

Current Topics in Law and Policy

A Contractual Solution to the Contraceptive Crisis

David Bernstein†

Over the last decade or so, there has been an explosion in litigation involving claims that certain pharmaceutical products cause birth defects. This litigation has dealt a major blow to the contraceptive industry in general, and in particular to efforts to research and develop a new generation of safer and more effective contraceptives.

Part I of this Current Topic will discuss litigation involving spermicides, Bendectin, and birth control pills, and show how that litigation has inhibited the development of new contraceptives. Part II will discuss possible solutions to the litigation problem, concluding that moving to a contract-based no-fault system, which would include binding arbitration by special science tribunals and a British-style “loser-pays” system, would best discourage unmerited litigation and, concomitantly, encourage pharmaceutical firms to reenter the contraceptive market.

I. The Birth Defect Litigation

Few things in life are more tragic than babies born with severe birth defects. Unfortunately, such tragedies are not uncommon. According to a 1986 study, three to six percent of all pregnancies result in children born with significant defects.¹ Occasionally, such defects will be caused by the ingestion of therapeutic drugs by a woman while pregnant. For example, thousands of European children were born with birth defects during the 1960s after their

† The idea for this Current Topic arose from research undertaken by the author on behalf of the Judicial Studies Project of the Manhattan Institute for Policy Research.

1. Austrian, *Expert Evidence in Toxic Tort Litigation*, FOR THE DEF., Feb. 18, 1989, at 18.

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mothers took the drug Thalidomide for sleeping disorders. The examples of Thalidomide and other drugs known to cause birth defects, such as the acne drug Accutane, together with the publicity surrounding "DES daughters,"² have led parents of children born with birth defects to seek an identifiable, man-made cause for their children's suffering. That quest, combined with some dubious scientific evidence and the prospect of large compensatory and punitive awards, has resulted in lawsuits against manufacturers of Bendectin, spermicides, and oral contraceptives.

A. Bendectin

In 1957, Merrell Dow introduced Bendectin, a drug designed to alleviate the symptoms of pregnant women suffering from morning sickness. Thirty-three million women used the drug during pregnancy. Reports began to surface, however, that some women who had taken Bendectin during pregnancy gave birth to babies with defects similar to those that resulted from the use of Thalidomide.³ Merrell Dow (then known as Richardson-Merrell) soon faced dozens of lawsuits asking for compensation for injuries allegedly caused by Bendectin. The first of these, *Mekdeci v. Merrell National Laboratories*,⁴ was filed in 1977, and the litigation continues to this day.

According to liability expert Peter Huber, "(t)hroughout [the Bendectin litigation], the overwhelming scientific consensus, in the FDA [(Food and Drug Administration)] and in all respectable scientific circles, had not moved an inch: Bendectin does not, in fact, cause birth defects."⁵ Because of that consensus, Merrell Dow has

2. Scientists originally speculated that women whose mothers had taken the female sex hormone DES during pregnancy might suffer an epidemic of cancer and sterility. Billions of dollars of claims have been filed against the manufacturers of DES and millions have been paid out. Fortunately, it seems that the scientists' original projections were severely overblown, and that DES was not nearly as dangerous as first feared; some of the alleged victims may have been compensated prematurely. Until the full medical record is in, it will be hard to say how much of the litigation was justified. But at least in the case of DES, unlike those that will be discussed below, the general scientific community thought at one time that it was dealing with an ultra-hazardous substance. *The Medical Record on DES Emerges After Years of Research and Anxiety*, N.Y. Times, Apr. 9, 1989, at E26.

3. According to defense lawyer Mark Austrian, a *National Enquirer* article actually referred to Bendectin as "a new Thalidomide." Austrian, *Defense Lawyer's Perspective: Justice Prevails in Litigation* 4 Civ. Trial Manual (BNA) 533, 534 (Jan. 1988).

4. 711 F.2d 1510 (11th Cir. 1983).

5. P. HUBER, LIABILITY: THE LEGAL REVOLUTION AND ITS CONSEQUENCES 102 (1988). In *Richardson v. Richardson-Merrell*, 649 F. Supp. 799 (D.D.C. 1986), *aff'd*, 857 F.2d 823 (D.C. Cir. 1988), *cert. denied*, 110 S. Ct. 218 (1989), Judge Thomas Penfield Jackson added: "Though [plaintiff's expert] may disagree, there is now a universal scientific consensus that Bendectin has not been shown to be a teratogen." *Id.* at 803. According to defense lawyer Mark Austrian:

been extremely successful in defending the safety of its product in court. Ten judges have granted summary judgment motions in favor of Merrell Dow in Bendectin cases.⁶ In another fourteen cases, trials on the merits resulted in judgments for Merrell Dow.⁷

But Merrell Dow has suffered a few losses, as well. In 1983, a Washington, D.C. jury awarded Mary Oxendine compensatory damages of \$750,000 for her birth defects, which the jury attributed to her mother's use of Bendectin. At the request of Merrell Dow, presiding D.C. Superior Court Judge Joseph M. Hannon granted a judgment n.o.v. (notwithstanding the verdict) because he believed that no jury could reasonably find Dow liable for Oxendine's birth

Numerous peer-reviewed journal articles and medical tests have been published that review the body of scientific literature on Bendectin. Not one concludes that Bendectin has been shown to cause birth defects. In addition to the [Food and Drug Administration], the World Health Organization and numerous health agencies around the world have made official pronouncements that, in their view, the scientific evidence has not demonstrated an association between Bendectin and birth defects. Not one government agency has concluded that Bendectin does cause birth defects.

