PROTECTING CONSUMERS, PRODDING COMPANIES, AND PREVENTING CONCEPTION: TOWARD A MODEL ACT FOR NO FAULT LIABILITY FOR CONTRACEPTIVES

JANET BENSHOOF*

I.
INTRODUCTION

Nearly forty years after the "contraceptive revolution," the demand for safe, effective and practical contraception remains unmet. Indeed, the range of contraceptive choices has diminished in recent years, as technologies are taken off the market more frequently than new ones are introduced.[1] While the scientific community reports on a number of promising new developments, such as male birth control methods, fertility-blocking vaccines, and vaginal preparations that would act as both contraceptives and barriers against sexually transmitted diseases,[2] their eventual appearance on the market is not guaranteed. No government entity is likely to finance the testing and marketing of these methods, and it is increasingly unlikely that any private corporation will undertake that investment.[3]

* President, Center for Reproductive Law and Policy (CRLP). Shortly after establishing CRLP in 1992, Ms. Benshoof received the MacArthur Foundation fellowship in recognition of her work involving women's reproductive rights. The author acknowledges Laura Katzive, currently a legal fellow at CRLP, for her invaluable contribution.

1. For example, the Today Sponge and all but one intrauterine device (IUD) have disappeared from the American market since the mid 1980s. *See* Michele Ingrassia, Karen Springen & Debra Rosenberg, *Still Fumbling in the Dark*, NEWSWEEK, Mar. 13, 1995, at 60 (noting that the Today Sponge manufacturer removed this product from the market in January 1995); Stephen L. Isaacs & Renee Holt, *Drug Regulation, Product Liability, and the Contraceptive Crunch*, 8 J. LEGAL MED. 533 (1987). Before Norplant, a hormonal implant which appeared in 1991, the most recent contraceptive innovations were the invention of oral contraceptives and the appearance of the IUD on the American market in the 1950s. *See* INSTITUTE OF MEDICINE, CONTRACEPTIVE RESEARCH AND DEVELOPMENT: LOOKING TO THE FUTURE 34, 35 (1996) [hereinafter CONTRACEPTIVE RESEARCH AND DEVELOPMENT]. In the 1990s, only three new contraceptive methods were approved by the U.S. Food and Drug Administration (FDA): a female condom; Norplant; and Depo Provera, an injectable hormone. Michael Klitsch, *Still Waiting for the Contraceptive Revolution*, 27 FAM. PLAN. PERSP. 246, 246 (1995). Another method currently available in Europe, a medical abortifacient known as RU 486, is awaiting clinical trials prior to FDA approval.

2. Telephone Interview with Dr. Sheldon Segal, Distinguished Scientist at the Population Council and Chairman of the Board of Trustees of the Marine Biological Laboratory, Woods Hole, Mass. (July 15, 1996).

3. Non-profit organizations, such as the Population Council, play a significant role in funding research, development, production and distribution of contraceptive products. CONTRACEPTIVE RESEARCH AND DEVELOPMENT, *supra* note 1, at 273, 277-87. However,

The inaction of both legislators and manufacturers in the face of an apparently impending contraceptive crisis is puzzling, given the significant public health implications of unwanted pregnancy[4] and the vast global market for contraceptive products. Combined political and commercial forces have stalled initiatives in both the public and private sectors. These barriers to development must be examined separately and confronted systematically.

Historically, public investment in contraceptive development has been sparing.[5] Controversy surrounding reproductive policy deters political initiatives.[6] This is especially the case with post-coital technologies, defined by some as abortifacients.[7] In addition, contraception has not yet been fully recognized as a public health need; rather, it is popularly considered a product for a discrete consumer group.[8] The lack of public investment is reflected in the activities of the scientific community, for whom contraception has been a second-class area of study. While this disfavor may derive in part from a general disregard for applied research, it is also very likely due to the fact that contraceptive research receives less funding than research in areas like cancer, genetic diseases, and molecular biology.[9]

---

the cost of bringing a new pharmaceutical product onto the market is estimated to be between $100 to $500 million, depending on variations in basic research costs, and costs associated with navigating the complex regulatory approval process, defending liability suits, and countering political opposition to controversial products. *Id.* at 255. Moreover, contributions by foundations to contraceptive research declined by $12 million between 1983 and 1993. The non-profit world is thus ill-equipped to undertake contraceptive development single-handedly. Karen Houppert, *The Politics of Birth Control: How Prolife Forces Strangle Research,* THE VILLAGE VOICE, Oct. 1, 1996, at 24.

4. *See* Houppert, *supra* note 3, at 23.

5. Leslie A. Rubin, *Confronting a New Obstacle to Reproductive Choice: Encouraging the Development of RU 486 Through Reform of Products Liability Law*, 18 N.Y.U. REV. L. & SOC. CHANGE, 131, 136 (1991); Houppert, *supra* note 3, at 23.

6. Former Surgeon General Jocelyn Elders is one political figure who attempted to alter the reproductive policies in the United States by making contraception more accessible through distribution of condoms in school. Many of Elders's views on contraception were highly controversial; she was labeled a "lightning rod for conservatives," and was eventually asked to resign. *Elders Quits U.S. Surgeon General Post*, CHICAGO SUN-TIMES, Dec. 9, 1994, at 3.

7. *See* CONTRACEPTIVE RESEARCH AND DEVELOPMENT, *supra* note 1, at 331 ("[T]he State of Pennsylvania just . . . appropriated state funds for contraceptives but excluded Norplant, Depo Provera, and IUDs from being provided because they are considered abortifacients, a definition that is scientifically incorrect."). An abortifacient is "a substance or device used to induce abortion." THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE 5 (3d ed. 1992).

8. *Cf.* Houppert, *supra* note 3 (discussing the failure of current methods to meet the contraceptive needs of all people in all phases of life); Gale Scott, *The New York Newsday Interview With Mark Green: '65,000 Frenchwomen Can't Be Wrong'*, NEWSDAY, Jan. 17, 1991, at 113.

9. Segal, *supra* note 2; Houppert, *supra* note 3, at 24 ("In 1992, for example, the U.S. Center for Population Research, a branch of the National Institutes of Health, spent only 10 percent of its $140 million reproductive-research budget on contraception.").

More harmful to the progress of contraceptive technology in recent years has been the diminished activity of private industry,[10] which is the real engine of development. Pharmaceutical companies, like politicians, steer away from bad publicity, and anti-choice factions have been remarkably successful in enmeshing contraceptives in controversy.[11] A common rationale of private industry for not pursuing contraceptive development is the state of products liability law in the United States: pharmaceutical manufacturers uniformly claim that the huge costs associated with products liability lawsuits deter contraceptive research and development and have prompted the removal of some existing products from the market.[12] Those costs include legal expenses, high products liability insurance prices, and large judgments awarded to injured consumers.[13] In particular, manufacturers point to the lawsuits surrounding the Dalkon Shield and, more recently, Norplant.[14]

A political climate that acknowledged contraceptive research and products as a public health priority could result in at least two constructive changes. First, more public money might go into contraceptive development. At the very least, more funds would increase the status of contraceptive development within the scientific community and more technological leads would emerge over time. Second, the liability concerns of private industry might be addressed legislatively. A no-fault compensation scheme could replace common law rules currently governing liability for injury resulting from use of new and existing contraceptive methods. Precedents for

10. *See* Robert F. Service, *Panel Wants to Break R&D Barrier,* SCIENCE, Friday May 31, 1996, at 1258; Houppert, *supra* note 3, at 24. In the 1960s, there were approximately 12 pharmaceutical companies involved in contraceptive research. *See,* Service, *supra,* at 1258. Today there are only two large pharmaceutical corporations that continue to invest in serious contraceptive research: Wyeth-Ayerst Laboratories and Ortho Pharmaceuticals. Worldwide, companies spend only $22 million researching new products while revenues from contraceptive products approach $2.9 billion. *See* Houppert, *supra* note 3, at 24.

11. CONTRACEPTIVE RESEARCH AND DEVELOPMENT, supra note 1, at 290 ("A very large concern . . . is the resurgence of political, judicial, and legislative controversy over family planning that is expressed in some measure in the November 1994 election of a new, more conservative U.S. Congress[,] ongoing attempts to reverse the Supreme Court's decision on abortion through adoption of a constitutional amendment . . . and the conceptual blurring of the lines of demarcation between contraception and abortion . . .."). *See also* Judy Mann, *In Abortion Wars, a Research Casualty,* WASH. POST, Oct. 3, 1997, at E3 (discussing the anti-abortion movement's derailment of RU 486 distribution in the United States); Houppert, *supra* note 3 (identifying the political controversy surrounding RU 486, Norplant, insurance coverage for birth control, and National Institute of Health grants for contraceptive research and development).

12. *See* Klitsch, *supra* note 1, at 246; Sylvia A. Law, *Tort Liability and the Availability of Contraceptive Drugs and Devices in the United States,* 23 N.Y.U. REV. L. SOC. CHANGE 3 (1998).

13. CONTRACEPTIVE RESEARCH AND DEVELOPMENT, *supra* note 1, at 303-304. Manufacturers also have concerns about negative publicity associated with lawsuits, delayed liability, government investigations following lawsuits, the unpredictability of liability deriving from variations in state laws, the role of uninformed juries in determining liability, and the political sensitivity of family planning issues. *Id.*

14. *See* Law, *supra* note 12, at Parts III.A.2. and III.C.2.

such a statutory scheme may be found among the several national and state laws replacing a tort scheme of recovery with a no-fault plan ensuring limited recovery from a compensation fund.

