NOTES

CONFRONTING A NEW OBSTACLE TO REPRODUCTIVE CHOICE: ENCOURAGING THE DEVELOPMENT OF RU-486 THROUGH REFORM OF PRODUCTS LIABILITY LAW

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INTRODUCTION

The recent medical discovery of the abortifacient RU-486[1] has the potential to promote greater reproductive freedom for women by making abortions safer, easier, less traumatic and less expensive. Known controversially as the "abortion pill," its developer calls RU-486 a "contragestive."[2] Others have referred to it as an "implantation inhibitor,"[3] and a "post-coital contraceptive."[4] The pill works by preventing the uterus from receiving progesterone, a hormone that is naturally secreted after fertilization to prepare the uterine lining for implantation of the fertilized ovum and to sustain that implantation. Without progesterone, the uterine lining breaks down and is expelled, as in

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1. Although the drug's scientific name is Mifepristone and its brand name is Mifegyne, it has become widely known as RU-486, the name first assigned to it during its experimental stages.

2. Beck, *Medical Technology Continues to Alter the Abortion Debate*, Chi. Tribune, Feb. 23, 1989, at 21.

3. Cohen, *Comparison-Shopping in the Marketplace of Rights*, 98 YALE L.J. 1235, 1256 n.66 (1989).

4. *Id.*

normal menstruation.[5]

RU-486, however, has yet to be developed for use in the United States. There are a number of factors preventing such development. First, there has been such intense opposition to the drug by anti-choice groups that the French manufacturer of RU-486, Roussel-Uclaf, has refused to license the drug to other companies or to market the drug in the United States out of fear of boycotts by these groups.[6] Another factor affecting the drug's development in this country, and the focus of this Note, is the potential liability of those manufacturing and marketing the drug should RU-486 prove unsafe. Although Roussel-Uclaf currently has no plans to license the drug to other companies, products liability law inevitably will have an impact on the development of the drug if and when it decides to do so.[7]

Underlying the concern expressed in this Note about the obstacles facing the manufacture of RU-486 is the belief that unless women themselves are afforded the choice whether and when to have children, it will be impossible for them to meaningfully control their own lives or participate fully in society. Legal, safe, and affordable abortions, the availability of which could be facilitated through introduction of RU-486, are necessary to provide that control. Women choose to have abortions for many reasons. Many women become pregnant because of inadequate birth control methods and choose not to carry a child to term.[8] Many women may feel compelled to end a pregnancy because of economic or personal circumstances. Still others may wish to end a pregnancy that was the result of rape, incest, or another form of the sexual

5. Couzinet, Le Strat, Ulmann, Baulieu & Schaison, *Termination of Early Pregnancy by the Progesterone Antagonist RU 486 (Mifepristone)*, 315 NEW ENG. J. MED. 1565, 1566-68 (1986) [hereinafter Couzinet].

6. *See* Kolata, *After Large Study of Abortion Pill, French Maker Considers Wider Sale*, N.Y. Times, Mar. 8, 1990, at 10, col. B. In addition to threatening wide-scale boycotts of any companies that develop or market RU-486, anti-choice groups are currently threatening to block Food and Drug Administration [hereinafter FDA] approval of the drug through legislation. A bill introduced in the House of Representatives in 1988 by Representative Robert K. Dornan would prohibit the FDA from using federal funds even to consider or review a new drug application for RU-486. H.R. 619, 101st Cong., 1st Sess. 1 (1989) ("no form of Federal financial assistance may be provided to any person for purposes of investigating the anti-progesterone steroid . . . to obtain its approval under the Federal Food, Drug, and Cosmetic Act").

7. Notably, American support for RU-486 has been growing among public health specialists and physicians. *See* Jackman, *RU 486 Drive Gears Up*, in FEMINIST MAJORITY REPORT 1 (Mar. 1991). In June, the American Medical Association passed a resolution supporting the availability of RU-486 for research and, potentially, general medical use. Toufexis, *Battle Over the Abortion Pill*, TIME, Aug. 6, 1990, at 79. In addition, California's Board of Drug Administration is expected to approve a proposal that the state fund research on RU-486, and the New York City Health & Hospitals Corporation is currently considering a plan to bring RU-486 into New York City hospitals on an experimental basis, pursuant to a New York State law regulating drug licensing applications for "investigational use only." Hancock, *RU 486 Hits Manhattan?*, Village Voice, Sept. 25, 1990, at 13, col. 4.

8. It is estimated that between 1.2 and 3 million accidental pregnancies occured in 1987 as a result of contraceptive failure, and that about half of the approximately 1.5 million abortions performed in the United States each year are the result of such contraceptive failure. NATIONAL RESEARCH COUNCIL INSTITUTE OF MEDICINE, DEVELOPING NEW CONTRACEPTIVES 22-23 (L. Mastroianni, Jr., P. Donaldson & T. Kane eds. 1990) [hereinafter Mastroianni].

coercion that is prevalent in our society.[9] Regardless of the reason underlying a woman's decision to have an abortion, her choice must be respected in any society that claims to value autonomy of conscience.

At present, the vast majority of abortions performed in the United States are done through vacuum suction which is known as aspiration.[10] While this procedure is relatively safe,[11] many women who have abortions suffer from complications such as infection, perforation of the uterus, hemorrhage and anesthesia-related problems.[12] In addition, Congress has denied federal funding for abortions,[13] and only thirteen states provide public funding for abortions.[14] As a consequence, millions of women in the United States today — especially those who are of color, young, rural and/or poor — do not have access to safe or affordable abortions. Women who cannot afford to pay for abortions are frequently forced to seek unregulated and, thus, illegal abortions, which are often dangerous and sometimes deadly.[15] Those who fear sufficiently the physical and psychological effects of abortion, or the presence of abortion protesters at a clinic, are forced to bring unwanted children into the world.

This Note examines ways to limit the potentially excessive liability of would-be manufacturers of RU-486 through the adoption of various legal reforms in order to encourage development of the drug. While this Note focuses on protecting manufacturers from excessive liability, this focus does not stem from concern for the plight of manufacturers, but from concern for the plight of women who are denied access to this important drug. Specifically, this Note analyzes the uniform products liability reform bill now before Congress, explores the probable and undesirable effects of the passage of such a bill on the development of RU-486 in the United States, and contemplates the reasons that the bill is unlikely to pass in the foreseeable future. This Note then examines the federal regulatory approach to tort reform and concludes that,

9. One out of every three women will be raped during her lifetime. BOSTON WOMEN'S HEALTH BOOK COLLECTIVE, THE NEW OUR BODIES OURSELVES 99 (1989). *See generally* L. TSCHIRHART SANFORD, SILENT CHILDREN — A BOOK FOR PARENTS ABOUT THE PREVENTION OF CHILD SEXUAL ABUSE (1980) (author notes that by the age of 18, 25% of girls will have experienced sexual abuse, probably by a family member).

10. BOSTON WOMEN'S HEALTH BOOK COLLECTIVE, *supra* note 9, at 294.

11. There is a one percent chance of complications developing as a result of a first-trimester abortion using aspiration. The later the abortion, the greater the chance of complications. *Id.* at 296.

12. *Id.* at 297-98.

13. *See* Hyde Amendment, Pub. L. No. 96-123, § 109, 93 Stat. 923 (1979) (prohibiting federal funding for abortions except in cases of danger to the life of the mother); *see also* Harris v. McRae, 448 U.S. 297 (1980) (holding that the existence of a constitutionally protected right to abortion does not obligate the government to grant the funds needed to exercise that right).

14. The following states provide funding to pay for abortions for low-income women: Alaska, California, Connecticut, Hawaii, Maryland, Massachusetts, New Jersey, New York, North Carolina, Oregon, Vermont, Washington, and West Virginia. THE ALAN GUTTMACHER INSTITUTE, FACTS IN BRIEF: ABORTION IN THE UNITED STATES 2 (1990).

15. An estimated 200,000 women die from improperly performed abortions worldwide each year. *Bitter Pill*, THE NATION, Nov. 21, 1988, at 515.

although such an approach might foster corporate development of RU-486, adoption of any of the proposed regulatory schemes would nevertheless be unwise. Finally, this Note explores the various ways that a no-fault tort scheme could be adopted with respect to the manufacture, development, and use of RU-486. It concludes that the best approach would be the establishment of a neo-no-fault program, either privately adopted or Congressionally mandated, that, while requiring the informed consent of any woman wishing to take the drug, would both provide complete and expeditious compensation to potential victims and protect private corporations from the arbitrary imposition of liability.

I.
RU-486

RU-486 acts to terminate a pregnancy by preventing the uterus from receiving progesterone, a hormone which sustains implantation of the fertilized ovum.[16] Developed in 1982 by Dr. Etienne-Emile Baulieu,[17] RU-486 has thus far been used by an estimated 55,000 women in fifteen countries.[18] Although the drug is still relatively new, all research on RU-486 to date has shown it to be a safe and effective method of pregnancy termination.[19] Other medical benefits unrelated to termination of pregnancy are associated with its use.[20] Even more importantly, the social implications of the availability of RU-486 are profound; the drug has the capacity to afford women greater control over their reproductive lives by providing them with a more private and potentially less expensive means of having an abortion.

A. Research on and Development of RU-486

Research in both the United States and France has shown that RU-486 is both safe and effective. In a recent study conducted by its manufacturer and published in *The New England Journal of Medicine*, ninety-six percent of the 2115 women given RU-486, followed thirty-six to fourty-eight hours later by a dose of prostaglandins,[21] had safe abortions within forty-nine days of their last menstrual period.[22] Only four percent of these women needed subsequent surgical abortions.[23] Women who took the drug suffered only what the researchers concluded were mild side effects, including abdominal pain and nausea.[24]

16. *See supra* note 5 and accompanying text.
17. Toufexis, *supra* note 7, at 79.
18. *Id.*
19. *See infra* text accompanying notes 53-57.
20. *See infra* text accompanying notes 62-67.
21. Prostaglandins are injected to induce mild contractions of the uterus.
22. Silvestre, DuBois, Renault, Rezvani, Baulieu & Ulmann, *Voluntary Interruption of Pregnancy with Mifepristone (RU486) and a Prostaglandin Analogue: A Large Scale French Experience*, 322 NEW ENG. J. MED. 645, 645-49 (1990) [hereinafter Silvestre].
23. *Id.* at 647.
24. *Id.* at 646-47.