Austrian, *supra* note 3, at 534.

6. *Daubert v. Merrell Dow Pharmaceuticals Inc.*, No. 84-2013-G (IEG) (S.D. Cal. Nov. 1, 1989) (mem. and order); *Ambrosini v. Richardson-Merrell Inc.*, No. 86-278 (D.D.C. June 30, 1989) (order); *Koller v. Richardson-Merrell Inc.*, No. 80-1258 (D.D.C. May 30, 1989) (order); *De Luca v. Merrell Dow Pharmaceuticals Inc.*, No. 87-226 (GEB) (D.N.J. May 7, 1989) (mem. and order); *Hull v. Merrell Dow Pharmaceuticals Inc.*, 700 F. Supp. 28 (S.D. Fla. 1988); *Monahan v. Merrell National Laboratories*, No. 83-3108-WD (D. Mass. Dec. 18, 1987) (mem. and order); *Lynch v. Merrell National Laboratories*, 830 F.2d 1190 (1st Cir. 1987); *Hagle v. Mount Clemens General Hosp.*, No. 83-3300-NM (Mich. Cir. Ct. [Macomb Cty.] Nov. 28, 1989); *DePyper v. Merrell Dow Pharmaceuticals Inc.*, No. 83-303-467 NM (Mich. Cir. Ct. [Wayne Cty.] March 10, 1989) (opinion and order); *Thompson v. Merrell Dow Pharmaceuticals Inc.*, 551 A. 2d 177 (N.J. Super. 1988).

7. *Richardson v. Richardson-Merrell Inc.*, 857 F.2d 823 (D.C. Cir. 1988), *cert. denied*, 110 S. Ct. 218 (1989); *Hoffman v. Merrell Dow Pharmaceuticals Inc.*, 857 F.2d 290 (6th Cir. 1988), *cert. denied*, 109 S. Ct. 788 (1989); *Brock v. Merrell Dow Pharmaceuticals*, 874 F.2d 307, *reh'g en banc denied*, 884 F.2d 167 (5th Cir. 1989); *Mekdeci v. Merrell National Laboratories*, 711 F.2d 1510 (11th Cir. 1983); *Rudell v. Merrell Dow Pharmaceuticals Inc.*, No. 85-0115-CV-W-5 (W.D. Mo. June 8, 1988) (order); *Hill v. Richardson-Merrell Inc.*, No. C83-74TB (W.D. Wash. June 7, 1988) (jury verdict); *Hagaman v. Merrell Dow Pharmaceuticals Inc.*, No. 84-2202-S (D. Kan. June 6, 1988) (jury verdict); *Wilson v. Richardson-Merrell Inc.*, No. 85-C-540-E (N.D. Okla. Dec. 14, 1987) (order); *Rosen v. Richardson-Merrell Inc.*, No. 82-0513 (E.D. Pa. Feb. 26, 1987) (jury verdict); *Will v. Richardson-Merrell Inc.*, 647 F. Supp. 544 (S.D. Ga. 1986); *Lanzilotti v. Merrell Dow Pharmaceuticals Inc.*, No. 82-0183 (E.D. Pa. July 10, 1986) (mem. and order) (WESTLAW); *Bityk v. Richardson-Merrell Inc.*, No. C-302-225, (Super. Ct. Cal. July 1, 1987) (jury verdict); *Cordova v. Philips Roxane Labs, Inc.*, No. 432656, (Super. Ct. Cal. [Santa Clara Cty.] June 21, 1985) (jury verdict); *Cosgrove v. Merrell Dow Pharmaceuticals Inc.*, No. 17451 (Idaho June 7, 1989) (Westlaw).

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defects based on the evidence presented at trial. The plaintiffs appealed; the D.C. Court of Appeals reversed the trial judge and restored the jury's verdict for the plaintiff.⁸ The case is still in litigation.

Soon after the original *Oxendine* jury verdict, U.S. District Chief Judge Carl B. Rubin of Cincinnati aggregated the approximately 750 pending Bendectin cases and certified the plaintiffs in those cases as a class. Without admitting liability, Dow offered to pay \$120 million to the class on the condition that the settlement would bind all of the plaintiffs. The deal was blocked, however, when the U.S. Court of Appeals for the Sixth Circuit ruled that Judge Rubin had exceeded his authority by forbidding plaintiffs who disliked the settlement offer to opt out of the class.⁹

Merrell Dow then withdrew its settlement offer and proceeded to fight in court with great overall success. Besides *Oxendine*, Merrell Dow has lost only two other Bendectin cases. One of those, however, involved a \$95 million judgment, later reduced to \$20 million.¹⁰ Both cases are presently on appeal.