This paper focuses on the latter suggestion, the development of a contraceptive no-fault compensation scheme. Part II describes generally the features of a traditional tort compensation system and a statutory compensation scheme; explains why contraception should be treated differently from other drugs and devices; and, discusses the special challenges of developing legislation appropriate for contraceptive development. Part III reviews five legislative initiatives providing compensation to injured parties while shielding enterprises from excessive tort liability: the National Childhood Vaccine Injury Act of 1986 (NCVIA);[15] the National Swine Flu Act;[16] the Price-Anderson Act;[17] the Virginia Birth-Related Neurological Injury Compensation Act;[18] and the Longshore and Harbor Workers' Compensation Act.[19] Part IV reviews these five schemes in light of the challenges discussed in Part II and makes recommendations for legislation directed at contraceptives. Part V summarizes the recommended features of a contraceptive compensation plan and evaluates the feasibility of each.

II.
TOWARD AN ALTERNATIVE COMPENSATION SCHEME FOR CONTRACEPTIVE-RELATED INJURY

A. The Traditional Adversarial Tort System

For several categories of injury, the adversarial tort system has been deemed by legislators to be an inappropriate means of compensation.[20] The prevailing criticisms of this system include the inordinate length of time cases take to reach disposition, the high variability of outcomes and their lack of connection to culpability or the plaintiffs' injuries, and excessive transaction costs, which often far outstrip the amounts paid out in compensation.[21] The adversarial tort system may be particularly problematic in contraceptive litigation: the experiences of the female plaintiffs in

15. 42 U.S.C. § 300aa-10 to -34 (1994) (officially designated The National Vaccine Injury Compensation Program).

16. 42 U.S.C. § 247b (j)-(l) (1976) (expired by own accord August 1, 1977).

17. 42 U.S.C. § 2210 (1994).

18. VA. CODE ANN. § 38.2-5000 to -5021 (Michie 1994).

19. 33 U.S.C. § 901-50 (1994).

20. For examples of injuries inadequately compensated through the adversarial tort system, *see* discussion *infra,* Part III.

21. Deborah R. Hensler and Mark A. Peterson, *Understanding Mass Personal Injury Litigation: A Socio-Legal Analysis*, 59 BROOK L. REV. 961, 962-63 (1991) (citing Judicial Conference Ad Hoc Committee on Asbestos Litigation, Report of the Ad Hoc Comm. (1991)). *See also* JOHN G. FLEMING, THE AMERICAN TORT PROCESS 19 (1988) ("The tort plaintiff's attorney's contingent fee consumes from one-third to one-half of the award . . .. [L]egal costs incurred by both parties alone statistically amount to more than the benefit to the victim.").

the Dalkon Shield litigation, who were interrogated at trial about their sexual and hygienic habits, is illustrative.[22] Traditional tort rules, in some contexts, have left injured parties under-compensated.[23] Broad tort liability also has threatened the retreat of some private sector parties from important services and production.[24]

B. No-Fault Injury Compensation Schemes

A no-fault scheme is an alternative system for compensating injury under which claimants may receive limited compensation, without proof of fault, if they qualify for coverage under the authorizing no-fault statute. The earliest no-fault schemes were Workers' Compensation schemes, enacted in forty-two states between 1910 and 1921.[25] Industrial growth brought a high volume of similar claims arising from industrial accidents into the courts.[26] Common law doctrine, based on pre-industrial labor customs and the liberal social philosophy of the period, barred recovery in most cases.[27] In addition, transaction costs diverted funds from the injured parties. One study in 1910 concluded that injured workers received only $37 of every $100 paid by employers in accident liability costs.[28]

---

22. *See* Law, *supra* note 12, at Part III.A.2.

23. *See, e.g.,* FLEMING, *supra* note 21. Injuries resulting from exposure to asbestos, Agent Orange, and DES often have been inadequately compensated by the adversarial tort system. "In such cases, complicated and diverse patterns of exposure, multiple actors introducing the same substance into the environment, possible interactions with other causal agents, and fundamental uncertainties regarding the etiology of the claimed harms often work together to cloud the basic issue of causation." John A. Siliciano, *Mass Torts and the Rhetoric of Crisis*, 80 CORNELL L. REV. 990, 992-93 (1995). As a result, in some cases recovery will be denied where causation probably exists because the plaintiff is unable to legally establish liability by a preponderance of the evidence. *Id.* at 995. *See also* Michael D. Green, *Statutory Compliance and Tort Liability: Examining the Strongest Case*, 30 U. MICH. J. L. REFORM 461, 468, 477 (1997) (noting that in the Bendectin litigation, the defendant manufacturer has not yet paid any legal damages despite the fact that plaintiffs have won approximately 40 percent of jury trials); Alvin B. Rubin, *Mass Torts and Litigation Disasters*, 20 GA. L. REV. 429, 430 (1986) ("Asbestos litigation has resulted in far more expense than in recovery of damages for injured persons.").

24. *See* Kristin White, *Notebook: Contraceptive Makers Chilled By Court Challenges*, 4 J. WOMEN'S HEALTH 223 (1995) (noting the potentially chilling effect of Norplant litigation on contraceptive options for women). *See also* discussion *supra* Part I.

25. Robert L. Rabin, *Some Reflections on the Process of Tort Reform*, 25 SAN DIEGO L. REV. 13, 16 (1988). There have been federal legislative initiatives for specific work-related injuries and diseases, such as the Black Lung Benefits Act, 30 U.S.C. § 901 (1994) and the Longshore and Harbor Workers' Compensation Act, 33 U.S.C. § 901-50 (1994). *See* discussion *infra* in Part III.

26. *See* Jill Williford, *Reformers' Regress: The 1991 Texas Workers' Compensation Act*, 22 ST. MARY'S L. J. 1111, 1113 (1991) (noting that the increase in work-related injuries after the Industrial Revolution led to the imposition of safety-based duties on employers by the courts).

27. *See* W. PAGE KEETON ET AL., PROSSER & KEETON ON THE LAW OF TORTS § 80, at 568-73 (5th ed. 1984) [hereinafter PROSSER & KEETON].

28. Rabin, *supra* note 25, at 16 n.9 (*citing* NEW YORK EMPLOYERS' LIABILITY COMM'N, FIRST REPORT, I, 31 (1910)).

Under Workers' Compensation plans, when a worker is injured, no inquiry is made into the employer's fault.[29] The only questions adjudicated are whether the worker and the injury fall within the statute and how much the worker should be compensated.[30] Awards are drawn from a fund financed through mandatory insurance premiums imposed upon employers.[31] Under Workers' Compensation schemes, the test for compensation and liability is simple and predictable, administrative costs are greatly reduced, and injured employees receive immediate relief.[32]

In recent years, no-fault compensation schemes have been established in a number of highly-focused areas, including vaccines, nuclear accident, medical malpractice, and occupational disease.[33]

C. *Why Contraceptives Should Be Treated Differently from Other Drugs and Devices*

Contraceptives are not the only pharmaceutical products that have led to massive litigation in recent years.[34] The excessive punitive damages awarded in litigation under traditional tort law have deterred pharmaceutical manufacturers from investing in the research and development of new technologies, threatening consumer access to many necessary products.[35] A no-fault compensation scheme for all pharmaceutical products could increase the availability of needed drugs and devices to many consumers.[36]

Strong arguments exist for prioritizing contraceptive development as a subject of legislative action. First, the assurance of contraceptive choice benefits all women. Women remain fertile for an average of thirty-five

29. Thomas A. Eaton, *Revisiting the Intersection of Workers' Compensation and Product Liability: An Assessment of a Proposed Federal Solution to an Old Problem*, 64 TENN. L. REV. 881, 887 (1997).

30. PROSSER & KEETON, *supra* note 27, at 573; *see also* Francis J. Mootz, *Principles of Insurance Coverage: A Guide for the Employment Lawyer*, 18 W. NEW ENG. L. REV. 5, 10-11 (1996) ('Workers' Compensation statutes vary from state to state, sometimes to a significant degree. Generally, these statutory schemes impose no-fault liability on employers to pay death benefits, medical and rehabilitation expenses, and/or lost wages to employees suffering injuries that arise out of and occur during the course of their employment; in exchange, the statutes insulate the employer from what would often be more expansive tort liability.").

31. PROSSER & KEETON, *supra* note 27, at 573. While these statutes are the sole avenue of recourse against employers, most states permit recourse against culpable third parties. *See* Eaton, *supra* note 29, at 887. Also, most statutes provide an exemption from protection for injuries that are intentionally inflicted by the employer. *See* PROSSER & KEETON, *supra*, at 576.

32. Richard B. Stewart, *Crisis in Tort Law? The Institutional Perspective*, 54 U. CHI. L. REV. 184, 197 (1987).

33. *See supra* notes 15-19 and accompanying text.

34. *See, e.g., In re* Silicone Gel Breast Implant Products Liability Litigation, No. CV 92-P-10000-S, 1994 U.S. Dist. LEXIS 12521, at *1, *10 (N.D. Ala. Sept. 1, 1994) (approximately 80,000 members of plaintiff class).