In another study, a team from the Hospital de Bicetre near Paris demonstrated that in 85 out of 100 cases, RU-486, taken in repeated oral doses within ten days of a missed menstrual period, induced menses and terminated pregnancy without major side effects.[25] A United States research team has suggested that a single dose of RU-486 late in the menstrual cycle might be an effective contraceptive strategy.[26] The study indicated that further research is necessary to evaluate such long-term monthly administration.[27] Furthermore, Dr. Daniel Mishell's trials at the University of Southern California revealed that a 100 milligram dose of RU-486 induced a complete abortion in the first six weeks of pregnancy in eighty percent of the women who took it.[28]

Roussel-Uclaf, the French pharmaceutical company which produces RU-486, is controlled by a West German company, Hoechst A.G.[29] On October 26, 1988, one month after it had publicized its discovery, Roussel-Uclaf announced that it would no longer distribute RU-486 in France.[30] The firm had succumbed to pressure from anti-choice groups in France and the United States, groups which threatened boycotts and violence.[31] The next day, in Rio de Janeiro, physicians and family planners attending the World Congress of Gynegology and Obstetrics united in opposition to the planned withdrawal of the drug.[32] On October 28, the French government, which owns 36% of Roussel-Uclaf, ordered the company to resume distribution of RU-486.[33] The French Minister of Health, in making this announcement, declared that RU-486 had become "the moral property of women."[34] He also threatened to invoke provisions of the French patent law that grant the Minister of Health

25. Couzinet, *supra* note 5, at 1565-70.

26. Nieman, Choate, Chrouson, Healy, Morin, Renquist, Merriam, Spitz, Bardin, Baulieu & Loriaux, *The Progesterone Antagonist RU 486: A Potential New Contraceptive Agent*, 316 NEW ENG. J. MED. 187, 187-90 (1987).

27. *Id.* at 190. For a thorough discussion of whether the federal government is likely to approve RU-486 for monthly use as a contraceptive, see Note, *The New French Abortion Pill: The Moral Property of Women*, 1 YALE J.L. & FEMINISM 75, 78 (1989).

It is important to note that the distinction between contraception and abortion in this context is an artificially constructed one. The principle function of both RU-486 and some common and widely accepted forms of birth control, such as the intra-uterine device [hereinafter IUD], is to interfere with the uterine environment to prevent continuation of the pregnancy and to induce menstruation. The only difference between the functioning of the IUD and RU-486 is that RU-486 is effective only following implantation, while the IUD works to expel the fertilized egg before implantation. This distinction lacks any real significance outside of the political arena. To say that the IUD is acceptable but that an abortifacient like RU-486 is not is to draw an arbitrary distinction that has no rational basis.

28. Kaye, *Are You For RU-486?*, THE NEW REPUBLIC, Jan. 27, 1986, at 14-15.

29. Hoechst A.G. owns 54.5% of Roussel-Uclaf. Riding, *France Is to Pay 80% of Cost of Abortion Pill*, N.Y. Times, Feb. 28, 1990, at A7, col. 1.

30. *Bitter Pill*, *supra* note 15, at 515.

31. M. KLITSCH, RU 486: THE SCIENCE AND THE POLITICS 1 (1989).

32. *Bitter Pill*, *supra* note 15, at 515.

33. *Id.*

34. Greenhouse, *France Ordering Company to Sell Its Abortion Drug*, N.Y. Times, Oct. 29, 1988, at A1, col. 6 (quoting speech made by Claude Evin, Minister of Health of France, during a televised news conference on Oct. 28, 1988).

power to transfer a drug patent to another individual or entity if the original holder fails to distribute the drug.[35]

Roussel-Uclaf complied with the Minister of Health's order.[36] Since then, the pill has been licensed for use in France. In addition, it is available for use in China.[37] Except for a few clinical trials underway elsewhere in the world, it remains unavailable to women outside of France and China.[38] American companies could develop the drug under a licensing agreement with Roussel-Uclaf, but none have sought to do so.[39] In fact, no American company currently funds any research on abortifacients.[40] Sterling Drug, Inc., the last American company to conduct such research, had an abortifacient under study four years ago but has since ceased research on and development of the drug entirely.[41]

Alternatives to corporate development of the drug have thus far proven unsuccessful. The World Health Organization [hereinafter WHO], which cosponsored clinical trials of RU-486 in China and other countries, has pressed Roussel-Uclaf to introduce the pill to wider and needier markets.[42] Although the WHO has the right to commandeer the drug and supply it to developing countries at cost, the agency has cautiously decided to await further trials before acting so that the drug will be "discreditproof."[43]

The Population Council, a non-profit research organization, has used private foundation money to support low-level research on RU-486 at the University of Southern California.[44] These are the only experiments in the United States that have studied RU-486's use as an abortifacient.[45] A lack of funds, however, has been a major barrier to the Population Council's continued research on and development of RU-486.[46] It is widely acknowledged in this country that the scarcity of government funding for research into contraceptive development has cast a pall over the state of reproductive science.[47] With the existence of the Hyde Amendment,[48] funds for research into RU-486 cannot be granted.

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35. M. KLITSCH, *supra* note 31, at 1.
36. *Id.*
37. Toufexis, *supra* note 7, at 79.
38. Segal, *Mifepristone (RU486)*, 322 NEW ENG. J. MED. 691, 692 (1990). While remaining publicly unavailable there, extensive testing on RU-486 has taken place in Scandinavia and the United Kingdom. *Id.*
39. *Abortion Drug Developer Gets Lasker Award*, N.Y. Times, Sept. 28, 1989, at A24, col. 4.
40. Suh, *RU Detour*, Ms., Feb. 1989, at 135-36.
41. *Id.*
42. MacFarquhar, *The Case of the Reluctant Drug Maker*, U.S. NEWS & WORLD REP., Jan. 23, 1989, at 54.
43. *Id.*
44. Fraser, *The 'Abortion Pill': Why America Trails Europe*, Newsday, July 5, 1988, at 49; *see also* text accompanying note 28.
45. *Id.*
46. *Id.*
47. *See* Mastroianni, *supra* note 8, at 87.
48. Pub. L. No. 96-123, § 109, 93 Stat. 923 (1979).

In France, the pill's use is highly regulated. It is administered only at designated family planning centers — the sole facilities where any type of abortion can be performed in that country — and is not available through individual doctors or pharmacies.[49] In instances where RU-486 is not successful in terminating a pregnancy, a surgical abortion is performed.[50] Although the cost of a drug-induced abortion in any of the authorized clinics is approximately $256, eighty percent of that cost is reimbursed by the French government.[51] RU-486 now accounts for one-third of the abortions performed in France.[52]

B. The Medical and Social Benefits of RU-486

RU-486 has been shown to be a safe and effective method of pregnancy termination. Rates of complications associated with the use of RU-486 have been very low. Side effects of RU-486 are minor abdominal pain, nausea, and vaginal bleeding.[53] The drug has not existed long enough, however, for there to have been any studies of the long-term effects of RU-486.

Aside from these effects, the only other known potential risk associated with RU-486 is that of delivering a child with disabilities. This could occur were a woman to bring her fetus to term after ineffective administration of the drug, which occurs approximately four percent of the time.[54] This potential situation, however, has not been documented extensively. To date, only one percent of those women studied proceeded to carry their pregnancies to term.[55] Animal studies have raised the possibility that RU-486 could cause deformities of the skull.[56] In addition, prostaglandins, which are often used in conjunction with RU-486, have been reported to cause disabilities in both animals and humans.[57] Nevertheless, this situation could be avoided were all women counseled to obtain a surgical abortion following a failed administration of RU-486.

As compared with the risks associated with the use of RU-486, the medical benefits of the drug are substantial. Currently, approximately fifty million women worldwide have surgical abortions each year;[58] an estimated 200,000 of them die as a result,[59] while countless others are left maimed and/or infer-

49. Herman, *In France — Ouil, In the U.S. — Not Yet; The Politics of the Abortion Pill*, Wash. Post, Oct. 3, 1989, Health, at Z12.

50. *Id.*

51. Riding, *supra* note 29. The French government, which has a national health care program that covers most medical and dental care costs, also subsidizes 80% of the cost of surgical abortions. *Id.*

52. *Id.*

53. Silvestre, *supra* note 22, at 647.

54. *Id.* at 645, 648.

55. *Id.* at 648.

56. *Id.*

57. *Id.*; *see also* Gladwell, *French Abortion Pill Safe and Effective, Study Says*, Wash. Post, Mar. 8, 1990, at A3.

58. Beck, *supra* note 2, at 21.

59. *Bitter Pill*, *supra* note 15, at 516.

tile. In the United States alone, where approximately 1.5 million abortions are performed every year,[60] there were 14,000 abortion-related deaths in 1985, the most recent year for which statistics are available.[61] If RU-486 were made widely available, its use could prevent much of the suffering that results from unsafe abortions by greatly reducing the percentage of women who require surgical abortions.

In addition to its use as an abortifacient, RU-486 has proven effective for a number of other medical purposes. RU-486 has been shown significantly to reduce endometriosis, the third leading cause of infertility in the United States.[62] Other potential uses for the drug include the efficacious treatment of prostate cancer, glaucoma, ovarian cancer,[63] certain forms of breast cancer, pituitary cancer,[64] ulcers[65] and inoperable menignoma.[66] It has also been shown to help reduce the need for caesarean sections when used to dilate the cervix during childbirth.[67]

In the United States, once a drug is licensed and marketed for a particular use, doctors are free to prescribe it for any other use.[68] Thus, if RU-486 were approved for treatment of one of the conditions mentioned above, doctors could also prescribe it for abortions. Roussel-Uclaf, however, has opposed this idea.[69] Dr. Baulieu has been quoted as saying, in response to the suggestion that RU-486 could thus enter the United States through the back door, "RU-486 has to be sold as the abortion pill that it is."[70]

The medical benefits of RU-486 are made more apparent when use of the drug is compared specifically with other methods of abortion. The most commonly used abortion technique is vacuum aspiration, in which the contents of the uterus are removed through a tube that is attached to a source of gentle suction — an electric or mechanical pump or a syringe.[71] Vacuum aspiration can only be performed during the first trimester of pregnancy.[72] The most common risks associated with the procedure include infection, retained tissue, perforation of the uterus, hemorrhage, cervical laceration and anesthesia-re-

60. O.B. GYN NEWS, Dec. 15-31, 1989, at 1.

61. 38 MORBIDITY & MORTALITY WEEKLY REP. 43 (1989).

62. Cohen, *supra* note 3, at 1254. Endometriosis occurs when the mucous membrane that normally lines the uterus grows outside the uterus.

63. Moran, *A Job for the Government*, Newsday, Jan. 12, 1989, Viewpoints, at 77.

64. Kolata, *Boycott Threat Blocking Sale of Abortion-Inducing Drug*, N.Y. Times, Feb. 22, 1988, at A1, col. 3 [hereinafter *Boycott Threat*].

