdiction as a source of isolation, entrenching national boundaries as false lines in a global reality.⁷³

Finally, thalidomide introduced to the United States a concern about individual mass-tort plaintiffs, focusing attention on individual victims at the expense of a thoughtful evaluation of toxic effects. Babies and children injured by thalidomide set a standard of innocence to which few subsequent toxic-substance victims could compare.⁷⁴ Elsewhere I have argued that American private law relies on dichotomous contrasts to support its rejections of plaintiffs' demands; such plaintiffs are deemed to fall short of an ideal that, if met, would have justified a favorable outcome in

69. See George Anastaplo, *The American Moralist: On Law, Ethics, and Government* 32 (1992) (criticizing the Moral Majority for its emphasis on the individual rather than community); Alexis de Tocqueville, *Democracy in America* 241 (J.P. Mayer ed., 1969) ("however annoying a law may be, the American will submit to it . . . ; he regards it as a contract to which he is one of the parties"); Cass R. Sunstein, *Rights and Their Critics*, 70 *Notre Dame L. Rev.* 727, 750 (1995) (agreeing with rights critics that "American legal discourse is fixated with individual rights").

70. Judge Weinstein has explored this paradox in numerous writings. See Weinstein, *Individual Justice*, *supra* note 1, at 1-4, 39; Jack B. Weinstein, *Ethical Dilemmas in Mass Tort Litigation*, 88 *Nw. U. L. Rev.* 469, 521-23 (1994).

71. See *Harvey v. Chemie Grünenthal*, 354 F.2d 428, 429-31 (2d Cir. 1965) (barring claim of American twins whose mother had brought thalidomide from Germany).

72. See *Henry v. Richardson-Merrell, Inc.*, 508 F.2d 28, 38-39 (3d Cir. 1975) (maintaining that Quebecois plaintiffs were bound by unfavorable Canadian law).

73. "[C]ourts failed to exercise the full scope of in personam jurisdiction available to them thereby insulating foreign manufacturers from suit in the United States." Stephen J. Werber, *The Constitutional Dimension of a National Products Liability Statute of Repose*, 40 *Vill. L. Rev.* 985, 1046 (1995) (citation omitted).

74. A book chapter title, "Alone in a World of Horror," conveys some of the isolation of thalidomide claimants. See Knightley et al., *supra* note 30, at 112-21. The innocence of victims did not spare thalidomide parents, who frequently blamed themselves for their children's disabilities, see *id.* at 115-16; mothers were accused of having "dosed themselves indiscriminately" during pregnancy because they were "neurotic," *id.* at 117. A psychologist who studied Canadian parents noted that professionals had faulted their various coping mechanisms, based on contradictory criteria. See Ethel Roskies, *Abnormality and Normality: The Mothering of Thalidomide Children* 14-21 (1972).

court.⁷⁵ Caselaw and scholarship reveal this tendency.⁷⁶ Robert Rabin, for example, has explored how cigarette manufacturers slurred plaintiffs' characters during litigation.⁷⁷ Judges have faulted asbestos plaintiffs for smoking, with little effort to measure the increment of extra harm that smoking could have caused.⁷⁸ Female victims in mass exposure cases have historically been easy to impugn.⁷⁹ Post-thalidomide toxics litigation, in sum, frequently appears to blame plaintiffs for being adult individuals.⁸⁰

B. *An Unattainable Ideal of Causation*

Although its mechanism of destruction is still not well understood, thalidomide easily met scientific and legal criteria necessary to prove causation in fact. Limb reduction birth defects (one among many harms thalidomide caused) appeared in about half the children born to mothers who took thalidomide during the fifteen-day period when organs are formed; the background rate of this birth defect is less than one

75. See Anita Bernstein, *Law, Culture, and Harassment*, 142 U. Pa. L. Rev. 1227, 1306-07 (1994).

76. See generally Gerald F. Tietz, *Strict Products Liability, Design Defects and Corporate Decision-Making: Greater Deterrence Through Stricter Process*, 38 Vill. L. Rev. 1361, 1409 n.248 (1993) (summarizing victim-blaming in various mass exposure cases).

77. See Robert L. Rabin, *Institutional and Historical Perspectives on Tobacco Tort Liability*, in *Smoking Policy: Law, Politics, and Culture* 110, 124 (Robert L. Rabin & Stephen D. Sugarman eds., 1993).

78. See *Dartez v. Fibreboard Corp.*, 765 F.2d 456, 466-67 (5th Cir. 1985) (refusing recovery for increased risk of cancer); *Special Project: An Analysis of the Legal, Social, and Political Issues Raised by Asbestos Litigation*, 36 Vand. L. Rev. 573, 631-33 (1983) (citations omitted) (noting that courts have reduced damages in cases where the plaintiff smokes).

79. See Morton Mintz, *At Any Cost: Corporate Greed, Women, and the Dalkon Shield* 194-209 (1985) (noting deliberate effort of defendant to humiliate plaintiffs during discovery); Anne E. Simon, *Whose Move? Breaking the Stalemate in Feminist and Environmental Activism*, 2 UCLA Women's L.J. 145, 153 (1992) (stating that courts tend to blame women and children for harms caused by ingesting lead paint). One feminist scholar suggests that the very concept of "mass tort" has been "created, defined, and legally recognized" in a way that excludes or slights the interests of female claimants. Carrie Menkel-Meadow, *Ethics and the Settlement of Mass Torts: When the Rules Meet the Road*, 80 Cornell L. Rev. 1159, 1175 n.58 (1995).