35. *See* Law, *supra* note 12, at Part II.C.

36. *Id.* at Part IV.A.

years, and it is likely that at some point all will wish to regulate their fertility for health, economic or personal reasons.[37] Second, unwanted pregnancy is a public health issue with overwhelming economic and social repercussions.[38] Third, given the crucial role of the private sector in undertaking the costs of contraceptive development, action must be taken to keep private players in the market.[39] Fourth, as noted above, contraceptive development faces an ideological barrier that other pharmaceuticals do not, making statutory incentives more necessary.[40] Fifth, choices regarding childbearing are fundamental to constitutionally protected rights.[41] Finally, it may be that manufacturers of contraceptives are exposed to greater liability than manufacturers of other pharmaceutical products. According to the Institute of Medicine:

> Like vaccines, contraceptives typically are administered to a huge market of individuals with normal health histories. As a result, the possibilities of side effects or unusual reactions, which may affect a very small fraction of the population, will yield a steady stream of claims. Moreover, many of these claims will be filed by healthy, often relatively young individuals and therefore may result in high damage awards. Thus, litigation risk in contraceptives appears to be unusually high relative to other pharmaceutical products.[42]

In addition, manufacturers of contraceptives are held to a higher standard of care than that to which other pharmaceutical producers are held; for example, they must meet more stringent warning requirements. Generally, in response to a claim that a manufacturer failed to warn of a risk inherent to the use of a given prescription drug, a manufacturer can present the "learned intermediary" defense.[43] Under the learned intermediary rule, it is reasonable for a manufacturer to rely on the prescribing physician

37. *See* INSTITUTE OF MEDICINE, DEVELOPING NEW CONTRACEPTIVES 13 (1990) [hereinafter DEVELOPING NEW CONTRACEPTIVES].

38. A woman with an unintended pregnancy is less likely to seek prenatal care, and more likely to ingest substances harmful to the fetus. She is at greater risk of depression and to experience strains on her relationship with her partner. The child of an unintended pregnancy is also at an increased risk for low birth weight, neglect or abuse, and other impediments to healthy development. INSTITUTE OF MEDICINE, THE BEST INTENTIONS: UNINTENDED PREGNANCY AND THE WELL-BEING OF CHILDREN AND FAMILIES 1 (Sarah S. Brown & Leon Eisenberg eds., 1995).

39. *See supra* note 10 and accompanying text.

40. *See supra* note 6 and accompanying text.

41. *See, e.g.,* Planned Parenthood v. Casey, 505 U.S. 833, 849 (1992) ("It is settled now . . . that the Constitution places limits on a State's right to interfere with a person's most basic decisions about family and parenthood . . ..").

42. CONTRACEPTIVE RESEARCH AND DEVELOPMENT, *supra* note 1, at 257.

43. Hill v. Searle Laboratories, 884 F.2d 1064, 1070-71 (8th Cir. 1989); West v. Searle Laboratories, 305 Ark. 33, 42 (1991) (noting that the learned intermediary doctrine is almost universally applied).

to warn patients of possible side effects.[44] Many courts do not, however, recognize the learned intermediary rule as a defense in cases of contraceptive injury.[45] Courts note that physician input is limited in a patient's choice of birth control, which is often influenced by non-medical factors that are undisclosed to physicians.[46] Courts also cite the clinic-type conditions in which many contraceptive products are distributed, where doctors have little contact with patients.[47] Likewise, there is little follow-up beyond annual check-ups.[48] Further, courts recognize that the FDA requires extensive warnings in contraceptive package inserts, which are directed at the ultimate consumer and intended to enable potential users to make an informed choice of methods.[49]

D. Special Challenges in Developing a Contraceptive Compensation Scheme

The creation of any no-fault scheme raises several challenges. First, the definition of a compensable event is crucial. Such a definition must be drawn narrowly enough to ensure that the compensation scheme's purpose is adequately advanced.[50] Second, there is the question of how to maintain incentives for optimal injury prevention, despite the decreased liability of operators and manufacturers. Third, setting up a compensation fund requires some prediction of the amount of compensation the fund will be required to distribute. Finally, legislators must establish a practical means for financing the compensation plan.

1. Defining a Compensable Event

Defining a compensable event is a key and difficult issue. This paper merely attempts to frame the issues involved in defining a compensable

44. Hill v. Searle Laboratories, 884 F.2d at 1070. ("There are several arguments supporting the application of [the learned intermediary rule] to prescription drug products. First, medical ethics and practice dictate that the doctor must be an intervening and independent party between the patient and drug manufacturer. Second, the information regarding risks is often too technical for a patient to make a reasonable choice. Third, it is virtually impossible in many cases for a manufacturer to directly warn each patient.").

45. *Id.* at 1071. *But see* West v. Searle Laboratories at 43-44 (applying learned intermediary doctrine to oral contraceptives, but noting that a minority of courts explicitly reject such application); *see also In re* Norplant, 955 F. Supp. at 705 (federal court holding that Texas state courts would apply learned intermediary doctrine to Norplant).

46. Hill v. Searle Laboratories, 884 F.2d at 1071.

47. *Id.*

48. *Id.* at 1071 n.11.

49. *Id; see also* 21 C.F.R. § 310.501 (1995). Despite this recognition, courts have allowed tort claims based upon improper warnings even though contraceptive manufacturers have complied with FDA labeling requirements. *See* MacDonald v. Ortho Pharm. Corp., 475 N.E.2d 65, 70-71 (Mass.) (rejecting defense that compliance with FDA warning requirements satisfies common law duty to warn), *cert. denied*, 474 U.S. 920 (1985).

50. 2 AM. L. INST., REPORTERS' STUDY, ENTERPRISE RESPONSIBILITY FOR PERSONAL INJURY, APPROACHES TO LEGAL AND INSTITUTIONAL CHANGE 458 (1991).

event in the contraceptive context. It does not purport to provide solutions. I hope that the Conference will do so, particularly given the familiarity Conference participants from European countries may have with these issues.

A no-fault compensation plan replacing common law product liability doctrine is premised on the existence of a causal link between a particular product and a particular kind of injury. The plan will thus only compensate for a fixed set of injuries: those that have been shown to arise from use of a particular product. A claimant will have to establish only that: (a) she used a product covered by the plan; and, (b) she suffered from one of the injuries enumerated in the plan within a certain time period after use of the product. From those facts arise a presumption that the product in question is the cause of the claimant's injury.

Defining a compensable event for a contraceptive scheme poses at least three difficulties. First, the diseases most commonly associated with the use of birth control could arise from other sources. Not every woman who suffers from pelvic infection and has an IUD was injured because of her use of the IUD.[51] Likewise, the risks associated with the use of oral contraceptives, such as the risk of stroke and breast cancer, are closely linked to family histories and may not be due solely to use of oral contraceptives.[52]

Second, some products covered by this scheme would be relatively unknown to the medical community and their injurious effects might not be easily predicted. Thus, use of a product could lead to injury unforeseen by the drafters of the legislation. Such unanticipated injuries could not be deemed compensable events without extensive fact-finding by an administrative body to determine causality. In addressing this issue, reference to the class settlement in the silicone breast implant case[53] is instructive and will be discussed in Part IV.

Third, in contraceptive product liability lawsuits, regardless of the theory of recovery, the adequacy of the manufacturer warning accompanying the product is often the issue that determines liability. In defining a compensable event for contraceptive legislation, we must consider whether an injury that results from the use of a contraceptive product that is accompanied by a proper warning merits compensation under the scheme. Do we want a compensation scheme that, through disclosure, shifts risks to consumers? Or, are contraceptives like vaccines in that we are willing to

51. *See* Kociemba v. G.D. Searle & Co., 680 F. Supp. 1293, 1303 (D. Minn. 1988).

52. *Cf.* Hallie Levine, *The 10 Myths That Stand Between You and the Pill*, COSMOPOLITAN, Mar. 1997, at 150 (citing studies that found no increase in risk of stroke or breast cancer among women who used oral contraceptives).

53. *In re* Silicone Gel Breast Implant Products Liability Litigation, 1994 U.S. Dist. LEXIS 12521.

spread the risks because everyone benefits from the prevention of unwanted pregnancy? It is important to note that the adequacy of the manufacturer warning is one of the most frequently litigated questions in contraceptive injury cases. To exclude adequately-warned injured parties from the scheme would significantly complicate the fact-finding duties of the administrators of the fund.[54]

2. *Incentives for Safety Precautions*

There is no question that vulnerability to a certain degree of liability provides incentives for manufacturers to take safety precautions when producing and labeling contraceptive products. Thus, a statutory scheme shielding manufacturers from products liability litigation could relieve manufacturers of any incentive to take extra precautions or improve products already on the market.[55] Ideally, a legislative compensation scheme would be able to distinguish dishonest and greedy manufacturers from those acting in good faith and from non-profit groups such as the Population Council.

3. *Prediction of Costs*

Necessary to an administrative compensation scheme is a reliable prediction of the likely cost of compensating injured claimants.[56] Without such a prediction, the compensation fund might be inadequate to cover the number of claims filed under the scheme. Alternatively, the fund might be too large, unnecessarily drawing resources away from other useful activities.