65. Kolata, *U.S. May Allow Anti-Ulcer Drug Tied to Abortion*, N.Y. Times, Oct. 29, 1988, at 1, col. 5.

66. Scott, *Abortion Pill May Help Treat Rare Tumor*, L.A. Times, Sept. 28, 1989, at 3, col. 1. Inoperable menignoma is a tumor of the covering of the brain and spinal cord. *Id.*

67. *See Boycott Threat*, *supra* note 64, at A1, col. 3.

68. Beck, *supra* note 2, at 21.

69. Toufexis, *supra* note 7.

70. *Id.*

71. BOSTON WOMEN'S HEALTH BOOK COLLECTIVE, *supra* note 9, at 294.

72. *Id.*

lated problems.[73] The risk of these complications is only about one percent; however, these risks are great compared to the main risk associated with use of RU-486, which is its failure to eliminate the pregnancy.[74] Other abortion methods include dilation and curettage (D and C),[75] dilation and evacuation (D and E),[76] saline or prostaglandin-induced abortions,[77] and hysterotomy,[78] all of which are usually performed during the second trimester of pregnancy and have higher complication rates than vacuum aspiration.[79] RU-486 is also considered safer than the so-called morning-after pill, which contains massive doses of estrogen and frequently causes unhealthy side effects, such as ectopic pregnancy, severe nausea, and vomiting.[80]

All of these methods, however, carry even fewer risks than pregnancy, labor, and delivery.[81] It is estimated that the number of women who die each year from pregnancy-related causes may be as high as 500,000 worldwide.[82] According to a recent study, between twenty-five and forty percent of all maternal deaths would be avoided if all unwanted pregnancies were avoided or terminated.[83] From a medical perspective, then, RU-486 is safer than pregnancy, labor, and delivery.

In addition to the medical implications, the ready availability of RU-486 has profound social implications. The drug offers women a safer, easier, less traumatic, and more private way to terminate a pregnancy than a surgical abortion. In the wake of the Supreme Court's recent decision in *Webster v.*

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73. *Id.* at 296-97. Vacuum aspiration is, however, the safest of all operations, including tonsillectomies or circumcisions. *Id.* at 294.

74. RU-486 fails to end pregnancy in only four percent of the cases in which it is administered. *See supra* text accompanying notes 22-23.

75. In dilation and curettage, the cervical opening is dilated and a sharp metal loop, attached to the end of a long handle (the curette), is inserted into the uterus and used to scrape out the uterine contents. This procedure requires hospitalization and a general anesthetic, and is performed between eight and twenty weeks after a woman's last menstrual period. J. HYDE, UNDERSTANDING HUMAN SEXUALITY 188 (3d ed. 1986).

76. Dilation and evacuation is essentially the same procedure as dilation and curettage, but is performed between fifteen and eighteen weeks after a woman's last menstrual period and is therefore more complicated because the fetus is larger. *Id.*

77. In a saline-induced abortion, a fine tube is inserted through the abdomen into the amniotic sac inside the uterus. Some amniotic fluid is removed through the tube, and an equal amount of saline solution is injected into the amniotic sac. The cervix then dilates, and the fetus is expelled though the contractions of labor. The prostaglandin method is a variation on this technique, in which prostaglandins (hormone-like substances that cause contractions) are injected into the amniotic sac. *Id.*

78. Hysterotomy is a surgical method of abortion that is performed from sixteen to twenty-four weeks after a woman's last menstrual period. Essentially, a cesarean section is performed, and the fetus is removed. *Id.* at 189.

79. BOSTON WOMEN'S HEALTH BOOK COLLECTIVE, *supra* note 9, at 295-96.

80. *Id.* at 248-49. The morning-after pill is designed to be taken within 24 hours following intercourse, engaged in without contraception, and thus before a woman will know whether or not she is pregnant. *Id.*

81. *Id.* at 294.

82. Mastroianni, *supra* note 8, at 24.

83. *Id.*

Reproductive Health Services,[84] which allows states to set limits on abortion services, the prospect of a non-surgical, "at home" abortion has taken on new significance for American women.

It is impossible to determine the potential cost to users of RU-486 were it available in the United States. The drug would have the greatest impact if the cost was not prohibitive and poor women were able to afford it, but government funding is usually not available for abortions,[85] and even a cursory evaluation of the current political environment in the United States indicates that such funding for RU-486 is unlikely in the foreseeable future.[86]

Nevertheless, even if an RU-486 induced abortion were as expensive as a surgical abortion, the development of RU-486 would still be beneficial because of its ability to enhance reproductive freedom for women. RU-486 would provide great psychological benefits for the women who use it, as they would be able to avoid the potentially traumatic effects of crossing picket lines to reach abortion clinics and enduring the bodily intrusion inevitable in a surgical abortion. In addition, the development of RU-486 would be important in encouraging the general development of new reproductive technologies that are necessary in order to provide women with greater control over their reproductive lives. As the only noteworthy advance in the technology of pregnancy avoidance to emerge in this country in years,[87] the development and funding of RU-486 could focus interest on the development of such products. Finally, RU-486 provides the added advantage of giving doctors an alternative to performing surgical abortions. Doctors unwilling to perform such abortions may find prescribing RU-486 to be an acceptable alternative.

While it would appear that drug companies should be attracted to RU-486 because of its substantial benefits and minor risks, the financial constraints on drug companies wishing to develop new products are tremendous. First, the costs of developing and licensing any drug are enormous. To bring a drug to the United States, a would-be manufacturer must pay millions of dollars for the extensive testing necessary to secure approval from the Food and Drug Administration [hereinafter FDA]. In addition, FDA approval of a new drug commonly takes as long as ten years.[88] Manufacturers of RU-486 face an additional obstacle not encountered by other drug manufacturers, as government money to subsidize testing is not available for RU-486 because, under the Public Health Act, federal funds may no longer be used to perform, and thus conduct research on, abortions.[89]

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84. 109 S. Ct. 3040 (1989).

85. *See supra* notes 13-14 and accompanying text.

86. *Id.*

87. *See* Gladwell & Zinman, *Focus on Birth Control; An Era of Promise Unfulfilled*, Newsday, Feb. 28, 1989, Discovery, at 7; Phillips, *Drug Firms Halting Contraceptive Study; Liability Fears Limit Innovation*, Chi. Trib., Jan. 8, 1989, Business, at 1C; *Birth Control Makers Weary of Controversy; Liability Problems Limit Contraceptive Choices as Drug Firms Leave the Field*, L.A. Times, May 3, 1988, § 4, at 15, col. 1.

88. Note, *supra* note 27, at 77.

89. *See* Departments of Labor, Health and Human Services, and Education and Related

Also discouraging to would-be manufacturers are the risks of potential liability suits. Although research to date has shown RU-486 to be safe, there are risks, as with any drug, of unforeseen injuries and, therefore, risks of legal liability for these injuries. The potential liability that can face a manufacturer, even one who takes reasonable precautions, can inhibit development of new and innovative drugs. The erosion of the concept of fault in our tort system has created a general disincentive to innovate and presents an obstacle to any manufacturer of RU-486.[90] Moreover, given the legal climate surrounding reproductive products, a company that produces RU-486 could incur huge court judgments even if medical studies regarding the injurious effects of the drug are inconclusive.[91]

II.
PRODUCTS LIABILITY LAW

There are three types of potential lawsuits that drug companies manufacturing RU-486 would have to fear. The first type of claim would be one for "wrongful birth" brought by parents whose child was born with disabilities after RU-486 failed to cause an abortion. The second type of claim would be a "wrongful life" claim brought by such a child herself. The third type of claim, and the primary focus of this Section, would be a claim for damages filed by a woman who suffers injuries as a result of having used RU-486 to end her pregnancy.

Wrongful birth cases usually involve a claim by the parents of a child born with disabilities that they would have terminated the pregnancy had they been properly advised of the risks involved in bringing the fetus to term.[92] Typically, the defendant in such a case is a doctor charged with negligence for failing to inform the parents that the child might be born with disabilities. The plaintiff parents seek recovery for expenses incurred in caring for the disabled child. The negligence charged, essentially, is failure to warn the parents of the likelihood or certainty of injury to the fetus. It follows that when a pharmaceutical company has included clear and proper warning materials with the product alerting consumers to the risks involved in bringing a pregnancy to term after a failed attempt to abort using RU-486, it should not be held responsible for the child's disabilities.[93] It is, therefore, unlikely that a

Agencies Apropriation Act, 1989, Pub. L. No. 100-436, § 204, 102 Stat. 1680, 1699 (1988) (to be codified at 42 U.S.C. § 300a-6); Fraser, *supra* note 44; *see also supra* note 13 and accompanying text.

90. *See infra* notes 115-23 and accompanying text.

91. *See infra* notes 122-34 and accompanying text.

92. *See generally* Comment, *"Wrongful Birth": Should Liability Be Imposed Upon a Physician Who Fails to Warn of the Risks of Defects in Their Unborn Children?*, 14 GONZ. L. REV. 891 (1979).

93. *See, e.g.*, Reeder v. Hammond, 125 Mich. App. 223, 336 N.W.2d 3 (1983) (Plaintiff sued for injuries suffered by her child, who was born with mental disabilities resulting from plaintiff's use of contraceptives during the pregnancy. The court held that materials provided warned adequately of the danger and consequently disallowed recovery).

manufacturer of RU-486 would be found liable in such a case.

An action for wrongful life differs from a wrongful birth case in that the suit is brought on behalf of the child rather than on behalf of the parents. In a wrongful life action, the child does not sue for her disability, but rather sues because of her very existence.[94] The child's claim is that, but for the defendant's negligence, she would never have been born at all.[95]

With the exception of two lower court holdings on this issue that were subsequently nullified by the high court of New York,[96] all jurisdictions[97] that have ruled on this issue have denied the child a wrongful life cause of action for general damages[98] resulting from the child's disabilities.[99] Troubled by both the philosophical difficulties of allowing a child to claim that she should never have been born[100] and the practical difficulties of calculating damages for such harm, courts have uniformly chosen to deny wrongful life claims brought by children. A court, therefore, would most likely deny such claims against a manufacturer of RU-486, especially where appropriate warnings had been provided.[101]

Litigation concerning direct injuries sustained by the use of a drug, such as the harms potentially suffered by a woman taking RU-486, are governed by

94. Comment, *Wrongful Life: Should the Action Be Allowed?*, 47 LA. L. REV. 1319, 1323 (1987).

95. *See, e.g.*, Smith v. Cote, 128 N.H. 231, 513 A.2d 341 (1986).

96. Becker v. Schwartz, 46 N.Y.2d 401, 386 N.E.2d 807, 413 N.Y.S.2d 895 (1978), *modifying* Becker v. Schwartz, 60 A.D.2d 587, 400 N.Y.S.2d 119 (App. Div. 1977) *and* Park v. Chessin, 60 A.D.2d 80, 400 N.Y.S.2d 110 (App. Div. 1977).