In 1983, Merrell Dow decided to pull Bendectin off the market because of the costs of litigation and insurance.¹¹ The most immediate victims of the Bendectin litigation (other than Merrell Dow shareholders) were pregnant women, who lost "their only certifiably safe relief from sometimes debilitating morning sickness."¹² According to the American College of Obstetrics and Gynecology, Merrell Dow's decision to discontinue the production of Bendectin "create[d] a significant therapeutic gap. Nausea and vomiting during pregnancy cannot always be treated by symptomatic means, and in the past year, severe cases have led to serious maternal nutritional as well as other deficiencies."¹³

In the longer term, contraceptive users have lost, as well. The Bendectin litigation has caused pharmaceutical companies to shy

8. *Oxendine v. Richardson-Merrell Inc.*, No. 1245-82 (D.C. Super Ct. 1983), *rev'd*, *Oxendine v. Merrell-Dow Pharmaceuticals*, 506 A.2d 1100 (D.C. App. 1986), *vacated*, No. 1245-82 (D.C. Super. Ct. Feb. 11, 1988) (mem. order), *rev'd*, 563 A.2d 330 (D.C. App. 1989).

9. *In re Bendectin Products Liability Litigation*, 749 F.2d 300 (6th Cir. 1984).

10. *Ealy v. Richardson-Merrell Inc.*, No. 83-3504 (D.D.C. June 13 1988) (WESTLAW) (order). The other case is *Raynor v. Merrell Dow Pharmaceuticals*, No. 83-3506 (D.D.C. May 20, 1987) (jury verdict).

11. Austrian, *supra* note 3, at 534.

12. P. HUBER, *supra* note 5, at 162.

13. Board of Trustees of the American Medical Association, Report A-88, *Impact of Product Liability on the Development of New Medical Technologies (Resolution 6, A-87)* 11 (1988) (on file with *Yale Law and Policy Review*) [hereinafter AMA Report].

away from products used during and associated with pregnancy and childbirth. Thus, the Bendectin cases, along with the cases discussed below, have had a chilling effect on the development of new contraceptive technology.

B. Oral Contraceptives

The first case alleging a causal relationship between the hormonal agents in birth control pills and birth defects came in 1973, in *Jorgensen v. Meade Johnson Laboratories*.¹⁴ The plaintiff claimed that her twins' birth defects were caused by their accidental exposure to birth control pills while she was pregnant. The trial court dismissed the case for failure to state a claim, but on appeal the court allowed the case to proceed to trial.¹⁵

In 1977, in response to studies that suggested a possible link between accidental use of birth control pills during pregnancy and birth defects,¹⁶ the FDA began to require oral contraceptive manufacturers to warn doctors that progestational agents, contained in oral contraceptives, should not be used by patients during the first four months of pregnancy.¹⁷ Still, no causal relationship between progestational drugs and birth defects had been established.¹⁸

By 1988, after more extensive studies had been done, the FDA's guidelines for oral contraceptive package inserts for patients stated:

There is no conclusive evidence that oral contraceptive use is associated with an increase in birth defects, when taken inadvertently during early pregnancy. Previously, a few studies had reported that oral contraceptives might be associated with birth defects, but these studies were not confirmed.¹⁹

The physician package inserts state:

Extensive epidemiological studies have revealed no increased risk of birth defects in women who have used oral contraceptives prior to pregnancy. Studies also do not suggest a teratological effect, particularly insofar as cardiac anomalies and limb reduction defects are concerned, when taken inadvertently during early pregnancy.²⁰

During the intervening years, the relationship between oral contraceptives and birth defects was the subject not only of scientific

14. 483 F.2d 237 (10th Cir. 1973).

15. No further published information is available regarding this case.

16. H. Dorfman, *Junk Science and Hormone Birth Defect Litigation: The Role of the Medical Hypothesis in Product Liability and Regulatory Activities* 3-4 (1989) (unpublished manuscript, on file with *Yale Law and Policy Review*).

17. *Id.* at 6.

18. 43 Fed. Reg. 47,178 (Oct. 13, 1978).

19. Quoted in Dorfman, *supra* note 16, at 7.

20. Quoted in Dorfman, *id.* at 8.

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inquiry but also of litigation. In *Rubenstein v. Ortho Pharmaceutical Co.*,²¹ the plaintiff alleged that her use of oral contraceptives caused birth defects in her twins. The judge granted summary judgment for the defendant.

There have also been a few cases related to the birth control pill/birth defect litigation in which plaintiffs have claimed that synthetic progesterone prescribed to avert miscarriage caused birth defects. In *Barson v. Squibb*,²² a jury awarded an infant plaintiff whose mother had used Delalutin, a progestational drug, during pregnancy \$1.5 million in compensation for "congenital defects." The Utah Supreme Court upheld the verdict,²³ despite the growing scientific consensus that, in the words of an FDA report, "progesterone [and other hormonal drugs] do not appear to have any significant teratogenic potential."²⁴ Later courts were more vigilant. In 1986, the Fifth Circuit Court of Appeals upheld a grant of summary judgment against a claim that synthetic progesterone caused a pair of twins' heart problems.²⁵ And, in a replay of the *Barson* case, a New Jersey Superior Court upheld a jury verdict that Delalutin did not cause Jeremy Zweig's birth defects, and held that the trial court was correct not to feel bound by the *Barson* verdict.²⁶

C. Spermicides

Katie Wells was born on July 1, 1981, with tragic birth defects. Her mother sued Ortho Pharmaceutical, claiming that the defects were caused by the company's spermicidal jelly, Ortho-Gynol. She alleged that the spermicide had damaged but not killed the sperm that had impregnated her. Despite "overwhelming scientific evidence that contraceptive gels are not teratogenic,"²⁷ Judge Marvin Shoob, sitting without a jury, found for the plaintiff.²⁸

21. No. CV-80-0177 (E.D.N.Y. Dec. 10, 1987) (WESTLAW).

22. 682 P.2d 832 (Utah 1984).