While injury associated with existing contraceptives would be covered by the compensation scheme, the proposed legislation is largely intended to encourage the development of new contraceptive technologies. Because new injury claims will inevitably follow the release of a new product, accurate prediction of the number of compensable claims is difficult.[57] The medical community is necessarily unfamiliar with the likelihood of injury associated with the use of a new product. However, the determination of the size of the compensation fund will depend on that likelihood.

---

54. *See also* MICHAEL D. GREEN, BENDECTIN AND BIRTH DEFECTS: THE CHALLENGES OF MASS TOXIC SUBSTANCES LITIGATION 55, 343 (1996) ("[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.").

55. At least two articles have suggested that the value of maintaining this incentive in the context of contraceptives is illustrated by the improvement in the safety of oral contraceptives that followed hundreds of products liability lawsuits. Isaacs & Holt, *supra* note 1, at 541; Michele Galen, *Birth Control Options Limited by Litigation, Whose Fault Is It?*, NAT'L L. J., Oct. 20, 1986, at 28.

56. *See* discussion *infra* Part IV.

57. *See* Law, *supra* note 12, at Part IV.A.

Predictability also requires a limit on non-monetary damages, such as compensation for pain and suffering and emotional distress. Such intangible damages are highly subjective and variable and could rapidly deplete the fund. However, because injury from contraceptive products can cause emotional distress and physical pain that are not reflected in out-of-pocket expenditures, it is not recommended that a compensation fund deny all damages for pain and suffering.

4. Source of Funding

Ideally, the compensation scheme will allow manufacturers to pay lower insurance premiums, fewer litigation expenses, and smaller judgments and settlements, making contraceptive production more profitable. With an assurance of greater profits, manufacturers could better absorb the costs of funding a compensation scheme without having to raise the price of contraceptives. Likewise, if the efficiencies of the new funding scheme resulted in a decrease in the price of contraceptives, consumers would be able to bear the cost of the fund. However, if no such savings is gained through the compensation plan, the burden will have to be borne by either the consumer, the manufacturer, or taxpayers at large.

III.
MODELS OF NO-FAULT INJURY COMPENSATION SCHEMES

A. The National Childhood Vaccine Injury Act of 1986

Congress enacted the National Childhood Vaccine Injury Act of 1986[58] (NCVIA) in response to a crisis in the supply of vaccines that threatened mandatory vaccination programs in every state.[59] Manufacturers, finding that exposure to liability made production of vaccines unprofitable, were increasingly exiting the market.[60] The NCVIA was intended to guarantee the supply of vaccines by protecting manufacturers from the large costs associated with products liability litigation.[61] The act also ensured injured consumers adequate compensation.[62] The NCVIA created "an expeditious, flexible, and quick alternative to the tort system."[63]

---

58. 42 U.S.C. § 300aa-10 to -34 (1994).

59. Mary Beth Neeras, *The National Childhood Vaccine Injury Act of 1986: A Solution to the Vaccine Liability Crisis?*, 63 WASH. L. REV. 149, 151-52 (1988).

60. *Id.*

61. *Id.* The NCVIA keeps legal costs lower than the traditional adversarial tort system. Patricia C. Kuszler, *Balancing the Barriers: Exploiting and Creating Incentives to Promote Development of New Tuberculosis Treatments*, 71 WASH. L. REV. 919, 964 (1996).

62. Neeras, *supra* note 59, at 150; *see also* Susan G. Clark, *The National Childhood Vaccine Injury Act, The National Vaccine Injury Compensation Program*, 94 ED. L. REP. 671, 681 (1994) ("Once an injury, condition, or death is found to be vaccine-related and within the time frame set forth, compensation may be awarded for both past and future unreimbursable expenses, losses, pain and suffering, and a variety of additional services.").

63. Clark, *supra* note 62, at 681.

1. Defining a Compensable Event

The NCVIA provides a relatively complete definition of a compensable event. Vaccine-related injuries are known to the medical community and they have a short latency period. There is little doubt that certain adverse reactions are tied to vaccines when the reactions appear within a certain period of time. For this reason, a Vaccine Injury Table has been devised, defining exactly which injuries appearing within a given period of time would be compensable.[64] Claimants must show by a preponderance of the evidence that they received a vaccine and suffered an injury enumerated on the Table within the time period prescribed on the Table.[65] No inquiry is made into the adequacy of the manufacturer warning. Establishing these facts creates a strong presumption of entitlement to compensation, rebuttable only if a preponderance of the evidence shows that an injury resulted from factors unrelated to the vaccine.[66]

The Vaccine Injury Table relieves claimants of the burden of establishing causation.[67] If a claimant's injury is not on the Table, the claimant must produce medical records or opinions that establish the causal connection by a preponderance of the evidence.[68]

2. Incentives for Safety Precautions

Compensation through the NCVIA is not an exclusive remedy; an award from the fund may be waived if the claimant wishes to pursue a civil remedy on a negligence theory.[69] However, individuals must fully adjudicate their claims through the compensation program prior to filing any civil claims against manufacturing companies.[70] In a civil action, the NCVIA provides that manufacturer fault must be demonstrated.[71]

With the threat of civil liability, manufacturers still have an incentive to prevent injury. However, to avoid problems of over-deterrence, the NCVIA provides that a showing of compliance with the Federal Food, Drug, and Cosmetic Act protects manufacturers from punitive damages.[72]

---

64. 42 U.S.C. § 300aa-14 (1994).

65. 42 U.S.C. § 300aa-13 (1994).

66. 42 U.S.C. § 300aa-13(a)(1)(B) (1994).

67. Daniel A. Cantor, *Striking a Balance Between Product Availability and Product Safety: Lessons from the Vaccine Act*, 44 AM. U. L. REV. 1853, 1861 (1995) ("A petitioner able to demonstrate both that she suffered an injury listed in the vaccine table and that the first manifestation of the injury occurred within the time limit prescribed by the table creates a presumption of causation.").

68. *See* Clark, *supra* note 62, at 677.

69. 42 U.S.C. § 300aa-21(a) (1994).

70. 42 U.S.C. § 300aa-11(a)(2)(A) (1994); *see* Neeras, *supra* note 59, at 156.

71. *See* Stephen Sugarman, *Should Congress Engage in Tort Reform?*, 1 MICH. L. & POL'Y REV. 121, 135 (1996). In addition, a manufacturer may not be held liable solely because of failure to provide a direct warning. 42 U.S.C. § 300aa-2(c) (1994).

72. 42 U.S.C. § 300aa-23(d)(2) (1994).

3. *Prediction of Costs*

The cost of a vaccine injury compensation scheme has been easily predicted from the start. The seven vaccines routinely administered[73] have been available for decades, and the incidence of injury resulting from their use is fairly predictable in light of past experience. Thus, in establishing a compensation fund, Congress was able to legislate the precise amount of tax to be paid per dose of vaccine.[74]

Damages for actual and projected pain and suffering and emotional distress are limited to $250,000.[75] Thus, non-economic losses are recognized, but the unpredictability of award size is minimized by the existence of a damages cap.

4. *Source of Funding*

Funding is provided by an excise tax on each dose of vaccine sold by a manufacturer, producer or importer.[76] Only those vaccines listed on the Injury Table are taxed.[77]

B. The National Swine Flu Act

Passed in 1976, expiring one year later, the National Swine Flu Act[78] was an attempt to encourage manufacturers to produce a swine flu vaccine by transferring to the federal government all liability for injury resulting from swine flu inoculations.[79] The Swine Flu Act was hastily passed by Congress in response to a new flu epidemic similar to one that was responsible for many deaths in 1918.[80] There was a sense of urgency in setting up a full, nation-wide immunization program prior to the onset of the flu season.[81] Insurance companies' fears that such a program could result in increased liability to manufacturers prompted the government to give the manufacturers protection from civil liability by shouldering the responsibility itself.[82] The swine flu vaccination program was discontinued three months after it was initiated, however, when the vaccine was linked to

73. They are vaccines preventing diphtheria, tetanus, pertussis, measles, mumps, rubella, and polio. Neeras, *supra* note 59, at 150.

74. 26 U.S.C. § 4131(b) (1994).

75. 42 U.S.C. § 300aa-15(a)(4) (1994).

76. 26 U.S.C. § 4131(a) (1994).

77. 26 U.S.C. § 4132(a)(1)(A) (1994).

78. 42 U.S.C. § 247b(j)-(l) (1976).

79. Okianer Christian Dark, *Is the National Childhood Vaccine Injury Act of 1986 the Solution for the DTP Controversy?*, 19 U. TOL. L. REV. 799, 835 (1988).