97. Some states have enacted legislation on the point. *See* CAL. CIV. CODE § 43.6(a) (Deering 1990) (prohibiting wrongful life claims against parents); MINN. STAT. § 145.424 (1989) (prohibiting wrongful life actions); S.D. CODIFIED LAWS ANN. § 21-55 (1989) (prohibiting wrongful life actions).

98. Both California and Washington permit the child in a wrongful life action to recover the costs of any special training or medical care as special damages, but not as general damages for her affliction. Turpin v. Sortini, 31 Cal. 3d 220, 239, 643 P.2d 954, 966, 182 Cal. Rptr. 337, 349 (1982); Harbeson v. Parke-Davis, Inc., 98 Wash. 2d 460, 482, 656 P.2d 483, 496 (1983).

99. Phillips v. United States, 508 F. Supp. 537 (D.S.C. 1980); *Turpin*, 31 Cal. 3d 220, 643 P.2d 954, 182 Cal. Rptr. 337; DiNatale v. Lieberman, 409 So. 2d 512 (Fla. Dist. Ct. App. 1982); Eisbrenner v. Stanley, 106 Mich. App. 357, 308 N.W.2d 209 (Ct. App. 1981); Gleitman v. Cosgrove, 49 N.J. 22, 227 A.2d 689 (1967); *Becker*, 46 N.Y.2d 401, 386 N.E.2d 807, 413 N.Y.S.2d 895; Speck v. Finegold, 497 Pa. 77, 439 A.2d 110 (1981); Dumer v. St. Michael's Hosp., 69 Wis. 2d 766, 233 N.W.2d 372 (1975). Courts have also denied such claims where the child was born without disabilities, but had nonetheless claimed that she should never have been born at all. *See, e.g.*, Elliott v. Brown, 361 So. 2d 546 (Ala. 1978) (failed vasectomy); Coleman v. Garrison, 349 A.2d 8 (Del. 1975) (failed salpingectomy).

100. Having to consider the child's very life as the injury for which damages are claimed leads courts to the unwanted task of determining whether it would have been better never to have been born, "a mystery more properly left to the philosophers and theologians." *Becker*, 46 N.Y.2d at 410, 386 N.E.2d at 812, 413 N.Y.S.2d at 900.

101. While the courts in general deny claims for wrongful birth or life, it does not reasonably follow that such claims do not have an inhibitory effect on the development of reproductive products, as many manufacturers are likely to settle such cases in order to avoid protracted litigation and the possibility, albeit slim, that the courts may eventually recognize such claims. Telephone interview with Warren Wood, President of Cabot Medical Corp. (May 25, 1990). Because courts have denied these claims, however, they will not be the focus of this Note.

products liability law. This law defines the rules used to determine whether a manufacturer is responsible for the harms alleged. Under common law tort principles, courts ordinarily impose strict liability whenever one is harmed by a product that is shown to be so inherently dangerous that, even when produced in exactly the form intended, it is considered unreasonably unsafe even when properly used for its intended purpose.[102] Under strict liability, the person harmed need not prove that the defendant was at fault for the injury but merely that her injury was caused by the defendant's dangerous product.[103]

Drugs and devices available exclusively by prescription, however, are treated differently under tort law from other products. The FDA classifies as prescription drugs all drugs which cannot be made completely safe due to their nature or to the current state of pharmacology.[104] The Restatement (Second) of Torts § 402A, comment k,[105] acknowledges that certain prescription drugs cannot be made completely safe for their intended use, but are so useful and desirable that they should not be held to a strict liability standard. Such products are labeled "unavoidably unsafe" products. If a product qualifies as "unavoidably unsafe" under comment k, courts hold the manufacturer to a standard of negligence,[106] under which it is not liable for injuries so long as the drug meets certain conditions: specifically, the drug must have been adequately designed and tested, properly manufactured, and packaged with adequate warnings of harmful side effects of which the manufacturer knew or had reason to know.[107]

To determine whether a specific drug qualifies as "unavoidably unsafe"

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102. *See* W. PROSSER & W. KEETON, TORTS 608, 698 (5th ed. 1984).

103. *Id.* at 534-38.

104. The Federal Food, Drug and Cosmetic Act of 1938, Pub. L. No. 717, 52 Stat. 1040 (codified as amended in scattered sections of 21 U.S.C.) defines a prescription drug as one which "because of its toxicity or other potentiality for harmful effect . . . is not safe for use except under the supervision of a practitioner licensed by law to administer such drug." 21 U.S.C. § 353 (1988).

105. Comment k provides:

> *Unavoidably unsafe products.* There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician . . . .

RESTATEMENT (SECOND) OF TORTS § 402A comment k (1965) (emphasis in original).

106. Note, *Comment K Immunity to Strict Liability: Should All Prescription Drugs Be Protected?*, 26 HOUS. L. REV. 707, 708 (1989); Graham v. Wyeth Laboratories, 906 F.2d 1399, 1406 (10th Cir. 1990).

107. Tinnerholm v. Parke Davis & Co., 285 F. Supp. 432, 446-53 (1968), *aff'd*, 411 F.2d 48 (2d Cir. 1969); *see also* W. KEETON, D. OWEN & J. MONTGOMERY, PRODUCTS LIABILITY AND SAFETY 41 (1980); L. FRUMER & M. FRIEDMAN, PRODUCTS LIABILITY § 50.03[2][d] (1986).

and thus receives the protection of the comment k defense, a court or a jury will generally apply a risk/benefit analysis:[108] it must decide whether the drug's utility outweighs its risk, whether the same benefits are not achievable through less dangerous means, and whether the risk is unavoidable under the present state of scientific knowledge.[109] In the event that someone claimed that RU-486 caused injury, a court would most likely engage in this risk/benefit analysis. It would not be fruitful, however, to speculate at this point as to whether comment k should be applied in the event that a woman is injured through the use of RU-486. Not knowing what the potential injury would be, it is impossible to argue that the benefits of RU-486 would inevitably outweigh its risks. As noted above, to date there is little evidence that legally compensable injuries are likely to occur.[110]

Although comment k suggests that highly beneficial prescription drugs should not be held to a standard of strict liability, courts nevertheless commonly subject many pharmaceuticals to such a standard.[111] The decision as to whether a drug is highly beneficial and, thus, whether to apply a negligence standard under comment k, is based on a very subjective judicial determination of the risks and benefits of the product in question.[112] For instance, there is a judicial consensus that the polio vaccine, which carries an unavoidable risk that some people receiving the vaccine will develop polio, has vast benefits that outweigh the risk of death to some.[113] It is not clear that the judiciary would be willing to afford the same protection to RU-486, even though the risks associated with the drug may be minor as compared with those associ-

108. Needham v. White Laboratories, 639 F.2d 394, 402-03 (7th Cir.), *cert. denied*, 454 U.S. 927 (1981); Reyes v. Wyeth Laboratories, 498 F.2d 1264, 1274 (5th Cir. 1974); Gaston v. Hunter, 121 Ariz. 33, 588 P.2d 326, 340 (Ct. App. 1978); Ortho Pharmaceutical Corp. v. Heath, 722 P.2d 410, 415 (Colo. 1986) (en banc); Belle Bonfils Memorial Blood Bank v. Hanson, 665 P.2d 118, 122 (Colo. 1983); Ortho Pharmaceutical Corp. v. Chapman, 180 Ind. App. 33, 388 N.E.2d 541, 545 (1979). One major exception is California, where, pursuant to a decision of the California Supreme Court, comment k automatically applies to *all* prescription drugs. Brown v. Superior Court, 44 Cal. 3d 1049, 751 P.2d 470, 245 Cal. Rptr. 412 (1988). Other courts have announced similar holdings. *See, e.g.*, Brooks v. Medtronic, Inc., 750 F.2d 1227, 1230-31 (4th Cir. 1984) (comment k applies to drugs and medical devices); McKee v. Moore, 648 P.2d 21, 24-25 (Okla. 1982) (comment k applies to "drugs, vaccines, and the like," including IUDs); Werner v. Upjohn Co., 628 F.2d 848, 858 (4th Cir. 1980), *cert. denied*, 449 U.S. 1980 (1981) (when it is admitted that a new drug is unavoidably dangerous, comment k prevents strict liability). The majority of jurisdictions that have clearly addressed the issue, however, have decided that comment k is not automatically available for all drugs. Note, *supra* note 106, at 725.

109. Ortho Pharmaceutical Corp. v. Heath, 722 P.2d at 415; *Belle Bonfils Memorial Blood Bank*, 665 P.2d at 122; *see also* Note, *supra* note 106, at 727-28.

110. *See supra* text accompanying note 53.

111. *See, e.g.*, Feldman v. Lederle Laboratories, 97 N.J. 429, 441-42, 479 A.2d 374, 380 (1984) ("We do not agree that the protective shield of comment k immunizes all prescription drugs. Moreover, we are of the opinion that generally the principle of strict liability is applicable to manufacturers of prescription drugs.").

112. *See, e.g.*, Ortho Pharmaceutical Corp. v. Heath, 722 P.2d at 415; *Belle Bonfils Memorial Blood Bank*, 665 P.2d at 122.

113. Schwartz & Mahshigian, *National Childhood Vaccine Act of 1986: An Ad Hoc Remedy or a Window for the Future?*, 48 OHIO ST. L.J. 387, 388 (1987).

ated with the polio vaccine. Such protection might not be forthcoming given the political climate surrounding the issue of abortion, the fact that the federal judiciary is dominated by recent Reagan appointees whose apparent litmus test for approval was their stance on the abortion issue,[114] and the presence of state judiciaries that are dominated by a white male establishment which is often disinclined to afford women power to control their own bodies and lives.[115] On the other hand, as long as some abortions remain constitutionally protected, it should be difficult for a state court to determine that a highly safe and efficient means of securing an abortion is not desirable and thus not worthy of protection under comment k.

Whether courts interpreting comment k will or should provide manufacturers of RU-486 with protection from the imposition of strict liability is, however, not a viable issue today given the crisis in the jurisprudence of tort liability. Although it is rare for courts explicitly to apply strict liability to prescription drugs, current decisions imposing liability are undermining the incentive for manufacturers to develop and innovate products. One of the greatest obstacles to making RU-486 available to potential users is the state of liability law itself. The problems involved in the application of comment k are only one aspect of a systemic failure in tort jurisprudence. The crisis has developed as courts and juries, while purportedly applying negligence standards, have essentially applied strict liability standards to many products and consequently undermined the traditional fault basis of tort liability and the purposes underlying comment k.[116] This dramatic expansion of liability is largely due to a general goal on the part of judges and juries of providing surrogate social insurance for injury victims.[117] Within the context of adjudicating individual claims, judges and juries have consciously or unconsciously made broad social policy judgments and have imposed a form of social insurance on defendants who are not necessarily to blame for the injuries, but who are deemed by judges and juries to be able to pay for them.

