TORT LIABILITY AND THE AVAILABILITY OF CONTRACEPTIVE DRUGS AND DEVICES IN THE UNITED STATES

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PART I.
INTRODUCTION

Almost sixty percent of all pregnancies in the United States are unintended.[1] In addition, many sexually active Americans are at risk for sexually transmitted diseases and AIDS.[2] Intrauterine devices are virtually unused in the U.S., even though they are widely utilized in Europe.[3] So far in the 1990s, only three new contraceptive methods have been approved by the U.S. Food and Drug Administration (hereinafter FDA).[4] One, Norplant, a hormonal implant, was quickly challenged by product liability lawsuits.[5] The second, a female condom, has not been widely used.[6] The third, Depo-Provera, an injectable hormone, won FDA approval twenty years after approval was first sought.[7] RU 486, a medical abortifacient commonly used in Europe, is in clinical trials in the United States.[8]

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1. COMMITTEE ON UNINTENDED PREGNANCY, INSTITUTE OF MED., THE BEST INTENTIONS: UNINTENDED PREGNANCY AND THE WELL-BEING OF CHILDREN AND FAMILIES 1 (Sarah S. Brown & Leon Eisenberg eds., 1995).

2. In a representative study of sexually active people, 17 percent of those studied suffered from sexually transmitted diseases (STDs). R. Turner, *Monogamy is the Rule, Many Partners the Exception Among Most Americans, First U.S. Sex Survey Finds*, 27 FAM. PLAN. PERSP. 37, 39 (1995). In 1989, 12 million people in the United States had STDs other than HIV. NATIONAL CENTER FOR HEALTH STAT., U.S. DEP'T OF HEALTH AND HUMAN SERVS., HEALTHY PEOPLE 2000 REVIEW 1994, at 117 (1995). In the 96 metropolitan statistical areas with a population greater than 500,000, there are an estimated 565,000 prevalent and 38,000 incident HIV infections. This translates into approximately 700,000 prevalent cases of HIV infection and an annual increase in new HIV infections of 41,000. Scott D. Holmberg, *The Estimated Prevalence and Incidence of HIV in 96 Large U.S. Metropolitan Areas*, 86 Am. J. Pub. Health 642, 642 (1996). As of Jan. 1, 1993, there were between 630,000 and 897,000 persons living with HIV infection. R.J. Biggar & P.S. Rosenberg, *Modeling HIV/AIDS Trends in the U.S. by Age, Gender, Race and Exposure*, AIDS WKLY. PLUS, Mar. 25, 1996, at 30.

3. In Scandinavia, 18.2 percent of married women of reproductive age use IUDs. In the rest of Europe, including the former Soviet Union, the figure is 7.2 percent. Katherine Treiman, Laurie Liskin, Adrienne Kols, Ward Rinehart, *IUDs—An Update, in* POPULATION REP., Dec. 1995, at 1, 23. The IUD is the principal method of birth control among women in Norway and Finland. ELISE F. JONES, JACQUELINE DARROCH FORREST, STANLEY K. HENSHAW, JANE SILVERMAN, AIDA TORRES, PREGNANCY, CONTRACEPTION, AND FAMILY PLANNING SERVICES IN INDUSTRIALIZED COUNTRIES 18 (1989). The availability of IUDs in the United States is discussed *infra* Part III.C.1.

4. Michael Klitsch, *Still Waiting for the Contraceptive Revolution*, 27 FAM. PLAN. PERSP. 246, 246 (1995).

5. *See infra* Part III.C.2.

6. In 1995, approximately 2.5 million female condoms were sold, while the number was more than 600 million for male condoms. Stephanie Schorow, *Female Condom is an Increasing "Reality" for Many Women*, BOSTON HERALD, May 30, 1996, at 41.

7. Michael Klitsch, *supra* note 4, at 246.

8. *See* discussion *infra* Part III.C.3.

This paper summarizes recent information and analysis addressing the following questions: How does the risk of liability contribute to the development of new contraceptives and the continued availability of those now used? Is this cause for concern? If it is, what proposals have been made to change liability processes and to make contraceptives more widely available? What are the strengths and weaknesses of these proposals? This article focuses on the availability of products, not on the organization and financing of family planning services. It seeks to present the facts and arguments, rather than to defend any particular approach.[9] I do, of course, bring a large set of values to this project. These values support information, choice, the availability of products, the benefits of innovation, the provision of fair and effective mechanisms to assure that products are reasonably safe, and compensation for people who suffer injuries that could reasonably have been avoided.

Part II supplements Professor Mark Mildred's discussion of the larger context of regulation and tort liability that explains many of the differences between the liability experience in the U.S. and Europe.[10] It examines recent federal proposals to reform U.S. liability law and litigation processes. Although most tort law in the United States is defined at the state level, federal reform is more attractive to drug manufacturers because they operate in national markets.[11] Nonetheless, proposals for radical change at the federal level have been rejected over the past two decades.[12] Instead, reform in the United States has more often been implemented in a focused, incremental manner, usually at the state level.[13]

Part III examines the liability history of particular contraceptive drugs and devices and other related products.

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9. In the 1980s, some commentators suggested that the costs of, and delays in, the FDA approval process were significant factors delaying the introduction of new drugs, particularly contraceptives. *See, e.g.*, Stephen L. Isaacs & Renee Holt, *Drug Regulation, Product Liability, and the Contraceptive Crunch: Choices Are Dwindling*, 8 J. LEGAL MED. 533, 534-538 (1987). In response to these criticisms, the FDA has streamlined its approval process. John Schwartz, *Americans Receive New Medicines as Quickly as Others, FDA Asserts: Red Tape Does Not Keep Lifesaving Drugs Off Market, Kessler Says*, WASH. POST, Dec. 13, 1995, at A3. Since the FDA approval process is no longer viewed as a major barrier to the introduction of new products, reforms in that process will not be addressed in this paper. The legal effect of FDA approval is discussed *infra* Part II.D.

10. *See generally* Mark Mildred, *Litigation Rules and Culture: The European Perspective*, 23 N.Y.U. REV. L. & SOC. CHANGE Part V (1998) (arguing that despite similar substantive law in the United States and Europe, significant procedural rules and cultural differences exist, leading to divergent experiences in the area of tort liability).

11. Gary T. Schwartz, *Product Liability and Medical Malpractice in Comparative Context*, *in* THE LIABILITY MAZE 28-80 (Peter W. Huber & Robert E. Litan eds., 1991).

12. The Contract with America, for example, included a pledge to enact tort reform measures and thereby federalize an area of law that has largely been left to the states. Patrick Hoopes, *Tort Reform in the Wake of United States v. Lopez*, 24 HASTINGS CONST. L.Q. 785, 785-86 (1997). Opponents have claimed that tort law is a traditional state function immune from federal preemption under federalist principles. *Id.*

13. *See id.* (noting "formidable grass-roots movements in many states have successfully promoted legislation to limit damage recoveries in tort actions").

Part IV uses the histories of particular drugs and devices to highlight reform strategies that have not been discussed in prior sections.

PART II.
THE LITIGATION RULES

The substantive rules defining when a drug manufacturer is liable for injuries suffered by a person who uses a drug are remarkably similar in the United States and Europe.[14] As Professor Mildred explains, the greater differences between the systems lie in the rules governing the litigation process.[15] The differences between the litigation processes in the United States and Europe are thought to increase the risks of liability in the United States. First, in the U.S., the general rule is that each party finances his or her own litigation, and plaintiffs may hire lawyers on a contingent fee basis.[16] Second, in the U.S., factual disputes are resolved by lay juries, rather than judges or expert panels.[17] Third, punitive damages, designed to punish wrongdoing, are more widely available in the United States.[18]

In recent years, changes in U.S. litigation rules have been proposed at the state and federal levels, both generally and with respect to particular types of litigation. This part briefly summarizes recent developments on these issues. Finally, it discusses the role of FDA approval in assessing tort liability[19] and considers recent developments in class action litigation.[20]

A. Paying Lawyers

The United States is one of a minority of nations that have adopted the principle, known as the American Rule, that absent an express statutory exception, each party must compensate its own attorney.[21] In contrast, under the English Rule, the losing party pays the prevailing party's

14. Schwartz, *supra* note 11, at 28-80; *see also* Mildred, *supra* note 10, at Part V (noting a shift in European substantive law toward the United States model of liability).

15. Mildred, *supra* note 10, at Part V.

16. John F. Vargo, *The American Rule on Attorney Fee Allocation: The Injured Person's Access to Justice*, 42 AM. U. L. REV. 1567, 1569, 1617 (1993).

17. *See id.* at 1603. Juries are used as fact-finders in civil cases according to the Seventh Amendment of the Constitution: "In suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved." U.S. CONST. Amend. VII.

Lay juries play less of a role in Europe than in the United States. Ernst C. Stiefel, *Resolution of International Products Liability Disputes: An Emerging Procedural Framework*, 16 BROOK. J. INT'L L. 267, 271 n.26 (1990); Sara F. Leibman, *The European Community's Products Liability Directive: Is the U.S. Experience Applicable?* 18 LAW & POL'Y INT'L BUS. 795, 797 (1986). Ireland is the only European Union country in which the right to a civil jury exists. *Leibman*, *supra*, at 811.

18. PRODUCT LIABILITY: EUROPEAN LAWS AND PRACTICE 11 (Christopher Hodges ed., Sweet & Maxwell 1993) (stating that punitive damages are not available in most European product liability cases).

19. *See infra* Part II.D.

20. *See infra* Part II.E.

21. Vargo, *supra* note 16, at 1569, 1587.

costs, including reasonable attorney's fees.[22] Also, ethical rules in the United States allow lawyers to represent injured people on a contingent fee basis, under which the lawyer's compensation is set as a proportion of the plaintiff's recovery and made contingent upon the success of the claim.[23] By contrast, contingent fees are regarded as unethical in many other legal cultures.[24]

In 1995 and 1996, Congress considered proposals to alter U.S. ground rules for paying lawyers.[25] Legal reform was a central component of the Republican Party's "Contract With America."[26] Among the Contract's many proposals for alteration of the civil litigation process was the institution of the English Rule, requiring that the losing party in a civil suit pay the attorneys' fees and other court costs incurred by the prevailing party.[27]

Defenders of the American Rule for paying lawyers argue that it is essential to enable all but the very rich to bring suits to vindicate rights and receive compensation, and that the uncertainties of litigation make it unfair to penalize someone for pressing a claim that proves unsuccessful.[28] Proponents of the English Rule argue that the common law principle that one whose rights have been violated should be made whole supports the idea that the loser should pay the winner's litigation costs.[29] Apart from considerations of fairness, proposals to change the U.S. rules for paying lawyers are driven by a perception that frivolous claims unfairly penalize defendants with deep pockets and unreasonably deter innovation.[30] However, in England many argue that the American Rule is more fair and the English are now experimenting with contingent fee arrangements.[31]

The 1995 Contract with America fee-shifting proposal encountered substantial opposition in the Congress, and the focus changed to proposals

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22. *Id.* at 1569.

23. *Id.* at 1617.

24. JOHN FLEMING, THE AMERICAN TORT PROCESS 17-21(1988).

25. *See, e.g.*, Civil Justice Fairness Act of 1995, S. 672, 104th Cong. § 304 (1995); Common Sense Legal Reform Act, H.R. 10, 104th Cong. § 101 (1995); Civil Justice Reform Act of 1995, S. 243, 104th Cong. § 2 (1995); Attorney Accountability Act of 1995, H.R. 988, 104th Cong. § 2 (1995).

26. CONTRACT WITH AMERICA: THE BOLD PLAN BY REP. NEWT GINGRICH, REP. DICK ARMEY AND THE HOUSE REPUBLICANS TO CHANGE THE NATION 151-52 (Ed Gillespie and Bob Schellhas eds., 1994) [hereinafter CONTRACT WITH AMERICA].

27. *Id.* H.R. 10, 104th Cong. § 101 (1995). Senator Grassley introduced a similar provision in the Senate. S. 243, 104th Cong. § 2 (1995).

28. *See, e.g.*, Fleischmann Distilling Corp. v. Maier Brewing Co., 386 U.S. 714, 718 (1967).

29. *See* Frances Kahn Zemans, *Fee Shifting and the Implementation of Public Policy*, 47 L. & CONTEMP. PROBS. 187, 188 (1984).

30. Justice O'Connor's opinion concurring in part and dissenting in part in *Browning Ferris Indus. of Vt., Inc. v. Kelco Disposal, Inc.*, 492 U.S. 257, 282 (1989), asserts that punitive damages have "a detrimental effect on the research and development of new products."

31. *See Order in the Tort: A Survey of the Legal Profession, Are America's Lawyers a Competitive Disadvantage?*, ECONOMIST, July 18, 1992, at 8, 12. ("The English system discourage[s] risk-averse plaintiffs with legitimate but not air-tight cases.").

to encourage settlement, rather than proposals to discourage litigation.[32] Proposals to encourage settlement provide that if an ultimate judgment is less favorable to an offeree than a rejected offer, the offeree must pay the attorney fees expended by the offeror from the date of the rejection of the offer.[33] These proposals were adopted in the House, but strongly opposed in the Senate. In March 1996, Congress reached agreement on a tort reform package providing strong incentives for settlement, but not adopting the loser pays provision; the President vetoed the bill.[34]

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32. THE COMMITTEE ON FEDERAL LEGISLATION, BAR ASS'N OF THE CITY OF NEW YORK, *Attorney Fee-Shifting and the Settlement Process*, 51 RECORD OF THE ASS'N OF THE BAR OF THE CITY OF N.Y. 391, 404 (1996) [hereinafter 1996 N.Y.C. BAR REP.].

33. These proposals differ in their details. Judge William W. Schwarzer presented a sophisticated version of this proposal in *Fee-Shifting Offers of Judgment—An Approach to Reducing the Cost of Litigation*, 76 JUDICATURE 147, 151-53 (1992). Judge Schwarzer would permit the shifting of attorney fees based on the rejection of settlement offers more favorable to the offeree (either plaintiff or defendant) than the ultimate outcome of the litigation. Recoverable costs would include reasonable attorney fees incurred following expiration of the time for acceptance of a settlement offer. Recoverable costs would be limited to the amount of the judgment, and reduced by the amount by which the offeror benefits from paying or receiving the judgment compared with what he or she would have paid or received under the original offer. Courts would retain discretion to reduce or reject fee-shifting where necessary to avoid undue hardship. *Id.*

The American Bar Association proposed a similar approach. However, under the ABA proposal, an offeree who rejects a settlement offer more favorable than the judgment would be liable for fee-shifting only if the judgment was *substantially* different than the rejected offer. More specifically, under the ABA proposal, fee-shifting kicks in only if a judgment is more than 125 percent of plaintiff's offer or less than 75 percent of the defendant's. *See* Henry J. Reske, *ABA Won't Endorse Fee Shifting, but OKs Model*, A.B.A. J., Apr. 1996, at 34.

On March 1, 1995, the House Judiciary Committee approved the Attorney Accountability Act of 1995. H.R. 988, 104th Cong. § 2 (1995). Passed by the House, it would shift fees in diversity cases where a litigant rejects a settlement offer and subsequently obtains a judgment less favorable than the rejected settlement offer. CONGRESSIONAL RESEARCH SERVICE, PRODUCT LIABILITY BILLS PASSED BY THE HOUSE AND THE SENATE: SIDE-BY-SIDE ANALYSIS 2 (1996). Unlike the Schwarzer and ABA proposals, a litigants' liability for attorneys' fees is not limited to the amount of recovery. *Id.* On April 4, 1995, Senator Orrin Hatch, Chair of the Senate Judiciary Committee, introduced a bill entitled the "Civil Justice Fairness Act of 1995." S. 672, 104th Cong. § 1 (1995). Like the Schwarzer proposal, the Hatch bill would require fee shifting when a settlement offer is rejected. *Id.* at § 304. Unlike the Schwarzer proposal it places no limits on the extent of an offeree's exposure to fee-shifting liability and limits the extent to which a fee-shifting award can be reduced in cases of undue hardship. *Id.*

34. The Common Sense Legal Reform Act, H.R. 10, 104th Cong. § 101 (1995), encompassed several bills, including the loser pays provision for diversity cases in the federal courts. H.R. 988, 104th Cong. § 2 (1995). House Republicans separated H.R. 988 from other tort reform legislation to give all measures a better chance of passage. *See* David Masci and Alan Freedman, *Sweeping Curbs on Lawsuits Headed to House Floor*, 53 CONG. Q. WKLY. REP. 605 (1995). *See also* Allan Freedman, *Product Liability: Narrow Bill Crafted to Avoid Bogging Down in Senate*, 53 CONG. Q. WKLY. REP. 1020, 1021 (1995) (discussing Senate opposition to loser pays rules). For an explanation of congressional compromise see *House-Senate Deal Struck on Product Liability Reform*, CONG. DAILY A.M., Mar. 14, 1996. For debate over the presidential veto see H.R. 956, 104th Cong. (1995).

A thoughtful report by the Committee on Federal Legislation of the Bar Association of the City of New York supports carefully crafted proposals to use attorney fee rules to encourage settlement of civil litigation in the federal courts:

> We should not, however, in the name of discouraging frivolous litigation, employ a draconian "loser pays" rule which would have the perverse effect of discouraging meritorious litigation as well. However, fee-shifting can and should be employed to discourage a litigant from continuing to litigate, and waste resources, after they have received a fair offer.[35]

Had they been enacted, the settlement rules adopted by the House and Senate Committees in 1995 and 1996 may have encouraged earlier settlement.[36] However, it is not clear whether the proposed rules would have forced settlement of meritorious claims. More significantly, it seems unlikely that adoption of the settlement rules would have provided significant reassurance to U.S. companies contemplating the marketing of contraceptive drugs and devices.[37]

B. Expert Testimony and Proof of Causation

Typically, a plaintiff who alleges that a drug or device causes injury will offer expert testimony about the connection between the product and the harm.[38] The defendant will offer expert testimony to deny that connection. The trial judge determines whether the expert testimony offered is admissible, and the jury decides, on the basis of expert and other testimony, whether the plaintiff has established that the defendant violated the applicable substantive legal norm, and whether the defendant's conduct or product caused the plaintiff's injury. When each party offers some admissible evidence to support their claim, the trial judge may decide that the evidence so strongly favors one party or the other, that no reasonable jury could conclude otherwise. In these circumstances the judge may grant summary judgment or direct a verdict.

Standards governing the admission of expert testimony have been debated in recent years. From the 1920s until the 1970s, the dominant standard for determining whether expert scientific evidence could be admitted at trial was whether the expert opinion was "generally accepted" as reliable

35. 1996 N.Y.C. Bar Rep., *supra* note 332, at 413.

36. *See supra* note 34 (discussing legislative bills to encourage settlement).

37. *See* Sheldon Segal, *Introduction*, 23 N.Y.U. REV. L. & SOC. CHANGE 3 (1998) (describing the conference's goals). The complexity of drug company decision-making, particularly in relation to a controversial product, such as contraception, makes it unlikely that settlement rules have a significant impact on a decision to develop and introduce a product.

38. *See, e.g.*, Mark S. Klein, *Expert Testimony in Pharmaceutical Product Liability Actions*, 45 FOOD DRUG COSM. L.J. 393 (1990) (explaining the role of expert testimony in establishing causation).

in the relevant scientific community.[39] The Federal Rules of Evidence, adopted in 1973, marked a change from the common law standard. The new rules provided instead that, "All relevant evidence is admissible, except as otherwise provided.... Evidence which is not relevant is not admissible."[40] The specific rule governing expert testimony provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training or education, may testify thereto in the form of an opinion or otherwise.[41]

Defendants, and some members of the scientific community, believe that this standard for the admission of expert testimony allows juries undue freedom to award damages to sympathetic plaintiffs in situations in which no reliable evidence supports the assertion that the defendant's product caused injury.[42] In 1993, the Supreme Court addressed this dispute in *Daubert v. Merrell Dow Pharm., Inc.*[43] In *Daubert* the plaintiffs asserted that their child's birth defects had been caused by the Bendectin that the mother took during her pregnancy.[44] The defendants introduced substantial evidence that Bendectin does not cause birth defects and plaintiffs introduced expert evidence of case reports purporting to show a connection between the drug and birth defects.[45] The district court granted the defendants' motion for summary judgment, holding that an expert opinion is not admissible to establish causation unless it is based on epidemiological evidence which is generally accepted in the relevant scientific community.[46]

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39. *See* Frye v. United States, 293 F. 1013, 1014 (1923). *Frye* held that evidence derived from a systolic blood pressure test was not admissible to show whether the subject was telling the truth. Because the test had "not yet gained such standing and scientific recognition among physiological and psychological authorities as would justify the courts in admitting expert testimony deduced from the discovery, development, and experiments thus far made," evidence of its results was ruled inadmissible. *Id.*

40. FED. R. EVID. 402.

41. FED. R. EVID. 702.

42. *See* Klein, *supra* note 38, at 394 ("'It has become all too common for 'experts' or 'studies' on the fringes of, or even well beyond, the outer parameters of mainstream scientific or medical views to be presented to juries as valid evidence from which conclusions can be drawn. The use of such invalid scientific evidence... has resulted in findings of causation which simply cannot be justified or understood from the standpoint of the current state of credible scientific and medical knowledge.'"(quoting U. S. ATT'Y GEN.'s TORT POLICY WORKING GROUP, THE CAUSES, EXTENT, AND POLICY IMPLICATIONS OF THE CURRENT CRISIS IN INSURANCE AVAILABILITY AND AFFORDABILITY 35 (1986)). *See also* Jay P. Kesan, *A Critical Examination of the Post-Daubert Scientific Evidence Landscape*, 52 FOOD & DRUG L.J. 225, 226 (1997) (arguing that juries give great deference to expert testimony which "invites lay jurors to reach conclusions not grounded in any specific theory or methodology.").

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

44. *Id.* at 582.

45. Bendectin is discussed *infra* Part III.A.3.

46. Daubert v. Merrell Dow Pharm., Inc., 727 F. Supp. 570, 575 (S.D. Cal. 1989).

While plaintiffs offered some epidemiological evidence, the trial court held that it could not be admitted because it had not been published in a peer-reviewed journal.[47] The Ninth Circuit Court of Appeals affirmed.[48]

A unanimous Supreme Court reversed.[49] The Court held that a rigid requirement limiting expert testimony to published, and generally accepted, epidemiological evidence was not consistent with the standards of the Federal Rules of Evidence.[50] However, the Court affirmed that the trial judge has a responsibility to assure that proposed expert testimony is both relevant and reliable under the Federal Rules of Evidence.[51] "[I]n the event the trial court concludes that the scintilla of evidence presented supporting a position is insufficient to allow a reasonable juror to conclude that the position more likely than not is true, the court remains free to direct a judgment, . . . and likewise to grant summary judgment . . . ."[52]

Because the lower courts had applied the wrong standard in excluding the "expert" evidence purporting to show that Bendectin causes birth defects, the case was remanded for a judgment on whether the evidence was admissible under the new standard articulated by the Supreme Court in *Daubert*.[53] The lower courts held that, even under the more expansive standard articulated by the Court, the plaintiff's proposed evidence was so unreliable that it could not be admitted.[54]

The standard for the admissibility of expert evidence raises knotty issues that are discussed below in the context of the Dalkon Shield, silicone breast implants, Bendectin and spermicides.[55] On the one hand, large scale epidemiological studies conducted by scientists who have no stake in the outcome of the research provide the most reliable evidence of causation. On the other hand, sometimes such evidence does not exist.[56] People who suffer injuries have little capacity to organize such studies.[57] Sometimes

47. *Id.*

48. Daubert v. Merrell Dow Pharm., Inc., 951 F.2d 1128 (9th Cir. 1991).

49. Daubert v. Merrell Dow Pharm., Inc., 509 U.S. at 587.

50. *Id.*

51. Before admitting proffered expert testimony, the trial judge must make a "preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." *Id.* at 592-93. "The fact of publication (or lack thereof) in a peer-reviewed journal thus will be a relevant, though not dispositive, consideration in assessing the scientific validity of a particular technique or methodology on which an opinion is premised." *Id.* at 594.