80. It is difficult to explain otherwise how asbestos and tobacco defendants could argue simultaneously, and with some success, that their products do not cause illness and that the product's dangers were obvious to the plaintiffs, or that the plaintiffs were contributorily negligent for not heeding information about these dangers. See, e.g., *Borel v. Fibreboard Paper Prods. Corp.*, 493 F.2d 1076, 1093 (5th Cir. 1973); *Cipollone v. Liggett Group, Inc.*, 683 F. Supp. 1487, 1492 (D.N.J. 1988), *aff'd in part and rev'd in part*, 505 U.S. 504, 520-31 (1992); see also Rabin, *supra* note 77, at 124 (arguing that the current wave of tobacco litigation, brought by government and class action plaintiffs, has been more successful than prior litigation because it escapes the character-flaw scrutiny that defendants deploy against individual plaintiffs).

per thousand.⁸¹ No substance known to toxic litigation has ever cleared the causation hurdle with so much room to spare. Thalidomide is the pinnacle toxin.

As Frances Kelsey has reflected, however, "teratogens less potent than thalidomide" pose "difficulties of recognition [that are] infinitely greater."⁸² Although teratogens as potent as thalidomide speak for themselves, weaker toxic effects will often be discernible only from epidemiological study (where a group of people, or "cohort," exposed to the substance should reveal significant increases in risk beyond a background rate), and some toxic effects will be too small to be detected in an epidemiological study, even though they are in fact caused by the substance. These findings cannot satisfy the burden of proof under a preponderance of the evidence standard.⁸³ Courts have relied heavily on the absence of strong epidemiological findings of teratogenicity: the epidemiological threshold set by Judge Weinstein in the Agent Orange litigation⁸⁴ and several judges in the Bendectin cases⁸⁵ precluded plaintiffs from meeting their burden of proof. As Michael Green and others argue, however, poisons can escape blame when epidemiological evidence is demanded, because of recurrent biases and flaws in epidemiological research and the tendency of aggregation to obscure effects on individuals.⁸⁶ When courts insist on epidemiological findings and reject as inadequate or irrelevant other types of evidence on causation (such as animal studies or *in vitro* research) they carry forward a memory of one toxin that could meet such high standards, to the detriment of persons injured by other substances.

Another scholar of causation in mass exposure cases, Troyen Brennan, identifies a different hierarchy. Professor Brennan argues that "corpuscularian" evidence, or reasoning based on Newtonian mechanistic

81. See Michael D. Green, *Expert Witnesses and Sufficiency of Evidence in Toxic Substances Litigation: The Legacy of Agent Orange and Bendectin Litigation*, 86 Nw. U. L. Rev. 643, 653 (1992) [hereinafter Green, *Expert Witnesses*].

82. Green, *supra* note 13, at 72 (quoting Frances Kelsey). A teratogen, literally "monster-maker," is a substance that causes birth defects. See Dowie, *supra* note 16, at 66.

83. See Green, *supra* note 13, at 305-06, 316-17; Green, *Expert Witnesses*, *supra* note 81, at 653.

84. See *In re "Agent Orange" Prod. Liab. Litig.*, 611 F. Supp. 1223, 1231 (E.D.N.Y. 1985), *aff'd* on other grounds, 818 F.2d 187 (2d Cir. 1987).

85. See *Raynor v. Merrell Pharm., Inc.*, 104 F.3d 1371, 1375 (D.C. Cir. 1997); *Brock v. Merrell Dow Pharm., Inc.*, 874 F.2d 307, 313 (5th Cir. 1989), modified, 884 F.2d 166 (5th Cir. 1989); *Richardson v. Richardson-Merrell, Inc.*, 649 F. Supp. 799, 803 (D.D.C. 1986), *aff'd*, 857 F.2d 823 (D.C. Cir. 1988).

86. See Green, *supra* note 13, at 319-20; Troyen A. Brennan, *Causal Chains and Statistical Links: The Role of Scientific Uncertainty in Hazardous-Substance Litigation*, 73 Cornell L. Rev. 469, 498 n.155 (1988); Heidi Li Feldman, *Science and Uncertainty in Mass Exposure Litigation*, 74 Tex. L. Rev. 1, 25 (1995); Green, *Expert Witnesses*, *supra* note 81, at 653. For a contrary view, defending the epidemiological threshold, see Gerald W. Boston, *A Mass-Exposure Model of Toxic Causation: The Content of Scientific Proof and the Regulatory Experience*, 18 Colum. J. Envtl. L. 181 (1993).

models of particles moving in response to earlier movements, has been unduly privileged to rank above "probabilistic" evidence, such as that of epidemiological studies.⁸⁷ Only a few toxins can meet this high standard of causation: "Unfortunately, toxic substance injury cases cannot produce mechanistic, deductively-derived causal evidence, and a corpuscularian judge cannot process the available probabilistic evidence."⁸⁸

A third type of hierarchy in the law of toxic causation ranks single, unitary causes ahead of contingencies and conditions that are part of a causal constellation. Kenneth Rothman, a leading epidemiologist whose work played a part in the Bendectin litigation,⁸⁹ has written that "[m]ost causes that are of interest in the health field are components of sufficient causes, but are not sufficient in themselves."⁹⁰ Thalidomide, a sufficient causal antecedent by itself, easily fulfills the high standard; whereas other toxins would require a modified standard of cause-in-fact in order to support a finding of liability in tort.⁹¹

Read against this backdrop of scholarly writing, case law emerges as strongly influenced by hierarchies of causation. In judicial opinions, substances that could be deemed toxic based on a record of scientific evidence are often exonerated. Courts tell plaintiffs, in effect, good evidence (that is, epidemiological for Green, "corpuscularian" for Brennan, and unitary and exclusive for Rothman) will deem true toxins to be toxic, but all that you, plaintiffs, have is low-grade causation evidence (for example, animal or in vitro studies in the Green hierarchy, probabilistic or statistical findings for Brennan, and "components" of constellations in Rothman's phrase) and accordingly you may not recover.⁹² That these hierarchies are inconsistent with one another—statistical evidence, for

87. "A corpuscularian judge would not want to deal with probabilistic notions, as he would regard these as inferior methods of reasoning." Brennan, *supra* note 86, at 490-91. 88. *Id.* at 491.