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114. Kelbley, *Bad Judgment on Judges: Why Screening Judges on Single Issues Threatens to Corrupt Our Legal System*, 15 HUM. RTS. 14, 15 (1987); Comment, *Unraveling Compromise*, 103 HARV. L. REV. 105, 135 n.122 (1989); *see also* Copelon, *Losing the Negative Right of Privacy: Building Sexual and Reproductive Freedom*, *supra* at —.

115. For an insightful discussion analyzing the cause of and suggesting a cure for the disempowerment of certain groups, including women, by much of the judicial establishment, see generally Matsuda, *Public Response to Racist Speech: Considering the Victim's Story*, 87 MICH. L. REV. 2320 (1989). Professor Matsuda maintains that the exclusion of certain groups from the system of jurisprudence perpetuates the oppression and disempowerment of those groups. She advocates use of an "outsider's jurisprudence" which would include the voices of groups whose perspectives have been suppressed or devalued within the legal system.

116. Note, *A Question of Competence: The Judicial Role in the Regulation of Pharmaceuticals*, 103 HARV. L. REV. 773, 778-79 (1990); Law Firm of Sidley and Austin, *The Need for Legislative Reform of the Tort System: A Report on the Liability Crisis from Affected Organizations*, 10 HAMLINE L. REV. 345, 349 (1987); Litan, Swire & Winston, *The U.S. Liability System: Background and Trends*, in R. LITAN & C. WINSTON, LIABILITY: PERSPECTIVES AND POLICY 6 (1988).

117. Law Firm of Sidley and Austin, *supra* note 116, at 373; Schuck, *The New Judicial Ideology of Tort Law*, in NEW DIRECTIONS IN LIABILITY LAW 12-14 (W. Olson ed. 1988).

There has also been a significant increase in the size of tort damage awards which acts to discourage innovation by manufacturers. This is largely attributable to dramatic increases in awards for pain and suffering and for punitive damages.[118] The amounts of money that a court or a jury will award for both pain and suffering and punitive damages are unpredictable and, in some cases, may bear no reasonable relationship to a plaintiff's actual economic injury. Juries awarding damages for pain and suffering have virtually unbridled discretion, as there is currently no meaningful way for anyone to measure such non-quantifiable losses monetarily.[119] The standards for how large a punitive damage award should be are equally vague.[120] Jury verdicts have become so great that the average verdict in products liability cases now exceeds one million dollars.[121]

Increasingly, these mechanisms of modern tort law are inhibiting the development and marketing of much-needed products.[122] The impact of this crisis on reproductive technologies has been devastating, as few industries have been harder hit by multimillion-dollar court awards than those involving contraception and reproduction.[123] A.H. Robins was driven into bankruptcy in 1985 after having paid $200 million to settle approximately 4400 lawsuits over its Dalkon Shield, an IUD which was found to cause pelvic infections in women.[124] The estimated potential liability is over $1 billion on the sale of approximately four million Dalkon Shield IUDs,[125] which earned Robins only

118. O'Connell, *Neo No-Fault: A Fair Exchange Proposal for Tort Reform*, in NEW DIRECTIONS IN LIABILITY LAW, *supra* note 117, at 186-88; Jeffries, *A Comment on the Constitutionality of Punitive Damages*, 72 VA. L. REV. 139, 139 (1986); Law Firm of Sidley and Austin, *supra* note 116, at 364-68; O'Connell, *A Neo No-Fault Contract in Lieu of Tort: Preaccident Guarantees of Post Accident Settlement Offers*, 73 CALIF. L. REV. 898, 899 (1985) [hereinafter *Neo No-Fault Contract*]; Seltzer, *Punitive Damages in Mass Tort Litigation: Addressing the Problems of Fairness, Efficiency, and Control*, 52 FORDHAM L. REV. 37, 91 (1983).

119. The law provides little guidance to aid the jury in the process of determining an appropriate award for pain and suffering. *See* Leebron, *Damages for Pain and Suffering Before Death*, 64 N.Y.U. L. REV. 256, 265 (1989). In addition, the standard of review articulated by most courts requires that an award for pain and suffering not "shock the conscience." *See, e.g.*, DeThomas v. Delta S.S. Lines, 58 F.R.D. 335, 340 (D.P.R. 1973); Estate of Neal v. Friendship Manor Nursing Home, 113 Mich. App. 759, 768, 318 N.W.2d 594, 598 (Ct. App. 1982); Bingman v. Gray's Harbor Community Hosp., 103 Wash. 2d 831, 835, 699 P.2d 1230, 1233 (1985) (en banc) ("[A]ppellate court will not disturb an award of damages by a jury unless it is outside the range of substantial evidence in the record, or shocks the conscience of the court, or appears to have been arrived at as a result of passion or prejudice").

120. *See, e.g.*, Sales & Cole, *Punitive Damages: A Relic That Has Outlived Its Origins*, 37 VAND. L. REV. 1117, 1145-48 (1984); Jeffries, *supra* note 118, at 139.

121. *Sorry, Your Policy Is Cancelled*, TIME, March 2, 1986, at 20. In one extreme case, later vacated on other grounds by the United States Supreme Court, an insurance company's failure to pay a $1,600 bill resulted in a punitive damage award of $3.5 million, more than two thousand times the amount in dispute. Aetna Life Insurance Co. v. Lavoie, 470 So. 2d 1060 (Ala. 1984), *vacated*, 475 U.S. 813 (1986) (vacated due to bias of judge, not size of award).

122. Law Firm of Sidley and Austin, *supra* note 116, at 349.

123. *See* Mastroianni, *supra* note 8, at 126-35 (discussing the impact of numerous lawsuits on the availability of contraceptives).

124. *Id.* at 128.

125. Thornton, *Intrauterine Devices: Malpractice and Product Liability*, 14 L. MED. &

$500,000 in profit.[126] In addition, G.D. Searle was ordered to pay $8.75 million to a Minnesota woman who claimed to have been injured by its Copper-7 IUD in September 1988.[127] The ultimate effect of these lawsuits was to drive almost all IUDs from the market, including those considered safe.[128]

The IUD lawsuits generated so much fear of and hostility toward reproductive products that other contraceptives that are considered safe have been hit with enormous court judgments. In 1985, for example, a federal judge awarded a woman from Georgia $4.7 million in damages against Ortho Pharmaceutical after she claimed that her child's birth defects were caused by her use of a spermicide made by Ortho.[129] Medical studies published before then, and since, have found no link whatsoever between spermicides and fetal injury.[130] The fact that Ortho Pharmaceutical makes only approximately $3 million a year on the spermicide[131] demonstrates that even single decisions such as the one in *Wells* can readily drive a drug from the market.[132] This case also demonstrates that courts are willing to stretch to find manufacturers liable, purportedly under a theory of negligence, when no actual fault has been established. The outcomes of such litigation may explain why the number of American companies conducting research on contraceptives has dwindled from about twenty in the 1970s to one at present.[133]

The lack of interest on the part of American companies in developing RU-486 is related to the tendency of the current tort liability system to impose liability regardless of fault. Only one American pharmaceutical company, Cabot Medical, located in Langhorne, Pennsylvania, has attempted, though not yet succeeded, to form an agreement with Roussel-Uclaf to market RU-486 in the United States.[134] The corporation's management has a firm belief in the drug's safety and efficacy and believes that it can protect the company

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HEALTH CARE 4, 7 (1986). In Palmer v. A.H. Robins Co., 684 P.2d 187, 219-20 (Colo. 1984), the court affirmed a $6.2 million punitive damages award against the company, which had been imposed by the lower court after it found Robins guilty of aggravated misconduct. Robins was eventually acquired by American Home Products Corp., and a $2.3 billion trust fund was created for women injured by the Dalkon Shield. Pogatchnik, *Contraceptive Studies at Standstill, Study Finds*, L.A. Times, Feb. 15, 1990, at 24, col. 1.

126. Kleinfield, *Ongoing Problem for Robins*, N.Y. Times, Aug. 1, 1984, at D1, col. 3.

127. Abrams, *Politics, Profits and a New Pill*, Newsday, Dec. 13, 1988, Discovery, at 1.

128. Schmid Laboratories withdrew the Saf-T-Coil in 1983. In 1985, Ortho Pharmaceutical discontinued marketing the Lippes Loop, and, in 1986, G.D. Searle discontinued marketing the Copper-7 and the Tatum-T. All of these devices were withdrawn even though the FDA did not raise questions about their safety and very few successful lawsuits had been brought against the manufacturers. Mastroianni, *supra* note 8, at 122. Only two firms are currently selling IUDs in the United States. ALZA has been marketing the Progestasert IUD since 1976, and GynoPharma has been marketing the ParaGard IUD (Copper T380A) since 1988. Both IUDs are accompanied by detailed informed consent guidelines. *Id.*

129. Wells v. Ortho Pharmaceutical Corp., 615 F. Supp. 262 (1985).

130. Savage & Tumulty, *French 'Abortion Pill' Stirs Behind-the-Scenes Battle*, L.A. Times, May 14, 1989, at 1, col. 5.

131. *Federal Judges vs. Science*, N.Y. Times, Dec. 27, 1986, at A22, col. 2.

132. *Wells*, 615 F. Supp. at 262.

133. *See* Abrams, *supra* note 127, at 1.

134. Telephone interview with Warren Wood, *supra* note 101.

from liability by providing women who take RU-486 with all pertinent information.[135] The management acknowledges, however, that as a small company, a single lawsuit could drive it into bankruptcy. It appears that other companies are not willing to assume such a risk.

III.
REFORM

A. The Federal Products Liability Bill

In addition to the blame that the judiciary must accept for the current tort liability crisis, much of the responsibility for this situation lies with Congress and inactive state legislatures that have been unwilling to attack the problem. Pressure for the enactment of a federal products liability bill began in the late 1970s;[136] legislation was first introduced in the House of Representatives in 1980 by Representative Richardson Preyer[137] and in the Senate in 1982 by Senator Robert W. Kasten.[138] Currently, the most heavily touted and discussed federal legislation is a products liability bill sponsored by Senator Kasten,[139] which would offer drug companies, as well as other manufacturers, some protection against liability.