52. *Id.* at 596.

53. *Id.* at 598.

54. Daubert v. Merrell Dow Pharm., Inc., 43 F.3d 1311 (9th Cir.), *cert. denied*, 116 S. Ct. 189 (1995).

55. *See infra* Part III.A.

56. Edward W. Kirsch, *Daubert v. Merrell Dow Pharmaceuticals: Active Judicial Scrutiny of Scientific Evidence*, 50 FOOD & DRUG L.J. 213, 233 (1995); *see also infra* Part III.A.1.

57. Kirsch, *supra* note 56, at 233. (explaining that the first plaintiff in a toxic tort litigation is at a disadvantage because he or she does not have the resources which defendants have to locate scientific evidence).

anecdotal reports of a connection between a drug and an injury seem reliable, in common sense terms. In any case, the *Daubert* approach to admissibility of expert evidence is a matter of construction of the words of Congress in the Federal Rules of Evidence. If the approach is unsound, Congress has the power to change the rule.[58] Alternatively, Congress could create special rules about expert testimony for cases involving drugs and devices, or for some other defined category of cases.[59]

C. *Punitive Damages*

The formal rules describing the circumstances under which punitive damages may be awarded vary from state to state. The American Law Institute reports that common criteria include requirements that the plaintiff show that the defendant's negligent conduct was "malicious," "outrageous," "oppressive," "fraudulent," "willful," "wanton," in "reckless disregard of the rights or safety of others," or "grossly negligent."[60] As a formal matter, these standards demand that plaintiffs prove that the defendant's conduct was more than simply careless or unreasonable.

In most common law cases, the availability of punitive damages is a matter of state law because the Supreme Court has held that the Constitution places few limits on punitive damages and federal law does not address the issue.[61] During the 1980s, more than thirty states enacted bills designed

58. For an analysis approving the approach adopted in *Daubert* see Bert Black, Francisco J. Ayala & Carol Saffran-Brinks, *Science and the Law in the Wake of* Daubert: *A New Search for Scientific Knowledge*, 72 TEX. L. REV. 715 (1994). For an analysis criticizing *Daubert* see MARCIA ANGELL, SCIENCE ON TRIAL: THE CLASH OF MEDICAL EVIDENCE AND THE LAW IN THE BREAST IMPLANT CASE 127-132 (1996). Several states, including New York and California, do not follow the precedent set in *Daubert*. *See, e.g.*, People v. Leahy, 882 P.2d 321, 323 (Cal. 1994) (continuing use of the *Kelly/Frye* standard in determining the admissibility of evidence); People v. Wesley, 633 N.E.2d 451, 454 n.2 (N.Y. 1994) (determining that *Frye* applies and *Daubert* is inapplicable); State v. Carter, 524 N.W.2d 763, 779 (Neb. 1994) (rejecting the *Daubert* standard and reaffirming the standard set by *Frye*); Flanagan v. State, 625 So. 2d 827, 829 n.2 (Fla. 1993) (continuing use of the *Frye* test for the admissibility of scientific techniques); State v. Bible, 858 P.2d 1152, 1183 (Ariz. 1993) (deciding to follow *Frye* and postponing deciding whether Arizona should follow *Daubert*), *cert. denied*, 511 U.S. 1046 (1994).

59. For example, Congress could provide that where a drug or device has been approved by the FDA, expert evidence must be limited to information that was not presented to the agency. *See* discussion of various forms of FDA defense, *infra* Part II.E. Another option, given the enormity and sympathy of claims based on birth defects, is the adoption of special rules by Congress to govern this category of cases. See NAT'L RESEARCH COUNCIL & INST. OF MED., *Products Liability and Contraceptive Development, in* DEVELOPING NEW CONTRACEPTIVES: OBSTACLES & OPPORTUNITIES 141-43 (Luigi Mastroianni, Jr., Peter J. Donaldson, Thomas T. Kane eds., 1990), for a general discussion.

60. AMERICAN LAW INSTITUTE, REPORTERS' STUDY: ENTERPRISE RESPONSIBILITY FOR PERSONAL INJURY: APPROACHES TO LEGAL AND INSTITUTIONAL CHANGE 243-44 (1991) [hereinafter ALI, ENTERPRISE RESPONSIBILITY].

61. *TXO Prod. Corp. v. Alliance Resources Corp.*, 509 U.S. 443 (1993) considered a claim that punitive damages may be so excessive as to violate the Due Process Clause of the Fourteenth Amendment. TXO bought rights to develop oil and gas under land owned by

to limit both the circumstances in which punitive damages may be awarded and the size of awards allowed.[62]

Many observers believe that the risk of punitive damage awards discourages innovation in the United States. Former Vice President, Dan Quayle, expressed the views of the Bush Administration on punitive damages:

> Even a casual observer knows that, in the last several decades, punitive damages have grown dramatically in both frequency and size. What began as a sanction only for the most reprehensible conduct has now become almost routine. . . . And as these awards become more common, so do the instances of their arbitrary, even freakish, application.[63]

Alliance Resources. After the agreement, TXO alleged a claim on Alliance's title, and Alliance Resources counterclaimed with a slander of title suit. The courts and jury agreed that TXO's claim was an intentional and bad faith ploy to renegotiate a better price, a tactic that the company had used in other oil and gas deals. *Id.* at 443, 450. The jury awarded $19,000 in compensatory and $10 million in punitive damages. *Id.* at 451. Justice Stevens, in a plurality opinion, held that punitive damage awards can be so "grossly excessive" as to violate the Due Process Clause of the Fourteenth Amendment, but that the award in this case did not do so. *Id.* at 462. Justice Stevens also reaffirmed that the financial status of the defendant can be taken into account when levying punitive damages. *Id.* at 464. Justices Scalia and Thomas concurred, but stated that there is no substantive Due Process right to be free from excessive punitive damage awards. *Id.* at 470-472. Justice O'Connor, joined by Justices White and Souter in part, dissented, arguing that the punitive damages awarded were so excessive as to violate due process and noting that the jury appeared to be taking revenge on a wealthy out-of-state defendant. *Id.* at 481-496 (O'Connor, J., dissenting).

In *BMW of N. Am., Inc. v. Gore*, 116 S.Ct. 1589, 1595, 1598 (1996), the Supreme Court (for the first time in decades) held that a punitive damage award was so excessive as to violate the Due Process Clause of the Fourteenth Amendment. *Gore* was a fraud suit. Dr. Ira Gore purchased a new BMW from the defendant and later discovered that it had been repainted before the sale (the parties believed that the original paint had probably been damaged by acid rain while the car was in transit). *Id.* at 1593. An Alabama jury awarded Dr. Gore $4,000 in compensatory damages and $4 million in punitive damages based on findings that BMW's conduct constituted "'gross, oppressive or malicious' fraud." *Id.* at 1593-94. The Alabama Supreme Court reviewed the award and granted remittitur to $2 million dollars. *Id.* at 1595. The Court did not draw a bright line for punitive damage awards but ruled that the Alabama award was "grossly excessive" and therefore beyond "the constitutional limit." *Id.* at 1604. Justice Breyer concurred and was joined by Justices O'Connor and Souter. Justice Breyer "conclude[d] that the award in this unusual case violates the basic guarantee of nonarbitrary governmental behavior that the Due Process Clause provides." *Id.* at 1609 (Breyer, J., concurring). Justices Scalia and Thomas dissented, holding that "there is no federal guarantee a damages award actually be reasonable." *Id.* at 1610 (Scalia, J., dissenting). Justice Ginsburg and The Chief Justice also dissented, finding that the Court's holding was an intrusion into an issue that should be decided by state courts and legislatures. *Id.* at 1614 (Ginsburg, J., dissenting).

62. According to Michael Rustad, who has studied the issue extensively, "[o]pponents of punitive damages have scored significant legislative victories at the state level in recent years. Since the mid-1980s, a majority of states have enacted tort reforms curbing punitive damages." Michael Rustad, *In Defense of Punitive Damages in Products Liability: Testing Tort Anecdotes With Empirical Data*, 78 IOWA L. REV. 1, 6 (1992).

63. Dan Quayle, Agenda for Civil Justice Reform in America, Address Before the American Bar Association (Aug. 13, 1991), *in* N.J.L.J., Aug. 29, 1991, at 15.

Quayle's view of punitive damages has been espoused by many other legal commentators. In 1988, Peter Huber asserted that punitive damages are "routine when the injury is serious and a wealthy institution is numbered among the accused."[64] He said that the punitive damages assessed against A.H. Robins, manufacturer of the Dalkon Shield, "opened the floodgates for punitive attacks on . . . safer [contraceptive] substitutes" and ultimately caused other IUD manufacturers to withdraw from the market.[65] In dicta, Supreme Court Justice O'Connor characterized punitive damage awards as "skyrocketing" and asserted that the "threat of such enormous awards has a detrimental effect on the research and development of new products."[66]

Despite these widely held opinions, the empirical evidence suggests that punitive damages are rarely awarded. In the quarter century from 1965 to 1990, punitive damages were awarded in a total of 355 cases involving all types of products in the United States.[67] Professor Teresa M. Schwartz observes that the "small number of cases in itself is noteworthy, given that in the period from 1974 to 1990 there were 161,686 product liability cases filed in the federal system alone, and a vastly larger number in the state system.[68] Professor Michael Saks' exhaustive empirical review of punitive damages concludes that punitive awards are infrequent and not exorbitant, especially when one takes into account judicial orders reducing the amount of damages awarded by juries.[69]

Despite these general patterns, many informed observers assert that punitive damages are sometimes awarded in violation of the formal standards and depart from generally observed patterns. For example, a 1993

64. PETER W. HUBER, LIABILITY: THE LEGAL REVOLUTION AND ITS CONSEQUENCES 127 (1988).

65. *Id.* at 128, 162.

66. Browning-Ferris Indus. of Vt., Inc. v. Kelco Disposal, Inc., 492 U.S. 257, 282 (O'Connor, J., concurring in part and dissenting in part). This was not a products liability case. Kelco sued Browning-Ferris for antitrust violations and the state tort of malicious interference with contract. The jury believed that Browning-Ferris had intentionally tried to drive Kelco out of business and awarded compensatory damages and $6 million in punitive damages. The Supreme Court held that the award did not violate the Excessive Fines Clause of the Eighth Amendment because the clause does not apply to punitive damage awards in cases between private parties. *Id.*

67. MICHAEL RUSTAD, DEMYSTIFYING PUNITIVE DAMAGES IN PRODUCTS LIABILITY CASES: A SURVEY OF A QUARTER CENTURY OF TRIAL VERDICTS 23 (Lee H. Romano ed., 1991).

68. Teresa M. Schwartz, *Punitive Damages and Regulated Products,* 42 AM. U. L. REV. 1335, 1359 (1993).

69. Michael J. Saks, *Do We Really Know Anything About the Behavior of the Tort Litigation System—And Why Not?*, 140 U. PA. L. REV. 1147, 1254-62 (1992). *See also* Stephen Daniels & Joanne Martin, *Myth and Reality in Punitive Damages*, 75 MINN. L. REV. 1, 31, 33 (1990) (analyzing punitive damage awards in selected counties and finding only a marginal increase); William M. Landes & Richard A. Posner, *New Light on Punitive Damages*, REGULATION, Sept.-Oct. 1986, at 33, 35 (studying treatment of punitive damage awards on appeal and finding that relatively few awards survive).

report published by the Rand Institute on Civil Justice asserts that "punitive damages have been assessed in cases where there is considerable doubt about injury causation. The most prominent examples may be punitive damages assessed against Bendectin."[70] The Rand Report cites statements by the Pharmaceutical Manufacturers' Association and the American Medical Association, and one case to support this claim. However, in the one cited case, the defendant paid *no* damages; the trial court reversed the jury's award of punitive damages and the appeals court granted the defendant's motion for a judgment notwithstanding the verdict.[71]

Advocates of restricting punitive damages also claim that damages were imposed against Ortho Pharmaceutical Company "for not providing a warning [about an oral contraceptive] that the FDA had in fact previously prohibited from appearing."[72] The facts do not support the claim that the FDA prohibited the company from providing a warning about the risk of kidney disease and oral contraceptives. On the other hand, the FDA's expressed lack of concern about the problem raises serious questions about the fairness of imposing punitive damages.[73]

Perhaps a case can be made for broader limits on punitive damages, *not* on the basis that they are, in fact, common, exorbitant and out of control, but rather on grounds that punitive damages are widely feared and unpredictable.[74] If a product has high utility and a low profit potential,

70. STEVEN GARBER, PRODUCT LIABILITY AND THE ECONOMICS OF PHARMACEUTICALS AND MEDICAL DEVICES 49-50 (1993).

71. Ealy v. Richardson-Merrell, Inc., 897 F.2d 1159 (D.C. Cir. 1990), *cert. denied*, 498 U.S. 950 (1990). A federal jury awarded the plaintiff $95 million in damages, $75 million of which was punitive. In a post-trial hearing, the trial court granted remittitur of the entire punitive damage award but let the $20 million actual damage award stand and denied the defendant's motion for a directed verdict. The Circuit Court granted the defendant a directed verdict, thereby reversing the entire judgment. *Id.*

72. Wooderson v. Ortho Pharm. Corp., 681 P.2d 1038, *cert. denied*, 469 U.S. 965 (1984), *quoted in* Jay M. Rector, *The Learned Intermediary Rule: What Should the Patient Know?*, FED'N OF INS. & CORP. COUNS. Q., Fall 1989, at 67, 76. The claim is repeated in GARBER, *supra* note 70, at 50.

73. The Court found that scientific evidence supported a relation between Hemolytic-uremic syndrome (HUS) and high estrogen birth control pills, that the defendant was aware of that evidence and failed to warn doctors of this possible side effect, and that plaintiffs' experts testified that oral contraceptive use was the direct cause of the loss of both her kidneys, among other injuries. Wooderson, 681 P.2d at 1064. The G.D. Searle company, another manufacturer of oral contraceptives, had sent the FDA several proposals for package insert warnings, including one warning about HUS. The FDA wrote to Searle, "... that it did not concur with the additional changes" included in the proposal. The court found that "[t]his letter cannot be construed as a clear determination by the FDA that contraceptive-induced HUS does not merit warnings." *Id.* at 1057.

74. My colleague, Professor Diane Zimmerman, observes, "the data does not necessarily tell us the whole story about punitive damages as a disincentive.... Even if the plaintiff does not prevail, a fair amount of energy and resources may be expended simply to combat the risk that a jury *might* award them. Also, the multiple awards risk ought to be mentioned. One thing that really seems to scare clients is the thought that if they begin losing cases, they will have to pay punies each time out." Letter from Diane Zimmerman, Professor, New York University School of Law, to author (Sept. 30, 1996) (on file with author).

limiting punitive damages might encourage development. An assurance by law that injuries produced by a particular product will never give rise to an award of punitive damages might make the manufacturer more willing to develop and market the product.

Further, assurance that a product will never give rise to an award of punitive damages might lead a manufacturer to set a lower price knowing that the cost of the product does not need to reflect the risk of punitive damages. Others argue that the slight risk of punitive damages performs a useful social function. Manufacturers, their lawyers, and political allies propagate myths that create an irrational fear of potential punitive damage awards. While it seems unwise to premise public policy on irrational myths and fears, if those sentiments are widely held and influence decisions about the availability of useful products, perhaps protection against punitive damages makes sense.

D. The Effect of FDA Approval

Evidence that a drug or device is approved by the FDA and meets FDA guidelines with respect to warnings is not a defense to a negligence claim based on inadequate warnings.[75] Instead, courts regard regulatory standards as minimum safety thresholds; compliance with regulatory standards is evidence of reasonable care, but not necessarily a shield against liability: "Under current law, compliance with the FDA requirements affords only modest protection against the successful lawsuit. . . . Conversely, evidence of non-compliance can be a highly valuable offensive weapon for the plaintiff, virtually establishing liability."[76]

Some people argue that compliance with FDA standards should provide immunity against a claim that a product is defective or inadequately

75. *See, e.g.*, MacDonald v. Ortho Pharm. Corp., 475 N.E.2d 65, 70-71 (Mass.) (rejecting a claim that FDA warning requirements preempt or define common law duty to warn), *cert. denied*, 474 U.S. 920 (1985). Most lawsuits seeking redress for injuries caused by prescription drugs allege that the defendant failed to provide reasonable warning of known adverse side effects. However, some claims assert that the drug itself is defective because it could have been designed more safely and a reasonable manufacturer would have done so. Courts have divided on the effect of FDA approval in these design defect cases. In Brochu v. Ortho Pharm. Corp., 642 F.2d 652 (1st Cir. 1981), the plaintiff suffered a stroke and alleged that the contraceptive she had used was defective because it contained high levels of estrogen even though lower-dose estrogen pills were equally effective. The court permitted the jury to find that the pill was unreasonably dangerous, though it had been approved by the FDA. *Id.* Other courts have held FDA approval provides immunity from strict liability claims of design defects in prescription drugs. *See, e.g.*, Grundberg v. Upjohn Co., 813 P.2d 89, 98-99 (Utah 1991); Collins v. Ortho Pharm. Corp., 231 Cal. Rptr. 396 (Cal. Ct. App. 1986).

76. Jeffrey N. Gibbs & Bruce F. Mackler, *Food and Drug Administration Regulation and Products Liability: Strong Sword, Weak Shield*, 22 TORT & INS. L.J. 194, 243 (1987). The proposed Restatement of Torts would affirm this law. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY §7(b) (Tentative Draft No. 2, March 13, 1995).

labeled.[77] The claim is that the judicial system should defer to safety standards set by regulatory agencies because the agencies have greater expertise than courts and juries in assessing risks and in determining what constitutes reasonable product safety.[78] Reliance on regulatory standards would provide greater uniformity, certainty about what is required of manufacturers, and ability to plan and invest.[79] Incentives for safety would still exist because consumers injured by products that did not meet regulatory standards could sue and recover damages for violations of federal standards.[80]

Opponents of the FDA regulatory defense offer several arguments. Regulations are sometimes not issued or updated promptly.[81] Regulatory "lag" may result because agencies do not have the resources to ensure that all regulations are current.[82] Furthermore, in relation to drug warnings, regulators are dependent upon the quality of information provided to them on an on-going basis.[83] Regulatory agencies sometimes lack the will to im-

77. NAT'L RESEARCH COUNCIL & INST. OF MED., *supra* note 59, at 142; Note, *A Question of Competence: The Judicial Role in the Regulation of Pharmaceuticals*, 103 HARV. L. REV. 773, 792-93 (1990).

78. *See* James A. Henderson, Jr., *Judicial Review of Manufacturers' Conscious Design Choices: The Limits of Adjudication*, 73 COLUM. L. REV. 1531, 1555-56 (1973) (stating that complete deference to Government standards is the best course for courts, although "such an approach is not sufficient to solve the problem of manufacturer liability in injury caused by conscious design choice"); W. Kip Viscusi & Michael J. Moore, *Rationalizing the Relationship Between Product Liability and Innovation*, *in* TORT LAW AND THE PUBLIC INTEREST: COMPETITION, INNOVATION AND CONSUMER WELFARE 105, 125 (Peter H. Schuck ed., 1991) (arguing that courts should take advantage of regulatory agencies' wealth of specialized knowledge that makes them better able than courts to make risk/benefit assessments).

79. *See, e.g.*, ALI, ENTERPRISE RESPONSIBILITY, *supra* note 60, at 87-89 (arguing that a dual system creates a "combination of legal constraints, delays, and uncertainties that imposes special burdens on new products and processes and threatens innovation").

80. In the recent Supreme Court ruling, *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), even the Justices who would have recognized a broad immunity from common law claims for injuries caused by devices approved by the FDA acknowledged the deterrent effect of liability. "Where a state cause of action seeks to enforce an FDA requirement the claim does not impose a requirement that is 'different from, or in addition to' requirements under federal law. To be sure, the threat of a damages remedy will give manufacturers an additional cause to comply . . ." *Id.* at 2264 (O'Connor, J., concurring in part and dissenting in part).

81. *See* U.S. DEP'T OF HEALTH & HUMAN SERVS. ADVISORY COMM., FINAL REPORT ON THE FOOD AND DRUG ADMINISTRATION 39 (1991) (finding that FDA's "grave" resource limitations impose "staggering burdens" on the Agency) [hereinafter FINAL REPORT ON THE FDA].

82. *Id.*

83. The FDA urges doctors to report adverse reactions to the manufacturer, but does not require them to do so. Fewer than ten percent of doctors do any adverse reaction reporting and those that do only report a portion of the reactions they observe. MICHAEL D. GREEN, BENDECTIN AND BIRTH DEFECTS: THE CHALLENGES OF MASS TOXIC SUBSTANCES LITIGATION 55 (1996) [hereinafter GREEN]. Manufacturers are required to report to the FDA "any adverse event associated with the use of a drug in humans, whether or not considered drug related." Postmarketing Reporting of Adverse Drug Experiences, 21 C.F.R. § 314.80 (1996). "Reporting by manufacturers to the FDA, despite the legal requirement,

pose requirements that are burdensome to politically influential actors.[84] Finally, if the availability of the regulatory compliance defense is made contingent upon compliance with FDA standards, including reporting adverse drug reactions, litigation would probably continue over the question of whether the manufacturer had complied with those standards.[85]

Professor Michael D. Green summarizes these concerns.

> [A] compliance defense does not hold much promise for reducing transaction costs; instead, it may exacerbate them by adding an additional layer of litigation filled with peripheral issues for meritorious cases.
>
> [In addition, there is a] concern about the adequacy of FDA resources to oversee the industry in the post-approval period when additional risks are identified. Removing the incentives provided by the tort system for prompt warnings of newly emergent risks and limitations on efficacy may have an unfortunate impact on prompt dissemination of this information.[86]

Congress, or the individual states, may, of course, modify the common law rule that compliance with FDA standards does not preclude tort liability.[87] Several states have adopted statutes that bar or limit liability for inju-

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has been less than perfect. . . . Countries with nationalized health care and centralized reporting have a considerably more effective post-approval surveillance system than exists in the United States. Because of these difficulties, virtually all knowledgeable experts agree that the adverse drug reporting system has been inadequate and unreliable." GREEN, *supra*, at 55.

