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THE UNINTENDED PREGNANCY CRISIS: A NO-FAULT FIX

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There is an ongoing and concerning public health problem in the United States relating to unintended pregnancies. Despite the fact that women consistently express dissatisfaction with existing contraception methods, the availability of cutting edge technologies remains stagnant. This paper argues that the threat of liability in the form on product liability lawsuits dissuades contraceptive manufacturers from innovating. This paper proposes a no-fault fix to the problem modeled around the National Childhood Vaccine Act of 1986.

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I. INTRODUCTION

In the United States, there is an ongoing and concerning public health problem: the large number of unintended pregnancies. Over one-half of the 6.6 million annual pregnancies in the United States are unintended.[1] According to some estimates, a woman in the United States should expect to have 1.42 unintended pregnancies by age forty-five.[2] The United States unintended pregnancy rate is considerably higher than the comparable rate in many other developed, first world countries.[3] While it is true that two-thirds of women in the United States are on some form of contraception,[4] almost half of all unintended pregnancies result from women who use their contraception inconsistently or incorrectly.[5] The remaining fifty-four percent of unintended pregnancies are a result of women who continue to abstain from any contraceptive method at all.[6]

The unintended pregnancy rate is particularly concerning given that childbirths that result from unintended or closely spaced pregnancies are correlated with negative outcomes for the parent and child.[7] For example, research has shown that, compared to women who become pregnant intentionally, "women who experience unintended pregnancies have a higher incidence of mental-health problems, have less stabled romantic relationships, experience higher rates of physical abuse, and are more likely to have abortions or to delay the initiation of prenatal care."[8] Similarly, children resulting from unintended pregnancies are at risk of experiencing negative physical and mental health issues, and "are more likely to drop out of high school and to

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1. *See Unintended Pregnancy in the United States*, GUTTMACHER INST. (July 2015), http://www.guttmacher.org/pubs/FB-Unintended-Pregnancy-US.html ("Currently, about half (51% of the 6.6 million pregnancies in the United States each year (3.4 million) are unintended.").

2. Lisa Campo-Engelstein, *Gender Norms and Contraceptive Trust*, 23 ALB. L. J. SCI. & TECH. 581, 599 (2013).

3. *See Unintended Pregnancy in the United States*, *supra* note 1.

4. *Id.*

5. *See* Campo-Engelstein, *supra* note 2, at 599-600 ("Women who are dissatisfied with their contraceptive method are at high risk for experiencing a gap in contraceptive coverage.").

6. *See Unintended Pregnancy in the United States*, *supra* note 1.

7. *Id.*

8. Adam Thomas & Emily Monea, *The High Cost of Unintended Pregnancy*, CTR. ON CHILDREN AND FAMILIES AT BROOKINGS 2 (July 2011), http://www.brookings.edu/~/media/research/files/papers/2011/7/uninteded-pregnancy-thomas-monea/07_unintended_pregnancy_thomas_monea.pdf.

engage in delinquent behavior during their teenage years."[9]

This paper proceeds in four parts. Part II of this paper details the unintended pregnancy crisis and explains how it can be attributed to dissatisfaction with existing contraceptive products. Part III offers an overview of the past forty years of product liability lawsuits for contraceptive products, and argues that the threat of liability is the reason for the lack of innovation of new, cutting edge contraceptive products. Part IV then explores, in depth, the theories proffered by advocates of federal preemption, ultimately concluding that it is a poor solution and an unnecessarily broad approach to the growing crisis. Having established the fundamental issues and misunderstandings, Part V argues that the most plausible solution to the unintended pregnancy crisis is a no-fault compensation plan for those injured by contraceptive products. Additionally, this Article argues that such a scheme could be modeled around the National Childhood Vaccine Injury Act of 1986 (NCVIA),[10] which has proven to be successful at insulating manufacturers from unpredictable liability[11] as well as stimulating research into cutting edge products.[12] Most importantly, NCVIA has been shown to be extremely effective in offering injured consumers an equitable form of compensation.[13]