The bill was proposed as an effort to resolve uncertainties in the products liability tort litigation system which are caused by conflicting state products liability rules.[140] Such uncertainties are inherent in the fact that products liability law is primarily judge-made common law.[141] Because products liability rules are developed almost exclusively by judges in state courts, the rules vary from state to state and often within one state. Even basic issues of products liability law, such as the standard for determining when a manufacturer is responsible for harm caused by a defectively designed product, are interpreted and settled differently in various states.[142] Manufacturers who do business on

135. *Id.*

136. For a history of federal legislative activity in this area, see Twerski, *A Moderate and Restrained Federal Product Liability Bill: Targeting the Crisis Areas for Resolution*, 18 U. MICH. J.L. REF. 575, 575 n.2 (1985).

137. H.R. 7921, 96th Cong., 2d Sess., 128 CONG. REC. 6878 (1980).

138. S. 2631, 97th Cong., 2d Sess. (1982).

139. Senator Kasten is chairman of the Subcommittee for Consumers of the Senate Committee on Commerce, Science, and Transportation. The current version of the bill is S. 1400, 101st Cong., 1st Sess., 135 CONG. REC. 58719-02 (daily ed. July 25, 1989), and H.R. 2700, 101st Cong., 1st Sess. (1989).

140. SENATE COMM. ON COMMERCE, SCIENCE, AND TRANSPORTATION, PRODUCT LIABILITY ACT, S. Rep. No. 670, 97th Cong., 2d Sess. 1 (1982) [hereinafter SENATE REPORT].

141. Some states have codified specific issues of product liability law. While this eliminates some uncertainty about the law within the state, it does not resolve the problems of uncertainty facing those who do business on an interstate basis.

142. For example, Alaska and California courts hold that a product is defectively designed if it fails to perform as safely as an ordinary consumer would expect when used in a reasonably foreseeable manner, or if the defendant is unable to prove that the benefits of the product outweigh its risks. *See, e.g.*, Caterpillar Tractor Co. v. Beck, 624 P.2d 790 (Alaska 1981); Barker v. Lull Eng'g Co., 20 Cal. 3d 413, 573 P.2d 443, 143 Cal. Rptr. 225 (1978). Texas courts determine that a product is defectively designed only if it is found to be unreasonably dangerous after

an interstate basis in the national marketplace are therefore unable to predict which of the multiple legal standards will apply to them, or whether a particular standard will remain constant. Moreover, expansion of liability based on a desire or need on the part of judges and juries to correct societal inequities[143] creates additional uncertainties in the tort system.

The bill was introduced as an attempt to address the problem of uncertainty in products liability law by establishing certain uniform standards.[144] Such uniform standards are meant to make the law more balanced and predictable. The current version of the bill pending in both branches of Congress would prevent courts from awarding punitive damages against any manufacturer when the product at issue had been approved by the FDA or another federal agency, so long as the defendant manufacturer did not deliberately withhold or misrepresent material information.[145] In addition, the bill would impose a uniform time limitation on the filing of civil actions. It would bar any complaint not "filed within two years of the time the claimant discovered or, in the exercise of reasonable care, should have discovered the harm and its cause."[146] Earlier drafts of the federal product liability reform bill offered much broader protection to manufacturers, including complete protection from the imposition of strict liability in the event of injury, so long as the product left the manufacturer in its intended and approved form.[147]

The bill, in its current form, would afford pharmaceutical companies some liability protection, but probably not enough to encourage the development of a drug like RU-486. This is due to the fact that the bill, if passed, would not remove the power of judges and juries to find a manufacturer liable regardless of fault. Consequently, even if a manufacturer sold RU-486 in a form approved by the FDA and the manufacturer was not shown to be negligent in any way, the bill would not prevent a court or a jury from stretching to hold a manufacturer liable. By merely addressing the punitive damages and statute of limitations issues, the bill does not adequately address the uncertainties and inequities created when judges and juries choose to hold liable companies viewed as having deep pockets, regardless of actual fault.

It is unlikely, in any event, that Congress will enact this bill in the foreseeable future, as there is a debate raging over the necessity and wisdom of a federal solution to the liability crisis. Advocates of a federal products liability

consideration of the utility of the product and the risk involved in its use. *See, e.g.*, Turner v. General Motors Corp., 584 S.W.2d 844 (Tex. 1979). In determining whether a product is defectively designed, Oregon courts look to whether the product would not have been put into commerce by a reasonable person were she aware of the harmful nature of the product. *See, e.g.*, Wilson v. Piper Aircraft Corp., 282 Or. 61, 577 P.2d 1322 (1978); Phillips v. Kimwood Mach. Co., 269 Or. 485, 525 P.2d 1033 (1974).

143. *See supra* text accompanying notes 117-18.

144. SENATE REPORT, *supra* note 140, at 1-9.

145. S. 1400, *supra* note 139, § 303(c)(1)(A)-(B).

146. *Id.* § 304(a).

147. *See generally* S. 2631, 97th Cong., 2d Sess. § 5(a), 128 CONG. REC. 6878 (1982); H.R. 7921, 96th Cong., 2d Sess. § 5(b) (1980).

bill maintain that a federal solution is necessary to promote nationwide distribution of goods.[148] They contend that a federal approach would be superior to the present system as it could eliminate duplicative and conflicting state efforts and provide uniformity and predictability in the law.[149] Moreover, they argue that Congress' power under the commerce clause is sufficient to pre-empt the field.[150]

Opponents are concerned with principles of federalism, however, and contend that such a federal approach would be too intrusive, as it would significantly increase federal control over state policy and encourage excessive federal intervention.[151] They assert that the federal bill shows an unwarranted lack of faith in and impatience with the states and point to the Uniform Commercial Code as an example of how the law can be made uniform across the country without the intervention of the federal government.[152] Other critics stress that the states are "laboratories of ideas," each experimenting with different legal approaches, changing with the times, gradually addressing social ills and responding to scientific advances. The state laboratories ultimately reach just solutions through the gradual evolution of the common law. They claim that a federal code would destroy the flexibility of the common law and stagnate the innovation and development provided by the evolving state law.[153]

The federal liability bill is also under siege by some women's groups who fear that the legislation provides too much protection to drug manufacturers. Focusing on the recent litigation regarding injuries to women from use of the Dalkon Shield, some feminist groups are pushing for the exclusion of all manufacturers of contraceptives and other reproductive drugs from the bill's protections.[154] This concern is understandable, as medical innovations have been accepted in the past without knowledge of the possible consequences and at the expense of women's bodies and lives.[155] In light of this history, their de-

148. *See, e.g.*, Coccia, *Uniform Product Liability Legislation: A Proposed Federal Solution*, 51 INS. COUNSEL J. 104, 118 (1984); Comment, *The Product Liability Crisis: A Federal Statutory Solution*, 1983 U. ILL. L. REV. 757, 765.

149. *E.g.*, Reed & Watkins, *Products Liability Tort Reform: The Case for Federal Action*, 63 NEB. L. REV. 389, 471 (1984); *see also Bush Seeking Limits on Products Liability*, L.A. Times, Feb. 22, 1990, at 3, col. 5.

150. *E.g.*, Reed & Watkins, *supra* note 149, at 468.

151. *See, e.g.*, Perlman, *Products Liability Reform in Congress: An Issue of Federalism*, 48 OHIO ST. L.J. 503, 508 (1987); Walters, *Federal Pre-emption of State Products Liability Laws*, 32 DRAKE L. REV. 961, 986 (1983).

152. Walters, *supra* note 151, at 986.

153. *See, e.g.*, Dworkin, *Federal Reform of Product Liability Law*, 57 TUL. L. REV. 602, 618 (1983); Reed & Watkins, *supra* note 149, at 461, 464.

154. Gladwell, *Birth Control Makers Weary of Controversy*, L.A. Times, May 3, 1988, at 15, col. 1.

155. For example, the enthusiasm surrounding the introduction of oral contraceptives led millions of women to use birth control pills before side effects such as anxiety, amenorrhea, acne, changes in libido, backache, breast enlargement, depression, dizziness, headache, leg cramps, nausea, pelvic cramps, fatigue, and stroke were discovered. *See* RUDEL, KINCL & HENZL, BIRTH CONTROL: CONTRACEPTION AND ABORTION 90 (1973). *See generally* MINTZ,

mand that long-term effects be proven and not assumed is legitimate; such concerns, however, could be addressed without imposing punitive damages on manufacturers who were not willfully negligent in their actions, thereby adding to the probability that no new freedom-enhancing products will be developed.

Since the proposed bill would not afford would-be manufacturers the protection from the arbitrary imposition of liability necessary to promote development of RU-486, however, its passage would have little positive impact on reproductive choice. Moreover, because the products liability bill is facing such fierce opposition[156] and is, therefore, unlikely to pass in the foreseeable future, advocating passage of the bill as a method of protecting manufacturers and thereby encouraging development of RU-486 would be futile.

B. A Federal Regulatory Approach

Another alternative to the current state of products liability law, and one that could limit obstacles to the manufacture of RU-486, is found in a federal regulatory approach to tort reform. Under this approach, it would be deemed that compliance with safety standards issued by the FDA, or other relevant regulatory agencies, either would create a rebuttable presumption that the requisite common law standard of care has been met[157] or would be an absolute defense to tort claims.[158] Currently, the judiciary regards both regulatory and statutory standards as good indications of the minimum, but not the maximum, standard of care required.[159] The courts regard violations of these standards as negligence per se, but have treated regulatory compliance as merely relevant evidence of due care deserving of no special weight.[160]

This federal regulatory approach to tort reform is intended to limit the

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THE PILL: AN ALARMING REPORT (1970) (discussing the risks associated with taking birth control pills as manufactured in the late sixties); SEAMAN, THE DOCTOR'S CASE AGAINST THE PILL (1969) (same). Recent federal regulations require that patients receive warnings about known dangers of oral contraceptives, including thrombophlebitis, stroke, links to cancer, and the specific dangers to smokers, 21 C.F.R. § 310.501(a)(2)(iv)-(vii)(c)(4), (7)-(9); *id.* § 310.515(b)(4)(i)-(v), (6), (7). The Pill is currently the most widely used reversible contraceptive both in the United States and worldwide. BOSTON WOMEN'S HEALTH BOOK COLLECTIVE, *supra* note 9, at 237.

156. *See Federal Products Liability Bill Closer to Reality*, NAT'L L.J., Mar. 14, 1988, at 5, col. 1.

157. *See, e.g.*, Foote, *Coexistence, Conflict and Cooperation: Public Policies Toward Medical Devices*, 11 J. HEALTH POL. POL'Y & L. 501, 512 (1986) (arguing that compliance with FDA requirements should create a rebuttable presumption that the product is not defective).

158. *See* Huber, *Safety and the Second Best: The Hazards of Public Risk Management in the Courts*, 85 COLUM. L. REV. 277, 344 (1985) (arguing that products that are "subject to the most searching and complete state and federal safety regulation" should not be subject to further evaluation under tort law); *see also* Epstein, *Legal Liability for Medical Innovation*, 8 CARDOZO L. REV. 1139, 1151 (1980) (stating that compliance with FDA-approved warnings should be conclusive in tort actions).