84. ALI, ENTERPRISE RESPONSIBILITY, *supra* note 60, at 86 (noting that regulatory failure may result from political and bureaucratic pressures); PAUL J. QUIRK, INDUSTRY INFLUENCE IN FEDERAL REGULATORY AGENCIES 13 (1981). From 1980 until 1992, the Reagan and Bush Administrations pressed for federal legislation limiting tort liability, while simultaneously trying to make federal regulations less burdensome to industry. Schwartz, *supra* note 68, at 1344-46. In this weak regulatory environment, a scandal arose, involving the bribery of FDA employees by generic drug company officials. FINAL REPORT ON THE FDA, *supra* note 81, at 1.

85. "Longer and more uncertain causal chains would be litigated, as questions arise about whether a violation of an FDA standard would have made any difference in the chain of events that led to the plaintiff's injury. . . . [A] regulatory compliance defense is unlikely to short-circuit a substantial amount of pharmaceutical litigation, and in some instances may make it yet more expensive by adding another layer of inquiry." GREEN, *supra* note 83, at 343.

86. Michael D. Green, *Statutory Compliance & Tort Liability*, 30 MICH. J. L. REFORM 461, 469 (1997).

87. Most recently *Medtronic Inc. v. Lohr*, 116 S. Ct. 2240, 2258 (1996) held that the Medical Device Amendments of 1976 did not preempt state tort claims based on product defect, negligent manufacture or inadequate warning. The Act, § 360k, pre-empts state requirements that are "different from, or in addition to, any requirement applicable" under the Act and regulations. In addition, FDA regulations provide that "State . . . requirements are preempted only when . . . there are . . . specific [federal] requirements applicable to a particular device . . ." 21 CFR § 808.1(d)(1995). Justice Stevens, for a four person plurality, said "[i]t will be rare indeed for a court hearing a common law cause of action to issue a decree that has 'the effect of establishing a substantive requirement for a specific device.'" Medtronic, 116 S. Ct. at 2259. Justice Breyer concurred, writing that he could "find no

ries caused by drugs approved by the FDA.[88] While Congress has often considered proposals to make compliance with regulatory standards a complete defense to tort liability, or to make such compliance a defense in particular cases, it has never acted on them.[89] Absent clear congressional action, the Supreme Court is closely divided on the question of whether federal statutes that might be read to bar state tort remedies should be interpreted broadly or narrowly.[90]

E. FDA Approval as a Bar to Punitive Damages

Another proposal, considered by Congress in 1991, combined limits on punitive damages with a regulatory defense.[91] The bill would have prohibited punitive damages for injuries caused by drugs approved by the FDA,

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actual conflict between any federal requirement and any of the liability-creating premises of the plaintiffs' state law tort suit . . ." *Id.* at 2261. However, he dissented from the plurality's prediction that "future incidents of MDA preemption of common law claims will be 'few' or 'rare.'" *Id.* at 2262 (Breyer, J., concurring). Justice O'Connor, joined by the Chief Justice and Justices Scalia and Thomas, concurred in the conclusion that plaintiffs' defective design claim was not preempted because the pacemaker alleged to be defective had been approved under the grandfather provisions, § 510(k), of the 1976 Act, exempting products then on the market and their "substantial equivalents" from full-blown FDA review and approval. "Because the § 510(k) process seeks merely to establish whether a pre-1976 device and a post-1976 device are equivalent, and places no 'requirements' on a device, the . . . [plaintiffs'] defective design claim is not preempted." *Id.* at 2264 (O'Connor, J., concurring in part and dissenting in part). However, Justice O'Connor would have held that because the FDA does regulate manufacturing practices and labeling, common law claims based on these theories impose requirements that are "different from" and in "addition to" the federal requirements, and are hence preempted. *Id.*

88. *See* Mich. Comp. Laws Ann. § 600.2946(5) (West Supp. 1996) (pharmaceutical manufacturer not liable for drug approved by FDA subject to exception for fraud on or bribery of FDA); N.J. Stat. Ann. § 2A:58C-4 (West 1987) (rebuttable presumption that a warning provided in FDA approved labeling is adequate); Ohio Rev. Code Ann. § 2307.80(C) (Banks-Baldwin 1996) (barring punitive damages against manufacturer of drug manufactured and labeled in compliance with FDA requirements); Or. Rev. Stat. § 30.927 (1995) (barring punitive damages in pharmaceutical cases in which drug and labeling is approved by the FDA, provided material information is not withheld or misrepresented); Utah Code Ann. § 78-18-2 (1996) (prohibiting the award of punitive damages if the drug causing the plaintiff's injury received pre-marketing approval by the FDA, unless it is shown by clear and convincing evidence that the drug manufacturer knowingly withheld or misrepresented material and relevant information). *See also* Schwartz, *supra* note 68, at 1341 n.37 (citing additional statutes).

89. Several versions of the Products Liability Bill of 1995 contained provisions that would have precluded awarding punitive damages against a manufacturer or product seller of a drug subject to pre-market approval by the FDA. H.R. 956, 104th Cong. (1995) (version 7). If the manufacturer or product seller of a drug intentionally withheld or misrepresented to the FDA information that is material and relevant to the claimant, the provision precluding punitive damages would not apply. *Id.* This provision was removed from the succeeding versions of the bill. H.R. 956, 104th Cong. (1995) (versions 8, 9). The most recent appearance of this provision was in H.R. 2425, 104th Cong. (1995), a bill to reduce Medicare benefits. *See* Cong. Research Serv., *Product Liability Bills Passed by the House and the Senate: Side-by-Side Analysis*, Oct. 18, 1996; T.R. Goldman, *Tort Reform: What Happened, What's Next*, LEGAL TIMES, July 8, 1996, at 1.

90. Medtronic Inc. v. Lohr, 116 S. Ct. at 2261-62.

91. S. 640, 102d Cong. § 303(a)(1991) (Product Liability Reform Act).

excepting cases of fraud, bribery or egregious misconduct.[92] The exceptions would have ensured that punitive damages would have remained available in extreme cases.[93] The proposal also would have provided a complete defense for products which met regulatory standards.[94] In these respects, the proposal would have provided some protection against unpredictable risk.[95]

The bill was not enacted, however, and faced opposition from both sides in the tort reform debate.[96] Those who wanted to protect access to the courts opposed it because they did not believe that punitive damages were either common or misused.[97] On the other side, those who wanted to limit liability did not think that the proposal went far enough; notably, their opposition was premised on the belief that, because punitive damages are so rarely imposed, the bill offered little protection from lawsuits.[98]

F. Class Actions

Recent developments in the use of class actions have had a profound impact on liability for injuries caused by drugs and medical devices. This section briefly describes some of the new developments in the use of class actions. The next section, which describes the liability history of particular drugs, notes the role that class actions played in those conflicts. Finally, the concluding section considers possible reform in class action law.

The class action is a procedural technique in which representatives of a group (class representatives) may assert against the defendants both their own claims and similar claims of other persons who share common interests. Federal Rule of Civil Procedure 23(a) requires that class actions meet four prerequisites, generally referred to as numerosity, commonality, typicality, and adequacy. First, the class must be so numerous that joinder of all members is impracticable. Second, questions of law or fact must be common to the class. Third, the claims or defenses of the representative parties must be typical of the class as a whole. Finally, the representative

92. *See, e.g., id.*; S. 687, 103d Cong. (1993) (Product Liability Fairness Act). For discussion see Schwartz, *supra* note 68, at 1336-40. Under § 303(a) of Senate Bill 640, the plaintiff has the burden of proving, by clear and convincing evidence, that the "harm suffered by the claimant was the result of conduct manifesting a manufacturer's or product seller's conscious, flagrant indifference to the safety of those persons who might be harmed by the product." *Id.*

93. For example, in the Dalkon Shield litigation, most of the cases in which punitive damages were imposed rested on a finding that the company had deceived the FDA and consumers. *See* discussion *infra* Part III.A.2. The bribery exception was included to respond to the generic drug scandal of the 1980s. *See supra* note 84, and accompanying text.

94. S. 640, 102d Cong. § 303(c)(1)(1991) (Product Liability Reform Act).

95. 138 CONG. REC. 513246 (1992).

96. 138 CONG. REC. 513154 (1992).

97. Schwartz, *supra* note 68, at 1363.

98. 138 CONG. REC. 513246 (1992).

plaintiffs and their lawyers must "fairly and adequately protect the interests of the class."[99]

Traditionally the class action technique was used in two types of situations. First, the consumer class action allowed large groups of people with small claims against a common defendant to pool their resources, making it possible for them to sue.[100] If substantive law provides for an attorneys' fee award to a prevailing plaintiff, lawyers are available to vindicate the rights of the class of consumers.[101] A classic example of a class action of this sort was a claim by thousands of airline passengers who were overcharged by a few dollars a ticket over a period of years.[102] Second, public interest suits seeking injunctive relief can be used to enforce federal statutory or constitutional principles on a prospective basis. Class actions of this sort have been used to desegregate public schools, to improve conditions in prisons and mental hospitals, and to enforce the requirements of federal social welfare programs.[103]

The class action suits against manufacturers of contraceptive drugs and devices do not fit either of these traditional models, but rather represent a new breed of class action. The paradigmatic examples of this new variety of class action are a class of veterans exposed to Agent Orange in Vietnam, millions of workers exposed to asbestos, more than a million women who received breast implants, and a class containing all the owners of Ford Bronco all-terrain vehicles.[104]

> This use of the class action device, like most other new developments, has both long- and short-term antecedents, such as the historic powers of equity judges and the modern phenomenon of "managerial judges" who actively participate in case handling and take a forceful role in pressing settlement. [These new class actions] which contain a novel combination of features, illustrate something quite new in degree and kind. For example, the cases were either brought or certified for settlement purposes rather than to be tried; the plaintiff class includes future victims, many of whom have yet to suffer a legally cognizable injury; approved settlements will bind absent class members, many of whom may not have had an effective opportunity to opt out of the class; the settlements affect claims nationwide and may have the effect of a

99. FED. R. CIV. P. 23(a).

100. Roger C. Cramton, *Individualized Justice, Mass Tort, and "Settlement Class Actions": An Introduction*, 80 CORNELL L. REV. 811, 824 (1995).

101. *Id.*

102. *In re* Domestic Air Transp. Antitrust Litig., 137 F.R.D. 677 (N.D. Ga. 1991).

103. JACK H. FRIEDENTHAL, MARY KAY KANE, ARTHUR R. MILLER, CIVIL PROCEDURE §16.1, at 722 (2d ed. 1993).

104. Cramton, *supra* note 100, at 811-12. *See also* Deborah R. Hensler & Mark A. Peterson, *Understanding Mass Personal Injury Litigation: A Socio-Legal Analysis*, 59 BROOK. L. REV. 961, 965-69 (1993) (describing characteristics of mass torts).

> federal decree eliminating claims governed by state law or a state decree eliminating claims governed by federal law; and in some of the cases, the plaintiffs' lawyers representing the class entered into side settlements with the defendants, giving their current clients different and more favorable relief than the class settlement provides to future claimants. A class action settlement with these features would have been unthinkable to lawyers of a decade or so ago.[105]

The new breed of mass tort class action is a by-product of mass production, distribution and marketing.[106] The class action offers many benefits. It avoids repetitive trials, duplicate discovery, and other high transaction costs of litigation.[107] It also helps to level the playing field between the litigation resources of a corporate defendant and an individual plaintiff.[108]

Mass tort class actions have been facilitated by changes in procedural rules. Since 1968, the Judicial Panel on Multidistrict Litigation has had the authority to consolidate in a single district all civil actions pending in federal district courts when the cases involve common questions of fact, and transfer would serve the interests of judicial economy, fairness, and the convenience of the parties and witnesses.[109] Many states have similar processes for the aggregation of claims.[110]

This new form of class action raises many problems. How can adequate and vigorous representation be provided to each member of a plaintiff class, when a lawyer represents thousands of people with claims that share some commonality, but that also present different, and sometimes conflicting, issues? For example, even if all class members claim that they were injured by a particular drug, those whose injuries are very serious may have interests that conflict with those plaintiffs who suffered less serious

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105. Cramton, *supra* note 100, at 812-13.

106. *Id.* at 815.

107. Heather M. Johnson, *Resolution of Mass Product Liability Litigation Within the Federal Rules: A Case for the Increased Use of Rule 23(b)(3) Class Actions*, 64 FORDHAM L. REV. 2329, 2366 (1996).

108. *Id.* at 2368-69.

109. 28 U.S.C. § 1407 (1988). *See* AMERICAN LAW INSTITUTE, COMPLEX LITIGATION: STATUTORY RECOMMENDATIONS AND ANALYSIS, WITH REPORTER'S STUDY 21-24 (1994) [hereinafter ALI, COMPLEX LITIGATION]; Judith Resnik, *From "Cases" to "Litigation,"* Law & Contemp. Probs., Summer 1991, at 5.

110. In *Judicial Federalism in Action: Coordination of Litigation in State and Federal Courts*, 78 VA. L. REV. 1689, 1733-44 (1992), William W. Schwarzer, Nancy E. Weiss, and Alan Hirsch describe cases in which state and federal judges have used informal methods to coordinate complex litigation which is taking place in both state and federal courts. The article also addresses the federalism concerns that might arise with this informal, intersystem coordination. *Id.* Some states have rules similar to Fed. R. Civ. P. 42(a) which would allow for this consolidation of similar claims to take place. *Id.* at 1751 (providing examples of such rules, including Cal. Civ. Proc. Code §§ 404 to 404.8 (West 1973 & Supp. 1995) and Iowa R. Civ. P. 42.01). Other states recognize an inherent judicial power to aggregate certain types of claims. Means v. Mont. Power Co., 625 P.2d 32, 36 (Mont. 1981).

injuries. Should federal courts have authority to enter a decree that eliminates or displaces the personal injury rights, otherwise governed by state law, of individuals who have been exposed to a product or substance, but have not yet suffered a legal injury? Must individuals be given the opportunity to opt out of the settlement?[111] How can adequate notice of opportunity to opt out of a class action be provided to people who do not yet know that they will suffer a future injury? What prevents the class action lawyer from trading the client's recovery for his or her own compensation? Do potential fees for class action lawyers provide incentives to bring large, but baseless, claims that deter innovation? These issues are addressed in the context of particular products.

PART III.
THE LIABILITY HISTORY OF PARTICULAR DRUGS AND DEVICES

Part III briefly describes the liability history of specific contraceptive drugs and devices which have been the subject of product liability litigation. It also discusses the history of RU 486, the abortion drug, and some other products that are not used to control reproduction: Thalidomide, Bendectin, and silicone breast implants. The choice to discuss these products is based on a judgment that the legal history of these products influences thinking about contraceptives. Because of limitations of time and space, the legal history of other products is not addressed in detail.[112]

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111. Federal courts conflict on this issue. *See, e.g.*, Brown v. Ticor Title Ins. Co., 982 F.2d 386 (9th Cir. 1992) (holding that absent plaintiffs are not bound by a Rule 23(b)(1) and (b)(2) class action for money damages because the original class action court did not have personal jurisdiction over the plaintiffs and did not provide them with an opt-out right), *cert. dismissed as improvidently granted*, 511 U.S. 117 (1994). *See also In re* Real Estate Title & Settlement Servs. Antitrust Litig., 869 F.2d 760 (3d Cir. 1989) (allowing collateral attack against a Rule 23(b)(1)-(b)(2) class action), *cert. denied*, 493 U.S. 821 (1989). *See also In re* Joint E. & S. Dist. Asbestos Litig., 982 F.2d 721 (2d Cir. 1992) (recognizing in dicta that plaintiffs seeking money damages must be given the opportunity to opt out). *But see* Flanagan v. Ahearn, 90 F.3d 963 (5th Cir. 1996) (rejecting a claim that plaintiffs must be given the opportunity to opt out).

112. The products most often identified as typical of contemporary mass torts are asbestos and the Dalkon Shield. *See, e.g.*, Hensler & Peterson, *supra* note 104, at 962; Cramton, *supra* note 100, at 811. These products may be atypical in several respects. First, it is widely believed that the companies manufacturing these products suppressed reliable evidence about their dangers. While all companies make judgments about whether a report of an adverse effect constitutes reliable evidence of danger, the level of conscious deception in relation to these two products appears to be unusual. Partly because of this deception, both of these products were subject to punitive damage judgments that drove the manufacturers into bankruptcy. Most mass tort defendants do not declare bankruptcy. The Dalkon Shield is discussed *infra* Part III.A.2. Asbestos is not discussed in this paper, though that experience has had a profound influence on the issues addressed here. For a description and sharp critique of the settlement of asbestos claims, see Susan P. Koniak, *Feasting While the Widow Weeps:* Georgine v. Amchem Products, Inc., 80 CORNELL L. REV. 1045 (1995).

This article does not examine in depth many drugs that have been the subject of mass tort litigation. MER-29, a cholesterol-lowering drug, was manufactured by Richardson-

A. Drugs and Devices No Longer Marketed in the United States

1. Thalidomide.

Louis Lasagna writes, "Thalidomide has achieved the dubious distinction of being the most maligned drug in the history of pharmaceutical medicine."[113] Introduced in Germany in 1957, in Great Britain in 1958, and in Canada in 1961, the drug quickly became a popular sleeping pill.[114] Thalidomide was never marketed in the United States, because it was not approved by the FDA.[115] Shortly after it went on the market, doctors began reporting cases of distinctive congenital anomalies associated with use of the drug.[116] The dangers of Thalidomide were discovered entirely by physicians who observed clusters of cases of unusual birth defects and connected them to the drug. "No case-control or cohort epidemiological study was ever performed, although more than a hundred papers were published in the aftermath cataloguing the effects of thalidomide on a variety of animal species."[117] By 1961, the drug had been withdrawn from the market.[118]

Thalidomide's short tenure as an available drug has had an enduring effect on the law. First, the problems with Thalidomide identified the risks

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Merrell., Inc. in the 1950s. In 1962, the company withdrew the drug from the market, after its use was linked to irreversible cataracts and skin and hair problems in 5,000 people. Morton Mintz, *Jail Terms Sought for Business Health, Environment Violators; Prison Terms Sought for Health and Environment Violators*, WASH. POST., Nov. 25, 1979, at A1. In 1963, company officials pleaded *nolo contendere* to federal charges of making false and misleading statements to FDA officials about the safety of the drug. Peter H. Stone, *Conservative Brain Trust,* N.Y. TIMES, May 10, 1981, § 6, at 18. The company was fined $80,000 and the officials were placed on probation. *Id.* Civil suits involving MER-29 eventually cost the company an estimated $200 million. Bill Coffin, *Elephant Hunt: Big-Game Attorneys Target Insurers,* BEST'S REV.-PROPERTY-CAS. INS. EDITION, March 1997, at 49. MER-29 is said to be the first mass tort litigation in which a plaintiff's attorney litigation group was established to coordinate efforts against the defendant. Paul D. Rheingold, *The MER/29 Story: An Instance of Successful Mass Disaster Litigation*, 56 CAL. L. REV. 116 (1968); *see also* David Ranii, *How the Plaintiffs' Bar Shares Its Information*, NAT'L L.J., July 23, 1984, at 1 (describing the work done by different litigation groups). *See also In re* General Motors Corp. Pick-Up Truck Fuel Tank Prods. Liab. Litig., 55 F.3d 768 (3d Cir. 1995) (describing and disapproving a settlement agreement), *cert. denied sub nom.* General Motors Corp. v. French, 116 S. Ct. 88 (1995); Hensler & Peterson, *supra* note 104, at 981-83 (describing DES litigation).

113. Louis Lasagna, *The Chilling Effect of Product Liability on New Drug Development, in* THE LIABILITY MAZE 334, 345 (Peter W. Huber & Robert E. Litan eds., 1991).

114. GREEN, *supra* note 83, at 64, 66. By December 1959, sales greatly increased worldwide, reaching approximately 300,000 in Germany alone. *Id.* at 64.

115. *Id.* at 66-69, 73.

116. Sheryl Gay Stolberg, *37 Years Later, A Second Chance for Thalidomide*, N.Y. TIMES, Sept. 23, 1997, at A1.

117. This fact suggests that a strict rule demanding that plaintiffs demonstrate causation through epidemiological studies might, in some cases, be unfair to plaintiffs. *See supra* Part II.B (discussion of causation).

118. For a history of Thalidomide see Kenneth I. Kaitin, *Thalidomide Revisited: New Clinical Uses for an Old Drug*, 3 PHARM. MED. 203, 203-04 (1988).

of exogenous agents on the fetus, and led the scientific world to major developments in teratology, pharmacology, and toxicology.[119] Second, women who had taken Thalidomide while pregnant and were unable to obtain abortions in the United States played an important role in the early movement for legalization of abortion.[120] Third, the Thalidomide tragedy led to the passage of the 1962 Kefauver-Harris amendments to the United States federal Food, Drug, and Cosmetic Act, which strengthened the pre-approval process for new drugs.[121]

Finally, Lasagna argues that the Thalidomide episode has generated a fear of liability that prevents use of the drug for other important purposes. He says, "it is generally acknowledged that Thalidomide has unique anti-inflammatory and immunosuppressant properties that make it valuable in managing [a variety of conditions that] . . . are debilitating, painful, and recurrent."[122] In the mid-1990s, the FDA approved clinical trials of Thalidomide, to test whether it is safe and effective in the treatment of serious mouth ulcers associated with AIDS and of multiple sclerosis.[123] Despite these potential uses of the drug, no company now markets it.[124]

If Thalidomide is effective in treating some conditions, and safe for people who are not pregnant, it is not clear why fears of liability would deter a company from marketing it. For example, the Roche Company's

119. T.V.N. Persaud, Environmental Causes of Human Birth Defects 39-40 (1990).

120. Sherri Finkbine was an Arizona housewife and the host of a local TV children's program. While pregnant, Finkbine took sleeping pills that her husband had brought back from Europe. The pills were Thalidomide and her doctor recommended an abortion. Worried about the wives of servicemen in Europe, who might unknowingly take the drug, she tried to publicize its dangers. Finkbine's story exposed the fact that many doctors performed "therapeutic" abortions in situations like hers, though they were then prohibited by law. The publicity forced her to travel to Sweden to abort the fetus which was so seriously deformed that it probably would not have survived had she given birth. The incident prompted many doctors to seek liberalized abortion laws because they realized that they were open to criminal prosecution for procedures they felt were medically correct. KRISTIN LUKER, ABORTION AND THE POLITICS OF MOTHERHOOD 62-65, 78-80 (1984).

121. Drug Amendments of 1962 (Kefauver-Harris Amendments), Pub. L. No. 87-781, 76 Stat. 780 (1962) (codified as amended at 21 U.S.C. §§ 321, 331, 348, 351-353, 357-360, 372, 374, 376, 381). Under the 1962 Amendments, manufacturers must prove, not only a drug's safety, but also its effectiveness for the proposed use. 21 U.S.C. § 355(a)&(b). There are four steps to the current approval process for new drugs: pre-clinical testing, investigational new drug testing, new drug application testing, and post-marketing surveillance. *See generally* Daniel D. Adams & William E. Nelson, *The Drug Amendments of 1962*, 38 N.Y.U. L. REV. 1902 (1963) (examining the effects of the Amendments on drug manufacturers from development to retail).