89. See *Turpin v. Merrell Dow Pharms., Inc.*, 959 F.2d 1349, 1354 n.1 (6th Cir. 1992); *DeLuca v. Merrell Dow Pharms., Inc.*, 911 F.2d 941, 945-48 (3d Cir. 1990); *McBride v. Merrell Dow & Pharms. Inc.*, 717 F.2d 1460, 1468 (D.C. Cir. 1983).

90. Kenneth J. Rothman, *Causes*, 104 *Am. J. Epidemiology* 587, 588 (1976); see also Richard W. Wright, *Causation in Tort Law*, 73 *Cal. L. Rev.* 1735, 1789 (1985) (referring to a "set of antecedent conditions . . . [that] is *sufficient* for the occurrence of the consequence").

91. For a proposal along these lines see Richard W. Wright, *Causation, Responsibility, Risk, Probability, Naked Statistics, and Proof: Pruning the Bramble Bush by Clarifying the Concepts*, 73 *Iowa L. Rev.* 1001, 1067-77 (1988).

92. See *Turpin*, 959 F.2d at 1360 (rejecting animal studies because they raise only a possibility rather than a probability of harm in humans); *Lynch v. Merrell-Nat'l Lab.*, 830 F.2d 1190, 1194 (1st Cir. 1987) (rejecting animal-studies evidence in the absence of confirmatory epidemiological evidence); *Hupp v. United States*, 563 F. Supp. 25, 30 (S.D. Ohio 1982) (holding that only epidemiological evidence could prove that a swine flu shot caused multiple sclerosis). But see *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1535 (D.C. Cir. 1984) (holding that "[a] cause-effect relationship need not be clearly established by animal or epidemiological studies"); *Wells v. Ortho Pharm. Corp.*, 615 F. Supp. 262, 266 (N.D. Ga. 1985) (stating that plaintiff's burden was not to "produce an unassailable scientific study" on causation), *aff'd* and modified in part, 788 F.2d 741 (11th Cir. 1986).

example, is high enough in the Green scheme but too low in the Brennan scheme—suggests that courts set up causation hurdles not in fidelity to one ideal but rather to assuage their concerns about the expanse and diffusion of mass-exposure litigation.⁹³ Thalidomide makes a useful contrast. As a matter of tort history it existed; its harms formed a basis of worldwide litigation; it can pass every feasible test for toxic causation including the difficult corpuscularian standard, if that standard can be interpreted to accommodate some peripheral ignorance about the mechanics of thalidomide on an embryo during organogenesis.⁹⁴ With thalidomide as a contrast, judges assure themselves that their high standards on causation are not too high for the real world.⁹⁵

III. CURRENT LESSONS FROM AN OLD CATASTROPHE

A. *The Poor Fit Between Liability and Mass Exposure*

As countless writers have noted, procedural elements of civil litigation such as the plaintiff's traditional burden of proof,⁹⁶ the preponder-

93. The approach to toxic-substance causation of the District of Columbia Court of Appeals, for instance, appears to favor results over principle. Compare *Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823, 832 (D.C. Cir. 1988) (rejecting plaintiff's claim because of the absence of epidemiological evidence) with *Ferebee*, 736 F.2d at 1535 (holding that neither animal nor epidemiological evidence is necessary to establish cause and effect). For an argument that courts fear opening the floodgates in toxic substance litigation, see Carl F. Cranor et al., *Judicial Boundary Drawing and the Need for Context-Sensitive Science in Toxic Torts After Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 16 Va. Envtl. L.J. 1, 4 (1996) (suggesting that judges following *Daubert* are excluding too much evidence); for a partial defense of this concern see Boston, *supra* note 86, at 187-91 (contrasting diffusion of mass-exposure cases with particularity of traditional torts and arguing that the former requires strict thresholds of causation).

94. Other criteria for causation that thalidomide would pass include case reports and disease clusters, see Jeffrey D. Cutler, *Implications of Strict Scrutiny of Scientific Evidence: Does Daubert Deal a Death Blow to Toxic Tort Plaintiffs?*, 10 J. Envtl. L. & Litig. 189, 204 (1995), as well as specific variations on the epidemiological standard that courts have discussed, see, e.g., *DeLuca*, 911 F.2d at 958-59 ("A relative risk greater than '2' means that the disease more likely than not was caused by the event."); *In re Paoli R.R. Yard PCB Litig.*, 916 F.2d 829, 856-57 (3d Cir. 1990) ("meta-analysis" of prior studies). Because thalidomide does not produce birth defects in many animals, however, it cannot be identified as a teratogen by animal studies on certain species, such as rats and mice. See Sanders, *supra* note 62, at 314 n.57.