159. *See* Schwartz, *The Role of Federal Safety Regulations in Products Liability Actions*, 41 VAND. L. REV. 1120, 1123 (1988).

160. *Id.*

scope of liability by eliminating strict liability in cases where manufacturers have complied with regulations and by increasing the plaintiff's evidentiary burden in such cases substantially.[161] Proponents of this type of reform argue that agencies, as specialists in particular fields, are superior to courts in determining product safety questions.[162] Proponents argue further that modern regulatory standards set stringent safety requirements that should be presumed adequate for purposes of tort law.[163] The proponents claim that a federal regulatory system will provide the kind of concrete, predictable liability standard lacking under the current products liability system,[164] and they criticize the courts for having failed to articulate clear legal standards under strict products liability.[165] Some argue that pharmaceuticals, specifically, are unique among products in the United States in the degree to which quality is regulated before a drug is released in the market, and that, therefore, the necessity for liability as a quality control mechanism is greatly reduced.[166]

A number of state tort reform statutes include similar regulatory compliance proposals. A New Jersey statute creates a presumption that if a manufacturer uses FDA-approved warnings, it will have met the requisite standard of care.[167] The statute also limits the availability of punitive damages when products approved by the FDA are challenged in court.[168] In addition, Kansas, Tennessee, and Utah have enacted statutes creating a legal presumption that products in compliance with government standards are reasonably safe and non-defective.[169]

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161. *Id.* at 1127.

162. *See* Huber, *supra* note 158, at 335. The author states:

> Regulatory agencies are equipped to make the risk comparisons on which all progressive transformation of the risk environment must be based. The courts are simply not qualified to second-guess such decisions; when they choose to do so they routinely make regressive risk choices. Requiring — or at least strongly encouraging — the courts to respect the comparative risk choices made by competent, expert agencies would inject a first, small measure of rationality into a judicial regulatory system that currently runs quite wild.

Id.

163. *Id.*

164. *See, e.g.*, R. EPSTEIN, MODERN PRODUCTS LIABILITY LAW 93-118, 192 (1980) (placing special emphasis on the importance of certainty and predictability in proposals for greater judicial deference to administrative safety standards).

165. *See* Birnbaum, *Unmasking the Test for Design Defect: From Negligence [to Warranty] to Strict Liability to Negligence*, 33 VAND. L. REV. 593, 600-02 (1980) (criticizing the failure of the courts to articulate clear legal standards with respect to claims of design defects); Twerski, Weinstein, Donaher & Piehler, *The Use and Abuse of Warning in Products Liability — Design Defect Litigation Comes of Age*, 61 CORNELL L. REV. 495, 513-17 (1976) (criticizing the failure of the courts to articulate clear legal standards with respect to claims of inadequate warnings).

166. *See* Mastroianni, *supra* note 8, at 4.

167. Act of July 22, 1987, ch. 197, 1987 N.J. Sess. Law. Serv. 188-93 (West).

168. *Id.*

169. KAN. STAT. ANN. § 60-3304(a)-(b) (1983) (requiring plaintiff to establish that defendant was negligent in failing to take greater precautions than those required by the regulatory standards); TENN. CODE ANN. § 29-28-104 (1978) (requiring that compliance with regulatory standards creates a rebuttable presumption that the product is not unreasonably dangerous); UTAH CODE ANN. § 78-15-6(3) (Supp. 1987) (requiring that compliance with regu-

Although a regulatory approach to tort reform would provide drug companies with the freedom from the arbitrariness of the liability system that is needed for them to be able and willing to produce drugs like RU-486, such an approach remains inadequate to solve the problems caused by the products liability crisis. First, the federal regulatory system is incapable of keeping product safety standards up-to-date due to the constraint of low budgets which renders agencies incapable of responding quickly to rapidly changing products. Thus compliance with regulatory standards may be unreasonable when standards become obsolete. Second, manufacturers would be motivated to increase their already substantial influence on the regulatory process to assure that standards are not upgraded or their requirements made too onerous.[170] Even more disturbing, the existence of a compliance defense might also encourage manufacturers to resist implementing new safety measures, though these measures may be readily available and known throughout the industry, until government standards compel their adoption. Lastly, the same federalism concerns discussed with regard to the federal products liability bill[171] apply to a regulatory compliance scheme. A federal regulatory approach to tort reform would deny individual states the ability to determine what constitute proper rules and solutions in products liability cases. For all of these reasons, a regulatory compliance scheme is an inadequate solution to the products liability crisis.

C. *No-Fault*

An alternative to a federal system of products liability or a regulatory compliance system is found in a no-fault compensation scheme. Under such a scheme, persons injured by a particular product would be compensated automatically for their injuries.[172] In return, they would elect not to bring litigation to determine a manufacturer's alleged liability, or would only bring suit as a last resort. The national government and private industry have, under specific circumstances, instituted no-fault compensation schemes to deal with situations in which there has been a breakdown in the common law tort system.[173] A no-fault system, whether privately elected or statutorily man-

latory standards creates a rebuttable presumption that the product is not unreasonably dangerous).

170. *See* D. BOLLIER & J. CLAYBROOK, FREEDOM FROM HARM: THE CIVILIZING INFLUENCE OF HEALTH, SAFETY AND ENVIRONMENTAL REGULATION 189 (1986) (stating that "by far the most influential force in the regulatory process is the political resistance of the affected industries.").

171. *See supra* text accompanying notes 151-53.

172. The term "no-fault" is used loosely in this section to refer to a variety of compensation schemes, including neo-no-fault systems that permit a party to bring suit after receiving compensation due to the willful or knowing causation of injury.

173. Workers' compensation is one example of a no-fault system. It was introduced in the United States between 1910 and 1920, and was designed such that injured workers would be automatically paid by their employers for their medical costs. For a summary of workers' compensation statutes, see O'Connell & Barker, *Compensation for Injury and Illness: An Update of the Conard-Morgan Tabulations*, 47 OHIO ST. L.J. 931, 931-33 (1987). In addition, no-fault

dated, offers a number of benefits. The key to the effectiveness of no-fault is balance. In order to gain the advantages of immediate compensation for injury and the economic loss that follows, the injured party gives up the opportunity to pursue the possible recovery of non-economic damages. At the same time, the party threatened with liability gives up its opportunity to pursue a verdict in which it would pay less than the full economic loss or nothing at all. Both sides avoid a lengthy struggle of litigation. Each side yields something and, in the exchange, ultimately benefits.[174] Our present system precludes many thousands of injured persons from obtaining compensation for their injuries and economic loss.[175] With a no-fault system, all injured persons receive compensation.

A good example of a workable and successful federally mandated no-fault scheme is the National Childhood Vaccine Injury Act of 1986,[176] which established a mandatory no-fault compensation system for persons injured through childhood vaccines. The Act was passed as a response to the concern that liability for injuries and the burden of defending suits was causing American manufacturers to discontinue the production of vaccines.[177] The Act established a mandatory no-fault system under which compensation for injuries related to childhood immunizations is to be paid out of a trust fund established by the Act.[178] The trust fund is financed with the proceeds of an excise tax imposed on each dose of the covered vaccines. If a person has been injured by a vaccine, she must bring an action through this no-fault compensation scheme before a tort lawsuit may be filed against the manufacturer.[179]

The Act also protects a vaccine manufacturer against punitive damages in a tort lawsuit if the manufacturer can show that the product in question was manufactured and marketed in compliance with the applicable requirements under the Federal Food, Drug and Cosmetic Act and other statutory require-

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insurance has presented an answer to the shortcomings of tort law with respect to automobile accidents. *See id.* at 930; *see also* J. O'CONNELL & R. HENDERSON, TORT LAW, NO-FAULT AND BEYOND 75-76 (1976); O'Connell & Joost, *Giving Motorists a Choice Between Fault and No-Fault Insurance*, 72 VA. L. REV. 61, 61-72 (1986).

174. For an overview of the policies underlying no-fault systems, see Keeton, *The Case for No-Fault Insurance*, 44 MISS. L.J. 1, 8-14 (1973); J. O'CONNELL, ENDING INSULT TO INJURY: NO-FAULT INSURANCE FOR PRODUCTS AND SERVICES 73-80 (1975). No-fault proposals have been offered in a wide variety of contexts. *See, e.g.*, Baxter, *The SST: From Watts to Harlem in Two Hours*, 21 STAN. L. REV. 1 (1968) (a proposal to compensate for damage from sonic booms); Kimball, *Compulsion Without Protection or Recourse: The Case for No-fault Accident Insurance for School Children*, 1975 UTAH L. REV. 925; Milford, *A No Fault Aviation Insurance Plan*, 41 J. AIR. L. 211 (1975).

175. Lazone, *A Defense Lawyer Views Products Liability and Professional Liability No-Fault*, 1975 INS. L.J. 82, 84.

176. Pub. L. No. 99-660, tit. 3, 100 Stat. 3755 (codified in scattered sections of 42 U.S.C.) [hereinafter The Act]. *See generally* Schwartz & Mahshigian, *supra* note 113.

177. H.R. REP. NO. 908, 99th Cong., 2d Sess. 3-5, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS 6344, 6344-46; *see also* Schwartz & Mahshigian, *supra* note 113, at 389.

178. 42 U.S.C.A. § 300aa-15(i) (West Supp. 1990); *see also* Schwartz & Mahshigian, *supra* note 113, at 389.

179. 42 U.S.C.A. §§ 300aa-11, -21 (West Supp. 1990).

ments.[180] This protection against punitive damages would not apply, however, if the manufacturer engaged in fraud or intentionally withheld information relating to the safety or efficacy of the vaccine from the Secretary of Health and Human Services either during any phase of a proceeding for approval of the vaccine or following approval.[181] This no-fault system was designed to provide a faster and more certain compensation alternative to the common law tort system so that litigation would become a last resort.[182]

Another federal no-fault scheme is the Price-Anderson Act,[183] which was passed in 1957 to aid the nuclear power industry in the face of refusals by insurance companies to underwrite what was perceived to be an unknown but potentially enormous liability risk in the event of a nuclear accident. The Federal Coal Mine Health and Safety Act of 1969,[184] which was passed to compensate miners disabled by black lung disease, is also an example of such a system.

A system based on these models could be developed to give manufacturers the financial confidence necessary to develop and market RU-486. Such an approach could take the form of legislation mandating the creation of a central fund from which compensation would flow to victims. The fund could be financed through a tax imposed on each purchase of RU-486[185] or through contribution by the manufacturers of the drug. Since such a scheme would remove the issues of damages and fault from the judiciary and provide drug companies with the protection from unlimited liability that is needed, manufacturers could be quite willing to fund the system. At the same time, this system would protect women by compensating them immediately for any injuries. In addition, it would neither be desirable nor necessary to eliminate the possibility of litigation completely. Allowing suits for punitive damages when a plaintiff can prove that a company willfully or knowingly caused harm would add the incentive necessary for companies to take safety seriously.