II. THE UNINTENDED PREGNANCY CRISIS

A. DISSATISFACTION WITH EXISTING CONTRACEPTIVE METHODS

The Guttmacher Institute has found that the most widely reported reason for contraceptive nonuse or misuse includes dissatisfaction with available contraceptive methods and concerns about side effects of alternatives.[14] For example, the Center for Disease Control (CDC) has found that nearly thirty

9. *Id.*

10. Joanna B. Apolinsky & Jeffrey A. Van Detta, *Rethinking Liability for Vaccine Injury*, 19 CORNELL J. L. & PUB. POL'Y, 537, 551 (2010)

11. Clare Looker & Heath Kelly, *No-Fault Compensation Following Adverse Events Attributed to Vaccination: A Review of International Programmes*, WHO (July 18, 2016), http://www.who.int/bulletin/volumes/89/5/10-081901/en/.

12. *Id.*

13. *Id.*

14. Sneha Barot, *In Search of Breakthroughs: Renewing Support for Contraceptive Research and Development*, 16 GUTTMACHER POL'Y REV. 1, 2 (2013), http://www.guttmacher.org/pubs/gpr/16/1/gpr160124.html.

percent of all users stop using the pill due to side effects that include "nausea, weight gain, sore or swollen breasts, spotting and mood changes."[15] In 2010, a study conducted by the Journal of Family Practice determined that only fifty-seven percent of women on the pill were happy with it.[16] In fact, studies still show that even the use of lower dose hormonal contraceptive pills subjects the user to high risks of depression and decreases in libido.[17] Most other methods of contraception have discontinuation rates of almost fifty percent after one year of use.[18] A more recent report published by the CDC has found that nearly half the women surveyed had discontinued some form of contraception because they disliked it or were concerned about its side effects, and almost one-third of all women tried five or more types of birth control.[19]

Despite the fact that women consistently express dissatisfaction with existing contraception methods, the availability of cutting-edge contraceptive methods remains stagnant.[20] To be clear, there have been important advances since the advent of the pill; developments such as contraceptive implants, patches, and vaginal rings have all attempted to meet the diverse needs of women throughout their reproductive lives.[21] However, these items have predominantly been variations of pre-existing technologies, such as variants of hormone dosage levels and delivery methods as opposed to any significant technological breakthrough.[22] Indeed, a close examination of the contraceptive landscape reveals that all birth control continues to fit into the following four categories: barrier method, hormonal method, natural method, and permanent method.[23] It appears then, that

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15. *See* Nadia Kounang, *For Birth Control, What's Old is New Again*, CNN (Jan. 8, 2015), http://edition.cnn.com/2015/01/08/health/fertility-awareness-methods/ ("Some 30& of women quit hormonal birth control because of the side effects.").

16. Ann Friedman, *Why Isn't Birth Control Getting Better?*, GOOD: A MAGAZINE FOR THE GLOB. CITIZEN (Apr. 24, 2011), https://www.good.is/articles/why-isn-t-birth-control-getting-better.

17. *Id.*

18. *See* Campo-Engelstein, *supra* note 2, at 600.

19. Madeleine Schwartz, *Where's Better Birth Control?*, NEW YORKER (Nov. 21, 2014) http://www.newyorker.com/business/currency/wheres-better-birth-control.

20. *Id.*

21. *See id.* ("There have been some new developments: contraceptive implants, patches, and vaginal rings, like the NuvaRing, free users from having to take a daily pill; ella, a pill that can be taken up to five days after sex, received F.D.A. approval in 2010.").

22. *See* Barot, *supra* note 14, at 1.