122. Lasagna, *supra* note 113, at 346. For a technical description of the therapeutic uses of Thalidomide in treating Erythema nodosum leprosum, a form of leprosy, rheumatoid arthritis, and other life threatening conditions, see Kaitin, *supra* note 118, at 204-07.

123. Kimberly J. McLarin, *Thalidomide: Old Horrors Clash with New Hope*, N.Y. TIMES, Dec. 28, 1995, at A1; Digest, WASH. POST, Sept. 28, 1995, at D11.

124. Sheryl Gay Stolberg, *Thalidomide, Once Banned Is in Demand*, N.Y. TIMES, Nov. 17, 1997, at A1. The FDA has approved use of the drug under tightly regulated conditions that demand extensive informed consent and require that women taking it use two forms of birth control. In October, 1997, one company, Celgene of New Jersey, sought FDA approval to market it under these restrictions. *Id.*

Accutane (isoretinoin), an acne medicine, was approved by the FDA in 1982, with full recognition of the fact that it can cause serious fetal abnormalities, and thus should not be used by women during or just before pregnancy.[125] By 1988, severe birth defects in sixty-two infants had been attributed to the use of Accutane during pregnancy, and the FDA's Epidemiology Unit estimated that the drug might have caused up to 1,300 birth defects in the U.S. between 1982 and 1988.[126] On the recommendation of the FDA, the company supplemented its warnings, providing instructional videotapes, brochures, a consent form, and a true-false test to be completed by the patient to ensure that she understands the risks.[127] By 1988, between ten and twenty lawsuits were pending for birth defects ascribed to the drug, and about the same number of cases alleging serious side effects in adult users;[128] the American Trial Lawyers Association formed the Accutane Litigation Group.[129] Judith P. Swazey observes:

> Because of the lasting and powerful memory of Thalidomide, many people familiar with Accutane's history are puzzled by the medical and legal risk-benefit calculus in Roche's decision to develop and market a potent teratogen [birth defect agent] for a disfiguring but not life-threatening condition. . . . And given the litigation that has followed its use, many also are puzzled that Roche has not withdrawn Accutane from the market or at least sought FDA permission to restrict its distribution solely to men.[130]

2. Dalkon Shield.

The Dalkon Shield was developed in 1968 by Hugh Davis, a gynecologist on the faculty of the Johns Hopkins Medical School, and his partner Irwin Lerner, an electrical engineer and part-time inventor.[131] An intrauterine device, or IUD, is inserted in a woman's uterus and prevents

125. Sheila R. Shulman, *The Broader Message of Accutane*, 79 AM. J. PUB. HEALTH 1565, 1565 (1989).

126. *Id.*

127. *Id.* at 1567.

128. Diane Acker Nygaard, *Accutane: Is the Drug a Prescription for Birth Defects?*, TRIAL, Dec. 1988, at 81, 82.

129. *ATLA Accutane Litigation Group Has Active Agenda*, TRIAL, Dec. 1988, at 83.

130. Judith P. Swazey, *Prescription Drug Safety and Product Liability, in* THE LIABILITY MAZE 313 (Peter W. Huber & Robert E. Litan eds., 1991). Other drugs raise similar questions. Clorazil was approved by the FDA in 1989 as a more powerful alternative to drugs used to manage severe schizophrenia. Because of its acknowledged dangers, it is distributed on a limited basis that requires careful monitoring. *Id.* at 313-14. *See also* Stolberg, *supra* note 116 (discussing similar issues associated with Thalidomide).

131. This account of the Dalkon Shield story is drawn from RICHARD B. SOBOL, BENDING THE LAW: THE STORY OF THE DALKON SHIELD BANKRUPTCY 1, 2-48 (1991). *See also* RONALD J. BACIGAL, THE LIMITS OF LITIGATION: THE DALKON SHIELD CONTROVERSY (1990) (evaluating the relationship between mass torts and bankruptcy); NICOLE J. GRANT, THE SELLING OF CONTRACEPTION: THE DALKON SHIELD CASE, SEXUALITY, AND WOMEN'S

pregnancy by interfering with the implantation of a fertilized egg.[132] Because the human body has a natural tendency to expel foreign objects, the inventors added several prongs which jutted out of each side to control expulsion of the IUD.[133] However, the prongs made both insertion and removal difficult, and the device had a tendency to embed itself in the uterine wall or to perforate the uterus.[134] The Dalkon Shield had another, even more serious design flaw: its string.[135] The string, attached to the shield, passed from the uterus, through the cervix, into the vagina.[136] Its purpose was to allow the woman to check that the device was in place and to facilitate its removal.[137] Although all IUDs have tailstrings designed for this purpose, on other brands of IUDs the tailstring is made of a single plastic filament to avoid the absorption of moisture, and with it bacteria, from the vagina into the uterus.[138] Davis and Lerner created a string that acted as a wick to carry bacteria into the uterus.[139]

In 1968, Davis and Lerner formed the Dalkon Corporation (owned 55 percent by Lerner, 35 percent by Davis, and 10 percent by Lerner's lawyer) and assigned it all rights to the Dalkon Shield.[140] Between September 1968 and September 1969, Davis fitted 640 of his patients with the device at his clinic at Johns Hopkins.[141] In October, 1969, Davis submitted a study entitled, *The Shield Intrauterine Device: A Superior Modern Contraceptive* to the American Journal of Obstetrics and Gynecology. The study, published in February 1970, claimed that "the superior performance of the shield intrauterine device makes this technique a first choice method of conception control."[142] In January 1970, just before the publication of his study, Davis gave testimony before a Senate subcommittee in which he condemned the

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AUTONOMY (1992) (analyzing women's relationships to the contraceptive and medical industries from a feminist perspective); KAREN M. HICKS, SURVIVING THE DALKON SHIELD IUD: WOMEN V. THE PHARMACEUTICAL INDUSTRY (1994) (critically assessing the contraceptive industry, and an analysis of the organizing tactics of the Dalkon Shield Information Network); MORTON MINTZ, AT ANY COST: CORPORATE GREED, WOMEN, AND THE DALKON SHIELD (1985) (providing a journalistic account).

132. SOBOL, *supra* note 131, at 1.

133. *Id.*

134. *Id.* at 2.

135. *Id.*

136. *Id.*

137. *Id.*

138. *Id.*

139. Davis and Lerner used a multifilament string (many strands of nylon in a nylon sheath) to avoid the problems associated with the monofilament strings, namely the weak string breaking during removal and the discomfort felt by a man during intercourse. But they did not seal the ends of the sheath, which allowed fluids to wick from the bottom to the top. Indeed, the nylon sheath protected the trapped bacteria from the antibacterial action of the cervical plug. Further, the sheath developed holes that allowed the bacteria to escape into the uterus without reaching the top of the string. *Id.*

140. *Id.* at 2-3.

141. *Id.* at 3.

142. Hugh J. Davis, *The Shield Intrauterine Device: A Superior Modern Contraceptive*, 106 AM. J. OBSTETRICS & GYNECOLOGY 455, 456 (1970).

birth control pill and touted the Dalkon Shield.[143] Davis denied that he had any "commercial interest in any of the intrauterine devices."[144] Unfortunately, his study was superficial and misleading.[145]

At that time, federal law did not require FDA approval of medical devices.[146] In February 1970, Davis and Lerner began commercial distribution of their product.[147] They knew that they would not be able to realize the Shield's full commercial potential unless it was marketed by a large company with an established distribution system.[148] In June 1970, the A.H. Robins Company purchased rights to the Dalkon Shield from the Dalkon Corporation for $750,000 plus 10 percent of net sales.[149] Before its acquisition of the Dalkon Shield, the Company had no experience with contraceptive devices.[150] Prior to the purchase, it had learned that Davis, the author of the only study of the Dalkon Shield, was also the co-inventor and co-owner of the product, that Davis' own data showed a pregnancy rate of 5.3 percent, rather than the 1.1 percent rate published in his study and that no information was available on the safety of the device.[151] "[T]he purchase agreement provided that, should Robins ever be required 'to prove safety or efficacy of the product,' it could deduct the cost of doing so from the royalty payments to the Dalkon Corporation."[152]

Robins promoted its new product intensively and by 1973 more than three million women were using the device.[153] From the beginning, Robins employees, doctors, and scientists warned management about the dangers

143. SOBOL, *supra* note 131, at 4.

144. SUBCOMM. ON MONOPOLY, SENATE SELECT COMM. ON SMALL BUSINESS, 91ST CONG., COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 5924-26 (Comm. Print 1970) (testimony of Hugh J. Davis), *quoted in* SOBOL, *supra* note 131, at 4.

145. The number of women studied was too small to produce reliable results. SOBOL, *supra* note 131, at 3. Only eight women had used the device for one year and the average length of use was less than six months. Davis did not reveal that he had advised patients to use contraceptive foam during the first few months after insertion of the Dalkon Shield. He compiled his statistics within days after the end of the twelve-month period and did not wait to discover that additional women in the study had become pregnant. After he had submitted his study, but before it was published, Davis learned of enough additional pregnancies during the study period to increase the annual pregnancy rate to over 5 percent. He nevertheless allowed his 1.1 percent figure to be published. Finally, he did not reveal his role in the development of the Dalkon Shield or his financial interest in the product.

146. Subsequently it was learned that, just before marketing, copper had been added to the Dalkon Shield, in an effort to make it more effective. *Id.* at 22. The addition of copper made the device subject to FDA approval, but this fact was concealed from the agency and the public. *Id.*

147. *Id.* at 4.

148. *Id.*

149. *Id.* at 5; Janet Bamford, *Dalkon Shield Starts Losing in Court*, AM. LAWYER, July 1980, at 31, 33.

150. SOBOL, *supra* note 131, at 5.

151. *Id.*

152. *Id.* at 6.

153. The Dalkon Corporation recommended that doctors administer a pain killer before insertion and that contraceptive foam be used for the first three months after insertion. To increase sales, Robins eliminated these precautions. Robins' medical advisory

of wicking and pelvic infection, high pregnancy rates, and the dangers of life-threatening septic abortions when pregnancy occurred with the IUD in place.[154] The company ignored these warnings.[155] In May 1973, Robins received reports about two young women who had died when they became pregnant with the IUD in place.[156] Robins did not respond to the dangers that the Shield presented until five months later when they added a mild warning to the package insert for the IUD.[157]

In the spring of 1974 the company learned that the American Journal of Obstetrics and Gynecology was about to publish an article, *Maternal Deaths Associated with an Intrauterine Device*.[158] The FDA held hearings in June of 1974 on the problem of septic abortions and the IUD and asked Robins to voluntarily suspend sales of the Dalkon Shield while the safety risks were studied.[159] Two days later, Robins suspended sales in the United States.[160] The company continued to sell the Dalkon Shield in forty foreign countries for another ten months.[161] It was not until six years later, in 1980, that Robins sent doctors a letter recommending that Dalkon Shields be removed.[162] In October 1984, after many more women had died from septic abortions with the IUDs in place, Robins began a broadcast and print campaign urging women to have the Shield removed.[163] The company offered to pay for the removal procedures.[164] In the months that followed,

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board recommended that the device only be marketed to gynecologists. The company ignored this advice and promoted the Dalkon Shield to general practitioners and directly to women through a public relations campaign which placed favorable and misleading articles in women's magazines. *Id.*

154. *Id.* at 7-9.; Bamford, *supra* note 149, at 33.

155. SOBOL, supra note 131, at 7-9. Subsequent studies confirmed the dangers of the Dalkon Shield. Women using the Dalkon Shield had an increased risk of developing ectopic pregnancy not associated with other IUDs. *Digest, Dalkon Shield Only IUD Linked to Heightened Ectopic Pregnancy Risk*, 18 FAM. PLAN. PERSP. 141, 141 (1986). Women who had used the Dalkon Shield also had a fivefold increase in the risk of developing pelvic inflammatory disease when compared with women using other IUDs and twice the occurrence of septic abortion than other IUD users. N. G. Lee, G. L. Rubin, H. W. Ory, R. T. Burkman, *Type of Intrauterine Device and the Risk of Pelvic Inflammatory Disease*, 62 OBSTETRICS AND GYNECOLOGY 1 (1983).

156. SOBOL, *supra* note 131, at 9.

157. *Id.*

158. C. D. Christian, *Maternal Deaths Associated with an Intrauterine Device*, 119 AM. J. OBSTETRICS & GYNECOLOGY 441 (1974).

159. SOBOL, *supra* note 131, at 10.

160. *Id.*

161. *Id.* Just before the suspension of foreign sales, the Journal of the American Medical Association published an article critical of the multifilament tailstring, by a leading contraceptive researcher. Howard J. Tatum, Frederick H. Schmidt, David Phillips, Maclyn McCarty, William M. O'Leary, *The Dalkon Shield Controversy: Structural and Bacteriological Studies of IUD Tails*, 231 JAMA 711 (1975). When foreign sales were suspended, 15 fatal and 245 nonfatal septic abortions with a Dalkon Shield in place had been reported. SOBOL, *supra* note 131, at 11.

162. SOBOL, *supra* note 131, at 15.

163. *Id.* at 22.

164. *Id.*

Robins paid for the removal of the Dalkon Shield from more than five thousand women.[165]

The first trial in a claim against the Dalkon Shield began in December 1974 on behalf of a woman who became pregnant with an IUD in place.[166] The plaintiff's lawyer discovered that, at the time of purchase, the Robins Company knew about the exaggerations and errors in Dr. Davis's article promoting the Dalkon Shield.[167] Dr. Davis originally testified that he had no financial interest in the product, and then was forced to change his testimony.[168] Roger Tuttle, Robins' defense lawyer, tried to place responsibility for the plaintiff's injury on her doctor.[169] A jury returned a verdict against Robins for $10,000 in compensatory damages and $75,000 in punitive damages.[170]

After this loss, Robins restructured its defense.[171] It assigned all the defense work to a large Richmond, Virginia firm.[172] Instead of blaming the doctors, Robins contested causation arguing that the injuries were caused by the women themselves.[173] To support this defense, Robins' attorneys would interrogate plaintiffs about their sexual and hygienic habits.[174] Attorneys for the company would ask the plaintiff to identify her sex partners so that these men could be subpoenaed and questioned about their medical histories.[175] Until 1979, this strategy was quite successful for the company.[176] By that year some three thousand cases had been filed and the vast majority had been settled at an average cost of $11,000.[177]

In 1980, almost a thousand new Dalkon Shield injury cases were filed, many based on injuries that had occurred after the Dalkon Shield went off the market.[178] "In 1983, events were set in motion in Minnesota that shattered Robins' strategy of 'toughing it out' case by case."[179] A small firm that represented Dalkon Shield plaintiffs was charged with improper advertising and was forced to transfer the cases to a high powered Minneapolis firm "quite unlike any firm A.H. Robins had yet faced in Dalkon Shield litigation."[180] The cases were assigned to Federal District Court Judge Miles Lord, who decided that it was inefficient to litigate common factual

165. *Id.*
166. *Id.* at 12.
167. *Id.*
168. *Id.* at 12-13.
169. *Id.*
170. *Id.* at 13.
171. *Id.*
172. *Id.*
173. *Id.*
174. *Id.*
175. *Id.*
176. *Id.*
177. Bamford, *supra* note 149, at 31.
178. SOBOL, *supra* note 131, at 15.
179. *Id.* at 16.
180. *Id.*

issues concerning the design, testing, and safety of the Dalkon Shield or the conduct of company officials.[181] He consolidated twenty-three cases for a joint trial on common issues, to be followed by separate hearings on issues related to injury and damages.[182] This process destroyed Robins' defense strategy of making the trial as unpleasant and expensive as possible for the plaintiff, and placing primary focus on her, rather than the product or the conduct of Robins officials.[183] Judge Lord authorized extensive discovery, though the company vigorously opposed the ruling.[184] In 1984, before discovery was completed, Roger Tuttle, the attorney who had defended the Dalkon Shield prior to 1975, testified that in 1974 Robins officials had ordered him to destroy hundreds of incriminating documents.[185] Tuttle had since experienced a moral conversion that changed his attitude toward his prior actions.[186] He revealed that he had retained the originals of the most damaging documents and turned them over to the court and the plaintiffs' lawyers.[187]

By the fall of 1984, juries in eight Dalkon Shield cases had imposed a total of more than $17 million in punitive damages against Robins and there were 3,500 pending cases which also demanded punitive damages.[188] The case for punitive damages was now strong as more detrimental evidence was uncovered.[189] The company's product liability insurance policy with Aetna did not cover punitive damages.[190] In October 1984, Robins filed a motion before Judge Robert Merhige, in Richmond, Virginia, asking him to certify a mandatory national class action for purposes of punitive damages.[191] Though Judge Merhige usually favored consolidation and settlement of claims, he denied the motion.[192] A few months later, one of the lawyers representing many Dalkon Shield plaintiffs filed a similar motion.[193] Judge Merhige was told by Robins's lawyers that the company viewed bankruptcy as a "last resort" that the company hoped to avoid.[194] After receiving this reassurance, he persuaded the other judges around the country hearing Dalkon Shield claims to cooperate with the plan.[195] Despite Robins's assurance that they would not file for bankruptcy if claims

181. *Id.* at 17.
182. *Id.*
183. *Id.*
184. *Id.* at 18.
185. *Id.*
186. *Id.*
187. *Id.* at 21.
188. *Id.* at 37.
189. *Id.*
190. *Id.*
191. *Id.*
192. *Id.* at 43.
193. *Id.* at 45.
194. *Id.*
195. *Id.*

were consolidated, on August 21, 1985, the A.H. Robins Company filed a petition for reorganization in the U.S. Bankruptcy Court in Richmond.[196]

It is not clear what effect the Dalkon Shield litigation has had on the availability and variety of contraceptive drugs and devices. One consequence was that Congress amended the Food and Drug Act to require prior approval for medical devices as well as drugs.[197] Devices already on the market were not immediately subject to the Act.[198] It is commonly asserted that another consequence of the Dalkon Shield experience has been to discourage other manufacturers from developing and selling contraceptives.[199] It is not obvious why this should be so. The Dalkon Shield experience can be seen as an instance of willful fraud and disregard for women's lives and health that has no implication for responsible manufacturers who take reasonable steps to minimize risks and to inform consumers about those risks that are unavoidable.

3. Bendectin.

Bendectin was the only prescription drug ever approved in the United States for the treatment of morning sickness.[200] The William S. Merrell Company of Cincinnati first marketed Bendectin in the United States in 1956.[201] By 1983, it was prescribed for about one quarter of all pregnant women in the U.S. and was marketed in twenty-two countries.[202] Beginning in 1977, a growing number of suits were filed alleging that Bendectin had caused birth defects.[203] Determining whether a medicine causes birth defects is always difficult. Even in the absence of a specific or known teratogen, such defects occur in one to seven percent of newborns depending

196. *Id.* at 47.

197. The Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (codified as amended at 21 U.S.C. §§ 360-360K (1995)). Anne-Marie Dega, *The Battle Over Medical Device Regulation: Do the Federal Medical Device Amendments Preempt State Tort Law Claims?*, 27 LOY. U. CHI. L.J. 615, 623 n.64 (1996). The public was also angry over a number of deaths caused by faulty pacemakers. Gary E. Gamerman, *Intended Use and Medical Devices: Distinguishing Nonmedical "Devices" from Medical "Devices" Under 21 U.S.C. § 321(h)*, 61 GEO. WASH. L. REV. 806, 821 n.89 (1993).

198. Medtronic Inc. v. Lohr, 116 S. Ct. at 2247.

199. For example, a thoughtful 1996 study by the prestigious Institute of Medicine asserts that because of the Dalkon Shield litigation, "other manufacturers, notably G.D. Searle, a Monsanto Company subsidiary, whose Copper-7 and Tatum-T IUDs had been tested before receiving FDA approval and were never found defective, pulled those products off the market in 1986." INSTITUTE OF MEDICINE, *Issues of Law, Regulation, Information, and the Environment for Contraceptive Research and Development, in* CONTRACEPTIVE RESEARCH AND DEVELOPMENT: LOOKING TO THE FUTURE, 294, 312 (Polly F. Harrison & Allan Rosenfield eds., 1996) [hereinafter LOOKING TO THE FUTURE].

200. Lasagna, *supra* note 113, at 337.

201. Joseph Sanders, *The Bendectin Litigation: A Case Study in the Life Cycle of Mass Torts*, 43 HASTINGS L.J. 301, 317 (1992).

202. Lasagna, *supra* note 113, at 338.

203. The Bendectin story is recounted in Lasagna, *supra* note 113, at 337-341.

on the definition of the defect and the skill of the diagnosing health professionals.[204] In the early 1980s, when the lawsuits were first litigated, there was little scientific evidence confirming or denying a causal connection between Bendectin and birth defects.[205] Individual women knew that they had taken the drug and had given birth to a baby with serious birth defects.[206] Some physicians saw a pattern of connection between the drug and birth defects.[207] Through the 1980s, in part in response to the legal claims, research was conducted that failed to demonstrate a connection between Bendectin and birth defects.[208]

In 1980, after extensive review of the evidence, the FDA declined to withdraw the drug from the market.[209] Instead, it suggested a package insert saying:

> Nausea and vomiting of early pregnancy (morning sickness) is very common but usually disappears in a few weeks with no treatment. . . . The simplest treatment for this condition is eating soda crackers or dry toast, or drinking hot or cold liquids, as soon as you wake up in the morning. If this does not work [Brand Name] may be tried.
>
> It is not possible to prove that any drug or other substance is totally free of risk, or absolutely safe, if taken during pregnancy. . . . [T]his drug has been the most carefully studied of all drugs which could be used to treat the nausea and vomiting of pregnancy. There is no evidence that any other drug is safer in treating the nausea and vomiting of pregnancy.[210]

Nonetheless, the number of claims continued to rise,[211] and in 1982, the Judicial Panel on Multidistrict Litigation transferred all Bendectin cases then pending in the federal courts to the District Court for the Southern District of Ohio.[212] In a consolidated trial, the jury deliberated whether

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204. Lasagna, *supra* note 113, at 339.

205. GREEN, *supra* note 83, at 21.

206. *See generally* Lasagna, *supra* note 113, at 339; Mark D. Nosacka, *Bendectin Birth Defects, and Brock: A Study in Appellate Review*, 13 J. PROD. LIAB. 231, 266 (1991).

207. Sanders, *supra* note 201, at 318.

208. *See* GREEN, *supra* note 83, at 173-77 and discussion of Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 583 (1993) (concluding that petitioners' evidence provided an insufficient foundation to allow admission of expert testimony that Bendectin caused their injuries).

209. Sanders, *supra* note 201, at 318-19

210. Draft Guideline Patient Package Insert: Bendectin and Other Combination Drugs Containing Doxylamine and Vitamin B6, 45 Fed. Reg. 80, 740 (1980). Given that Bendectin was the only drug ever approved by the FDA for morning sickness, this comparative claim is curious.

211. *Bendectin*, 2 INSIDE LITIG. 44 (1988).

212. *In re* Richardson-Merrell, Inc. "Bendectin" Prods. Liab. Litig. (No. II), 533 F. Supp. 489 (1982). By 1985, more than 1,100 Bendectin claims were pending before the court. Nosacka, *supra* note 206, at 233.