95. See, e.g., *Richardson v. Richardson-Merrell, Inc.*, 649 F. Supp. 799, 803 (D.D.C. 1986) ("[t]he ominous hypothesis of two decades ago, namely, that Bendectin might be another Thalidomide, has been reduced to the status of a perdurable superstition"), *aff'd*, 857 F.2d 823 (D.C. Cir. 1988); *Oxendine v. Merrell Dow Pharms., Inc.*, 506 A.2d 1100, 1108 (D.D.C. 1986) (quoting an expert's statement that "Bendectin is not an obligatory teratogen as Thalid[omide] (for example)" (alteration in original)); see also *United States v. 38 Cases, More or Less*, 35 F.R.D. 357, 359 (W.D. Pa. 1964) (describing product as not "dangerous like thalidomide").

96. See Leslie Bender, *Feminist (Re)Torts: Thoughts on the Liability Crisis, Mass Torts, Power, and Responsibilities*, 1990 Duke L.J. 848, 879 (proposing burden-shifting scheme for toxic torts); Richard Delgado, *Beyond Sindell: Relaxation of Cause-in-Fact*

ance of the evidence standard,⁹⁷ statutes of limitation,⁹⁸ class action prerequisites,⁹⁹ jurisdictional requirements,¹⁰⁰ discovery procedures,¹⁰¹ choice-of-law rules,¹⁰² and settlement practices¹⁰³ have functioned poorly in American mass tort cases. One scholar devotes 549 pages of her casebook to a part called "Mass Tort Litigation and the Failure of the Procedural System."¹⁰⁴ Notwithstanding the familiar bias in favor of attacks and critiques in legal scholarship, this consensus about failure is striking.¹⁰⁵

Rules for Indeterminate Plaintiffs, 70 Cal. L. Rev. 881, 886-87 (1982) (recommending shifting burden to defendants).

97. See, e.g., Delgado, *supra* note 96, at 892, 900 (recommending recovery in proportion to probability of causation); Green, *Expert Witnesses*, *supra* note 81, at 644 (suggesting that "acceptable evidence of causation" has been confused with "enhanced judicial scrutiny of expert testimony"); Steve Gold, Note, *Causation in Toxic Torts: Burdens of Proof, Standards of Persuasion, and Statistical Evidence*, 96 Yale L.J. 376, 380-82 (1986) (discussing confusion between burden of proof and preponderance standard); cf. D.H. Kaye, *Science in Evidence* 30 (1997) (stating that Minnesota excludes "well-founded, numerically expressed probabilities and population proportions" in its law of evidence, although this exclusion is equivocal).

98. See 2 ALI, *Reporters' Study on Enterprise Responsibility for Personal Injury* 362-64 (1991); Michael D. Green, *The Paradox of Statutes of Limitations in Toxic Substances Litigation*, 76 Cal. L. Rev. 965, 968 (1988); Note, *The Fairness and Constitutionality of Statutes of Limitations for Toxic Tort Suits*, 96 Harv. L. Rev. 1683, 1684 (1983).

99. See *In re "Agent Orange" Prod. Liab. Litig.*, 506 F. Supp. 762, 784-85, 787-92 (E.D.N.Y. 1980) (Pratt, J.) (weighing advantages and disadvantages of class action device before certifying the class), *rev'd*, 635 F.2d 987 (2d Cir. 1980); James W. Elrod, Comment, *The Use of Federal Class Actions in Mass Toxic Pollution Torts*, 56 Tenn. L. Rev. 243, 243-49 (1988); Linda S. Mullenix, *Class Actions, Personal Jurisdiction, and Plaintiffs' Due Process: The Implications for Mass Tort Litigation*, 28 U.C. Davis L. Rev. 871 (1995).

100. See *Carlough v. Amchem Prods., Inc.*, 10 F.3d 189, 198-202 (3d Cir. 1993) (discussing personal jurisdiction and subject matter jurisdiction); Jonathan M. Gutoff, Comment, *Admiralty Jurisdiction Over Asbestos Torts: Unknotting the Tangled Fibers*, 54 U. Chi. L. Rev. 312, 320-32 (1987) (arguing that the federal circuit courts have misconstrued admiralty jurisdiction as an entrée to federal court); Christopher J. Willis, *Aggregation of Punitive Damages in Diversity Class Actions: Will the Real Amount in Controversy Please Stand Up?*, 30 Loy. L.A. L. Rev. 775, 795-98 (1997) (discussing preferred judicial rationale concerning diversity jurisdiction in mass exposure claims).

101. See *Mirak v. McGhan Medical Corp.*, 142 F.R.D. 34, 37 (D. Mass. 1992) (evaluating confidentiality order after a protest by an activist with a "mission of educating women"); Weinstein, *Individual Justice*, *supra* note 1, at 76 (detailing burdens of discovery); Richard A. Nagareda, *In the Aftermath of the Mass Tort Class Action*, 85 Geo. L.J. 295, 319 (1996) (discussing how the expense of discovery distorts litigation).

102. Compare Larry Kramer, *Choice of Law in Complex Litigation*, 71 N.Y.U. L. Rev. 547 (1996) (challenging the idea of a uniform federal rule for choice of law in complex litigation), with Robert A. Sedler & Aaron Twerski, *State Choice of Law in Mass Tort Cases: A Response to "A View from the Legislature"*, 73 Marq. L. Rev. 625 (1990) (defending state choice-of-law rules).

103. See Boston & Madden, *supra* note 7, at 648-55 (describing settlement strategies and problems in toxic tort litigation).