80. *Id.*

81. *Id.*

82. *Id.*

Guillain-Barre syndrome, a neurological disorder with potentially paralyzing effects.[83]

1. Defining a Compensable Event

It appears that compensable events were described in no greater detail than as "personal injury or death arising out of the administration of swine flu vaccine under the swine flu program and based upon the act or omission of a program participant in the same manner[.]"[84] Claims included suits for injuries related to vaccine recipients' development of Guillain-Barre syndrome, as well as for a number of other injuries, including neurological diseases and allergies.[85]

Under the Act, claimants could sue on any theory of liability available to them in the state in which the allegedly tortious acts or omissions took place.[86] In many federal courts, liability was conceded if a plaintiff could prove that he or she suffered from Guillain-Barre syndrome as a result of the vaccination.[87] Plaintiffs in that situation were thus not required to allege negligence or breach of a duty to warn.[88] However, no provision for a presumption of specific causation was included in the legislation and protracted litigation took place in federal courts.[89] The Swine Flu Act was ultimately deemed a failure because "requiring proof led to different standards of liability across the states," which was highly inconsistent with the goal of a national immunization policy.[90]

2. Incentives for Safety Precautions

Because the Swine Flu Act provided an exclusive remedy for injured consumers, manufacturers were entirely shielded from liability for negligence. They thus had no immediate financial incentive to continue improving the safety of their vaccines.[91] Critics of the Swine Flu Act argue that its primary goal was to shield the manufacturers of the vaccine from liability,

83. Paul D. Rheingold & Clifford J. Shoemaker, *The Swine Flu Litigation*, LITIG., Fall 1981, at 28. One out of every 100,000 of the 45 million vaccine recipients contracted the Guillain-Barre syndrome. Dark, *supra* note 79, at 837.

84. 42 U.S.C. § 247b(k)(2)(A) (1976).

85. Dark, *supra* note 79, at 837.

86. 42 U.S.C. § 247b(k)(2)(A)(i) (1976); *see* Dark, *supra* note 79, at 836 ("More than fifty sets of product liability and malpractice laws were applicable to this litigation.").

87. *See also* Joseph Earley, *Can Biotechnology Immunize Vaccine Manufacturers from the Products Liability Crisis?*, 30 JURIMETRICS J. 351, 359 (1990); Harold M. Ginzburg, *Use and Misuses of Epidemiological Data in the Courtroom*, 12 AM. J. L. AND MED. 423, 429-30 (1986) (noting that relief was granted to anyone who could demonstrate that onset of Guillain-Barre syndrome occurred within 10 weeks of vaccination).

88. Rheingold & Shoemaker, *supra* note 83, at 29.

89. Dark, *supra* note 79, at 837-38. *See* Lima v. United States, 708 F.2d 502 (10th Cir. 1983) (plaintiff denied recovery because he failed to prove causation).

90. Keith M. Garza, *Administrative No-Fault Recovery for Transfusion-Related HIV Infection*, 60 DEF. COUNS. J. 384, 387 (1993).

91. Dark, *supra* note 79, at 838.

rather than to compensate victims.[92] In the urgency in which the legislation was conceived, the government eliminated many economic safety incentives for manufacturers.[93]

3. Prediction of Costs

At the time of the program's enactment, manufacturers had no idea what sort of adverse reactions might result from use of the vaccine,[94] making cost predictions impossible. Additionally, there was apparently no limit to compensation funds and, therefore, predicting costs in advance was unnecessary. Almost $135 million was appropriated for the program, and by 1985 costs had reached nearly $100 million,[95] suggesting that the program might exceed its budget. However, since the vaccination program was discontinued and the effects of the inoculation are known, statutes of limitation have barred most suits since the mid-1980s.[96]

4. Source of Funding

Compensation for injury came directly out of the U.S. Treasury from Congressionally-appropriated funds.[97]

C. The Price-Anderson Act

The Price-Anderson Act[98] (Price-Anderson) was passed in 1957 to encourage the entry of private industry into the field of nuclear energy, and to ensure that funds would be available to compensate for injuries and damages sustained by the public in the event of a nuclear accident.[99] Congress originally legislated this act for a duration of ten years, but extended its life in 1965, 1975 and 1988, substantively amending it on each occasion.[100] Congress recognized that the threat of liability from a catastrophic accident was grave enough to deter participation in nuclear activities.[101] Further,

92. *Id.*

93. *See also id.* (discussing the legislation's elimination of safety incentives).

94. Sally-Anne Danner, *The Vaccine Ailment: A Cure to Encourage Litigation-Shy Pharmaceutical Companies to Manufacture an AIDS Vaccine*, 14 HAMLINE J. PUB. L. & POL'Y 67, 75 (1993).

95. H. William Smith III, *Vaccinating AIDS Vaccine Manufacturers Against Product Liability*, 42 CASE W. RES. L. REV. 207, 219 (1992).

96. *Cf. In re* Swine Flu Immunization Products Liability Litigation, 880 F.2d 1439 (D.C. Cir. 1989) (allowing suit to go forward because statute of limitations does not start running until plaintiff learns of illness and its cause); *see also In re* Swine Flu Products Liability Litigation, 764 F.2d 637 (9th Cir. 1985) (holding that whether suit is time-barred is a question of fact for the trial court).

97. Dark, *supra* note 79, at 841.

98. 42 U.S.C. § 2210 (1994).

99. Marcie Rosenthal, *How the Price-Anderson Act Failed the Nuclear Industry*, 15 COLUM. J. ENVTL. L. 121 (1990).

100. For a discussion of the history of the Price-Anderson Act and its amendments, *see* Dan M. Berkovitz, *Price-Anderson Act: Model Compensation Legislation?—The Sixty-Three Million Dollar Question*, 13 HARV. ENVTL. L. REV. 1 (1989).

101. *See also id.* at 4.

because of the lack of experience with this technology, insurance companies were not willing to provide the necessary coverage to protect new entrants into the atomic energy field.[102] Price-Anderson was designed to provide this protection as a temporary measure.[103]

Price-Anderson was largely successful in increasing the participation of the private sector in the development of nuclear energy: in the 1950s, six nuclear reactors were ordered by the industry; in the 1960s, eighty-eight reactors were ordered; and in the 1970s, a total of 155 reactors were ordered.[104] However, critics of Price-Anderson argue that it does not sufficiently protect the public from the danger of catastrophic nuclear accidents, and that it has outlived its usefulness in promoting the development of nuclear energy, as the need for encouraging industry participation has greatly diminished.[105]

1. Defining a Compensable Event

The threshold question is whether the nuclear accident giving rise to the claim is an "extraordinary nuclear occurrence."[106] It is not until the Nuclear Regulatory Commission (N.R.C.) has declared an extraordinary nuclear occurrence that the provisions of Price-Anderson apply.[107] Because it would be difficult for plaintiffs to prove negligence after a nuclear accident, Price-Anderson provides for the waiver of defenses in the event of an extraordinary nuclear occurrence. The Act makes unavailable several defenses commonly asserted in tort law: contributory and comparative negligence; charitable and governmental immunities; and any defense based on a statute of limitations shorter than three years (there is no limitations defense available if the claim is filed within three years from the date on which the claimant first knew or could reasonably have known about the cause of her injuries).[108] The waiver of defenses essentially accomplishes the same result as a system of strict liability, and only minimally interferes with state tort law.[109]

---

102. *Id.* at 6.

103. *See* Rosenthal, *supra* note 99, at 121.

104. *Id.* at 128.

105. *See generally id.* (arguing that the Price-Anderson Act no longer serves its intended purpose).

106. Kiick v. Metropolitan Edison Co., 784 F.2d 490, 494 (3d Cir. 1986). 42 U.S.C. § 2014 (j) defines an "extraordinary nuclear occurrence" as "any event causing a discharge or dispersal of source, special nuclear, or byproduct material from its intended place of confinement in amounts offsite, or causing radiation levels offsite, which the Nuclear Regulatory Commission or the Secretary of Energy, as appropriate, determines . . . has resulted or will probably result in substantial damages to persons offsite or property offsite."

107. For example, "[p]rior to the N.R.C. determination, a state court cannot know what affirmative defenses will or will not be available." Kiick, 784 F.2d at 495 (citing 42 U.S.C. § 2210(n)(1)). In addition, plaintiffs do not have access to federal courts until the N.R.C. declares that an accident is extraordinary. *Id.*

108. 42 U.S.C. § 2210(n)(1)(F) (1994).

109. Berkovitz, *supra* note 100, at 13.

However, there is no definition of a compensable event that serves as the basis for a presumption of causation. Plaintiffs have the burden of proving that radiation-induced injuries resulted from a nuclear power plant accident.[110] As one commentator has pointed out, the "limited extent of scientific knowledge about the biological effects of human exposure to radiation poses a handicap to victims attempting to prove causation."[111] The process of obtaining compensation may therefore be as cumbersome and expensive under Price-Anderson as it is under a tort regime.[112]

2. *Incentives for Safety Precautions*

Incentives for providing optimal safety may be weakened by Price-Anderson's use of the compensation fund, which softens the negative consequences of individual irresponsibility. The fund is amassed through a pooling mechanism.[113] Each nuclear licensee is required to purchase $160 million in private liability insurance[114] and to contribute a maximum of $10 million yearly (up to a maximum of $63 million) to the compensation fund when there is a nuclear incident at any plant.[115] As one critic notes, although the mandatory contributions are large enough "to cover most accidents . . . [they are] not so big as to frighten too many people."[116]

Price-Anderson shields a contractor regardless of the conduct of the individual indemnified.[117] Under no circumstances can an individual manufacturer be held liable for negligence.[118] Thus, Price-Anderson removes the nuclear industry from market risks and imposes the risk on the public by limiting its right to recover fully.[119] Arguably, negligence is adequately deterred by the predictability of the destruction of the nuclear facility in the event of an accident.[120] Further, the nuclear industry has an interest in earning the public trust.[121]

---

110. Rosenthal, *supra* note 99, at 127.

111. *Id.*

112. AM. L. INST., *supra* note 50, at 448.

113. Robert L. Rabin, *Some Thoughts on the Efficacy of a Mass Toxics Administrative Compensation Scheme,* 52 MD. L. REV. 951, 955 (1993).