23. *Id.*

24. This language is from a 1981 FDA Committee report suggesting modifications to the mandated hormone drug package inserts and warnings. *Quoted in Dorfman, supra* note 16, at 7 n.6.

25. *Fontenot v. Upjohn Co.*, 780 F.2d 1190 (5th Cir. 1986).

26. *Zweig v. Squibb*, 536 A.2d 1280 (N.J. Super. 1988).

27. AMA Report, *supra* note 13, at 9. *Cf. Brennan, Causal Chains and Statistical Links: The Role of Scientific Uncertainty in Hazardous-Substance Litigation*, 73 CORNELL L. REV. 469, 517 n.244-45 (listing scientific articles rejecting association between spermicides and birth defects).

28. *Wells v. Ortho Pharmaceutical Corp.*, 615 F. Supp. 262 (N.D. Ga. 1985), *aff'd*, 788 F.2d 741, *reh'g denied*, 795 F.2d 89 (11th Cir.) (en banc), *cert. denied*, 479 U.S. 950 (1986).

Judge Shoob found that the statistical studies offered by experts at trial were inconclusive as to whether the spermicide caused Katie Wells' birth defects. But while the defense had presented much credible evidence that spermicides were safe, the only study provided by the plaintiff showing a relationship between spermicide use and birth defects had been reviewed by the FDA and found inconclusive.²⁹ One of the researchers for that study appeared at the trial to repudiate its use for proving a link between spermicides and birth defects. Judge Shoob, he said, either did not understand him, or ignored him.³⁰

In the end, Shoob based his opinion on his evaluation of the trustworthiness of each expert rather than the scientific evidence. The *New York Times* pointed out that Ortho's witnesses were prominent epidemiologists, but, according to Shoob, were gravely lacking in demeanor and tone.³¹ On the other hand, plaintiff's experts, none of whom had any expertise in epidemiology, had "excellent" demeanor.³²

On appeal by Ortho, the Eleventh Circuit Court of Appeals reduced the award to \$4.7 million but upheld the verdict.³³ The court declared that the plaintiffs were not required to produce scientific studies showing a statistically significant association between spermicides and birth defects, nor to defer to two FDA studies finding no link between spermicides and birth defects.³⁴ The court said that because Judge Shoob's finding was not "clearly erroneous" it would not reverse.³⁵

Ortho appealed to the Supreme Court, but the Court refused to hear the case.³⁶ At the time, Ortho had "less than a handful" of similar suits pending.³⁷ According to an Ortho lawyer, those suits "never got anywhere" because the *Wells* case was such a fluke.³⁸

29. *Contraceptive Jelly-Birth Defect Study Repudiated by its Authors*, United Press Int'l, Dec. 11, 1986 (NEXIS). The FDA had also previously reviewed all the data and concluded that no warning about possible teratogenicity on spermicide packages was necessary. AMA Report, *supra* note 13, at 9.

30. *Contraceptive Jelly-Birth Defect Study Repudiated by its Authors*, *supra* note 29.

31. *Federal Judges v. Science*, N.Y. Times, Dec. 27, 1986, at A22.

32. *Id.*

33. *Wells v. Ortho Pharmaceutical Corp.*, 795 F.2d 89 (11th Cir.), *cert. denied*, 479 U.S. 950 (1986).

34. P. HUBER, *supra* note 5, at 103.

35. *Wells*, 788 F.2d at 744.

36. *Wells*, 479 U.S. 950 (1986).

37. Telephone interview with in-house counsel of Johnson & Johnson, July 6, 1989.

38. *Id.*

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Much to the relief of family planning advocates,³⁹ the absence of further successful lawsuits allowed Ortho and other companies to keep their spermicides on the market. The \$4.7 million ruling was thought to be larger than Ortho's yearly profits from spermicides.⁴⁰ A few more successful suits could have driven that product and other spermicides off the market; the active ingredient in Ortho-Gynol gel is Nonoxynol-9, also used in most other foams, gels, condoms, and contraceptive sponges.⁴¹

In reaction to *Wells*, Drs. James Mills and Duane Alexander of the National Institute of Child Health and Human Development announced: "The . . . decisions are of great concern to the medical community because they indicate that the courts will not be bound by reasonable scientific standards of proof."⁴² The decisions were of even greater concern to pharmaceutical companies, which bear the economic costs of such unreasonableness.

D. *The Reaction*

In 1980, experts writing in *International Family Planning Perspectives* predicted that "long-acting hormonal rings, vaginal rings, new injectable preparations, postaglandins to induce early abortions, IUDs causing less bleeding and pain, and cervical caps are in advanced field trials with thousands of women, and *should be widely available within the next three to five years.*"⁴³ Though some of these products are now available in Europe, ten years later not one is available in the United States. No new active ingredients have appeared in the birth control pills sold in the United States since the 1960s.⁴⁴ Meanwhile, three new ingredients were introduced in Europe during the 1980s.⁴⁵ The RU-486 once a month pill, a non-surgical alternative to traditional abortion, is still unavailable in the United States, despite its availability abroad. No new contraceptive chemical entities have been introduced in the United States since 1968.⁴⁶ The United

39. Shortly after the *Wells* decision, Eve Paul, legal counsel for Planned Parenthood, said, "It would be a tragedy for women if Ortho-Gynol were to be taken away." Lewin, *Contraceptive Suits a Concern*, N.Y. Times, June 10, 1986 at D2, col. 2.