104. Linda S. Mullenix, *Mass Tort Litigation: Cases and Materials* 103-651 (1996).

105. The law review bias in favor of attacks allows for defenses of the status quo. See, e.g., Boston, *supra* note 86, at 211-74, 351-81 (defending traditional approaches to toxic

Although some British writers have supposed that American legal procedures might have permitted thalidomide plaintiffs to flourish in mass-exposure litigation,¹⁰⁶ this bit of wishful thinking is misplaced. Thalidomide litigation in countries similar to the United States produced settlements that have been labeled, without challenge, "relatively modest,"¹⁰⁷ "inadequate,"¹⁰⁸ and "a pittance."¹⁰⁹ Thalidomide claimants obtained next to nothing directly from U.S. courts.¹¹⁰

The bigger lesson is that mass-tort litigation will provide neither just compensation nor meaningful deterrence for the benefit of those persons at risk from a toxic substance. Demonstrably inadequate according to theory¹¹¹ and experience,¹¹² tort liability cannot cope with the unanswerable questions of fact, temporal changes, multiples sets of conflicting interests, and onerous default rules (particularly the plaintiff's burden of proof and condoned delays in the payment of damages) that inevitably accompany toxic-substance litigation. When ruling against plaintiffs, American courts have been tempted to believe that these problems would not have obstructed a hypothetical mass-exposure thalidomide lawsuit.¹¹³ They have used this belief to convince themselves that a strong mass-exposure case could exist—that civil litigation can cure the ills of mass exposure—in the teeth of every possible kind of evidence, including the history of thalidomide.

causation); David Rosenberg, Comment, *Of End Games and Openings in Mass Tort Cases: Lessons from a Special Master*, 69 B.U. L. Rev. 695, 729 (1989) (phrasing a defense of the traditional approach to mass torts as a critique of administrative-compensation alternative proposals); J.B. Ruhl, *Toxic Tort Remedies: The Case Against the "Superduper Fund" and Other Reform Proposals*, 38 Baylor L. Rev. 597, 601–02 (1986) (arguing for retention of traditional procedures and rules in toxic tort claims). It also permits recommendations of relatively modest change. In light of these freedoms, the widely held view that civil litigation procedures fail in toxic tort cases is noteworthy.

106. See Knightley et al., *supra* note 30, at 136; Harvey Teff & Colin R. Munro, *Thalidomide: The Legal Aftermath* 138 (1976).

107. *Holmes v. Syntex Lab., Inc.*, 156 Cal. App. 3d 372, 386 (Cal. Dist. Ct. App. 1984).

108. Stephen J. Krause, *Punishing the Press: Using Contempt of Court to Secure the Right to a Fair Trial*, 76 B.U. L. Rev. 537, 541 (1996).

109. Carey, *supra* note 35, at A1; Lynda Hurst, *Thalidomide Betrayal*, *Toronto Star*, Feb. 12, 1989, at S12; see also Leslie Adler, *Guinness Rejects More Aid for Thalidomide*, *The Reuter Bus. Rep.*, May 18, 1995, available in LEXIS, NEWS Library, WIRES File (quoting description of settlement demand as "small beer for Guinness").

110. Some American families exposed to thalidomide while Richardson-Merrell was scattering the drug throughout the United States in ill-supervised clinical trials received settlements. Of these plaintiffs, some may have received the drug while abroad. One plaintiff, Shirley McCarrick, brought the only thalidomide action in the world that went to a verdict: in 1971 a California jury awarded her and her daughter Peggy a then-astronomical \$2.7 million, although Richardson-Merrell ultimately paid them significantly less. See *Drugs in Litigation: Damage Awards Involving Prescription and Nonprescription Drugs* 918 (1992); Knightley et al., *supra* note 30, at 131–34.

111. See *supra* notes 96–104 and accompanying text.

112. See *supra* notes 107–110 and accompanying text.

113. See *supra* notes 92–95 and accompanying text (suggesting that thalidomide is part of the reason that proof rules on causation are inconsistent and burdensome).

Attention to evidence, however, also indicates that the drastic remedy of eliminating or preempting tort law for claims of toxic exposure is a bad idea, at least for the moment. Administrative compensation schemes are especially vulnerable to many of the charges now levied at tort liability: similar problems of causation, transaction costs, and defining what is compensable would persist in such a plan.¹¹⁴ Mass torts are a false cure for toxic exposure not because tort liability is pernicious but because it is inadequate. Accordingly, tort law should not be "preempted," in Mary Lyndon's phrase, but rather supplemented by regulation and other policy initiatives.¹¹⁵ The thalidomide experience gives focus and particularity to the effort of balancing difficult choices.

B. *Living with Causal Uncertainty in Policymaking*

In the forum of public debate, as in the courts, assertions about toxicity fall short of causation ideals. Yet a brief survey of literature describing Gulf War syndrome, breast implant accusations, endocrine disruptors, chronic fatigue syndrome, fibromyalgia syndrome, and the like reveals that although skeptics publish trenchant and persuasive arguments they cannot defeat the believers.¹¹⁶ The confidence of claimants and their spokespersons is equalled, but not bested, by the confidence of self-appointed rationalist defenders of truth.

A memory of thalidomide ought to squelch this feeling of certainty on both sides of the new-syndrome debates over substances alleged to be toxic. Thalidomide demonstrates that a synthesized toxin can poison thousands of people, and rationalists must respect the reality of this point. For their part, new-syndrome claimants must recall all the certainty that thalidomide offered observers—short limbs and other stark consequences, strong correlation between exposure and effect, and (subsequent) replications of phocomelia in laboratory animals. Vaguer claims and a long list of symptoms or manifestations dilute this certainty.