114. *Id.*

115. 42 U.S.C. § 2210(b)(1) (1994).

116. Berkovitz, *supra* note 100, at 54.

117. *Id.* at 58.

118. *Cf.* Rosenthal, *supra* note 99, at 122-23.

119. *Id.* at 131, *citing* Tomain, *Law and Policy in the Activist State: Rethinking Nuclear Regulation,* 38 RUTGERS L. REV. 187, 195 (1986).

120. AM. LAW INST., *supra* note 50, at 448.

121. Rosenthal, *supra* note 99, at 131, *citing* L. ROCKETT, FINANCIAL PROTECTION AGAINST NUCLEAR HAZARDS: THIRTY YEARS' EXPERIENCE UNDER THE PRICE-ANDERSON ACT 77 (1984).

3. Prediction of Costs

No effort is made to predict expenses. Rather, Price-Anderson imposes a $560 million cap on all liability for nuclear accidents.[122] However, if a nuclear incident involves damages exceeding $560 million, Congress will determine whether it should act to provide greater public compensation.[123] Price-Anderson guarantees a pool of funds of approximately $7 billion—an amount that was not determined by any careful calculus of potential damages.[124] While successful plaintiffs could theoretically collect noneconomic damages,[125] the statute allows courts to reduce awards proportionately if the fund's resources are inadequate.[126] Price-Anderson has been criticized for setting a limit on liability, in light of the possibility that $7 billion may not be enough to compensate claimants adequately in the event of an extraordinary nuclear occurrence.[127]

4. Source of Funding

As stated above, the compensation plan is funded in part through mandatory insurance obtained by licensed operators,[128] and in part through mandatory contributions (not exceeding $63 million) to a common fund established after a nuclear accident has occurred at any plant.[129]

D. The Virginia Birth-Related Neurological Injury Compensation Act

The Virginia Birth-Related Neurological Injury Compensation Act[130] (Virginia Birth Injury Act) was the first reform effort in the United States to adopt no-fault compensation for medical liability.[131] This legislation was

122. 42 U.S.C. § 2210(e) (1994). The U.S. Supreme Court held that this limitation on damages did not violate due process, noting that Price-Anderson "guarantees a level of net compensation generally exceeding that recoverable in private litigation" and contains a statement of congressional commitment to adequately protect those injured by nuclear accident. Common law rights, the Court held, are replaced by a remedy that is at least reasonably just. Duke Power Co. v. Carolina Environ. Study, 438 U.S. 59, 93 (1978).

123. 42 U.S.C. § 2210(e)(2) (1994).

124. Rosenthal, *supra* note 99, at 124.

125. As the Supreme Court held in *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 256 (1984), Price-Anderson did not preclude the availability of state-law remedies, including punitive damages, for plaintiffs injured in a nuclear accident.

126. 42 U.S.C. § 2210(o) (1994).

127. Rosenthal, *supra* note 99, at 124. One critic has stated, "Price-Anderson simply works to defer responsibility and resolution of important issues." *Id.* at 127.

128. 42 U.S.C. § 2210(a) (Supp. 1996).

129. 42 U.S.C. § 2210(b)(1) (Supp. 1996).

130. Virginia Birth-Related Neurological Injury Compensation Act, VA. CODE ANN. § 38.2-5000 to -5021 (Michie 1994).

131. Mary A. Cavanaugh, *Bad Cures for Bad Babies: Policy Challenges to the Statutory Removal of the Common Law Claim for Birth-Related Neurological Injuries*, 43 CASE W. RES. L. REV. 1299, 1317 (1993).

reportedly enacted in response to the refusal of medical malpractice insurers to provide coverage to obstetricians.[132] The statute provides for optional no-fault medical malpractice insurance, providing an exclusive remedy for total and permanent neurological injuries to infants resulting from deprivation of oxygen or mechanical injury during labor, delivery or immediately after delivery.[133] Claims are adjudicated by the Virginia Workers' Compensation Commission.[134] A criticism of the Virginia compensation program is that it has been under-utilized.[135]

1. Defining a Compensable Event

If it has been demonstrated that "the infant has sustained a brain or spinal cord injury caused by oxygen deprivation or mechanical injury, and that the infant was thereby rendered permanently motorically disabled," a rebuttable presumption arises that the injury was birth-related.[136] For each case, a panel of physicians is assembled to submit an opinion on whether the injury is birth-related and this opinion is considered by the Commission, but is not a binding determination of fact.[137]

2. Incentives for Safety Precautions

To ensure the availability of obstetrical services throughout the state, the Virginia Birth Injury Act shields physicians from tort liability by providing an exclusive remedy, except in the case of willful mistreatment.[138] For this reason, it has been criticized for undermining the deterrent goal of the tort system.[139] The statute provides for the review of claims by the Board of Medicine and the Department of Health, a process which can result in sanctions including revocation of professional licenses. However, disciplinary mechanisms are often ineffective within the medical profession.[140] It has also been noted that there is no guarantee that a definitive determination regarding a physician's fault will ever be made.[141] Nevertheless, the adverse effects of patient injury on a physician's reputation may serve as adequate deterrence from negligent behavior as reputation is closely linked to a physician's livelihood.

---

132. Jane R. Ward, *Virginia's Birth-Related Neurological Injury Compensation Act: Constitutional and Policy Challenges,* 22 U. RICH. L. REV. 431, 431 (1988).

133. *Id.* at 433-35.

134. VA. CODE ANN. § 38.2-5008 (Michie 1994).

135. Eleanor D. Kinney, *Malpractice Reform in the 1990s: Past Disappointments, Future Success?,* 20 J. HEALTH PUB. POL'Y & L. 99, 111 (1995).

136. VA. CODE ANN. § 38.2-5008 (Michie 1994).

137. *Id.*

138. Ward, *supra* note 132, at 433 n.16.

139. *Id.* at 433.

140. *Id.* at 452.

141. *Id.* at 451.

3. Prediction of Costs

There is no indication that the size of the compensation fund reflects a prediction of the number of claims or the cost of compensating injuries. The Virginia Legislature must have relied on statistics of past injuries, just as a private insurance company would. The probability of injury is calculable because the delivery procedure is routine and highly familiar to the medical community.

Claimants may recover costs for "medically necessary and reasonable expenses of medical and hospital, rehabilitative, residential and custodial care and service, special equipment or facilities and related travel."[142] Reasonable expenses incurred in filing the claim may also be recovered.[143] The legislation makes no provision for noneconomic losses.

4. Source of Funding

The compensation fund is financed by obstetrician payments of $5,000 per year and hospital payments of $50 per delivery.[144] Participation in the plan is elective for physicians.

E. The Longshore and Harbor Workers' Compensation Act

The Longshore and Harbor Workers' Compensation Act[145] (Longshore Act) is a federal no-fault compensation scheme for occupational injury and disease claims. The Longshore Act was initially enacted in 1927 to provide federal compensation for workers who were not entitled to coverage under state compensation laws.[146] In 1972, the Longshore Act was amended to increase benefits and broaden compensation coverage to all persons "engaged in maritime employment,"[147] except for the master and crew of any vessel.[148] The amendments simultaneously eliminated covered workers' use of the unseaworthiness remedy against vessels while retaining tort remedies for a vessel owner's negligence. Although the Longshore Act originally was designed to compensate for traumatic injuries only, it

142. VA. CODE ANN. § 38.2-5009(1) (Michie 1994).

143. VA. CODE ANN. § 38.2-5009(4) (Michie 1994).

144. VA. CODE ANN. § 38.2-5020 (Michie 1994).

145. Longshore and Harbor Workers' Compensation Act, 33 U.S.C. § 901-950 (1994).

146. Charles Clark, *Maritime Personal Injury: The Expanding Coverage of the Longshoremen's and Harbor Workers' Compensation Act*, 43 LA. L. REV. 849, 852 (1983).

147. 33 U.S.C. § 902 (3) (1994), (amended 1972). In order to be covered under the Longshore Act, a worker must prove both "status" and "situs"that he or she is a longshore or harbor worker as defined under the act, and that the injury occurred upon the navigable waters of the United States. Robert Force, *Federalism and Uniformity in Maritime Law: Post-Calhoun Remedies for Death and Injury in Maritime Cases: Uniformity, Whither Goest Thou?*, 21 MAR. LAW 7, 14 (1996).

148. Clark, *supra* note 146, at 854.

was amended again in 1984 to address occupational diseases, which often have long latency periods and slowly progressive symptoms.[149]

One of the main problems with the Longshore Act was that judicial interpretations interfered with the uniform application of the law.[150] The 1972 amendments attempted to clarify this problem by imposing a clear standard, but again court interpretations have created a diverse set of standards.[151]

1. Defining a Compensable Event

Courts have interpreted the Longshore Act as allowing a presumption of causation if the worker proves that she was exposed to an injurious substance, that she has a disease, and that the toxic substance exposure could have caused her disease.[152] In order to show the causal link between exposure and the disease, the worker may either prove that she has a known occupational disease or that workers in a particular industry are disproportionately affected by a particular disease, compared to the general public.[153] Once the presumption of causation is established, the burden shifts to the employer to provide substantial evidence of a lack of causation.[154] If that burden is carried, the court drops the initial presumption and makes a factual determination.[155] As one commentator has pointed out, because the Longshore Act was originally designed to compensate traumatic injuries and not occupational diseases, the mechanisms for determining causation are inadequate.[156] For example, the statute does not specify how a worker could prove that his or her risk of contracting a non-occupational disease was increased through work in a particular industry.[157]

2. Incentives for Safety Precautions

Although the fund provides the exclusive remedy for occupational injury and disease, operators retain a financial incentive to ensure worker safety. The Longshore Act preserves a private tort action if the vessel owner's actions constitute negligence.[158] Moreover, because contributions to the fund are prorated according to the number of payments made to

149. Lawrence P. Postol, *The Federal Solution to Occupational Disease Claims—The Longshore Act and Proposed Federal Programs*, 21 TORT & INS. L. J. 199, 201-02 (1986).