40. *Supreme Court Lets Stand Damage Award in Birth Defects Case*, Wash. Post, Nov. 11, 1986, at A3.

41. P. HUBER, *supra* note 5, at 102-103.

42. United Press International, Nov. 6, 1986 (NEXIS).

43. Atkinson, Schearer, Harkavy & Lincoln, *Prospects for Improved Contraception*, INT'L FAM. PLAN. PERSP., June 1980, at 43 (emphasis added).

44. Jerassi, *The Bitter Pill*, 245 SCIENCE 356, 357 (1989).

45. *Id.*

46. P. HUBER, *supra* note 5, at 155.

States was once the leader in contraceptive technology and research. Yet today, contraceptive research has stalled and only one major company, Ortho Pharmaceutical, continues to invest heavily in birth control technology.⁴⁷

Despite the expectations of the past, birth control options in the United States remain few and unattractive. The greatest victims of the crisis in contraception are teenage girls and older women. The United States has the highest teenage pregnancy and teenage abortion rates in the industrialized world.⁴⁸ Over one million American teenagers get pregnant each year,⁴⁹ making teenage pregnancy one of America's leading health problems. Women over age thirty-five, for whom birth control pills pose the greatest health risks, often resort to sterilization, which has a small but significant risk of serious complications.⁵⁰

Many experts allege that the main cause of the contraception crisis is product liability litigation.⁵¹ The litigation detailed above shows that pharmaceutical companies are not necessarily protected from expensive litigation even when they manufacture what is thought by the scientific community to be a safe and effective product. This places pharmaceutical companies which might otherwise wish to explore new birth control alternatives in an especially vulnerable position. Causal links between a product and birth defects are difficult to prove, but are also difficult to disprove, and when faced with a child stricken with birth defects, jurors and judges might give otherwise dubious claimants the benefit of the doubt. As the Bendectin litigation shows, just a few such verdicts can have a ferocious impact.

Moreover, the manufacturers of Bendectin, birth control pills, and spermicides were insulated from even greater liability because their products had been on the market for a long time, and were therefore able to generate reliable epidemiological studies to back up their safety claims. Because new products do not have such records they are more vulnerable to litigation. A bias against new contraceptive technologies is thus inherent in the system. It is no

47. Phillips, *Drug Firms Halting Contraceptive Study*, Chi. Trib., Jan. 8, 1989, § 7, at 1.

48. Jerassi, *supra* note 44, at 358.

49. Connell, *The Crisis in Contraception*, TECH. REV., May-June 1987, at 47-48.

50. Tubal ligation is often performed under general anesthesia. *Id.* at 48.

51. One family planning expert says that "product liability has brought contraceptive research . . . to a screeching halt, and is reducing already available forms of contraceptives." Galen, *Birth Control Options Limited by Litigation: Whose Fault is it?*, NAT'L L.J., Oct. 20, 1986, at 1. See also Jerassi, *supra* note 44, at 357; Phillips, *supra* note 47; Sugarman, *Claims, Not Courts, For Injuries*, L.A. Times, Aug. 28, 1989, Part II at 5.

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wonder that the president of a large pharmaceutical company asks, “[w]ho in their right mind would work on a product today that would be used by pregnant women?”⁵²

II. Solutions

A. Judicial Control of Scientific Evidence

Some judges have made valiant efforts to separate “junk science” from legitimate scientific claims in trials involving birth defect causation claims. After some initial setbacks,⁵³ the momentum clearly seems to be on the side of those judges who insist on strictly scrutinizing the evidence that comes before them.

As mentioned above,⁵⁴ D.C. trial court Judge Hannon granted a judgment n.o.v. to the defense in an early Bendectin case. Unfortunately, that decision was overruled.⁵⁵ Judge Thomas Penfield Jackson was more successful in *Richardson v. Richardson-Merrell*. He banned the plaintiffs from presenting any statistical or scientific evidence absent a showing of statistical significance.⁵⁶ When the jury returned with a verdict for the plaintiffs in the amount of \$1,160,000, Judge Jackson granted a motion for a judgment n.o.v. in favor of the defendant.⁵⁷ On plaintiff’s appeal, a unanimous panel of the United States Court of Appeals for the District of Columbia upheld Judge Jackson’s decision, finding that the plaintiffs had not carried their evidentiary burden.⁵⁸ In a rare show of ecumenicism on the D.C. Circuit, the opinion of Judge Robinson, a liberal, was joined by two conservative members of the D.C. Circuit, Judges Laurence Silberman and Douglas Ginsburg. The Supreme Court refused to hear the case on appeal.⁵⁹

52. Huber, *Litigation Thwarts Innovation in the U.S.*, SCI. AM., March 1989, at 120.

53. See, e.g., *Lanzilotti v. Merrell Dow Pharmaceuticals*, No. 82-0183 (E.D. Pa. July 10, 1986) (mem. and order) (WESTLAW) (judge denied defendant’s motion for directed verdict in Bendectin case); *Ramirez v. Richardson-Merrell*, No. 85-1504 (E.D. Pa. Sept. 4, 1986) (mem. and order) (WESTLAW) (judge denied plaintiff’s motion for summary judgment in Bendectin case). The *Ramirez* plaintiffs later withdrew their claim with prejudice.

54. *Supra* note 7 and accompanying text.

55. *Supra* note 8 and accompanying text.