The post-thalidomide approach to toxic exposure requires a change from all-or-nothing causation standards to graded responses. Some allegations about dangerous conditions and the harms they cause are strong enough to support the proverbial further study; stronger claims warrant regulatory action; a different set of claims may justify special compensation plans; other claims are, have been, and will always be arrant non-

114. See Rosenberg, *supra* note 105, at 726–30; Ruhl, *supra* note 105, at 653–56.

115. Mary L. Lyndon, *Tort Law and Technology*, 12 *Yale J. on Reg.* 137, 143 (1995).

116. Prominent skeptical works include Marcia Angell, *Science on Trial: The Clash of Medical Evidence and the Law in the Breast Implant Case* (1996); Elaine Showalter, *Hystories: Hysterical Epidemics and Modern Culture* (1997); Michael Fumento, *A Confederacy of Boobs: Breast Implants, Reason*, Oct. 1995, at 36, available in LEXIS, NEXIS Library, MAGS File; Michael Fumento, *Gulf Lore Syndrome. (Myths About Illnesses Suffered by Gulf War Veterans)*, *Reason*, Mar. 1, 1997, at 22, available at 1997 WL 9426590. One environmentalist urges skepticism about skepticism. See David Helvarg, *Poison Pens*, *Sierra*, Jan.–Feb., 1997, at 31.

sense.¹¹⁷ All these gradations occupy lower places than traditional positivist standards of causation that scientists often favor,¹¹⁸ and will also frequently fail the preponderance-of-the-evidence rules of civil liability. But they do not all deserve equal measures of the same skeptical dismissal.

Unvarying skepticism about toxic risks is an irresponsible stance. "Innocent until proven guilty," writes journalist Mark Hertsgaard, "may sound fine in theory, but it lets the bodies pile up before the truth gets written."¹¹⁹ Conventions of scientific knowledge, research design, and business practice limit the accretion of evidence about toxicity.¹²⁰ For example, most studies about exposure hazards look at one substance rather than combinations;¹²¹ low doses and slow exposure are seldom investigated, in part because of methodological difficulty;¹²² and the risk of cancer has tended to be overemphasized at the expense of studying other health effects.¹²³ Add to these biases the staggering quantity of possible sources of harm—in 1989 the United States made and imported 5.9 trillion pounds of industrial chemicals, excluding pesticides, pharmaceuticals and food additives,¹²⁴ to say nothing of natural poisons and alleged toxins, such as Gulf War exposure, that implicate sources beyond the list—and the conclusion of "proven guilty" becomes even more impossible. Environmental scholars have struggled mightily with such questions

117. For analogies from the regulation literature, see Ian Ayres & John Braithwaite, *Responsive Regulation: Transcending the Deregulation Debate* 35 (1992) (describing "pyramid" of regulatory options, ranging from "persuasion" at the bottom to "license revocation" at the apex); Dale Gieringer, *The FDA's Bad Medicine: Overregulation is Dangerous to Your Health*, Heritage Found. Pol'y Rev., Summer 1985, available in LEXIS, NEXIS Library, POLICY File (outlining drug regulations in the range between approval and no approval).

118. See Angell, *supra* note 116, at 108–10 (describing traditions of scientific knowledge); see also Feldman, *supra* note 86, at 42 (noting tendency of scientists to favor delay rather than closure in the face of uncertainty).

119. Mark Hertsgaard, *Benefit of the Doubts*, *Nation*, July 8, 1996, at 10.

120. See Wendy E. Wagner, *Choosing Ignorance in the Manufacture of Toxic Products*, 82 *Cornell L. Rev.* 773, 784–90 (1997).

121. See Theo Colborn et al., *Our Stolen Future: Are We Threatening Our Fertility, Intelligence, and Survival?—A Scientific Detective Story* 220 (1996); see also Mark Hertsgaard, *A World Awash in Chemicals*, *N.Y. Times Book Rev.*, Apr. 7, 1996, at 25 (reviewing Colborn et al., *supra*).

122. See Maurice Zeeman, *Our Fate Is Connected with the Animals*, 46 *BioScience* 542, 544 (1996) (reviewing Colborn et al., *supra* note 121); Joel A. Tickner, *Draft Dissertation Proposal 1–2* (1997) (unpublished Ph.D. dissertation proposal, University of Massachusetts, Lowell, Work Environment Program) (on file with the Columbia Law Review).

123. See Colborn et al., *supra* note 121, at 198–203. Cancer is elevated to a high place among diseases in the federal Delaney Clause, which bans food additives that cause cancer in any animal species. See 21 U.S.C. § 348(c)(3)(A) (1994).

124. See Zeeman, *supra* note 122, at 544.

of risk assessment and so, rather than belabor the subject of a mature literature,¹²⁵ I would only add a word related to thalidomide.

In 1965 the term *vorsorgeprinzip* emerged in Germany soon after the devastation of thalidomide, a time when policymakers surveyed industrial expansion and the weaknesses of pollution-control legislation.¹²⁶ The *vorsorgeprinzip*, or precautionary principle, asserted that society should seek to avoid harm to the environment by blocking the flow of potentially harmful activities.¹²⁷ Expressly endorsed in the 1992 Rio Declaration and other international agreements,¹²⁸ the precautionary principle is an influential reminder of past industrial calamity. One critic writes that “[t]he theory can be traced back to Rachel Carson’s *Silent Spring*,”¹²⁹ but its public acceptance must owe some credit to the concrete, particular disaster of thalidomide.