150. George R. Alvey, Jr. and John O. Pieksen, Jr., *Falling In and Out of Coverage: Jurisprudential Legislating Eviscerates the Status Requirement of the Longshore and Harbor Workers' Compensation Act*, 19 MAR. LAW. 227, 227 (1995).

151. *Id.* at 227, 232.

152. Postol, *supra* note 149, at 234.

153. *Id.* at 236-38.

154. *Id.* at 236.

155. *Id.*

156. *Id.* at 202.

157. *Id.* at 237-38.

158. Kaye A. Pfister, *A Review of Shipowners' Statutory Duty Under Section 905 (b) of the Longshoremen's and Harbor Workers' Compensation Act: Does Scindia Require a Change in Course?*, 1983 Duke L. J. 153, 156 (1983).

each operator's employees during the previous year, a higher incidence of injury leads to greater operating expenses.[159] Thus, taking safety precautions can potentially lower the cost of operations.

3. Prediction of Costs

Costs of the compensation scheme are predicted at the beginning of each calendar year.[160] Nothing in the statute provides for how these predictions are made, although it is likely that estimates are based on the previous year's data. The statute does give the Secretary power to investigate and gather data from each operator.[161]

4. Source of Funding

As noted above, the compensation fund is financed, in part, through annual contributions by operators. The size of contributions, determined annually, is fixed in proportion to the number of claims made against each operator during the previous year.[162] When a worker dies and there is no person entitled to compensation under the statute, the employer must contribute $5,000 to the fund.[163] In addition, all amounts collected as fines and penalties under the statute are paid to the fund.[164]

IV.
CRAFTING LEGISLATION FOR CONTRACEPTIVE DEVELOPMENT

Clearly there is precedent for encouraging private action in needed areas, while ensuring victim compensation by statutorily altering traditional tort rules on liability. This section revisits the concerns stated in Sections I and II and considers which elements of the legislative schemes discussed in Section III would be appropriate for legislation concerning contraceptives.

A. Defining a Compensable Event

As noted above, this paper does not attempt to define all the possible compensable events in a contraceptive injury compensation scheme. Hopefully, the above examples have been helpful in demonstrating the function of such a definition and the difficulties of constructing one in the contraceptive context.

The NCVIA, the Virginia Birth Injury Act, and to some extent the Longshore Act provide a definition of a compensable event.[165] When claimants show that they have suffered an injury that meets this definition,

159. *See* 33 U.S.C. § 944(c)(2) (1994).
160. *Id.*
161. 33 U.S.C. § 944(d) (1994).
162. 33 U.S.C. § 944(c)(2) (1994).
163. 33 U.S.C. § 944(c)(1) (1994).
164. 33 U.S.C. § 944(c)(3) (1994).
165. *See supra* Part III.

a presumption of causality is established.[166] Defendants are given an opportunity to rebut this presumption by showing a lack of causal connection between the injury and activities covered by the compensation plan.[167]

A statutory presumption relies on a degree of familiarity with the likely incidence of injury resulting from certain activities. A strong nexus between the injury and the activity makes it more efficient to presume causation, even at the risk of compensating some people whose injuries did not arise from that activity. The alternative would be to litigate numerous individual cases, all at huge administrative expense, despite the numerical probability of causation. In addition, it is likely that for some injuries, such as those arising during childbirth, the societal interest in compensating the victim influences the public's willingness to presume causation.

In the contraceptive context, some injuries, such as pain and scarring during Norplant removal, are sufficiently linked to particular contraceptive methods to justify the use of a causal presumption. Other types of injuries, such as cancer or stroke, may be so difficult to link to contraceptives that an individualized fact-finding process is needed to determine causation. In a third category of injury are those that result from use of new contraceptives: where causal links are unclear, but a plaintiff's general complaint is similar to that of many other women. For this type of injury, a compensation scheme would be much more efficient than the adversarial tort process in compensating claimants. In the words of one commentator, "[d]espite the enormous number of claims, each mass tort situation features common, if not identical issues of causation, standard of conduct, and damages—issues, in many instances, of great scientific complexity that are ill-suited for determination through the adversary process."[168] Rather than having thousands of similar tort claims brought separately to the courts, incurring huge administrative and legal costs, generic findings of fact could be made by panels of experts.

What may be necessary in the contraceptive context is a hybrid approach. There may be a limited number of injuries closely associated with contraceptive use that could be presumed to be compensable under the scheme. In addition, for any new product that appears on the market, often antecedent products exist that are familiar to the medical community. Certain risks are thus known in advance of the product's release to the public. Norplant, for example, relied on hormones similar in effect to those in oral contraceptives. The silicone used as casing was also well-known from use in other products, such as pacemakers. Causation could thus probably be presumed for injury following use of a number of new and existing contraceptive products, and a provisional injury table could be included in the legislation.

166. *Id.*
167. *Id.*
168. Rabin, *supra* note 25, at 47.

Once causation issues are determined, money that would otherwise have been spent on litigation by individual parties would be available for compensating victims. Countering the risk of overcompensation would be the ability of defendants to rebut the causal presumption by proving that the individual claimant's injury did not arise from use of the product under dispute.

A phase-in mechanism could be built into legislation. Once a threshold number of tort claims reporting the same injury are filed in court, all claims could be transferred into the alternative compensation mechanism.[169] For example, lawsuits centering on questions regarding the safety of the silicone used in Norplant could be transferred for one fact-finding determination. As in the Virginia Birth Injury Act,[170] a panel of experts could be assembled to give an opinion on the likelihood of a causal link between the contraceptive method and the injury. When the initial claims are resolved, the new injury information could be added to the injury table. While such an open-ended approach is less efficient than that devised for the NCVIA, it will ultimately result in increased expedience in adjudicating contraceptive injury claims.

The approach adopted in the silicone breast implant class settlement is instructive.[171] The settlement effectively established an injury compensation scheme, including a program for receiving claims over a 30-year period, a non-adversarial claims procedure, and a list of injuries that entitle claimants with breast implants to recovery without proof of causation. Most useful for our purposes is the plan's method for adding compensable injuries to the existing list:

> Under the agreement, a new disease or condition can be added by the court to the Ongoing Disease Compensation program during its 30-year period, but only after a determination by a 5-person court-appointed Medical Panel that the then-existing medical and scientific evidence demonstrates that the disease or condition is caused by breast implants . . .. Recognizing that inclusion of new diseases is problematic at best, the settlement has . . . provided a means for implant recipients to pursue through the tort system a claim that they suffer from a serious disease which they believe was caused by a breast implant but which is not included in the Disease Schedule.[172]

169. AM. L. INST., *supra* note 50, at 462-65. The author notes that this "switching mechanism" would require additional provisions for assuring payment of attorneys' fees for initiators of transferred cases. Absent such a provision, lawyers would have no incentive to undertake cases involving injuries potentially falling under the compensation scheme. *Id.* at 463.

170. *See supra* Part III.D.1.

171. *In re* Silicone Gel Breast Implant Prods. Liab. Litig., 1994 U.S. Dist. LEXIS 12521, at *5.

172. *Id.* at *25-*26.

Cancer, a disease with a high incidence in the general population, is not included on the disease schedule.[173]

An alternative solution is to ignore altogether problematic causal links and narrow the scope of the proposed legislation. Again, a limited number of causal presumptions can be made with confidence in the area of contraceptive injury. In addition, for certain kinds of injuries, the societal interest in assuring victim compensation may outweigh potential problems of overcompensation. For example, if a child is born with birth defects to a mother who had been using contraception, a presumption that the injured fetus was harmed by the mother's use of contraception may be established with relatively little controversy.

The question whether to allow recovery under the scheme for injuries of which contraceptive users were warned remains difficult to answer. As noted above, determining whether a manufacturer warning was adequate would require burdensome fact-finding on the administrative level. Claims would be better expedited if this issue were excluded from consideration. On the other hand, the main purpose of the proposed legislation is not the increased use of contraceptives by women—a purpose that would militate in favor of relieving women of the risk of contraceptive use. Rather, it is largely concerned with promoting contraceptive development and assuring compensation for injured parties. Thus, the proposed legislation differs from the NCVIA in that there is no particular reason to shift known risks to the fund rather than to impose them on the consumer.