56. *Richardson v. Richardson-Merrell*, No. 83-3505 (D.D.C. June 9, 1986) (order). See also *Koller v. Richardson-Merrell Inc.*, No. 80-1258, mem. op. at 1 (D.D.C. Feb. 25, 1983) (statistical confidence level of 95% needed for admittance).

57. *Richardson v. Richardson-Merrell Inc.*, 649 F. Supp. 799 (D.D.C. 1986).

58. *Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823 (D.C. Cir. 1988).

59. *Richardson v. Richardson-Merrell, Inc.*, 110 S. Ct. 218 (1989).

In the *In re Bendectin* class action case,⁶⁰ Judge Rubin banned the word "Thalidomide" and visibly deformed children from the courtroom to prevent the plaintiffs from playing on the jury's fears and sympathies. He also "trifurcated" the trial, asking the jurors first to decide whether Bendectin caused birth defects. If they had answered "yes," a second trial would have followed to determine liability, and then a third to determine damages. This was to prevent a situation in which damages could be awarded out of sympathy without a finding of causation.⁶¹ After listening to nineteen experts, the jury found that Bendectin did not cause the birth defects, making the issue of liability moot. The Sixth Circuit Court of Appeals upheld that verdict despite challenges to Rubin's unorthodox methods.⁶² The plaintiffs made a final appeal to the U.S. Supreme Court, but the Court let the verdict for the defense stand.⁶³

Another Bendectin case, *Lynch v. Merrell-National Laboratories*,⁶⁴ became a powerful precedent for judges to exclude expert scientific evidence that had not been subject to rigorous peer review,⁶⁵ as well as testimony regarding human birth defects based on studies of animals. In proceedings below, the trial court had granted summary judgment for the defense on both causation and collateral estoppel grounds. If the collateral estoppel decision had been upheld, it could have set a precedent barring all future Bendectin claims. The appeals court overturned the grant of estoppel, though it upheld the summary judgment ruling on the causation issue.⁶⁶

The plaintiffs' case in *Lynch* had been based on a reanalysis by Dr. Shanna Swan of the data used in a study conducted by the Center for Disease Control [CDC]. Dr. Swan came to a different conclusion than the CDC, but the court rejected her conclusions, writing:

Swan's study has never been refereed or published in a scientific journal or elsewhere. We are informed of it only by the defendant's excerpts. On the basis of what we have, it could not form the foundation

60. *In re Richardson-Merrell, Inc. "Bendectin" Prod. Litig.*, 624 F. Supp. 1212 (S.D. Ohio 1985), *aff'd*, 857 F. 2d 290 (6th Cir. 1988), *cert. denied*, 109 S. Ct. 788 (1989).

61. This happened at the trial level in *Mekdeci v. Merrell Nat'l Laboratories*, N. 77-225-ORL-CIV-Y (M.D. Fla., Mar. 21, 1980) (jury verdict). The trial court then ordered a retrial, which was won by the defendants and upheld on appeal. *See Mekdeci*, 711 F.2d 1510 (11th Cir. 1983).

62. *In re Richardson-Merrell*, 857 F. 2d 290 (6th Cir. 1988).

63. 109 S. Ct. 788 (1989).

64. 646 F. Supp. 856 (D. Mass. 1986).

65. *See also Brock*, 874 F.2d at 313 ("courts must . . . be especially skeptical of medical and other scientific evidence that has not been subjected to thorough peer review.").

66. *Lynch v. Merrell-National Laboratories*, 830 F.2d 1190 (1st Cir. 1987). The court pointed out that in an "opt-out" case, Judge Rubin himself refused to give estoppel effect to his prior ruling in favor of the defendant. *Id.* at 1193.

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for an expert opinion challenging the scientific consensus and making the issue of causation a factual question to be decided by the jury.⁶⁷

Moreover, the *Lynch* appeals court also upheld the trial court's exclusion of in vivo and in vitro animal studies and studies of "chemically analogous drugs," because these studies were not of a type reasonably relied upon by experts on the causation of birth defects.

Most recently, in *Brock v. Merrell Dow Pharmaceuticals*,⁶⁸ the Fifth Circuit Court of Appeals overturned a jury verdict in favor of a Bendectin plaintiff. The court held that "unproven medical speculation lacking any sort of consensus," such as plaintiff's case in *Brock*, has no probative value.⁶⁹ In denying a petition for rehearing, the court warned that judges should "be especially vigilant in scrutinizing the basis, reasoning and statistical significance" of epidemiological studies.⁷⁰

Unfortunately, extreme vigilance by judges is not always enough. If an "expert" of dubious expertise is theatrically skilled and persistent, she may well be able to fool even conscientious judges and jurors, who, because of their general ignorance of scientific technique, are susceptible to well-presented quackery. The frustration judges feel in having to police the scientific profession was summed up by Judge Glasser in *Rubinstein v. Ortho*.⁷¹ Disturbed by what he considered to be a lack of professional ethics on the part of some witnesses at the trial, Judge Glasser thundered:

Perhaps the time has come for a vigorous discussion and examination of the problem by professional schools, bar associations and learned societies with a view towards re-examining the criteria for qualifying an expert witness and developing stringent protocols and ethical guidelines by which the testimony of such witness may be governed.⁷²

B. The FDA

Because of the difficulties involved in requiring judges and juries to sort through contradictory expert scientific testimony, some observers have advocated removing the process from the tort system completely. One suggested approach would give the FDA sole and

67. *Id.* at 1195. *But see* *Rudell v. Merrell Dow Pharmaceuticals Inc.*, No. 85-0115-CV-W-5 (W.D. Mo. Feb. 19, 1987) ("The jury can decide how much credence to give to any or all of the reports.").