Thalidomide continues to have meaning for policymakers seeking to live by the cryptic precautionary principle.¹³⁰ It focuses concern: because regulation is constrained by scarcity, serious and real risks to human beings ought to be at the center of public health regulation, with lesser hazards—trivial risks, risks for which there is only weak causal evi-

125. See Stephen Breyer, *Breaking the Vicious Circle: Toward Effective Risk Regulation* (1993); Carl F. Cranor, *Regulating Toxic Substances: A Philosophy of Science and the Law* 11 (1993); *Risk Versus Risk: Tradeoffs in Protecting Health and the Environment* (John D. Graham & Jonathan Baert Wiener eds., 1995); *Valuing Health Risks, Costs, and Benefits for Environmental Decision Making* (P. Brett Hammond & Rob Coppock eds., 1990); Viscusi, *supra* note 63; Richard B. Howarth, *Sustainability Under Uncertainty: A Deontological Approach*, 71 *Land Econ.* 417 (1995).

126. See Konrad von Moltke, *The Vorsorgeprinzip in West German Environmental Policy*, reprinted in *Royal Comm. on Envtl. Pollution, Twelfth Report: Best Practical Environmental Option* 57–58 (1988); Alex Milne, *The Perils of Green Pessimism*, *New Scientist*, June 12, 1993, at 34, 35.

127. See Tickner, *supra* note 122, at 3–4.

128. See David A. Wirth, *The Rio Declaration on Environment and Development: Two Steps Forward and One Back, or Vice Versa?* 29 *Ga. L. Rev.* 599, 634 (1995).

129. Frank B. Cross, *Paradoxical Perils of the Precautionary Principle*, 53 *Wash. & Lee L. Rev.* 851, 851 (1996). Many credit *Silent Spring*, published in 1962, with crystallizing modern environmental philosophy and the environmental movement. See Fred P. Bosselman & A. Dan Tarlock, *The Influence of Ecological Science on American Law: An Introduction*, 69 *Chi.-Kent L. Rev.* 847, 864–65 (1994).

130. The maxim “better safe than sorry” is often inane, even destructive in application. Regulators have invoked it against new technologies that are safer than old ones, see Peter Huber, *Safety and the Second Best: The Hazards of Public Risk Management in the Courts*, 85 *Colum. L. Rev.* 277, 292 (1985), and in its name have ignored fatal hardships—malaria, starvation, contaminated medical supplies—while fretting over synthetic chemicals that have ameliorated these hardships for millions, see Louis W. Sullivan, *Chemical Villains: A Case Unproved*, *L.A. Times*, Apr. 1, 1996, at B5. Targeted selectively at chemicals and industry, the precautionary principle has begotten environmental regulations whose costs in public health outweigh benefits, even though it could with equal logic be applied against proposed new regulations themselves. See Cross, *supra* note 129, at 859–61.

dence, and dangers to plants and animals—at the periphery.¹³¹ Thalidomide provoked extensive research about hazardous substances,¹³² an initiative of staggering value that must persevere in light of evidence that environmental hazards to human health have been increasing.¹³³ Thalidomide disrupted settled beliefs about causation of injury; today's policymakers and researchers ought to permit their own beliefs—especially the dread of false-positive errors—to be disrupted as they investigate environmental culprits.

C. Regulation and the Welfare State

Academic critics of mass tort litigation as a source of compensation, deterrence, corrective justice, or any other goal are often enthusiastic partisans of strong regulation and social insurance, ideas whose time in the United States they have deemed unlikely to come.¹³⁴ Again thalidomide serves as a pertinent reminder. Though impervious to tort liability and unsatisfactory as a source of principle about causation, a thalidomide-style catastrophe—either the historical event or a similar dis-

131. For suggestions on how to allocate scarce resources in making judgments about human health risks, see Brennan, *supra* note 86, at 502–09 (discussing tests for carcinogenicity); Wagner, *supra* note 120, at 780–82 (describing National Academy of Sciences recommendations for tests to determine certain chemicals' potential health risks). Although the thalidomide experience indicates that serious health risks are indeed central, it frowns on scarcity or "cost-benefit" arguments against burdening manufacturers and regulators with duties to test. Dangers to plants and animals, for example, warrant serious attention, even if costs and benefits to human beings cannot yet be quantified. See Colborn et al., *supra* note 121, *passim* (relying heavily on animal evidence to support broad-scale environmental reform proposals).

132. See Dowie, *supra* note 16, at 60–62.

133. See Colborn et al., *supra* note 121, at 179–95 (noting increases in age-adjusted rates of prostate cancer, ectopic pregnancies, endometriosis, and breast cancer (among postmenopausal women with estrogen-responsive tumors); authors also suggest that increases in hyperactivity and learning disabilities are related to exposure to endocrine disruptors); L.F. Seachrist, Estrogen Linked to Adult Asthma Risk, *Science News*, Oct. 28, 1995, at 279 (noting that women receiving estrogen replacement therapy are 50% more likely to suffer from asthma).