Bendectin caused any of the eight different classes of birth defects in women given the therapeutic doses.[213] The jury ruled that the plaintiffs had not established that use of Bendectin during pregnancy was a proximate cause of birth defects.[214] After the verdict, many cases were withdrawn, and those that proceeded were most often decided in favor of the defendant, often on motions for summary judgment.[215] Of the cases tried by juries, plaintiffs won almost half of their claims, virtually all of which were then set aside by trial or appellate courts.[216]

In 1983, Merrell removed Bendectin from the market.[217] While litigation costs were certainly a major factor leading to Bendectin's withdrawal from the market, other factors were also at play. "[A]s questions about its safety were raised, demand for the drug dropped, and Merrell responded by raising prices, which continued the declining spiral of demand."[218] The active ingredients in Bendectin are still available in over-the-counter form, and some women and physicians continue to use them.[219]

The history of Bendectin generates divergent responses. Some people believe that litigation drove a useful product from the market. Louis Lasagna argues that the "seemingly endless parade of claims" meant that "pregnant women and their physicians lost a therapeutic option. . . . It seems safe to predict that never again will a manufacturer petition the FDA to approve for marketing a new prescription drug for the nausea and vomiting of pregnancy."[220] Withdrawal of Bendectin from the U.S. market appears to have produced "an increase in hospitalizations for hyperemesis gravidarum, a severe form of morning sickness that requires medical intervention, often by intravenous rehydration."[221] The Wall Street Journal opines that the Bendectin experience has deterred research on all drugs to treat various conditions in pregnant women, many of which are far more serious than morning sickness and lack alternative non-prescription remedies.[222]

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213. *In re* Bendectin Litig., 857 F.2d 290, 294 (6th Cir. 1988).

214. *In re* Richardson-Merrell, Inc. "Bendectin" Prods. Liab. Litig., 624 F. Supp. 1212 (S.D. Ohio 1985), *aff'd sub nom. In re* Bendectin Litig., 857 F.2d. 290 (6th Cir. 1988), *cert. denied sub nom.* Hoffman v. Merrell Dow Pharm., Inc., 488 U.S. 1006 (1989).

215. *See* Sanders, *supra* note 201, at 374-77.

216. *See generally id.*(stating that *Oxendine v. Merrell Dow Pharmaceuticals*, 506 A.2d 1100 (D.C. 1986) is one of only three verdicts against Merrell that has not been overturned by a trial or appellate court).

217. Nosacka, *supra* note 206, at 232.

218. GREEN, *supra* note 83, at 21, 180-187.

219. Bendectin consists of vitamin B6, available at the grocery store, and a sedative antihistamine, available in over the counter sleeping pills called "Unisom" (sold by Pfizer, Inc.), "Bonine" (sold by Pfizer, Inc.), and "Dramamine" (sold by Upjohn Co.). The warnings on all products indicate that they should not be used by pregnant women. Elyse Tanouye, *Medicine: Suits Involving Defunct Bendectin Chill Development of Pregnancy Medications*, WALL ST. J., June 22, 1993, at B1.

220. Lasagna, *supra* note 113, at 340.

221. GREEN, *supra* note 83, at 336.

222. Tanouye, *supra* note 219, at B1.

Others argue that the gravity of birth defects, uncertainty about the effectiveness of Bendectin, and the availability of alternative approaches to dealing with morning sickness through diet, exercise and other means, suggest that the loss of Bendectin is not disturbing.[223] However, even if most women experiencing morning sickness might prefer crackers and tea to a drug, like Bendectin, that posed an uncertain and small risk to their fetuses, others, particularly those experiencing serious morning sickness, might prefer Bendectin. Further, women might be willing to take a drug with comparable or greater risks to treat more serious problems such as diabetes, clinical depression or high blood pressure.[224] Women have been systematically excluded from research on the diagnosis and treatment of illnesses, and many who have studied the issue, including the American Women's Medical Association, have concluded that this hurts women.[225] Not only have women been excluded from clinical studies, but illnesses afflicting women have been neglected as well.[226]

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223. *See* GREEN, *supra* note 83, at 181 (describing reaction to the withdrawal of Bendectin from the U.S. market).

224. The Wall Street Journal alleges that the Bendectin experience discouraged drug companies from marketing drugs for many serious conditions encountered by pregnant women including high blood pressure, asthma, and infections. Tanouye, *supra* note 219, at B1.

225. Until recently the Department of Health and Human Services and the FDA had an official policy of excluding pregnant women and women of childbearing potential from clinical studies except in special circumstances. INSTITUTE OF MEDICINE, WOMEN AND HEALTH RESEARCH: ETHICAL AND LEGAL ISSUES OF INCLUDING WOMEN IN CLINICAL STUDIES 1, 11-16 (Anna C. Mastroianni, Ruth Faden, Daniel Federman eds., 1994). The "childbearing potential" exclusion extended to women who were not having sex at the time of the trials and women who were using contraceptives. J. Claude Bennett, *Special Reports—Inclusion of Women in Clinical Trials—Policies for Population Subgroups*, 329 NEW ENG. J. MED. 288, 289 (1993). In 1990, the GAO issued a report revealing that though federal policy had changed, women were still not being adequately represented in clinical trials. Rebecca Dresser, *Wanted: Single, White Male for Medical Research; Males as Prototype of Human Research Subject*, 22 HASTINGS CTR. REP. 24, 24 (1992)[hereinafter Dresser, *Wanted*]. The NIH's study showing that an aspirin every other day could reduce heart attacks was done exclusively on men, though coronary heart disease is the leading cause of death in women. Most biomedical and psychosocial research on AIDS has excluded women. Vanessa Merton, *The Exclusion of Pregnant, Pregnable, and Once-Pregnable People (a.k.a. Women) from Biomedical Research*, 19 AM. J.L. & MED. 369, 370 n.5 (1993). Unbelievably, a study of the effect of obesity on breast cancer was done on men. Dresser, *Wanted, supra*, at 24. Since testing is done almost exclusively on subjects who are incapable of becoming pregnant, "we know almost nothing about therapeutics for pregnant women." Merton, *supra*, at 381. As a result, pregnant women are often prescribed drugs for ailments such as hypertension though there is very little data on what effect the drugs may have on pregnancy. *Id.* at 385-386 n.76. For example, after a drug for hypertension went on the market it was discovered that it could cause neonatal renal failure. The drug had not been tested on pregnant women but was administered to them before the discovery was made. Ruth B. Merkatz, Robert Temple, Solomon Sobel, Karyn Feiden & David A. Kessler, *Women in Clinical Trials of New Drugs: A Change in Food and Drug Administration Policy*, 329 NEW ENG. J. MED. 292, 295 (1993).

226. Michele Turk, *The Neglected Sex, Lack of Attention to Women's Diseases*, AM. HEALTH, Dec. 1993, at 54. There has been some response to the neglect of women's health. In 1990 the National Institutes of Health founded The Office of Research on Women's

The Bendectin story raises other complex questions. Products, devices and procedures that pose risks to fetuses and newborns raise particularly acute liability problems. The birth of a child with a serious disability is emotionally devastating to the parents. There is a powerful impulse to find an explanation external to the parents, or to "fate." Further, parents confronting the costs of caring for a child with disabilities may feel a responsibility to obtain as much financial help as they can through the courts. Juries may be especially sympathetic to claims on behalf of infants born with disabilities. In the context of medical malpractice liability, these factors have led commentators and some states to propose special legal treatment for negligence claims based on causation of birth defects.[227] The premise of these proposals is that compensation, at reasonable levels, should be guaranteed for injuries resulting from negligent pre-natal and delivery care.[228]

Many see the Bendectin story as illustrative of larger problems in the tort liability system. The scientific evidence makes it "reasonably clear that no plaintiff should be able to satisfy the burden of proof on causation in a Bendectin case. Yet, approximately 40 percent of all juries found for plaintiffs."[229] At the same time, "no plaintiffs have recovered money pursuant to a judgment, and only a handful of trivial nuisance settlements have resulted in any transfers, [from the defendants to the plaintiffs]. . . . The transaction costs of Bendectin litigation are awfully close to 100 percent."[230] "Bendectin is the Taj Mahal of horror stories about the tort system: the single most criticized piece of large-scale litigation of all time."[231]

Others view the Bendectin experience as distinctive, and caution against generalizing it to other cases of drug liability or toxic torts. First, by the late 1980s, the scientific record against Bendectin's teratogenicity had become unusually rich.[232] Bendectin was probably more rigorously studied than any other product discussed in this paper, with the possible exception of the birth control pill. Second, "Bendectin [is] a drug whose toxicity was more readily investigated than that of many other suspected toxic substances. The majority of birth defects are apparent at birth, which means

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Health to increase research on diseases afflicting women, to ensure that women are represented in clinical trials, and to increase the number of women in biomedical professions. Vivian W. Pinn, *The Role of the NIH's Office of Research on Women's Health*, 69 ACAD. MED. 698, 698 (1994). The FDA has since changed its policy of excluding pregnable women from trials. Merkatz, *supra* note 225, at 292.

227. NAT'L RESEARCH COUNCIL & INST. OF MED., *supra* note 59, at 141-42.

228. *Id.* at 141.

229. GREEN, *supra* note 83, at 328.

230. *Id.* at 335.

231. *Id.* at 328. "Perhaps that is why critics of the tort system promote it so tirelessly." *Id.*

232. *Id.* at 314.

that the latency period from exposure to disease is less than nine months."[233]

4. Silicone Breast Implants.

While not a contraceptive device, the history of silicone breast implant liability is important to understanding issues about proof of injury, the nature of the plaintiffs' bar, class actions, punitive damages, and the uncertainty of liability that surrounds products marketed to women.

Introduced in 1963, when the FDA did not regulate medical devices,[234] silicone breast gel implants have been used by between one and two million American women, some for as long as 30 years.[235] The silicone breast implant consists of a rubbery silicone envelope containing silicone gel.[236] Silicone is a synthetic compound widely used in medical devices, including artificial joints, heart valves, shunts and other tubing.[237] It is useful because it does not degrade easily, is resistant to bacterial contamination, and is accepted by living tissue.[238] It is not clear whether the liquid silicone used in the breast implants poses dangers that are not presented by hard silicone used in other medical devices.[239] Some of the risks of silicone breast implants are long established and are not disputed.[240] Scar tissue may form around the implant, which can constrict the implant and produce painful bulges.[241] The implant can leak or burst.[242] Efforts to correct these problems can cause painful complications and necessitate further surgery.[243] However, these localized injuries will not garner large monetary awards, particularly if a woman is warned of the risks.[244] The more serious and controversial question is whether silicone migrating through the body produces systemic, and possibly life-threatening injuries, such as immune

233. *Id.* at 315. The DES experience illustrates that this is not true of all birth defects.

234. In 1976 Congress provided for FDA regulation of medical devices. *See* discussion, *supra* note 197 and accompanying text. However, it was not until 1988 that the FDA classified silicone gel-filled breast implants as a Class III device, requiring manufacturers to establish their safety. 21 C.F.R. § 878.3540 (1997).

235. Hensler & Peterson, *supra* note 104, at 992. About 20 percent of women had silicone implants inserted after mastectomies or to correct congenital deformities, and 80 percent had them for purely cosmetic reasons. Alison Frankel, *From Pioneers to Profits*, AM. LAW., June 1992, at 82, 84.

236. Boyce Rensberger, *Silicone Gel Found to Cause Cancer in Laboratory Rats; Citizen's Group Calls For Ban on Breast Implants*, WASH. POST, Nov. 10, 1988, at A3.

237. ANGELL, *supra* note 58, at 36.

238. *Id.*

239. *Id.* at 37-38.

240. Rebecca S. Dresser, Wendy E. Wagner, Paul C. Giannelli, *Breast Implants Revisited: Beyond* SCIENCE ON TRIAL, 1997 WISC. L. REV. 705, 716 [hereinafter Dresser, *Implants Revisited*].

241. *Id.*

242. *Id.*

243. *Id.* at n. 29. In addition, the implant makes it difficult to perform a mammography to detect breast cancer. *Id.*

244. ANGELL, *supra* note 58, at 22-23.

diseases, neurological disorders, lupus, connective tissue disorders, and cancer.

The initial suits, the first ending in 1977 with a jury award of $170,000, complained that the implant had ruptured and required corrective surgery.[245] The second, more serious round of litigation involved claims of systemic injuries. In 1982, Maria Stern went to Nancy Hersh, a San Francisco lawyer specializing in products liability, for help.[246] Stern's breast implant had ruptured and she suffered from chronic fatigue and joint pains.[247] Her doctors, and her lawyers, thought that the ruptured implant may have caused her illness.[248] Dow Corning, manufacturer of the silicone breast implant, opened its records to Dan Bolton, Nancy Hersh's then law clerk, who later became a major plaintiffs' representative in the breast implant litigation.[249] The records revealed that many responsible people within the company were concerned about the fact that the silicone gel leaked, and that the company did not know much about the effects this might cause.[250] That evidence, and a sympathetic plaintiff, persuaded a jury to award Ms. Stern $1.7 million dollars, including $1.5 million in punitive damages. The case was settled for far less, but the jury believed that Dow Corning had acted improperly.[251]

In 1988, the FDA asked the manufacturers to supply evidence of the safety and effectiveness of the implants and gave the companies thirty months to supply the data.[252] That same year, Ralph Nader's Health Research Group called for a ban on silicone gel implants, complaining that the companies had never submitted the information requested by the FDA in 1982.[253] In addition, the group cited internal documents from the FDA and Dow Corning, which report, among other things, that animal tests showed that injected silicone gel caused malignant cancers in 20 to 26 percent of

245. Joseph Nocera, *Fatal Litigation*, FORTUNE, Oct. 16, 1995, at 60, 62. Hensler & Peterson, *supra* note 104, at 992. *See also* Deborah Tedford, *Revelation Old News to East Texas Woman*, HOUS. CHRON., Feb. 11, 1992, at A6 (reporting facts of first case).

246. Nocera, *supra* note 245, at 62.

247. *Id.*

248. *Id.*

249. ANGELL, *supra* note 58, at 52, 55.

250. Internal memos recounted company concerns about lack of long term safety testing and complaints from surgeons who wrote that implants had ruptured while they were trying to insert them. JOHN A. BYRNE, INFORMED CONSENT 97-99 (1996) (providing journalistic account following the path of a Dow executive whose wife had the company's implants inserted and thereafter began to suffer from an array of unexplained illnesses). *See* ANGELL, *supra* note 58, at 52 (Internal documents and minutes of Dow Corning employee meetings, animal tests dating back to the 1960s, and various complaints from plastic surgeons indicated that Dow Corning was concerned about the effects of implant leakage.).

251. ANGELL, *supra* note 58, at 57-60. The jury found Dow Corning guilty of fraud and deceit, probably based on memos from the company files. *Id.* at 55.

252. *Id.* at 52.

253. *Id.* at 53. Angell chastises the FDA for not finalizing the 1982 proposal to require safety information from implant manufacturers.

animals tested.[254] The consumer group also released FDA memoranda in which some FDA scientists argued that the evidence about silicone gel implants required the agency to issue a public warning.[255] When the FDA failed to respond to this complaint, the consumer group filed a Freedom of Information Act suit to force the FDA to release the results of the animal tests of silicone injections.[256]

In 1991, an FDA advisory panel recognized that there was an "appalling" lack of information about the safety of breast implants.[257] Through the early 1990s, it became apparent that Dow Corning had withheld data from doctors, patients, and the FDA about the risks of seepage and rupture.[258] Between 1982 and 1991, six silicone gel implant cases went to trial; five resulted in verdicts for the plaintiffs.[259]

In 1992, the FDA placed limits on the use of gel implants and Dow Corning announced that it would no longer manufacture them.[260] Dr. Marcia Angell, Editor of the *New England Journal of Medicine*, summarizes: "The company was right about the lack of evidence that the implants" caused connective tissue disorders.[261] "But there was also little evidence that they were safe, because the manufacturers had not fulfilled their responsibility to look for it."[262]

Between 1992 and 1994, more than 16,000 lawsuits were filed on behalf of women with breast implants.[263] Since many American women (about 1 percent) suffer from connective tissue diseases, and a similarly large number have breast implants, random chance would mean that 10,000 of the 100 million adult American women possess both characteristics.[264] Basic tort law demands that the plaintiff establish that injury was caused by the defendant's wrongdoing.[265] The simple facts that a woman had a breast implant and suffered connective tissue disease do not establish causation.

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254. Rensberger, *supra* note 236, at A3. Dow-Corning conceded that silicone caused cancer in rats, but argued that it was "uniquely a rodent phenomenon." *Id.*

255. ANGELL, *supra* note 58, at 53.

256. Teich v. FDA, 751 F. Supp. 243 (D.D.C. 1990) (granting a summary judgment for the plaintiff upon finding that neither the results of the animal studies nor summaries of consumer complaints were exempt from disclosure).

257. Hensler & Peterson, *supra* note 104, at 993-94.

258. In 1991 a San Francisco federal jury awarded $7.3 million to a woman who claimed that her implants had caused a permanent auto-immune disorder. Marlene Cimons, *Breast Implant Maker Falsifies Data, FDA Says*, L.A. TIMES, Dec. 31, 1991, at A1.

259. Frankel, *supra* note 235, at 84.

260. Joel Kurtzman, *Dow Gives Up Implants*, N.Y. TIMES, March 22, 1992, §3, at 2.

261. ANGELL, *supra* note 58, at 57.

262. *Id.*

263. Gina Kolata, *Details of Implant Settlement Announced by Federal Judge*, N.Y. TIMES, Apr. 5, 1994, at A16 [hereinafter Kolata, *Details of Implant*].

264. ANGELL, *supra* note 58, at 111-112.

265. *See supra* Part II.

The Judicial Panel on Multidistrict Litigation assigned the federal cases to Alabama District Court Judge Sam C. Pointer.[266] On April 1, 1994, plaintiffs and defendants agreed to a settlement of the class action providing $3.726 billion to be set aside for women who claimed specific injuries and who had received breast implants prior to June 1, 1993.[267] Women were entitled to opt out of the settlement and pursue individual claims, and the defendants could back out of the agreement if too many women opted out of the settlement.[268]

In 1994, the *New England Journal of Medicine* published the first retrospective cohort study examining whether women with silicone breast implants were more likely to suffer from connective tissue diseases than those who did not have them.[269] The study found no correlation between implants and the disease.[270] A larger study, in 1995, also found no correlation.[271] An even larger study found a slight increase in reports of connective tissue disease among women with breast implants.[272] All of the studies are subject to criticism. The first study was small and was financed, in part, by plastic surgeons.[273] Both of the studies denying a connection between implants and connective tissue disorder included some women who only had implants for one month and the average follow-up was 7.8 years, though autoimmune disorders can have a latency of 8-15 years.[274] The latest and largest study was based on the women's own reports and did not include confirming medical diagnoses.[275] In the mid-1990s several

266. *In re* Silicone Gel Breast Implants Prod. Liab. Litig., 793 F. Supp. 1098, 1099-1100 (1992).

267. *In re* Silicone Gel Breast Implant Products Liab. Litig., No. CIV.A. CV94-P-11558-S, 1994 WL 114580, at *11, *12 (N.D. Ala. Apr. 1, 1994).

268. *Id.*

269. Sherine E. Gabriel, W. Michael O'Fallon, Leonard T. Kurland, C. Mary Beard, John E. Woods, L. Joseph Melton, *Risk of Connective-Tissue Diseases and Other Disorders after Breast Implantation*, 330 NEW ENG. J. MED. 1697, 1697 (1994). Researchers compared 749 women in Olmsted County, Minnesota (the location of the Mayo Clinic), who had received breast implants between 1964 and 1991, and a group of 1,498 women without implants, matched for age. *Id.*

270. *Id.*

271. Jorge Sanchez-Guerrero, Graham A. Colditz, Elizabeth W. Karlson, David J. Hunter, Frank E. Speizer, Matthew H. Liang, *Silicone Breast Implants and the Risk of Connective-Tissue Diseases and Symptoms*, 332 NEW ENG. J. MED. 1666, 1666 (1995) (discussing a study of approximately 90,000 nurses, 1,183 of whom had breast implants).

272. Charles H. Hennekens, I-Min Lee, Nancy R. Cook, Patricia R. Hebert, Elizabeth W. Karlson, Fran LaMotte, JoAnn E. Manson, Julie E. Buring, *Self-reported Breast Implants and Connective-Tissue Diseases in Female Health Professionals*, 275 JAMA 616, 616 (1996). The group studied included 395,543 American women in the health professions, 10,830 of whom reported having breast implants. *Id.*

273. BYRNE, supra note 250, at 238.

274. *Id.* at 237-38.

275. ANGELL, *supra* note 58, at 101-02.

other studies failed to confirm a connection between breast implants and several serious diseases.[276]

Dr. Marcia Angell, in her book *Science on Trial: The Clash of Medical Evidence and the Law in the Breast Implant Case*, expresses amazement that juries could have found that implants cause connective tissue disease without controlled epidemiological evidence to support that conclusion.[277] While it is true that plaintiffs offered no evidence of this nature, because no such study had been published until 1994, they did present other forms of evidence in support of their claims.[278] Clinicians with large practices caring for women with connective tissue disorders observed a correlation between the implants and the disease, and reported that women's health improved when the breast implants were removed.[279] Other reputable doctors explained how silicone leaking through the body could cause the disease.[280] The plaintiffs demonstrated that defendants had done nothing to determine the safety of the implants and had aggressively suppressed and denied evidence that the implants leaked silicone into women's bodies.[281] Even if the leaking silicone is, as Angell argues, completely harmless, the fact that the defendants intentionally concealed the risk of leakage from doctors and patients lends some support to the claim that the company was not sure of the product's safety.[282] In 1994, the Ninth Circuit Court of Appeals applied

276. Sherine E. Gabriel, W. Michael O'Fallon, C. Mary Beard, Leonard T. Kurland, John E. Woods, L. Joseph Melton III, *Trends in the Utilization of Silicone Breast Implants, 1964-1991, and Methodology for a Population-Based Study of Outcomes*, 48 J. CLINICAL EPIDEMIOLOGY 527 (1995).

277. ANGELL, *supra* note 58, at 111-32. For an excellent skeptical review of Angell's book see Rochelle Dreyfus, *Galileo's Tribute: Using Medical Evidence in Court*, 95 MICH. L. REV. 2055 (1997).

278. ANGELL, supra note 58, at 97-110.

279. F. B. VASEY & J. FELDSTEIN, THE SILICONE BREAST IMPLANT CONTROVERSY: WHAT WOMEN NEED TO KNOW (1993). *See* discussion, Hopkins v. Dow Corning Corp., 33 F.3d 1116, 1124-25 (9th Cir. 1994), *cert. denied*, 513 U.S. 1082 (1995) (concluding that Doctors Lappe, Kossovsky, and Vasey were expert witnesses).