A number of private, as opposed to statutorily mandated, no-fault plans have proven successful as well. One such agreement created a no-fault system for compensating victims of asbestos-related injuries. By the end of 1985, more than 35,000 personal injury actions had been filed against asbestos manufacturers, and estimates of total asbestos-related liability were running as high as $87 billion.[186] In order to centralize the processing and defense of

180. *Id.* § 300aa-23(d)(2).

181. *Id.*

182. *See supra* notes 172-75 and accompanying text.

183. Pub. L. No. 85-256, 71 Stat. 576 (1957) (codified as amended at 42 U.S.C. § 2210 (1988)).

184. Pub. L. No. 91-173, 83 Stat. 742 (1969) (codified as amended at 30 U.S.C. § 801 (1988)).

185. Imposing a tax on RU-486 would create an additional problem by raising the price of the drug, thus imposing additional financial burdens on poor women. Efforts should therefore be made either to avoid charging a tax or to exempt those women who cannot afford the extra fee.

186. K. FRANKLIN & R. RABIN, TORT LAW AND ALTERNATIVES 745 (1987).

these claims and provide an alternate method of dispute resolution, fifteen insurance companies and thirty-four of the largest asbestos manufacturing firms signed the *Agreement Concerning Asbestos Related Claims*, known as the Wellington Plan, which established what is called an "Asbestos Claims Facility."[187] Under the *Agreement*, claimants submit their claims against member companies directly to the Facility. Each claim is then considered in a non-binding arbitration. Claimant participation at this stage is voluntary, with recourse to the tort system allowed at any time. Following a decision by an arbitrator either side can appeal to a binding arbitration process.

Liability under this plan is determined on a no-fault basis, and plaintiffs must prove only that they suffer from an asbestos-related disease.[188] Under the scheme no punitive damages are provided and settlement is conditioned on a waiver of future litigation rights against all Facility members.[189] In cases in which claimants choose to forego the claims process offered by the Facility and instead file suit, the Facility provides joint litigation defenses for its members.[190] This joint defense is intended to combine resources and cut legal costs.

Concern over the delay and legal costs imposed by the tort system in high school athletic injury cases motivated high school athletic conferences in forty-nine states to arrange another private elective no-fault program, *The Scholastic Lifetime Medical and Disability Policy*.[191] Under this plan, each school wanting to participate is required to pay a premium calculated on the basis of the number of students the school determines should be covered.[192] The fund then provides a no-fault settlement offer to any high school athlete who receives injuries leading to at least a $10,000 loss.[193] The fund compensates the athlete for all medical and rehabilitation expenses, transportation costs, wages lost by parents forced to miss work, and up to $300 per week to cover lost income if the victim is unable to work after rehabilitation.[194] The plan provides no benefits for pain and suffering,[195] and is constructed so that a victim is afforded 90 days in which to make an irrevocable decision to accept the proffered settlement or to resort to the courts.[196] Coverage is provided only if the victim and her family agree not to file a tort suit against the school, school district, or state athletic association. If the student chooses to sue, the fund will cover a judgment against the school of up to $5 million.[197]

No-fault has thus proven, in some circumstances, to be an effective strat-

187. *Id.*
188. *Id.*
189. *Id.*
190. *Id.*
191. *See Neo No-Fault Contract, supra* note 118, at 914.
192. *Id.*
193. *Id.* at 914-15.
194. *Id.* at 915.
195. *Id.*
196. K. FRANKLIN & R. RABIN, *supra* note 186, at 746.
197. *See Neo No-Fault Contract, supra* note 118, at 915.

egy for compensating victims quickly while protecting defendants from the unpredictable and often arbitrary products liability system. There are problems, however, with no-fault systems. One major problem with compensating injured parties through such a scheme is that it is impossible to predict the potential number of injuries or the cost of compensating such injuries before they occur. Unlike injuries to a high school athlete, when a product is mass-produced and marketed it has the potential to injure hundreds of thousands of users. In the event that the product does injure or kill vast numbers of people, the company that established the no-fault compensation fund may not have, or may not be willing to contribute, enough money to compensate all victims. A well-known example of this occurred with the fund established to compensate victims of the Dalkon Shield IUD. When A.H. Robins declared bankruptcy in 1985, American Home Products Corporation agreed to purchase the company and set up a $2.475 billion trust fund to compensate women injured by the Dalkon Shield.[198] Many victims claim, however, that the fund is inadequate to compensate the hundreds of thousands of women injured by the device.[199] Many warn that the fund established by the Price-Anderson Act will also prove to be inadequate to compensate injured victims should a severe nuclear accident occur in the future.[200] In addition, because a no-fault scheme requires a substantial initial monetary investment, small pharmaceutical companies and privately funded not-for-profit organizations may not be able to afford to institute a no-fault plan. At the same time, large companies possessing the necessary capital may be unwilling to implement a program to facilitate development of RU-486 specifically so long as anti-choice groups continue to threaten to boycott their other products.

However, the other two tort reform proposals discussed previously, the federal products liability bill and the federal regulatory approach, represent even less adequate responses to the problems created by the liability crisis. The bill now under consideration in Congress would offer pharmaceutical manufacturers protection from punitive damage awards in cases involving FDA-approved drugs, but would not offer needed protection from the arbitrary imposition of liability and awards for pain and suffering.[201] The bill is also facing fierce opposition due to federalism concerns, and is therefore unlikely to pass in the foreseeable future.[202] The federal regulatory approach would offer predictability as well as protection from the arbitrary imposition of liability and unreasonably large punitive damage awards, but would discourage research into product improvement by manufacturers. It could also

198. Gladwell, *Group Seeks to Block Dalkon Shield Settlement*, Wash. Post, Dec. 7, 1988, at F1.

199. *Id.*

200. *See, e.g.*, Welch, *Tightening Nuclear Liability*, N.Y. Times, Jan. 7, 1986, at 21, col. 1.

201. *See supra* text accompanying notes 136-56.

202. *Id.* While a nationwide no-fault scheme with regard to RU-486 may raise similar federalism concerns, this Note concludes that no such Congressionally mandated scheme is forthcoming in the foreseeable future. It is therefore unnecessary to address the federalism issue in this context.

lead to an unwanted and dangerous increase in corporate influence on the regulatory process.[203] A no-fault approach would, therefore, be a preferable means of encouraging the development of RU-486 in the United States.

In recognition of the fact that Congress is currently unlikely to create a no-fault compensation scheme for abortifacients due to the controversial nature of the issue, a drug company or non-profit organization could develop a private scheme of compensation themselves which would reduce the risk of great liability. Such a scheme could take the form of a contract pursuant to which a woman taking RU-486 would give her informed consent to take the drug and promise to bring any tort claims directly to the attention of the pharmaceutical manufacturer before deciding to file a complaint. The company would then have the option of offering to compensate the woman for any injuries. Once an offer is extended, the woman would have a specified period of time in which to accept. Upon acceptance, she would waive all claims for compensatory damages. No woman would be forced to accept a company's compensation offer, but most victims, when faced with the expense, delay, and risks of a tort claim, will probably be inclined to accept the benefits of full and immediate compensation for economic loss. The best possible scheme, from a victim's perspective, would also allow plaintiffs to sue companies guilty of willfully causing harm for punitive damages.[204] This would ensure that manufacturers were held accountable for their actions and would thus further the non-compensatory functions of tort law, such as the provision of incentives for product safety and the punishment of blameworthy tortfeasors. In the final analysis, the adoption of this proposal could facilitate the innovation of new drugs, such as RU-486, while guaranteeing complete and expeditious recovery for a potential victim's economic injury.

In order to facilitate the development of RU-486 in the United States, pro-choice organizations should consider implementing this neo-no-fault proposal in conjunction with the creation of a not-for-profit corporation. Many wealthy investors would probably be willing to invest in a private, not-for-profit organization formed for the explicit purpose of developing and manufacturing RU-486 for the benefit of American women. Such an undertaking would, no doubt, require substantial contributions of both money and time, but would make a serious political statement that women are determined to

203. *See supra* note 170 and accompanying text.

204. This provision allowing a woman to bring suit in a court of law if she finds the company's offer inadequate or chooses to seek punitive damages for intentional or knowing causation of injury is important, as it prevents a scheme such as the one proposed from being considered unconscionable as a contract of adhesion. A contract of adhesion is a standardized contract offered to consumers of essential or necessary goods and services on a "take it or leave it" basis. In a contract of adhesion, the weaker party often agrees to unfair or disadvantageous terms without any realistic choice. *See* Kessler, *Contracts of Adhesion — Some Thoughts About Freedom of Contract*, 43 COLUM. L. REV. 629 (1943) (describing the various forms of adhesion contracts, enforceability of their terms, and remedies for their breach); Rakoff, *Contracts of Adhesion: An Essay in Reconstruction*, 96 HARV. L. REV. 1173 (1983).

see their needs fulfilled and will take the action necessary to exercise their reproductive rights.

While such a not-for-profit corporation could certainly be formed without instituting a neo-no-fault compensation plan, doing so would help to protect the corporation from being forced into bankruptcy due to an arbitrary finding of liability by a court or jury should someone claim to have suffered an injury as a result of using RU-486. At the same time, adopting a no-fault plan would send a message that the corporation is willing to protect women's interests by compensating them completely and immediately for all economic injury that could potentially be caused by RU-486.

CONCLUSION

Even though surrounded by controversy and ensnared in politics, abortions remain legal in this country. For a woman early into an unwanted pregnancy, being afforded the option of ending her pregnancy by taking RU-486 could be liberating. Successful use of the drug would mean no waiting, no walking past picket lines, no complications from surgery, and no side effects from anesthesia. There is no good reason why women are presently denied access to this important drug.

A neo-no-fault tort reform scheme that would compensate potential victims for their injuries completely and expeditiously, give manufacturers the financial confidence to innovate without fear of bankruptcy when they act reasonably, and impose no restriction on the bringing of liability suits when companies intentionally, knowingly, or recklessly cause injury could open the door to the development of RU-486 in this country. The market for RU-486 is vast. That fact, combined with a lower liability risk, could be the incentive necessary to encourage drug companies to develop and market RU-486. Should established pharmaceutical manufacturers fail to take the lead, prochoice Americans should consider creating a not-for-profit corporation to develop and market the drug using the proposed neo-no-fault plan to protect itself from the arbitrary imposition of liability and to protect women from the risk, expense, and delay inherent in the tort system should unexpected injuries occur.