134. See David G. Owen, Deterrence and Desert in Tort: A Comment, 73 Cal. L. Rev. 665, 675 (1985) (calling widespread social insurance "a long way off"); Robert L. Rabin, Some Thoughts on the Efficacy of a Mass Toxics Administrative Compensation Scheme, 52 Md. L. Rev. 951, 975 (1993) (suggesting that hostility to "welfare" makes social insurance a remote prospect); Jack B. Weinstein & Eileen B. Hershenov, The Effect of Equity on Mass Tort Law, 1991 U. Ill. L. Rev. 269, 324 (stating that authors favor government action rather than tort as a source of medical insurance and compensation, but "as realists, we deal with the system we have"). Not all admirers of regulation and social insurance are liberal Democrats. See, e.g., Peter W. Huber, Liability: The Legal Revolution and Its Consequences 18 (1988) (endorsing a combination of regulation and insurance in place of liability); Richard A. Posner, The Path Away From the Law, 110 Harv. L. Rev. 1039, 1041 (1997) (suggesting that if the law heeded the teachings of social science, tort would be replaced by social insurance); W. Kip Viscusi, Toward a Diminished Role for Tort Liability: Social Insurance, Government Regulation, and Contemporary Risks to Health and Safety, 6 Yale J. on Reg. 65, 66 (1989) (recommending increased regulation and insurance).

aster in the future—can be handled by the welfare state and its regulation of hazardous substances. Industrial calamities of the future will be neither prevented nor remedied by tort law; the thalidomide experience tells us that public monies must be spent.

Scholars have made valuable contributions to the welfare-state cause, complementing the law-review attacks on mass torts¹³⁵ with writings that defend state regulation of health risks¹³⁶ and explain how the fragmentary American safety net might be extended to provide social insurance.¹³⁷ These ideas cannot be dismissed as idle, gauzy theorizing disconnected from the real world; the real world has progressed. The second Clinton administration has taken a firm proregulatory stand, for example, and efforts by state attorneys general against cigarette manufacturers depict tobacco exposure as “compensable” (via Medicaid recoupment) as well as “tortious.”¹³⁸

In a welfare state persons injured by thalidomide would be compensated; so too would persons with birth defects whose mothers took Bendectin during pregnancy and who have, in the main, been turned away from American courts.¹³⁹ Perhaps the regulatory powers of the welfare state will forestall the next thalidomide.¹⁴⁰ If they fail, social insurance would remain. This new society might even be attainable—who knows? Thalidomide is, among other things, a lesson in possibilities, a warning to expect the unexpected—and it would behoove persons who understand the effects of a disability whether through personal experi-

135. See *supra* notes 96–104 and accompanying text.

136. See Peter L. Kahn, *Regulation and Simple Arithmetic: Shifting the Perspective on Tort Reform*, 72 N.C. L. Rev. 1129, 1134–35 (1994); Susan Rose-Ackerman, *Tort Law in the Regulatory State*, in *Tort Law and the Public Interest: Competition, Innovation, and Consumer Welfare* 80, 82 (Peter H. Schuck ed., 1991).

137. See Stephen D. Sugarman, *Doing Away with Personal Injury Law: New Compensation Mechanisms for Victims, Consumers, and Business* 127–48 (1989) (proposing extensions of current mechanisms); Kenneth S. Abraham & Lance Liebman, *Private Insurance, Social Insurance, and Tort Reform: Toward a New Vision of Compensation for Illness and Injury*, 93 Colum. L. Rev. 75, 109–16 (1993) (detailing three models of social insurance, all derived from existing practices); *id.* at 117 (calling national health insurance “the necessary first step”).

138. See Graham E. Kelder, Jr. & Richard A. Daynard, *The Role of Litigation in the Effective Control of the Sale and Use of Tobacco*, 8 Stan. L. & Pol’y Rev. 63, 70 (1997) (noting a more promising outlook for current tobacco-related litigation); Michael K. Mahoney, *Coughing Up the Cash: Should Medicaid Provide for Independent State Recovery Against Third-Party Tortfeasors Such as the Tobacco Industry?*, 24 B.C. Envtl. Aff. L. Rev. 233, 268–69 (1996) (arguing that the case for allowing Medicaid recoupment is strengthened by reference to insurance needs rather than to the “evil” of tobacco). But see David R. Henderson, *Joe Camel: Brought to You by the FTC: Do Washington Regulators Cause Cancer?*, *Fortune*, July 21, 1997, at 31, 32 (criticizing efforts of Clinton administration to increase regulation of tobacco).

139. See Feldman, *supra* note 86, at 4; *supra* notes 85–86 and accompanying text.

140. John Goldberg argues persuasively, following Judge Weinstein, that they will not. See John C.P. Goldberg, *Misconduct, Misfortune, and Just Compensation: Weinstein on Torts*, 97 Colum. L. Rev. 2034, 2037–38 (1997).

ence, caregiving, advocacy, research, or the practice of law to lend their firsthand knowledge to the cause of building regulation and social insurance.¹⁴¹

CONCLUSION

To bury or praise thalidomide? News stories describe a substance that can wreak its destruction in a beneficial way, fighting malignant growths, unwanted new blood vessels, painful symptoms, and a host of diseases.¹⁴² In this Essay, thalidomide has served as a contrary metaphor, invoking malformation and error rooted in iterations of the past. I have argued in particular that thalidomide not only left American plaintiffs uncompensated but put future mass-tort plaintiffs in a worse position, having set up perilous ideals of individualism, self-congratulation, and unattainable certainty about causation.

Yet I have also confessed my hope that thalidomide might be put to beneficial use in law and policy, just as it continues to serve humanity in medicine and public health. Like other countries, the United States has a thalidomide heritage, and that heritage ought to limit, not bolster, the American faith in mass torts. Mass-tort liability has done much good in the United States, but not enough. A wealthy nation has the money—as well as the pressing challenges created by threats to public health—to invest much more, through regulation and social welfare spending, in its own prosperity.

141. Randy Warren of Canada and Freddie Astbury of Britain are two thalidomide-afflicted activists whose efforts could be extended to argue more generally for the kind of social insurance available to all citizens of their countries.

142. See Sherman & Strauss, *supra* note 58, at 468; Ready, *supra* note 5, at A1; Stolberg, *supra* note 5.