280. Nir Kossovsky & C.J. Freiman, *Immunology of Silicone Breast Implants*, 8 J. BIOMATERIALS APPLICATIONS 237 (1994); Nir Kossovsky, *Surface Dependent Antigens Identified by High Binding Avidity of Serum Antibodies in a Subpopulation of Patients with Breast Implants*, 4 J. APPLIED BIOMATERIALS 281 (1993), *cited in* ANGELL, supra note 58, at 107. *See also* M. A. Lappe, *Silicone-Reactive Disorder: A New Autoimmune Disease Caused by Immunostimulation and Superantigens*, 41 MED. HYPOTHESES 348 (1993) (proposing connection between silicone implants and autoimmune disease). For a discussion, see *Hopkins*, 33 F.3d at 1124-25 (concluding that expert testimony was based on scientific techniques).

281. In 1975, when Dow received complaints from surgeons that their new implant had an oily coating, suggesting that it was leaking, it instructed its sales people to "change demonstration samples often," and make sure they are clean and dry by washing them with soap and water in the nearest washroom and drying them with hand towels immediately prior to showing them to physicians. ANGELL, *supra* note 58, at 59. Hopkins, 33 F.3d at 1127, found "that Dow was aware of possible defects in its implants, that Dow knew long-term studies of the implants' safety were needed, that Dow concealed this information as well as the negative results of the few short-term laboratory tests performed, and that Dow continued for several years to market its implants as safe despite this knowledge. . . ."

282. *See* ANGELL, *supra* note 58, at 59.

the *Daubert* standard described in Part II.B. to allow a plaintiff to introduce expert testimony of this nature and upheld a jury award of $840,000 in compensatory and $6.5 million in punitive damages for connective tissue disease allegedly caused by a breast implant.[283]

The number of women filing claims under the April 1994 settlement order far exceeded the predictions of both plaintiffs and defendants and the fund that had been set aside was inadequate to cover claims.[284] In May 1995, Dow Corning, which marketed about half of the breast implants in the United States, filed for Chapter 11 bankruptcy protection.[285] The parties in the New Orleans class action reached a new settlement agreement.[286]

Dow Chemical and Dow Corning sought to have the issue of whether silicone breast implants cause connective tissue disorder resolved in one consolidated proceeding in the Bankruptcy Court in Michigan, one which would not include testimony from individual women.[287] In 1997, after the defendants succeeded in their effort to have the claims consolidated in the Bankruptcy Court, the bankruptcy judge ruled that the question of whether the implants cause systemic disorders should be tried in the federal court proceeding in New Orleans.[288]

In December, 1996, a federal judge in an Oregon class action ruled, on the basis of extensive expert evidence, that there was no credible scientific evidence linking breast implants to disease.[289] In February 1997, the prestigious British medical journal, *The Lancet*, published a study describing a newly developed blood test for antibodies that the researchers say are produced in response to leaking silicone.[290] The claims of these researchers are controversial and further research is underway.[291] In July 1997, the Federal Panel on Multidistrict Litigation asked Judge Sam C. Pointer, Jr. to convene a scientific panel to resolve the disputed issues about silicone

283. *Hopkins*, 33 F.3d at 1125, 1126.

284. *Money Shortage Looms in Implant Case*, N.Y. TIMES, June 17, 1995, at A8.

285. *Dow Corning Action to Result in Charges Against Earnings for Dow Chemical*, PR NEWSWIRE, May 15, 1995, at 1.

286. *See* Barry Meier, *3 Implant Companies Offer New Settlement*, N.Y. TIMES, Oct. 3, 1995, at A14. Current information on the progress of the settlement is provided on an information hotline at 1-800-887-6828.

287. Thomas M. Burton, *Dow Chemical Wins Victory on Suit Site*, WALL ST. J., May 12, 1997, at B2.

288. *Breast-Implant Claims Against Dow Chemical Will Proceed in Trial*, WALL ST. J., May 23, 1997.

289. Hall v. Baxter Healthcare Corp., 947 F. Supp. 1387 (D. Or. 1996).

290. Scott A. Tenenbaum, Janet C. Rice, Luis R. Espinoza, Marta L. Cuéllar, Douglas R. Plymale, David M. Sander, Linda L. Williamson, Allyson M. Haislip, Oscar S. Gluck, John R. P. Tesser, Leigh Nogy, Kathleen M. Stribrny, Julie. A. Bevan, Robert F. Garry, *Use of Antipolymer in Antibody Assay in Recipients of Silicone Breast Implants*, 349 THE LANCET 449, 449-454 (1997).

291. Terence Monmaney, *Study Claims to Link Disease, Breast Implants*, L.A. TIMES, Feb. 15, 1997, at A1.

breast implants and systemic disorders for cases pending in the federal courts.[292]

In 1998, it remains to be seen what impact the new evidence on the link between silicone and connective tissue disease will have on the silicone breast implant litigation or cases alleging injuries caused by other silicone implants.[293] The silicone breast litigation has produced an organized group of lawyers accustomed to representing large classes of clients.[294] The litigation has also allegedly produced a group of doctors who are reaping profits by providing class action lawyers with favorable diagnoses.[295] Second, the experience with breast implants has encouraged these lawyers, and the doctors who work with them, to challenge other products in which silicone is used.[296] Some manufacturers attribute their decisions to discontinue sales of the materials used in medical implants to the threat of litigation.[297] Industry officials assert that they cannot risk the kind of liability that was imposed in the Dalkon Shield and silicone breast implant trials.[298]

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292. Thomas M. Burton, *Top Judge in Breast-Implant Case Calls on Doctors to Hear Evidence*, WALL ST. J., July 22, 1997, at B6.

293. In the fall of 1995, after publication of the study showing no correlation between connective tissue disease and silicone breast implants, a Nevada jury awarded $14.1 million ($10 million of which was punitive damages) to a woman with Dow Corning implants. Mahlum v. American Heyer-Schulte Corp., No. CV93-05941 (Nev. Dist. Ct. Oct. 28 and 30, 1995), is not published but is noted in, *Breast Implant Litigation: Dow Chemical Liable for $14 Million in Nevada Jury Award*, PROD. LIAB. REP., Nov. 13, 1995, at 1. The sole defendant in this case is Dow Chemical because Dow Corning is shielded from litigation while in bankruptcy. *Id.* The plaintiff got her implants after a double mastectomy, they ruptured and leaked and she developed neurological symptoms similar to multiple sclerosis. The jury found that Dow Chemical had fraudulently concealed the dangers of liquid silicone and helped Dow Corning to fraudulently misrepresent the product. *Id.* The jury also found liability for negligent undertaking. *Id.* The punitive damage award was for Dow Chemical's conscious disregard for the plaintiff's safety. *Id.* Dow Chemical presented the studies described above. *Supra* notes 270-276 and accompanying text. The plaintiff argued that the studies were "affected by statistical and methodological limitations." PROD. LIAB. REP., Nov. 13, 1995, at 1. Dow Chemical plans to appeal on the grounds that it did not make, test or sell the implants. *Id.*

294. Nocera, *supra* note 245, at 80-82.

295. *See* ANGELL, *supra* note 58, at 81 (noting requirement that women submit substantiating medical records to share in settlement, but finding that no verification of diagnosis would follow).

296. In 1994, Dan Bolton, one of the leading breast implant lawyers, filed a class action suit in San Francisco on behalf of 300,000 men with penile implants. Seth Rosenfeld, *Penile Implant Maker Sued; Health Problems, Defects Concealed, Three Men Allege*, S.F. EXAMINER, May 21, 1994, at A1. *See generally* ANGELL, *supra* note 58, at 82-84. Norplant is discussed *infra*, Part III.C.2.

297. ANGELL, *supra* note 58, at 85 reports that DuPont announced in 1993 that it would no longer supply any material for use in permanent medical implants, and that Dow Chemical announced that it would no longer supply components for pacemakers. *See also* Barnaby J. Feder, *Implant Industry is Facing Cutback by Top Suppliers*, N.Y. TIMES, Apr. 25, 1994, at A1 (noting the withdrawal of DuPont and Dow Chemical from the medical business and the subsequent impact on medical equipment companies)[hereinafter Feder].

298. ANGELL, *supra* note 58, at 85; Feder, supra note 297, at A1.

Angell, and the defendants in the *Daubert* litigation, argue that the experience with silicone breast implants and Bendectin suggests that legal rules should be modified to require that plaintiffs alleging that a product has caused injury must produce published studies reporting on controlled epidemiological studies widely accepted in the scientific community.[299] Professor Michael D. Green, and the Supreme Court in *Daubert*, disagree with this broad conclusion. Green writes:

> Toxic causation should be assessed with due regard for the available evidence. When the epidemiological record is substantial, reliable, and consistent, the saliency of animal studies or other evidence of toxicity is quite low. However, if epidemiological evidence is lacking, thin, of questionable validity, and ultimately inconclusive, other toxicological evidence should be given consideration. Plaintiffs should be required to prove causation by a preponderance of the available evidence, not by some predetermined standard that may require nonexistent studies.[300]

Another recent assessment of the breast implant litigation argues that both the manufacturers[301] and the medical profession[302] were negligently irresponsible in failing to conduct research to determine whether the implants were safe. Research was conducted only in response to lawsuits holding manufacturers liable and the subsequent FDA ban.[303] The authors conclude that the legal system performed a socially useful function by stimulating research, and that the law continued to perform well by denying liability when research failed to reveal a causal relation between implants and connective tissue disorders.[304]

B. Contraceptive Methods Not at RiskUnder United States Law

1. Birth Control Pill.

In the 1990s, the pill has been the most commonly used form of reversible contraceptive in the United States and Europe.[305] First developed in the mid-1950s, and approved by the FDA in 1960, the pill has been subject to more studies to identify serious side effects than any other medicine in

299. ANGELL, *supra* note 58, at 90-110. *See supra* Part II.B.

300. GREEN, *supra* note 83, at 316 (footnote omitted).

301. Dresser, *Implants Revisited*, *supra* note 240, at 731.

302. *Id.* at 722-24.

303. *Id.* at 731-34.

304. *Id.* at 743-46.

305. Because the IUD is so commonly used in China, it is the most common form of reversible contraception in the world. Roberto Rivera, *Oral Contraceptives: The Last Decade*, *in* CONTRACEPTIVE RESEARCH AND DEVELOPMENT 1984 TO 1994: THE ROAD FROM MEXICO CITY TO CAIRO AND BEYOND 24, 24 (Paul F.A. Van Look & G. Perez-Palacios eds., 1994)[hereinafter CONTRACEPTIVE RESEARCH].

history.[306] Over the years, scientists and drug companies have developed new formulations, with lower doses, and determined that they are both safer and more effective.[307] These studies have determined that low dose pills have little effect on the risks of heart disease or stroke in healthy women who do not smoke.[308] While the relation between any drug and cancer is difficult to evaluate, it appears that the pill does not increase the risk of breast cancer, reduces the risk of cancer of the ovaries and of the endometrium, but may increase the risk of uterine cancer.[309]

In the 1970s and 1980s, many claims were filed against manufacturers of oral contraceptives alleging that the pills had caused injury and challenging the adequacy of the warnings provided.[310] For the most part, courts rejected manufacturers' claims that compliance with FDA standards provided a complete defense to product liability actions.[311] Most claims against the pill challenged the adequacy of the warnings provided against adverse side effects.[312] One case held that an older, high-dose, version of the pill was defective, in light of the availability of safer low-dose alternatives.[313] As pills have become safer, and warnings more comprehensive, litigation against oral contraceptives has nearly disappeared.[314]

Some commentators assert that pills are safe today because they were subject to litigation in the early years that they were marketed.[315] It is not clear whether this is true. Pill manufacturers had many incentives, other than the risk of liability, to improve pills, including public scrutiny from the Congress, the FDA, and the press, as well as a desire to market a product that was safe and effective to maximize sales.

The number of companies selling contraceptive pills and doing research to develop new ones has decreased in the United States in the past

306. Sharon Snider, *The Pill: 30 Years of Safety Concerns*, FDA CONSUMER, Dec. 1990, at 8, 9.

307. Rivera, *supra* note 305, at 24.

308. Snider, *supra* note 306, at 9. Contraceptives that are low in estrogen do not seem to increase the risk of stroke, which is normally low among women of child-bearing age. Diana B. Petitti, Stephen Sidney, Allan Bernstein, Sheldon Wolf, Charles Quesenberry, Harry K. Ziel, *Stroke in Users of Low-Dose Oral Contraceptives*, 335 NEW ENG. J. MED. 8, 8 (1996).

309. Rivera, *supra* note 305, at 30-32.

310. Michele Galen, *Birth Control Options Limited by Litigation, Whose Fault Is It?*, NAT'L L.J., Oct. 20, 1986, at 1, 28.

311. *See supra* Part II.D.

312. Galen, *supra* note 310.

313. Brochu v. Ortho Pharm. Corp., 642 F.2d 652 (1st Cir. 1981).

314. "Oral contraceptives were the subject of hundreds of lawsuits years ago until their safety increased to the point that they are rarely the subject of litigation today." Isaacs & Holt, *supra* note 9, at 541.

315. *Id. See also* Galen, *supra* note 310 (describing plaintiffs' argument that "litigation forces manufacturers to make their products safer").

three decades.[316] Again, the current disinterest in research and development is commonly attributed to the risks of litigation.[317]

2. Barrier Methods.

The global spread of sexually transmitted diseases (STDs) including the HIV virus has made it imperative to create effective barrier methods that protect against both conception and STDs. Nonetheless, in the past three decades "[v]aginal contraception has become the 'ugly step-child' of our birth control methodology and is given little research emphasis."[318]

Fear of liability does not seem to be a factor in the availability and marketing of barrier methods, including the diaphragm and the male and female condom.[319] The greatest risk associated with barrier methods is that they are less effective in preventing pregnancy than pills, Norplant, or IUDs.[320] This risk is well known and no court has held a distributor liable for unintended pregnancy or sexually transmitted disease allegedly caused by the failure of a barrier method. Because the condom is also useful in preventing the spread of STDs, condom use has become more popular in recent years.[321]

3. Spermicide Jell.

Ortho-Gynol Contraceptive Jelly is a vaginal spermicide with the active ingredient Octoxynol-9. Marketed in 1950 by the Ortho Company, a subsidiary of Johnson & Johnson, the package insert warned that the spermicide may cause irritation to genitalia, that it is not 100 percent effective, and that it should be kept away from children.

Liability for birth defects allegedly caused by spermicide jell was imposed in one reported case.[322] The plaintiff became pregnant while using the jell and gave birth to a child with serious disabilities. She alleged that the spermicide caused the birth defects and that the manufacturer did not warn against this risk. Defendants presented many experts who denied the connection between the jell and birth defects, while plaintiffs relied on the testimony of doctors who had treated the child and two small studies, one

316. BERNARD ASBELL, THE PILL: A BIOGRAPHY OF THE DRUG THAT CHANGED THE WORLD 310-311 (1995).

317. Galen, *supra* note 310.

318. Lourens J.D. Zaneveld, *Vaginal Contraception Since 1984: Chemical Agents and Barrier Devices*, *in* CONTRACEPTIVE RESEARCH, *supra* note 305, at 69.

319. Galen, *supra* note 310.

320. Among abortion patients who were using a method of contraception during the month they became pregnant, the condom was the method most commonly used. Stanley K. Henshaw & Kathryn Kost, *Abortion Patients in 1994-1995: Characteristics and Contraceptive Use*, 28 FAM. PLAN. PERSP. 140, 146 (1996).

321. *Id.*

322. Wells v. Ortho Pharm. Corp., 615 F. Supp. 262 (N.D. Ga. 1985), *aff'd in part, modified in part, and remanded by*, 795 F.2d 89, 788 F.2d 741 (11th Cir.), *cert. denied*, 479 U.S. 950 (1986).

of which had not been published. The trial court, sitting without a jury, found liability, asserting that the plaintiff's witnesses were credible and defendant's witnesses were not, but not offering much explanation for this conclusion.[323] Many later studies have failed to find a connection between spermicide jell and birth defects.[324] In subsequent cases claiming damages for birth defects caused by spermicide jell, courts have granted summary judgments for the defendant.[325] No other reported cases have found a defendant liable for birth defects allegedly caused by spermicide gel.[326]

C. *Drugs and Devices Currently Contested Under United States Liability Law*

1. *IUD.*

The intrauterine device is the most popular contraceptive in the world.[327] The IUD is highly effective, inexpensive, and easy to use.[328] However, the IUD has two major disadvantages. First, some women's uteri, particularly young women who have not had children, reject the device.[329] Second, the IUD causes pelvic inflammatory disease (PID) in a significant minority of women.[330] In addition, the IUD, like every other method of contraception except for the condom, provides no protection against sexually transmitted disease. Between 1970 and 1974, many U.S. women used the Dalkon Shield.[331] IUDs have not been widely available to U.S. women since the Dalkon Shield was withdrawn from the U.S. market.[332]

In February 1974, the FDA approved an application from the G.D. Searle Company to market the Copper-7 intrauterine contraceptive device.[333] In 1977, the FDA modified the warnings required for the Copper-

323. *Id.* In the district court, the judge awarded damages of $5.1 million. The circuit court affirmed the decision, but reduced the damages to $4.7 million. Several months before the trial in *Wells*, the FDA's Fertility and Maternal Health Drugs Advisory Committee unanimously concluded that "there was not enough evidence to say the spermicide could cause birth defects." Galen, *supra* note 310.

324. *See* Zaneveld, *supra* note 318, at 83 (summarizing the data).

325. *See, e.g.,* Smith v. Ortho Pharm. Corp., 770 F. Supp. 1561, 1582 (N.D. Ga. 1991).

326. Indeed, even in the Northern District of Georgia, where *Wells*, 615 F. Supp. 262 was decided, *Wells* has not been followed. *See* Smith v. Ortho Pharm. Corp., 770 F. Supp. at 1582.

327. *Supra* SOBOL, note 131, at 24.

328. Irving Sivin, *IUDs: A Look to the Future, in* CONTRACEPTIVE RESEARCH, *supra* note 305.

329. *Id.*

330. *Id.* at 42-43. *See also* BOSTON WOMEN'S HEALTH BOOK COLLECTIVE, THE NEW OUR BODIES, OURSELVES, 295, 297 (Simon & Schuster, Inc. 1992).

331. *Supra* Part III.2.A.

332. *See* Trieman, *supra* note 3, at 3.

333. Kociemba v. G.D. Searle & Co., 680 F. Supp. 1293, 1295 (D. Minn. 1988). Prior to the Medical Device Amendments of 1976, Pub. L. No. 94-295, § 1(a), 90 Stat. 539, medical devices did not generally require FDA approval or pre-market clinical testing. However, in 1971, the FDA classified medical devices incorporating heavy metals as prescription drugs.

7, specifically citing the risk of pelvic inflammatory disease (PID).[334] Over the next twenty years 2,063 suits were filed against Searle seeking recoveries for injuries alleged to have resulted from the IUD.[335] Although Searle will not reveal the total cost of its IUD litigation, about half of the suits were dismissed and most of the rest were settled. Searle went to trial twenty-four times, winning nineteen cases and losing five.[336] Four of the losses cost a total of $689,300.[337] In the fifth case, before a federal court in Minnesota, Searle was required to pay $8.15 million to a woman who said the Copper-7 made her infertile.[338] The plaintiff had received a Copper-7 in June, 1977, a few months before the warnings about the risks of PID and infertility were provided to doctors and patients.[339] Evidence from corporate records revealed that during the period that the plaintiff sought treatment for pelvic infection and infertility, the company debated whether the evidence supported recognition of a connection between IUDs and pelvic infections.[340]

Through the 1980s, new forms of the IUD have been developed and extensive studies have demonstrated that the IUD is safe and effective.[341] Many factors contribute to the low rates of IUD use in the U.S. Memories of the Dalkon Shield lead women, physicians and sex educators to avoid the IUD.[342] Physicians are not trained to insert the IUD during internship or residency.[343] The IUD also provides no protection against sexually transmitted diseases.[344] It is also possible that drug companies have not actively marketed IUDs, whether because of fear of liability, profit margins that are low relative to other forms of contraception, or other factors.

In 1995, 95 percent of the IUDs in the United States were manufactured by one company, GynoPharma.[345] This IUD, the ParaGard 380A, has had only one lawsuit filed against it since it was introduced in 1988.[346] In 1992, only one percent of American women between the ages of 15 and

21 C.F.R. § 310.502 (1977). Thus Searle sought and obtained FDA approval of the Copper-7 prior to marketing. 680 F. Supp. at 1295.

334. 21 C.F.R. § 310.502 (1977).

335. Robert Steyer, *Searle Nearing End of Lawsuits Over Copper-7 Contraceptive*, ST. LOUIS POST-DISPATCH, Oct. 15, 1995, at 1E.

336. *Id.*

337. *Id.*

338. Kociemba v. G.D. Searle & Co., No. 3-85-1599, 1988 U.S. Dist. LEXIS 10580 (D. Minn., Sept. 13, 1988).

339. *Kociemba*, 680 F. Supp. at 1296.

340. *Id.* at 1303.

341. Sivin, *supra* note 328, at 37, 39-44 (collecting data on studies of the IUD).

342. *See id.* at 37; Patricia Cohen, *The IUD: Birth-Control Device That the U.S. Market Won't Bear*, WASH. POST, Aug. 6, 1996, at A1.

343. *See generally* Cohen, *supra* note 342 (noting that "some physicians may never have even inserted an IUD").

344. Sivin, *supra* note 328, at 45; Cohen, *supra* note 342.

345. *J&J Moves Back into IUD Market, Buying Gynopharma*, MARKETLETTER, Aug. 21, 1995 [hereinafter *J&J Moves Back*].

346. *Id.*

44 using contraceptives used IUDs.[347] In 1995, Johnson & Johnson, a major manufacturer of U.S. contraceptives, purchased GynoPharma.[348]

Given the reliability of IUDs, and their popularity in the rest of the world, the difficulties American women confront in obtaining IUDs and the resulting low utilization rates raise serious concerns.

2. Norplant.

The observation that steroid hormones can be released at a constant rate from silicone tubes for long periods of time led to the development of subdermal implants for contraception in humans.[349] Norplant, the first implant contraception, consists of six match-stick-size capsules containing the hormone progestin and covered by soft plastic tubing.[350] It is implanted under a woman's skin and will prevent pregnancy for five years.[351] During the 1970s and 1980s the non-profit New York group, Population Council, conducted extensive research and development of the device, at a cost of over $20 million.[352] Norplant proved to be more effective than any other form of reversible contraception. The major adverse side effect is irregular bleeding.[353] The efficacy and safety of Norplant led the Population Council to explore other implants for both men and women.[354] The FDA approved it for marketing in the U.S. late in 1990.[355] Wyeth-Ayerst Laboratories, a division of the American Home Products Corporation, agreed to market Norplant, under an arrangement with the Population Council.[356] Many in the U.S. hailed Norplant as a "dream contraceptive."[357] As of 1995 nearly 1 million U.S. women and nearly 2.5 million women worldwide had used Norplant.[358]

Norplant quickly encountered several problems. Within two days of the FDA approval, an editorial in the *Philadelphia Inquirer* suggested that Norplant should be used as a tool in the fight against poverty; talk show

347. Treiman, *supra* note 3, at 3.

348. *J&J Moves Back*, *supra* note 345.

349. Sheldon Segal, *A New Delivery System for Contraceptive Steroids*, 157 AM. J. OBSTETRICS AND GYNECOLOGY 1090 (1987).