B. Incentives for Safety Precautions

The NCVIA maintains manufacturer incentives to take safety precautions by providing a non-exclusive remedy.[174] If claimants are dissatisfied with the awards they receive through the compensation fund, they may file suit under a tort theory.[175] The Longshore Act deters unsafe behavior through its funding mechanism, which makes operators with the worst accident record responsible for a greater proportion of the compensation fund.[176]

In contrast, the Swine Flu Act, the Price-Anderson Act, and the Virginia Birth Injury Act all provide an exclusive remedy for injury.[177] Each has been criticized for compromising the deterrent function of liability for injury.[178] However, it is not at all clear that liability is the only source of deterrence. In the case of the Virginia obstetricians, their livelihood relies

173. *Id.*
174. *See supra* Part III.A.2.
175. *Id.*
176. *See supra* Part III.E.2.
177. *See supra* Parts III.B.2, III.C.2, III.D.2.
178. *See supra* Parts III.B, III.C, III.D.

on their reputation; negligent behavior can thus have a devastating financial effect, even without the prospect of having to pay large malpractice awards.[179] Similarly, the operators covered by Price-Anderson are deterred from negligence by the possibility of total destruction of an extremely expensive facility.[180]

If the issue of over-deterrence is to be fully addressed, the contraceptive compensation scheme should follow the Virginia Birth Injury Act and serve as an exclusive remedy. However, in order to deter dishonest and greedy behavior on the part of corporations who may think they can escape reputational damage, exceptions to the exclusivity of the remedy could be carved out in the case of willful wrongdoing, such as lying to the FDA. Injured parties in those situations could sue the manufacturers directly in a tort action for unlimited damages. Allowing such a remedy would serve to distinguish well-meaning manufacturers and non-profits from those who intentionally disregard the health of women. Because the NCVIA attempts to balance the goals of vaccine safety and vaccine availability with similar safety incentives, it can serve as a model for a contraceptive scheme.[181]

In addition, the funding scheme should reflect each company's injury causation record. A flat annual tax could be imposed initially, and an assessment fine-tuned to each manufacturer's injury record could be phased in.[182]

C. Prediction of Costs

Central to determining a funding scheme is a prediction of how much money will be needed to compensate all injury claims. For the NCVIA, because so much information was available on the likelihood of injury resulting from vaccines, necessary compensations were predictable and Congress was able to devise precise excise tax amounts.[183] Likewise, the Virginia Birth Injury Act and the Longshore Act appear to calculate likelihood of injury based on past experience, just as a private insurance company would.[184]

Two of the schemes studied here, the Swine Flu Act and the Price-Anderson Act, do not reflect an attempt to predict costs.[185] In the case of the Swine Flu legislation, this lack of planning may be attributed to hasty drafting.[186] In Price-Anderson, however, the omission may reflect a lack of

179. *See supra* Part III.D.2.
180. *See supra* Part III.C.2.
181. *See* Cantor, *supra* note 67, at 1856.
182. AM. L. INST., *supra* note 50, at 473-75.
183. *See supra* Part III.A.3.
184. *See supra* Parts III.D.3, III.E.3.
185. *See supra* Parts III.B.3, III.C.3.
186. *Cf.* Rheingold & Shoemaker, *supra* note 83, at 28 (discussing the speed with which Congress drafted the legislation).

experience with the activity in question.[187] Nuclear plant accidents occur so rarely that injuries are nearly impossible to predict. Awards are thus contingent on the availability of money in the fund. Price-Anderson, however, provides for consideration by Congress of whether it should appropriate more funds for victim compensation.[188]

New contraceptive technologies resemble nuclear power plants because the injuries that are likely to occur cannot be predicted in advance. A central goal of contraceptive legislation should be to ensure that all those injured by use of contraceptives are compensated to a satisfactory degree. If it is impossible to predict with precision the size of the fund, the contraceptive legislation should follow the example of Price-Anderson and provide some allowance in the legislation for emergency funding from the national treasury. The size of the fund should be increased the following year to reflect actual demand. If there is ever a surplus, perhaps funds can be re-channeled into the national treasury.

As for noneconomic damages, such as emotional distress and pain and suffering, the NCVIA should serve as a model.[189] A generous maximum amount should be included in the legislation and be distributed when the administrative body overseeing the fund sees fit.

D. Source of Funding

This survey of five representative statutes reveals three models for financing a compensation scheme. The first is an excise tax, employed in the NCVIA.[190] The excise tax was practical in that statute because it dealt with a one-time purchase; a slight increase in price was not significant enough to deter purchase. In addition, demand for mandatory vaccines would not be affected by a price increase.

The second mode of financing a fund is an annual tax on the enterprises or operators themselves, as was done in the Price-Anderson Act, the Virginia Birth Injury Act, and the Longshore Act.[191] Price-Anderson and the Virginia Birth Injury Act were passed in response to an unavailability of adequate insurance.[192] It is likely that any cost to parties imposed by these pieces of legislation was less than, or comparable to, the cost of insurance and therefore not overly burdensome.

If the proposed contraceptive legislation is enacted, pharmaceutical companies producing contraceptives should enjoy considerable savings.

187. *Cf.* Rosenthal, *supra* note 99, at 127-28.

188. 42 U.S.C. § 2210(e)(3) (1994).

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

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

191. *See supra* Parts III.C.4, III.D.4, III.E.4.

192. *Cf.* Rosenthal, *supra* note 99, at 121-22 and text accompanying note 158.

There will be fewer large judgments awarded against the companies, products liability insurance rates should decrease, and time-consuming, expensive litigation will fall to a minimum. This savings to the manufacturer would ideally result in a decrease in the overall cost of producing contraceptives. Whether or not such a decrease in cost occurs should affect the choice of funding source for the compensation plan. If the proposed legislation is determined to result in a decrease in the cost of contraceptive production, either the cost of an excise tax or an annual tax can be absorbed by manufacturers without a sales price increase.

In the event that the proposed legislation makes no significant difference in the cost of marketing contraceptives, a funding scheme that results in a significant increase in the price of contraceptives is undesirable. If manufacturers are reluctant to shoulder the additional cost of financing the compensation fund, they may have to be given incentives. As in the Orphan Drug Act,[193] manufacturers could be given exclusive markets for a fixed period of time in exchange for developing the new contraceptive technology. That exclusivity would allow manufacturers to recoup any extra costs associated with funding a compensation plan.[194]

A final mode of financing a compensation scheme is through federal appropriations, as was done in the Swine Flu Act.[195] This legislation was criticized for creating a bottomless pit of liability, straining the national treasury.[196] The NCVIA may be viewed as a reflection of the hard lessons learned during the Swine Flu litigation.[197] The Swine Flu funding scheme should thus probably not be replicated unless there is a mechanism to keep costs predictable and contained. Perhaps a hybrid solution would be appropriate. A fund could be financed in part from an excise tax and in part from the government treasury.

V.
CONCLUSION

This paper has examined models of legislative no-fault compensation schemes and assessed the feasibility of devising such a plan for injuries resulting from contraceptive use. Elements of several of the compensation

193. 21 U.S.C. § 360aa-360ee (1994). An orphan drug is one that treats a rare disease and thus has a limited market. Because the cost of developing that drug would exceed any expectation of profit, manufacturers would be deterred from marketing a potentially valuable medication. Veronica Henry, *Problems with Pharmaceutical Regulation in the United States*, 14 J. LEGAL MED. 617, 629 (1993).

194. A similar provision was included in the California AIDS statute. CAL. HEALTH & SAFETY CODE § 199.51 (West 1995), *repealed by* 1995 CAL. STAT. 415 § 22. That legislation guaranteed the purchase of 500,000 units of an AIDS vaccine, if not by private parties then by the State of California. *Id.*

195. *See supra* Part III.B.4.

196. *Cf.* Rheingold & Shoemaker, *supra* note 83.

197. *Cf. id.*

schemes reviewed could be adapted to legislation focused on contraceptive injury.

In defining a compensable event, the NCVIA provides a useful starting point. To the extent that an injury table can be created based on available knowledge of contraceptive injury, drafters of the statute should include such a table. Injuries that are not clearly causally linked to contraceptive use, such as cancer, may require too much individualized fact-finding to be listed on the table, and they should be excluded from the compensation scheme.

However, if a wave of tort claims over a particular reaction to a contraceptive method hits the courts, a panel of experts should be assembled to determine whether a presumption of causation can be established. If so, the claims should be transferred to the compensation system and from that point on, that injury should be a compensable event, defined on the Injury Table. In the alternative, a compensation system can be focused even more narrowly and include only limited injuries, such as birth defects, as compensable events.

While compensation through the no-fault scheme should be the exclusive remedy, incentives for maximizing contraceptive safety should be built into the funding scheme. Contributions from manufacturers should reflect the degree to which manufacturers have been responsible for injury in the past, thus tying a company's operating expenses to its injury rate.

If costs of the compensation scheme cannot be predicted with precision, the legislation should include a provision for emergency funding from the national treasury. Under no circumstances should an inadequately financed fund dictate the number or size of awards distributed from it. Predictability will be enhanced if non-economic damages are capped, preferably at a generous level.

Funding for the compensation plan should come from the manufacturers. Ideally, use of the compensation fund will cut expenses dramatically, and manufacturers will have little difficulty absorbing the cost of the fund without raising prices. If the legislation results in no great cost savings, the burden should nevertheless remain on the manufacturers and not be passed on to consumers in the form of a higher price for contraceptives. If necessary, incentives for contraceptive development should be included in the legislation, such as an exclusive market for a limited period of time.