68. 874 F.2d 307, *petition for reh'g denied*, 884 F.2d 166, *reh'g en banc denied*, 884 F.2d 167 (5th Cir. 1989) (*per curiam*).

69. *Id.* at 316.

70. 884 F.2d at 166.

71. No. CV-80-0177 (E.D.N.Y. 1988) (WESTLAW).

72. *Id.*

final responsibility to determine which products are safe and may be marketed.⁷³ FDA approval would immunize products from suit by alleged victims.

While theoretically plausible, this solution suffers from practical problems. The FDA, like other regulatory agencies, is prone to "capture" by the interests it is supposed to regulate. Companies with the right political connections might convince the FDA to look the other way as they introduced unsafe products, in the same way that some members of the Savings and Loan industry used their congressional allies to prevent an early investigation into their fraudulent and reckless practices.⁷⁴ Victims of drugs that came to market in such a manner would be as legally helpless against the drug companies as taxpayers are against the S&Ls.

While the FDA might be lax in some cases, it is perhaps even more likely to be too cautious overall. Already, along with the liability situation, the FDA's cumbersome, expensive and time-consuming approval process is cited as a major factor in discouraging contraceptive research.⁷⁵ The reason behind the FDA's overcautiousness is clear: if the agency allows a drug such as Thalidomide to be marketed without being absolutely certain of its safety, the agency will be blamed for its sin of commission if the product causes harm. If, on the other hand, the FDA delays the approval of a safe drug, the victims of its sin of omission are invisible and the agency suffers few repercussions.⁷⁶

If the FDA had sole authority to determine the safety of drugs, and victims had no legal recourse, the agency would be pressured to make its approval process even stricter and more Byzantine. Such a turn of events would further curtail contraceptive research and development.⁷⁷

73. See Olson, *Judge Bork, Contraceptives, and Liability Reform*, Manhattan Inst. for Pol'y Res. Civ. Just. Memo 3 (Sept. 22, 1987) (judges should defer to the FDA in deciding whether a product is safe).

74. See, e.g., Carlson *\$1 Billion Worth of Influence: How a Shaky Businessman Put Five Senators in His Corner*, TIME, Nov. 6, 1989, at 27.

75. Jerassi, *supra* note 44, at 357; Hansen, States News Service, July 20, 1989 (NEXIS).

76. This situation is changing with the development of a large, vocal gay community which has pressured the FDA to change its procedures in the case of AIDS drugs. See, e.g., Groopman, *Rx for the FDA: Breaking the Drug Approval Logjam*, NEW REPUBLIC, Feb. 13, 1989, at 17 (gay activists have teamed with traditional "right-wing" advocates of reform to form a powerful coalition in favor of overhauling the current drug approval process).

77. Some critics might argue that there is no such thing as "overdeterrence" when it comes to preventing birth defects, and that it is perhaps worth limiting women's reproductive options in order to prevent such tragedies. But the availability of safe and effective contraceptives also prevents birth defects. For example, as discussed earlier in this

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C. *Neocontract*

The best way to attack the birth defect litigation crisis is not to have a solution imposed from above, but to allow the marketplace to solve the problem through contract. Peter Huber has suggested replacing the tort system in birth defect cases with a system of “neo-contract.”⁷⁸ Manufacturers of products used by pregnant women, such as the products discussed above, would include an insurance package with every dose of their product. The company would agree to pay, for example, \$1 million per birth defect caused by its product. In return, the purchaser would agree in advance not to sue. The expense of the tort system would be replaced by a relatively efficient “no-fault” system.

This proposal works well when applied to situations in which the chains of causation are relatively clear. In such cases, compensation must be paid in any event, and neo-contract is the most efficient way of delivering the compensation. But the main problem in the litigation discussed in this Current Topic is that providers of products used by pregnant women must engage in expensive litigation over birth defect claims against products that are safe and effective and could not have caused the alleged injury.

If Huber’s proposal were applied unmodified to that litigation, a no-fault system would have to be established through which all babies born with birth defects could be compensated for their injuries by pharmaceutical companies. Since three to six percent of all babies are born with severe birth defects, giving contraceptive or Bendectin purchasers *carte blanche* to receive compensation if their babies are born with injuries would quickly either bankrupt the producers or put the price of the product well out of the reach of the average consumer.

However, Huber’s proposal could be modified slightly to avoid this problem. His proposal for *ex ante* agreement to compensate injured children for the defects they suffer could be combined with a stipulation that the company and parents of the alleged victim submit to arbitration before a panel of “judges” knowledgeable about the issue at hand to determine whether the birth defects were more

Current Topic (*supra* notes 48-50 and accompanying text), older women and teenagers are especially victimized by the contraceptive crisis. These women also give birth to a higher percentage of babies with birth defects than other women. By limiting the availability of contraceptives, overdeterrence by the FDA would probably lead to a large increase in the number of babies born with birth defects.