350. Rosemarie Thau & Ann Robbins, *New Implant Systems for Men and Women*, *in* CONTRACEPTIVE RESEARCH, *supra* note 305, at 92.

351. *Id.*

352. *Id.* at 91, 92.

353. *Id.* at 94-95.

354. *Id.* at 92.

355. F.D.C. REPORTS, Pink Sheet, Dec. 17, 1990, at T&G 3.

356. Gina Kolata, *Will the Lawyers Kill Off Norplant?*, N.Y. TIMES, May 28, 1995, § 3, at 1 [hereinafter Kolata, *Will the Lawyers*].

357. Tamar Lewin, *'Dream' Contraceptive's Nightmare*, N.Y. TIMES, July 8, 1994, at A10; *See also* Kolata, *Will the Lawyers*, *supra* note 356.

358. Albert G. Thomas Jr. & Stephanie M. LeMelle, *The Norplant System: Where Are We in 1995?*, 40 J. FAM. PRAC. 125, 125 (1995).

hosts opined that Norplant offers a "solution" to teen pregnancy.[359] Trial court judges, who were consistently reversed on appeal, required use of Norplant as a condition of probation for mothers convicted of child abuse or drug use.[360] Dr. Segal, developer of Norplant, protested:

> I am totally and unalterably opposed to the use of Norplant for any coercive or involuntary purpose. It was developed to improve reproductive freedom, not to restrict it. My colleagues and I worked on this innovation for decades because we respect human dignity and believe that women should be able to have the number of children they want, when they want to have them. Not just educated and well-to-do women, but all women.[361]

There is no evidence today that Norplant is forced upon women as a condition of probation or public aid.[362] Nonetheless, the suggestion that the drug had been, and should be, used as an instrument of social control may have tarnished its reputation.

In addition, Norplant has been challenged in tort litigation. As of 1996, more than 200 lawsuits, at least 50 of which are class actions have been filed against Wyeth-Ayerst.[363] Media reports suggest that Norplant

359. Donald Kimelman, *Poverty and Norplant: Can Contraception Reduce the Underclass?*, PHILA. INQUIRER, Dec. 12, 1990, at A18. For a response, see Sheldon J. Segal, *Norplant Developed For all Women, Not Just the Well-To-Do*, N.Y. TIMES, Jan. 6, 1991, §4, at 18 [hereinafter Segal, *Norplant Developed*].

360. Stacey L. Arthur, *The Norplant Prescription: Birth Control, Woman Control, or Crime Control?*, 40 U.C.L.A. L. REV. 1, 4-7 (1992).

361. Segal, *Norplant Developed*, *supra* note 359, at 18.

362. *But see* Stuart Taylor, Jr., *Give Norplant a Chance*, AM. LAWYER, Oct. 1996, at 34 (arguing that teenagers receiving welfare should be offered incentives to use Norplant).

363. *The Class Ends Here*, NAT'L L.J., Mar. 18, 1996, at A8. Plaintiffs in *Williams v. Wyeth-Ayerst Lab., Inc.* are seeking recovery for Norplant side-effects. Williams v. Wyeth-Ayerst Lab., Inc., No. 956198 (Cal. Super. Ct. S.F. County filed Nov. 8, 1993), *reported in Norplant: Class Action Filed Against Manufacturers and Distributors in California State Court*, BNA TOXICS L. DAILY, Dec. 6, 1993. In *Ullrich v. Wyeth-Ayerst Lab., Inc.*, No. 955163 (Cal. Super. Ct. S.F. County), the judge dismissed, with prejudice, the plaintiff's claims that exposure to silicone casing could result in autoimmune or neurological disorders; her attorney then withdrew from the case. *Silicone Claim Dismissed, Counsel Bows Out in Norplant Case, Drugs & Medical Devices*, MEALEY'S LITIG. REP., Mar. 18, 1996. Wyeth-Ayerst's motion for summary judgment was delayed while plaintiff amended her complaint and looked for new counsel. *Id.* Other cases have sought damages resulting from the manufacturer's failure to properly train medical personnel on the removal of the Norplant device. Smith v. Wyeth-Ayerst Lab., Inc., No. 94-3650-CIV-RYSKAMP (D.C. Fla. filed July 15, 1994) *reported in Norplant: Florida, Illinois Class Complaints Filed, Allege Faulty Warning, Training on Removal*, BNA PROD. LIAB. DAILY, July 26, 1994 [hereinafter *Norplant: Florida, Illinois Class Complaints*]. In August 1996, Judge Richard Schell denied class certification to more than 50,000 women who filed suit claiming that they have suffered medical problems resulting from their use of Norplant. Richard Stewart, *Judge Denies Class Status For Suit Against Norplant*, HOUS. CHRON., Aug. 8, 1996, at 36. Schell cited the fact that no individual cases had gone to trial as the basis for the ruling, and invited plaintiffs to seek class action status after the completion of a trial. Many cases from other jurisdictions have been transferred to Texas. *Id.* Schell had planned to try fifteen cases by mid-1997. *Id.* By the end of 1997, five of the thousands of cases filed in Texas had been tried. *In re* Norplant

may be the next Dalkon Shield litigation wave and report that some of the lawyers involved in the silicone breast implant litigation are now soliciting clients to challenge Norplant.[364] In addition, there are allegations that anti-abortion groups have fueled opposition to Norplant.[365]

Despite the challenges to Norplant, the issues seem to be fundamentally different than those presented in the Dalkon Shield, Bendectin, and silicone breast implant litigation. First, and most important, unlike these other products, Norplant was tested extensively in large, well designed studies.[366] Second, unlike the Dalkon Shield, there is no evidence that Norplant causes serious side effects.[367] The major claims against Norplant are not directed at the effects of the hormone, but rather at the effects of the silicone casing.[368] Plaintiffs allege that the silicone casing causes autoimmune disorders, seizures, blindness, cancer and heart attacks.[369]

Contraceptive Projects Liability Litigation, 955 F.Supp 700 (E.D. Tex. 1997). The Texas court granted the defendant's motion for a summary judgment in all five cases. *Id.* at 700. The court granted the defendant, Wyeth-Ayerst, summary judgment on the issue of whether they had provided physicians adequate warnings of the possible adverse side effects of Norplant. *Id.* at 710-11. The court found that all of the known adverse side effects had been communicated to physicians. In dismissing plaintiffs' claims for strict product liability, negligence, breach of implied warranty of merchantability, misrepresentation, and consumer fraud, the court found that the plaintiffs failed to demonstrate that product warnings were legally inadequate. *Id.* The court also found that the plaintiffs had failed to show that prescribing physicians would have made different judgments if given more information. *Id.* at 710.

On June 20, 1994 an Illinois judge certified a class action against Wyeth-Ayerst for women who suffered "mental anguish and physical pain" from complicated removals of the Norplant device. Doe v. Wyeth-Ayerst Lab., Inc., No. 92 L 11096 (Ill. Cir. Ct. Cook Co. 1994), *reported in Norplant: Florida, Illinois, Class Complaints, supra.* However, the same judge refused to expand this class action to include women who are suing over adverse side effects. Cook County Circuit Judge James S. Quinlan, held that complications due to removal, and complications due to side-effects while Norplant was in place, are two separate legal issues and, therefore, the other women will have to file individual claims. Wyeth-Ayerst has filed a motion to have the original class (the removal plaintiffs) decertified. M.A. Stapleton, *Judge Won't Expand Class Suing Over Norplant Removal*, CHI. DAILY L. BULL., Mar. 6, 1996, at 3.

In 1996, a Phoenix court granted summary judgment for the defendant in *Lowe vs. American Home Prods. Wyeth-Ayerst: Recent Rulings in Norplant Suits Favor Co.*, DOW JONES INT'L NEWS SERVICE, Mar. 7, 1996. In 1996, a judge denied class certification in Illinois. *Norplant Class Certification Denied in Illinois*, WEST'S LEGAL NEWS, Mar. 8, 1996, at 1257, available in 1996 WL 25897.

364. Kolata, *Will the Lawyers, supra* note 356. On May 12, 1994, a reporter for Connie Chung's prime-time news magazine *Eye to Eye* interviewed two angry women who are suing over Norplant. They reportedly experienced irregular cycles and weight gain when their implants were removed. *Eye To Eye With Connie Chung: Profile—Under My Skin; Norplant Users Find They Were Not Fully Informed About Possible Difficult Removals* (CBS television broadcast, May 12, 1994).

365. Karen Houppert, *Killing Contraceptives*, VILLAGE VOICE, Oct. 1, 1996, at 23.

366. *See generally* Thau & Robbins, *supra* note 3505, at 95 (summarizing the literature regarding Norplant studies).

367. *Id.*; Kolata, *Will the Lawyers, supra* note 356.

368. Kolata, *Will the Lawyers, supra* note 356.

369. *Id.*

The lawyers and experts challenging Norplant are the same people who challenged the silicone breast implants.[370] Norplant contains 0.75 grams of silicone, compared with 250 to 500 grams in a typical breast implant.[371] The silicone in Norplant is harder and less likely to leak than the silicone in the breast implant.[372] Silicone has long been used in pacemakers, artificial joints and insulin pumps.[373] Used in this context, it has not attracted significant litigation or criticism in scientific studies or professional literature.[374] Most Norplant claims assert side effects—menstrual irregularity and weight gain—that are far less serious than the adverse side effects attributed to the Dalkon Shield and silicone breast implants. These side effects are carefully described in the warnings that accompany Norplant.[375] Another major complaint is that health care practitioners have difficulty removing the Norplant, and Wyeth-Ayerst has established a toll free number to supply women with the names of experienced Norplant providers.[376] Some complainants argue that the manufacturer has a duty to do more.[377] But the bottom line is that none of these are big money claims. Nonetheless, bad publicity surrounding Norplant and the lawsuits has caused sales of the drug to drop dramatically, from 800 a day in 1993 to 60 a day in 1995.[378]

The Dalkon Shield experience should cause little concern to Norplant manufacturer, Wyeth-Ayerst. The more difficult question is whether judges, juries, and consumers will liken the Norplant claims to those against breast implants because both devices contain silicone. But, given the long and safe history of using silicone in forms and quantities more similar to

370. *Id.*

371. *Id.*

372. *Id.*

373. *Id.*

374. *See* Sharyn Rosenbaum, *Implant Suppliers Prepare for FDA Ruling*, HEALTH INDUS. TODAY, Mar. 1992, at 1 (industry official claims that in 20 years of manufacturing silicone pacemakers there has never been a problem).

375. Swazey discusses the problems that confront drug companies in deciding whether to provide warnings about unsubstantiated medical evidence of possible hazards. On the one hand, the package insert should provide authoritative information based on substantial evidence. On the other hand, it should be up to date. It is difficult for a warning to be simultaneously authoritative and up to date. Swazey, *supra* note 130, at 317-318.

376. Toll free number is 1-800-934-5556.

377. Four hundred women are seeking to join a class action lawsuit against Wyeth-Ayerst Laboratories, contending that they suffered severe pain and scarring when their doctors removed the Norplant. Lewin, *supra*, note 357 at A10. The suit was filed on behalf of an unidentified plaintiff in September, 1993 and a class action was certified in June, 1994. *Id.* The suit argues that the drug company has an obligation to train doctors to remove the device and seeks $20,000 to $50,000 damages for each plaintiff. *Id.*

378. Kolata, *Will The Lawyers*, *supra* note 356. A 1995 study of family planning clinics in Dallas, Pittsburgh, and New York shows that Norplant insertion went from a high of 180 per month in the Summer of 1993 to 15 per month by early 1995. *Study Shows Dramatic Drop Off in Norplant Use*, MEALEY'S LITIG. REP., Sept. 8, 1995, at 7 [hereinafter *Dramatic Drop Off in Norplant Use*].

Norplant than to breast implants, this seems unlikely.[379] The litigation to date suggests that courts are skeptical of complaints against Norplant.[380]

An additional factor that may inhibit the use of Norplant is the cost of the product and patterns of reimbursement for contraceptive services in the United States. While birth control pills are actually more expensive than Norplant, Norplant's costs are paid once in five years, rather than spread month to month over the same period.[381] Most American women pay for contraceptives out of pocket, even if they have health insurance.[382] It seems likely that many women would find it difficult to pay for Norplant. On the other hand, the publicly funded health care programs, Medicaid and Title X, finance Norplant for low income women. As a consequence, Norplant is more often used by low income women than by working poor women and some middle-income women.[383]

One concern about Norplant is that, like all other contraceptive methods that do not protect against sexually transmitted diseases, it may undermine efforts to prevent the spread of STDs, including HIV.[384] One study demonstrates that among teenagers, Norplant was 19 times more effective than the pill in preventing conception, but did not change other behavior, including condom use or doctor visits.[385] In this small study, 98 new mothers from inner-city Philadelphia were offered the choice of Norplant or pills. Forty-eight selected Norplant and 50 chose birth-control pills. Eighteen months later, only one Norplant user had become pregnant, while 19 of those on the pill (38 percent) did. The rates of sexual activity, multiple sexual partners, infections with sexually transmitted disease, and doctor visits were similar in the two groups. The sad news is that rates of sex without protection against sexually transmitted disease and the rates of those diseases were high in both groups.[386]

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379. *See generally* Rosenbaum, *supra* note 374; Kolata, *Will the Lawyers, supra* note 356.

380. See cases cited, *supra* note 363.

381. *Birth Control Implant Gains Among Poor Under Medicaid*, N.Y. TIMES, Dec. 17, 1992, at A1 [hereinafter *Birth Control Implant Gains Among Poor*].

382. About 17 percent of American women have no health insurance. Forty-nine percent of women insured through large group insurance programs have no coverage for contraceptives, while only 15 percent of large group plans cover all of the most commonly used reversible methods, including Norplant. ALAN GUTTMACHER INSTITUTE, UNEVEN & UNEQUAL: INSURANCE COVERAGE FOR REPRODUCTIVE HEALTH SERVICES 8 (1995).

383. Since Norplant is covered by Medicaid in all 50 states and the District of Columbia, those eligible for Medicaid are more capable of getting the device than the working poor. In a survey of 149 Planned Parenthood affiliates, 69 percent of those getting the device through clinics were on Medicaid. *Birth Control Implant Gains Among Poor, supra* note 381, at A1. In a recent study of Norplant users who went through family planning clinics, 54 percent were on Medicaid. *Dramatic Dropoff In Norplant Use, supra* note 378.

384. Margaret Polaneczky, Gail Slap, Christine Forke, Aviva Rappaport, Steven Sondheimer, *The Use of Levonorgestrel Implants (Norplant) for Contraception in Adolescent Mothers*, 331 NEW ENG. J. MED. 1201, 1205-06 (1994).

385. *Id.* at 1204-05.

386. *Id.* at 1205-06.

3. RU 486.

In 1984, the results of the first clinical dose finding study of mifepristone—RU 486—for termination of early pregnancy were published.[387] Since then, this and related compounds have been the subject of more than a thousand research papers, a number of major reviews, and two scientific books, as well as a number of articles in the popular press.[388] RU 486 is currently marketed in France, the United Kingdom, and Sweden, and has been synthesized for use in China.[389] The drug has been used by over 200,000 European women.[390] By 1990, almost one-third of French women who wanted to terminate a pregnancy of nine weeks or less chose RU 486 over the surgical procedure.[391] When followed by a dose of prostaglandin, RU 486 is 96 percent effective in inducing abortion.[392]

In France, the drug is only available at approved clinics, and may only be administered within seven weeks of the woman's last menstrual period.[393] The procedure involves a four step process.[394] The first visit includes a physical exam and information session. On the second visit the pill is administered, and on the third visit the prostaglandin dose is given and the woman stays in the office for three or four hours while the fetus is expelled. The fourth visit consists of an examination to ensure that the abortion was successful.[395] The process requires supervision because, in a small number of women, the abortion may be incomplete or the drug could cause excessive bleeding.[396] The more common, less serious side effects are nausea, cramping, and moderate bleeding.[397]

In the 1980s, a small group of anti-choice activists in the United States attacked the parent company of Roussel-UCLAF, threatening to boycott all of their products and to encourage women around the world to join

387. Paul F. A. Van Look & Helena von Hertzen, *Post-ovulatory Methods of Fertility Regulation: The Emergence of Antiprogestogens*, *in* CONTRACEPTIVE RESEARCH, *supra* note 305, at 152.

388. *Id.*

389. Andrzej Kulczycki, Malcolm Potts, Allan Rosenfield, *Abortion and Fertility Regulation*, 347 THE LANCET 1663, 1666 (1996).

390. Gina Kolata, *Abortion Pill Reaches New U.S. Juncture*, N.Y. TIMES, July 19, 1996, at A10 [hereinafter Kolata, *Abortion Pill*].

391. LAWRENCE LADER, RU 486: THE PILL THAT COULD END THE ABORTION WARS AND WHY AMERICAN WOMEN DON'T HAVE IT 54-55 (1991).

392. Louise Silvestre, Catherine Dubois, Maguy Renault, Yvonne Rezvani, Etienne-Emile Baulieu, Andre Ulmann, *Voluntary Interruption of Pregnancy With Mifepristone (RU 486) and a Prostaglandin Analogue: A Large-Scale French Experience*, 322 NEW ENG. J. MED. 645, 645 (1990).

393. Allan Rosenfield, *Mifepristone (RU 486) in the United States: What Does the Future Hold?*, 328 NEW ENG. J. MED. 1560, 1561 (1993).

394. LADER, *supra* note 391, at 59.

395. *Id.*

396. Rosenfield, *supra* note 393, at 1561.

397. *Id.*

world-wide class action law suits against them.[398] Roussel briefly withdrew the drug from the market, a decision that many medical professionals received with alarm.[399] Roussel resumed distribution of RU 486 in response to a petition, circulated by the World Health Organization, the World Bank, and the Rockefeller Foundation, and signed by many of the doctors at the World Conference in Gynecology and Obstetrics.[400] The lobbying contest became academic in the United States when the Bush administration banned importation of the drug.[401] In Congress, anti-abortion members fought RU 486, arguing that it would trivialize abortion.[402] Feminist reaction was divided. Many women welcomed the availability of an alternative choice, while many others questioned whether RU 486 had been proven safe and whether it was really preferable to accessible, surgical abortion.[403]

Prior to 1994, only one small clinical trial of RU 486 had been done in the United States.[404] In 1993, President Clinton issued a directive to review ways to test RU 486, and Roussel-UCLAF donated its U.S. patent rights for the drug to the Population Council so that the non-profit organization could conduct clinical trials.[405] The Population Council began trials in 1994 that eventually involved approximately 2,100 adult women.[406] In July 1996, the Population Council reported that the preliminary data was identical to the results of the French studies and recommended that the product be approved for general use.[407]

In France and Britain, the cost of RU 486 is approximately equivalent to a first trimester surgical abortion.[408] Even though ending a pregnancy with RU 486 is not without pain and inconvenience, many women report that they prefer it to surgical abortion.[409]

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398. Judy Foreman, *France Orders Sale of Abortion Pill*, BOSTON GLOBE Oct. 29, 1988, at 1, *available in* 1988 WL 4638867.

399. *Id.*

400. *Id.*

401. ASBELL, supra note 316, at 359-64; *Talk of the Town, The Next Abortion Battle*, NEW YORKER, Oct. 18, 1993, at 41, 41-42.

402. Sara Ricks, *The New French Abortion Pill: The Moral Property of Women*, 1 YALE J.L. & FEMINISM 75, 92-98 (1989).

403. *Id.* at 94-95.

404. The Population Council sponsored clinical trials at the USC Medical Center. David A. Grimes, Leslie Bernstein, Maria Lacarra, Donna Shoupe, Daniel R. Mishell, Jr., *Predictors of Failed Attempted Abortion with the Antiprogestin Mifespristone (RU 486)*, 162 AM. J. OBSTETRICS AND GYNECOLOGY 910 (1990).

405. Gina Kolata, *Panel Advises FDA to Allow Abortion Pill*, N.Y. TIMES, July 20, 1996, at A1 [hereinafter Kolata, *Panel Advises FDA*].

406. Michael Klitsch, *Update: Let the Trials Begin!*, 26 FAM. PLAN. PERSP. 244, 244 (1994).

407. Kolata, *Panel Advises FDA*, *supra* note 405.

408. ASBELL, *supra* note 316, at 352-53.

409. *Id.* at 357.

4. Morning-after Pill.

For more than 25 years ordinary birth control pills have been known to prevent pregnancy post-coitally.[410] In many countries, including Britain, New Zealand, Switzerland and France, the pills are sold in special packages, with specific instructions regarding such use.[411] In the U.S., many providers of birth control and rape crisis counseling centers have provided this service. The pharmaceutical companies that market birth control pills do not inform patients and providers about this use of pills, asserting that the risks of liability are too great.[412] In 1994, the Center for Reproductive Law and Policy filed a petition with the FDA asserting that failure to inform doctors and patients about the post-coital use of the pill to prevent pregnancy constituted false and misleading information.[413] While the FDA declined to order the drug companies to relabel the pills, it did study the post-coital use and agreed to publish a notice in the Federal Register affirming the safety and efficacy of such use.[414] The action was highly unusual for the FDA, which ordinarily only passes judgment on the safety and efficacy of drugs in response to a petition from a manufacturer seeking to market the product.[415]

PART IV.
FACTORS THAT MAY INFLUENCE DRUG MANUFACTURERS' WILLINGNESS TO DEVELOP AND MARKET CONTRACEPTIVES

A. Uncertainty and the Difficulty of Risk Assessment

Judith Swazey observes:

410. Judy Peres, *FDA Panel Pushes Another Use for Pill: Contraceptive Also is Effective "Morning-After,"* CHI. TRIB., June 29, 1996, at 3.

411. Tamar Lewin, *U.S. Agency Wants the Pill Redefined*, N.Y. TIMES, July 1, 1996, at A1 [hereinafter *U.S. Agency Wants the Pill Redefined*]. *See* The Center for Reproductive Law & Policy Memorandum of Law in Support of Citizen's Petition prepared by the American Medical Women's Association, the American Public Health Association & Planned Parenthood of New York City at 5-6 (Nov. 28, 1994) (on file with author).

412. At the FDA hearing approving such use, a lawyer for the Wyeth Co., manufacturer of four of the six pills studied by the FDA "said the threat of liability lawsuits in this country was so great that it would not be willing to market morning-after pills here." Lewin, *supra* note 411, at B6.

413. Petition from the Center for Reproductive Law and Policy to the Food and Drug Administration (Nov. 23, 1994) (on file with *N.Y.U. Review of Law & Social Change*).

414. Carol Jouzaitis, *FDA Says Double Dose of Pills Can be Used as Emergency Morning-After Contraception*, SEATTLE TIMES, Feb. 25, 1997, at A4. The notice placed in the Federal Register by the FDA listed specific brands of birth control pills that may be used post-coitally, the proper dosages for each brand, and the procedures doctors and patients should follow. Prescription Drug Products; Certain Combined Oral Contraceptives for Use As Postcoital Emergency Contraception, 62 Fed. Reg. 8610 (1997); *see also Panel Finds Birth Control Pills Safe for "Morning-After" Use*, WASH. POST, June 29, 1996, at A9.