78. P. HUBER, *supra* note 5, at 196-97. See *id.* at 190-206 for a broad discussion of “neo-contractual” solutions to tort problems.

probably than not caused by the product. In cases where the evidence was as yet inconclusive, the panel could require the company to put aside in a trust enough assets, either in cash or in insurance policies, to pay the claim in the future. If it turned out that the product was safe and effective, the assets would revert to the company.

Selection of an expert panel in a manner agreeable to both parties is problematic. A system similar to jury selection, with each side being allowed to veto prospective judges, might solve the problem. A clause added to the contract requiring both sides to be "reasonable" in using the veto power would make refusal by either party to accept acknowledged scientific experts grounds for a breach of contract suit. A British-style "loser pays" system would discourage frivolous litigation over this issue.⁷⁹

The proposal outlined above is not intended to describe the exact contours of the contracts that would evolve if *ex ante* contract were adopted. Innovation among producers in a competitive market situation would lead to a more efficient system of settling birth defect litigation through contract than anything a "central planner" such as the author of this Current Topic could invent.⁸⁰

The major barrier to implementation of some type of neocontractual program is the American legal system's current hostility to contractual solutions to tort issues.⁸¹ Contracts between individuals and large companies are routinely voided on the grounds of "unequal bargaining power," "unconscionability," "public policy" and other such judicial doctrines. If companies tried to avoid liability to true victims of defective products through neocontract, the courts almost certainly would refuse to enforce those contracts in an effort to protect the rights of assumedly ignorant consumers. But if the contracts guaranteed significant and fair compensation to victims who could trace their injuries to oral contraceptives or morning sickness medication in a scientifically acceptable manner, then the

79. See *infra* § III(D).

80. See generally F. HAYEK, *THE FATAL CONCEIT: THE ERRORS OF SOCIALISM* (1989) (major error of many modern thinkers is their desire to plan the economy from above using inherently limited human reason and knowledge rather than letting the greatest repository of economic knowledge, the free market, make economic decisions).

81. See *infra* § III(D). See generally, P. HUBER, *supra* note 5; G. GILMORE, *THE DEATH OF CONTRACT* (1974). Walter Olson of the Manhattan Institute points out the irony in the fact that at about the same time the Supreme Court guaranteed the right to use contraception in *Griswold v. Connecticut*, 381 U.S. 479 (1965), other judicial decisions were eviscerating the traditional distinction between tort and contract law, with the result that available contraceptive technology has barely progressed. Personal communication with Walter Olson, Senior Fellow, Manhattan Institute (Aug. 24, 1989).

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only people who could reasonably object would be the products liability bar, which collects a large portion of the money presently spent on toxic tort suits.

D. Loser Pays

Whether or not a neocontractual solution is adopted, the current fee system should be replaced with a British style "loser pays" system.⁸² Such a rule would preserve the ability of impoverished plaintiffs to acquire legal assistance, but only if their lawyers thought they had a respectable chance to win.⁸³ Currently, because there is no penalty when they lose a case except for wasted time and effort, plaintiffs' lawyers have every incentive to file dozens of lawsuits against safe and effective products in the hopes of winning one or two huge judgments, or of coercing a large settlement from a company seeking to avoid the costs and negative publicity of protracted litigation.⁸⁴

III. Conclusion

The results of our current system are quite clear — a few random plaintiffs and their lawyers share hundreds of thousands, even millions, of dollars. Meanwhile, others do without new contraceptive technologies, and old, safe technologies such as Bendectin are no longer available to those who need them. Under the system I propose, the spermicide, Bendectin, and oral contraceptive litigation would have been settled *ex ante* by contract and never reached the courtroom. It is unlikely that the manufacturers of these products would have paid out any money in claims, and litigation costs would have been minimal. Yet, true victims of genuinely unsafe products,

82. For more on fee-shifting and related issues, see Katz, *Measuring the Demand for Litigation: Is the English Rule Really Cheaper?*, 3 J. LAW ECON. & ORG. 143 (1987); Priest, *Regulating the Content and Volume of Litigation: An Economic Analysis*, 1 SUP. CT. ECON. REV. 163 (1982); Shavell, *Suit Settlement and Trial: A Theoretical Analysis Under Alternative Methods for the Allocation of Legal Costs*, 11 J. Legal Studies 55 (1982); 47 J. LAW & CONTEMP. PROBS. (Winter 1984) (special issue on fee-shifting).

83. Indeed, a loser-pays system might even enhance the opportunities of true victims, as the losing party could be forced to pay the other side's experts' fees. Currently, some valid but not overly remunerative claims are not brought because the plaintiffs' lawyers do not want to expend large sums of unrecoverable money on experts. In such cases, the company that caused the damage knows that it can escape liability for the injuries it caused if it refuses to settle.

84. A perfect example of this phenomenon is the protracted Bendectin litigation, which Merrell Dow offered to settle for \$120 million, and through which a few plaintiffs and their attorneys have won millions of dollars in judgments while the rest have left the courtroom empty-handed. See *supra* notes 3-13 and accompanying text.

such as Thalidomide and the Dalkon Shield, would receive a predetermined compensatory award, without one-third or more of their compensation being swallowed by the legal community.

Creative contractual solutions to the contraception crisis such as the one outlined in this essay would permanently solve a judicially created problem. But as long as the courts remain hostile to contract and companies remain too timid to test neocontract, we will have to rely on a combination of judicial wisdom and professional ethics. Unfortunately, while most judges are wise and most paid experts honest, those qualities are not always present. And Americans, especially women of child-bearing age, are paying the price.