415. Anita Womack, *FDA Panel Backs Contraceptive Pills for Emergency Use*, WALL. ST. J., July 1, 1996, at B7.

> There are many anecdotes, opinions, claims and counterclaims, and some limited case studies and survey reports about the effects of product liability on prescription drug safety but virtually no solid data. If such data exist—and it is interesting to wonder how policy is made in their absence—they certainly are not accessible to those outside industry.[416]

Uncertainty, and lack of data, breeds hysteria.[417] For example, the Pharmaceutical Manufacturers Association calls for changes that would radically restrict injured plaintiffs' ability to sue. It says:

> [T]here has been an explosion in the number and cost of tort cases . . . [T]he tort law system has broken down . . . [P]eople are filing suit in record numbers and reaping huge windfalls. A lottery mentality now infects the tort system.
>
> Because of these developments, insurance underwriters have no way to predict the kinds or amounts of claims they may have to pay. The result: broad classes of liability insurance are now unavailable or unaffordable.[418]

Potential defendants always benefit from restrictions on plaintiffs' ability to sue and to recover damages, regardless of whether there actually is a "liability crisis." But if the claims of limitless and unpredictable liability are not accurate, there is a negative effect, for both manufacturers and consumers. Manufacturers will needlessly forego marketing potentially profitable products, and consumers will be deprived of their benefits.

More careful studies do not support the claim that the tort system is a lottery. While there was an increase in product liability suits in the federal courts between 1974 and 1985, three products were responsible for much of that increase: asbestos for forty percent, the Dalkon Shield for twelve percent, and Bendectin for five percent.[419]

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416. Swazey, *supra* note 130, at 292.

417. A parallel phenomena is observed in relation to medical malpractice. Periodically, in response to financial changes in the insurance industry, wholly unrelated to malpractice payments, rates increase and there is broad perception of a crisis that may drive doctors from practicing medicine. *See* Patricia M. Danzon, *The "Crisis" in Medical Malpractice: A Comparison of Trends in the United States, Canada, the United Kingdom and Australia*, 18 LAW MED. & HEALTH CARE 48 (1990). In 1985, in response to such a perceived crisis, New York created an excess medical malpractice insurance pool, designed to protect doctors and malpractice insurers by paying claims above a designated amount and funded by a surcharge on health insurance premiums. By 1995, the fund had collected over one billion in funds and paid less than two million in awards. The disparity is a graphic representation of the degree to which the fear of liability exceeded its threat. Sarah Lyall, *$700 Million Malpractice Insurance Fund is Viewed as a Source of Blue Cross Aid*, N.Y. TIMES, Dec. 26, 1992, at 26.

418. *Quoted in* Swazey, *supra* note 130, at 294.

419. GENERAL ACCOUNTING OFFICE, BRIEFING REPORT TO THE CHAIRMAN, SUBCOMMITTEE ON COMMERCE, CONSUMER PROTECTION AND COMPETITIVENESS, COMM. ON ENERGY AND COMMERCE, HOUSE OF REPRESENTATIVES: PRODUCTS LIABILITY, EXTENT OF THE "LITIGATION EXPLOSION" IN FEDERAL COURTS QUESTIONED 2-3, 20-28 (1988).

The history of various products presented in Part III illuminates manufacturers' fears of liability in marketing contraceptive products. On the one hand, the Dalkon Shield experience—which accounts for the vast majority of liability imposed against manufacturers of contraceptive products—should not produce anxiety on the part of responsible manufacturers. The Dalkon Shield led to high liability costs because A.H. Robins aggressively promoted a product they knew to cause serious injury, engaged in deception, and got caught. Similarly, responsible manufacturers should see the liability history of the hormonal pill as reassuring. While there have been a few cases, virtually all have been unsuccessful as manufacturers have worked to make pills safer and more effective, and to provide clear warnings of the dangers that cannot be avoided.

On the other hand, the Bendectin experience underscores that a manufacturer can be held liable even when it is clear in retrospect that no scientific evidence supports the claim that the product causes injury.[420] Similarly, the early cases finding that silicone breast implants cause connective tissue disorders, may well provide another example of the risk of liability in the absence of scientific support that the product causes injury.[421]

Nonetheless, the liability histories of silicone breast implants and Norplant are still unfolding, and the lessons of the history of these products have yet to be revealed. Thus, it would probably be wrong to see these experiences as red flags against marketing any contraceptive or any product for women. Bendectin underscores the special liability problems in relation to any product alleged to cause birth defects, and cautions a need for careful research on products targeted to pregnant women. Indeed, in the years since Thalidomide and Bendectin, sensitivity to these dangers has grown exponentially.[422]

B. Potential Plaintiffs and Their Lawyers

As noted above, mass tort class actions represent a relatively new development in American law. Manufacturers, and those who are sympathetic to them, see the pervasive risk of class actions asserting baseless claims leading ineluctably toward bankruptcy. For example, a 1995 issue of *Fortune* magazine features a cover story picturing two men and proclaiming, *Lawyers from Hell: Slip Up and Guys Like These Can Bankrupt Your Company—Just Ask Dow Corning*, describing class action litigation involving Agent Orange, asbestos, the Dalkon Shield, and silicone breast implants.[423] In the Dalkon Shield context, plaintiffs initially sought

420. *See supra* Part III.A.3.

421. *See supra* Part III.A.4.

422. *See, e.g.*, T. V. N. Persaud, *Environmental Factors in the Etiology of Human Malformations: Perspectives and Problems of Evaluation, in* PROBLEMS OF BIRTH DEFECTS: FROM HIPPOCRATES TO THALIDOMIDE AND AFTER, 294-95 (1974) (discussing environmental chemicals' impact on fetuses).

423. Nocera, *supra* note 245, at 61.

consolidation of claims to seek redress against a powerful and aggressively defended company.[424] In the end, the Dalkon Shield defendants sought consolidation to limit liability.[425] From a defense perspective, the breast implant cases are far more troubling. They suggest that the mass tort class action device allows lawyers to impose significant liability, without firm evidence that the product causes serious harm.[426] However, it remains to be seen what will happen with the breast implant cases if evidence continues to cast doubt upon the connection between implants and systemic bodily injury.

Concern about mass tort class actions is not limited to defendants, but is shared by responsible plaintiffs' lawyers, scholars, and activists supportive of plaintiffs' interests and traditional civil rights class actions. In a Symposium in the Cornell Law Review in May 1995, seventeen scholars representing a broad range of political perspectives addressed these issues in the context of the asbestos class actions.[427] The commentators differ in their assessment of whether the class action settlement in the asbestos case was substantively fair.[428] They also differ in their assessment of whether traditional ethical constraints are fully applicable to class action lawyers.[429] But all agree that something is seriously wrong.

Charles W. Wolfram, Cornell Law Professor and Chief Reporter for the Restatement (Third) of the Law Governing Lawyers, argues, "that class actions are working so badly . . . not because the actors in class actions are making irrational choices. To the contrary, one can readily understand why everyone acts as they do. What is badly broken, and what badly needs mending, is the basic class action and mass-litigation system of litigation."[430] Wolfram goes on to explain why remedies are not likely to be forthcoming from judges, lawyers, or professional disciplinary committees. In short, this wise symposium provides a richly detailed description of serious problems, but little in the way of practical, constructive solutions.

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424. SOBOL, *supra* note 131, at 37.

425. *See supra* Part III.A.2.

426. Problems about causation are not limited to class actions. *See, e.g., supra* note 323 (discussing the unique case imposing liability for birth defects allegedly cause by spermicide jell). The class action exacerbates these problems.

427. *See* Cramton, supra note 100 (introducing the symposium, *Mass Torts: Serving up Just Desserts*).

428. Koniak, *supra* note 112, passionately denounces the settlement, while Carrie Menkel-Meadow, *Ethics and the Settlements of Mass Torts: When the Rules Meet the Road*, 80 CORNELL L. REV. 1159 (1995), offers a tepid approval of it.

429. Menkel-Meadow, *supra* note 428, argues for more flexible, individuated ethics in mass tort cases, while Koniak, *supra* note 112, argues for adherence to the traditional rules.

430. Charles W. Wolfram, *Mass Torts—Messy Ethics*, 80 CORNELL L. REV. 1228, 1233 (1995).

C. Causation and Proposals for Reform

The analysis presented in this paper suggests that a key question is whether some clearer and more reliable rule or form of fact-finding could prevent the risk of liability to manufacturers in cases in which causation is weak, but still treat plaintiffs fairly. Prior sections discuss two proposals: FDA approval could be made a strong defense to tort liability,[431] and/or the rules of evidence could demand that plaintiffs produce epidemiological evidence, supported by scientific consensus.[432] Prior sections also document serious objections to these proposals. This section explores other alternatives.

One proposal for reform would employ science panels to advise courts on difficult questions of toxic causation.[433] Such panels may provide a fair and helpful reform for mass tort cases. However, science panels would need to be instructed about the differences between scientific and legal causation. Michael D. Green observes:

> Scientists are much more cautious about declaring a proposition "proved" than the law is when resolving a civil case. The luxury of reserving judgment and advocating further investigation to resolve an uncertainty is not one available to the legal system, yet is frequently invoked by scientists. Courts must resolve disputes based on their best estimate of the truth, regardless of the uncertainty that infects that assessment.
>
> A solution lies in plainly and frankly explaining to experts who provide advice to the civil justice system that legal standards of "proof" are not the same as the scientific standards with which they are familiar. The question of interest in the civil justice system is which of two alternatives is more probable: causation or not?[434]

Court-appointed experts are used successfully in many European countries, and broader use of such panels has been recommended.[435] An expert science panel might well have reduced the costs of the Bendectin litigation. Such panels may make a valuable contribution to the silicone breast implant litigation. It is not clear what impact such a reform would have on the availability of IUDs.

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431. *See supra* Part II.D (discussing effect of FDA approval on tort liability litigation).

432. *See supra* Part II.B (discussing expert testimony and proof of causation in tort liability law).

433. 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, 10-19 (1989).

434. GREEN, *supra* note 83, at 318 (footnote omitted).

435. *See, e.g.* Order 33 Rule 6 of the Supreme Court and Supreme Court Act 1981 section 70 (permitting courts in the United Kingdom to appoint experts and assessors). Lord Woolf has proposed to make more use of court appointed experts. Op. Cit. Chapter 13 and pp. 113-14.

Another proposal would address the need for reliable scientific evidence. Large scale epidemiological research is the gold standard of proof or disproof of causation.[436] Injured plaintiffs have virtually no capacity to organize such research.[437] In many cases the people who have both the incentive and capacity to organize such research are drug companies looking to market a product.[438] The FDA is largely dependent on drug company research. However, when drug companies sponsor and fund research, it is subject to charges of bias.[439]

An alternative worth considering is to empower the FDA to administer its own clinical safety testing, including selection of the researchers. Interested companies could pay for the costs of the study, but the FDA would be interposed between the sponsor and investigator, to ensure both independence and the perception of that independence.[440]

D. Politics and Public Opinion

In the past thirty years, while the availability of contraception has increased, political support for it has seriously eroded. In the 1950s, when the pill was introduced, the liberal wing of the Republican party, along with the medical profession, were the primary political forces pressing for the broader availability of contraception. For example, in Connecticut, Republicans worked for decades to persuade the state legislature to repeal that state's ban on contraception, and to organize the litigation strategy that eventually led the Supreme Court to recognize a constitutional right to use birth control in *Griswold v. Connecticut* in 1965.[441] Republicans in Congress led the effort to create the federal Title X program in 1970[442] that, to this day, serves as the principal provider of family planning services

436. RAND E. ROSENBLATT, SYLVIA A. LAW, SARA ROSENBAUM, LAW AND THE AMERICAN HEALTH CARE SYSTEM 252 (1997); Sanders, *supra* note 201, at 328.

437. *See* Dresser, *Implants Revisited, supra* note 240, at 715-24 (arguing that doctors have an ethical obligation to inquire into the safety of new treatments provided to patients because patients have little ability to do so); Kirsch, *supra* note 56, at 233.

438. Kirsch, *supra* note 56, at 233; *see also* INSTITUTE OF MEDICINE, *The Translators: Sectoral Roles in Contraceptive Research and Development, in* LOOKING TO THE FUTURE, *supra* note 199, at 236-41 (discussing stages of industry's role in contraceptive research and development).

439. For example, some studies which found no connection between silicone breast implants and connective tissue disorder were funded by people who were subject to a risk of suit, and the methodology of those studies was strongly criticized. BYRNE, *supra* note 250, at 177, 219, 236-38.

440. GREEN, *supra* note 86 at 335.

441. 381 U.S. 479 (1965). *See* DAVID J. GARROW, LIBERTY AND SEXUALITY: THE RIGHT TO PRIVACY AND THE MAKING OF ROE V. WADE 40-53 (1994) (detailing strategy meetings of early birth control proponents in Connecticut).

442. George Bush, as a freshman member of the House Ways and Means Committee between 1967 and 1970, "was so tenacious in arguing for family planning that the committee's chairman nicknamed him 'Rubbers.'" TANYA MELICH, THE REPUBLICAN WAR AGAINST WOMEN: AN INSIDER'S REPORT FROM BEHIND THE LINES 104 (1996). Tanya Melich has been a party official in the Republican Party since the 1960s and is the co-founder of the Republican Women's Movement.

in the United States.[443] Birth control advocates were motivated both by concern for individual well-being and by a social concern about population growth, particularly among poor and non-white populations.[444] In addition to these major political forces, beginning in the late 1950s, broader access to contraception was also promoted by a male-led challenge to conventional sexual mores, exemplified by Hugh Hefner and his Playboy philosophy.[445] During this period, the Catholic Church provided the most significant political opposition to birth control, and in some places, such as Connecticut, exerted significant influence within the Democratic Party.[446]

In the early 1970s feminism became a significant political force. Feminists have always supported birth control. Yet in the early 1970s, birth control was not an issue of central political controversy. The legalization of abortion was a top priority of the growing feminist movement. In 1973, *Roe v. Wade* transformed the political debate about abortion, galvanizing abortion opponents. The Catholic Church immediately launched a political campaign against legalized abortion, wholly unprecedented in the history of the Church in the United States.[447] Through the 1970s, growing numbers of Christians, espousing traditional patriarchal family values, joined the anti-abortion movement.[448] Politically, however, the key development occurred when the conservative wing of the Republican Party perceived that support for "traditional family values" and opposition to abortion provided a politically attractive centerpiece for political action.[449] Anti-communism was becoming increasingly irrelevant as a core political organizing principle; "family values" and opposition to abortion appealed to the disquiet generated by women's increasingly effective claims for gender equality.[450]

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443. Title X is the popular name for the Family Planning Services and Population Research Act of 1970, Pub. L. No. 91-572, 84 Stat. 1506 (codified as 42 U.S.C. §§ 300-300a-8). It provides block grants to states, which allocate funds to qualified family planning providers. In enacting Title X, Congress sought "to make comprehensive, voluntary family planning services, and information relating thereto, readily available to all persons . . . ." 116 Cong. Rec. 24,094 (1970). In 1994, almost 6.6 million women in the U.S. received contraceptive services from more than 7,000 subsidized family planning clinics. Jennifer J. Frost, *Family Planning Clinic Services In the United States*, 1994, 28 FAM. PLAN. PERSP. 92, 92 (1996). In 1994, nearly three-quarters of U.S. counties had at least one Title X-funded provider. *Id.* at 97. Nonetheless, the subsidized family planning clinics serve—on the average—44 percent of all low income, sexually active women who need subsidized contraceptive services. *Id.* at 100.

444. ROSALIND POLLACK PETCHESKY, ABORTION AND WOMAN'S CHOICE 121-25 (1986).

445. *See* BARBARA EHRENREICH, THE HEARTS OF MEN 42-51 (1983)(describing Playboy's criticism of men who are tied down to just one woman).

446. GARROW, *supra* note 441, at 40-53.

447. FREDERICK S. JAFFE, BARBARA L. LINDHEIM, PHILIP R. LEE, ABORTION POLITICS: PRIVATE MORALITY AND PUBLIC POLICY 149-164 (1981).

448. LUKER, *supra* note 120, at 137-157.

449. MELICH, *supra* note 464, at 184-85.

450. Phyllis Schlafly, long an activist in the Republican Party, was instrumental in promoting anti-feminism as a core Republican issue. *See* PHYLLIS SCHLAFLY, THE POWER OF

In the 1980s, anti-choice forces persuaded President Ronald Reagan to initiate measures to require Title X clinics to notify the parents of teenagers seeking contraceptives and to terminate international family planning funds to organizations that also provided abortions.[451] Most dramatically, the Reagan Administration issued regulations prohibiting health care professionals working in Title X clinics from referring women for abortions, even if the woman requested such a referral or if a continued pregnancy posed a grave risk to her health.[452] In 1992, the Supreme Court (in a 5-4 decision) rejected arguments that the regulations violated both the Title X statute and the First Amendment rights of physicians.[453]

Thus by the 1990s, anti-choice forces have come to dominate the Republican Party and the opposition to choice has come to encompass contraception as well as abortion.[454] In addition, the larger anti-abortion movement has broadened their attack to include contraception.[455] Pharmaceutical companies, like any rational market actor, must take account of these sources of criticism.

On the other hand, it is clear that the majority of the American people are pro-choice with respect to abortion and contraception.[456] The Republi-

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THE POSITIVE WOMAN (1977). For a critique see ANDREA DWORKIN, RIGHT-WING WOMEN (1982); Ann E. Freedman & Sylvia A. Law, *Thomas I. Emerson: A Pioneer for Women's Equality*, 38 CASE W. RES. L. REV. 539, 546-547 (1987).

451. On parental notification, see Melich, *supra* note 442, at 185. On international family planning funds, see United Nations International Conference on Population, *Policy Statement of the United States*, 2d Sess., Mexico City (Aug. 6-13, 1984). *See also* Sylvia A. Law & Lisa F. Rackner, *Gender Equality and the Mexico City Policy*, 20 N.Y.U. J. INT'L L. & POL. 193 (1987).

452. The regulations specified that a "Title X project may not provide counseling concerning the use of abortion as a method of family planning or provide referral for abortion as a method of family planning." 42 C.F.R. § 59.8 (1988). Title X projects must refer every pregnant client "for appropriate prenatal and/or social services by furnishing a list of available providers that promote the welfare of mother and unborn child." *Id.* The Title X project is expressly prohibited from referring a pregnant woman to an abortion provider, even upon specific request. One permissible response to such an inquiry is that "the project does not consider abortion an appropriate method of family planning and therefore does not counsel or refer for abortion." *Id.*

453. Rust v. Sullivan, 500 U.S. 173 (1992). A majority of Congress sought to override the Reagan Administration's gag rule, but President Bush twice vetoed the legislation. Adam Clymer, *The 1992 Campaign; Bush Wins the Battle to Bar Abortion Counseling*, N.Y. TIMES, Oct. 2 1992, at A10. In one of his first official acts, President Clinton rescinded the Title X gag rule. Robin Toner, *Settling In: Easing Abortion Policy; Clinton Orders Reversal of Abortion Restriction Left by Reagan and Bush*, N.Y. TIMES, Jan. 23, 1993, at A1.

454. MELICH, *supra* note 442, at 184-85, 292.

455. Houppert, *supra* note 365, at 23.

456. In 1996, the Los Angeles Times reported that approximately 50 percent of people support a woman's right to an abortion, while 35 percent oppose it. Melissa Healy, *Abortion Bill Reveals Fight for the Unconvinced*, L.A. TIMES, March 31, 1996, at 1. In 1990, the Wall Street Journal reported that elections demonstrate that the abortion issue is slightly "more helpful to candidates who support abortion than to those who oppose it." David Shribman, *Abortion-Rights Activists Gain Ground in Elections but Face New Challenges*, WALL ST. J., Nov. 9, 1990, at A12.

can Party is deeply divided on issues of reproductive choice.[457] Many Republican activists are strongly pro-choice as a matter of principle, and the Party's anti-choice stance hurt it in the Presidential elections of 1992 and 1996.[458]

While the Democrats, a strong minority of the Republican Party, the medical profession, and feminists all strongly support choice in relation to both contraception and abortion, the pro-choice forces have not done all they can to encourage and support the development and dissemination of alternative forms of contraception. They have not provided the leadership on access to contraception that was provided by the Republican Party in the 1950s. For example, the pro-choice forces have not aggressively supported the few companies that seek to provide IUDs or protested the fact that IUDs are, as a practical matter, unavailable to U.S. women.[459] In addition, pro-choice forces have not spoken strongly in defense of Norplant.[460] Pro-choice supporters must, of course, address concerns about the safety and effectiveness of alternative forms of contraception, as well as concerns about access.[461] I hope that the Bellagio Conference and this

457. *See* Katharine Q. Seelye, *G.O.P. Moderates Vow to Revive Provisions on Abortion Tolerance*, N.Y. TIMES, Aug. 7, 1996, at A1 (reporting heated dispute within Republican party over abortion stance in presidential election-year platform); Dan Balz, *Former GOP Official Warns of Rightward Lean*, WASH. POST, Feb. 15, 1997, at A8 (noting that former finance chairman of Republican party warned major donors in letter of growing dominance of Christian right within the party).

458. *See generally* Selva Roosevelt, *Dear Haley Barbour*, WASH. POST, Jan. 26, 1997, at C7 (asserting that loyal Republican women voters were being pushed away from the party because of the leadership's anti-abortion stance).

459. *Supra* Part III.C.1. BOSTON WOMEN'S HEALTH BOOK COLLECTIVE, THE NEW OUR BODIES, OURSELVES: A BOOK BY AND FOR WOMEN (1992) is the gold standard for feminist information and a political analysis of reproductive health. Its discussion reflects a strong bias against use of the IUD. *Id.* at 294-300. Women are "strongly advised" not to use the IUD if they have multiple sex partners. No such advice accompanies the description of birth control pills or Norplant; indeed, women with multiple sexual partners are not even included on the list of those who "probably should not use" the birth control pill. *Id.* at 282-283, 290. The book also asserts that between 2 and 20 percent of women using IUDs expel them within two years, and claims that PID is more likely to occur in women using IUDs. *Id.* at 295, 297. This view of the IUD is quite different than the perception held by others. *See supra* Part III.C.1. More importantly, even if the IUD is not the right choice for every woman, it may be the safest, most effective, and most economical method for some. Finally, while the book provides a political discussion about the availability of women's health services providing other contraceptives, it does not do so with respect to the IUD.

460. *Supra* Part III.C.2. The absence of feminist voices has left the Population Council as the major defender of Norplant. While the Council has mounted a sensitive and effective defense of the Norplant choice, its role as a provider and promoter makes that support less credible than the support of independent feminist and other pro-choice voices would be.

461. Petchesky makes this point in relation to feminists. She documents that the early history of the "pill is sullied with racism, profiteering, and collusion among researchers and drug companies." PETCHESKY, *supra* note 444, at 171. Feminist critics were vital in pushing for improvements in the pill, as were plaintiffs product liability lawyers in pushing for the ban on the Dalkon Shield and subsequent improvements in IUDs. Nonetheless, Petchesky concludes that any feminist tendency to view the pill as a "male medical conspiracy" is wrong. *Id.*

Symposium will contribute to the development of a movement that reflects the real support that exists for contraceptive services.