23. *What Are The Different Types of Contraception?*, EUNICE KENNEDY SHRIVER

any new contraceptives marketed today are simply modifications of technologies and sciences that are more than fifty years old.[24]

B. RESEARCH AND DEVELOPMENT INTO ALTERNATIVES REMAIN STAGNANT

It should not come as a surprise that technological developments in the contraceptive arena is moribund—investment in this field is at an all-time low.[25] Commercial investment for research of new contraceptive methods accounted for only $33 million in 2013.[26] Pharmaceutical companies are simply not interested in developing contraceptive products. For example, a survey conducted by the Pharmaceutical Research and Manufacturers of America (PhRMA), has indicated that, for 371 female-specific new drugs on the market, only ten were contraceptives; there were, however, "71 new drugs for women's cancers, 55 for arthritis, 45 for autoimmune diseases, 41 for diabetes, and 31 for psychiatric conditions."[27] Since, generally speaking, new drug discovery and development is led by the private sector, it is troubling that most large pharmaceutical and biotechnology companies have largely abandoned the field of contraceptive research and development.[28]

This extreme lull in contraceptive research exists despite clear indications that women are desperately searching for alternative options.[29] For example, a recent study indicated that women would enjoy the option to take the "Pericoital" contraceptive, a discreet alternative to an everyday pill.[30] In effect, Pericoital would allow women a safe option to take a

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NAT'L INST. OF CHILD HEALTH AND HUMAN DEV. (last reviewed Apr. 3, 2013), https://www.nichd.nih.gov/health/topics/contraception/conditioninfo/Pages/types.aspx .

24. Elizabeth Siegel Watkins, *How the Pill Became a Lifestyle Drug: The Pharmaceutical Industry and Birth Control in the United States Since 1960*, 102 AM. J. PUB. HEALTH 1, 1 (2012), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3464843/.

25. *See* Barot, *supra* note 14, at 7-8.

26. Mary Moran et al., *Reproductive Health: R&D For the Developing World*, Pol'y Cures: G-Finder 11 (2014), http://www.policycures.org/downloads/RH%20full%20report.pdf (last visited Aug. 1, 2016).

27. ROBERT A. HATCHER ET AL., CONTRACEPTIVE TECHNOLOGY 437-38 (19th ed. 2007).

28. *See* Barot, *supra* note 14, at 7.

29. *See* Schwartz, *supra* note 19, at 2.

30. Jane K. Cover et al., *Consumer Perspectives on a Pericoital Contraceptive Pill in India and Uganda*, 39(4) GUTTMACHER INST. 1, 6 (2013), https://www.guttmacher.org/pubs/journals/3919513.html (last visited Aug. 1, 2016).

contraceptive before or after sex rather than on an everyday basis.[31] However, as of yet, Pericoital has not been brought to market in the United States.[32] Similarly, movement on a contraceptive gel that women could rub on their arm or leg has been slow, despite reports that the drug could be a revolutionary, and almost side effect-less alternative to the birth control pill.[33] Multipurpose prevention technologies, which would simultaneously protect against pregnancy and sexually transmitted diseases have also been slow to come to market.[34] Finally, while there has been talk for over thirty years about a male contraceptive, none have yet been brought to market in the United States.[35] Commentators have suggested that this lack of contraceptive research development is not a result of any demand-based deficiency.[36]

III. CONTRACEPTIVES AND PRODUCTS LIABILITY

It has been argued that threat of liability is the primary reason for private sector abandonment of the field of contraceptive research and development.[37] Pharmaceutical companies, driven largely by profit, are simply responding to the legitimate threat of large-scale lawsuits. Given the tremendous risk of liability, and the associated damaging publicity, investments in contraceptive

31. Evette Dionne, *A Different Kind of Birth Control Pill*, N.Y. TIMES: THE OPINION PAGES, Jan. 10, 2014, http://www.nytimes.com/roomfordebate/2014/01/01/thinking-beyond-the-birth-control-pill/a-different-kind-of-birth-control-pill.

32. *See id.*

33. Clay Dillow, *Daily Rub-On Contraceptive Skin Gel Could Replace the Pill*, POPULAR SCIENCE, Oct. 26, 2010, http://www.popsci.com/science/article/2010-10/daily-contraceptive-gel-effective-pill-without-side-effects.

34. *See* Schwartz, *supra* note 19, at 2.

35. *Latest Research on New Birth Control Methods*, Epigee Women's Health, http://www.epigee.org/guide/future.html (last visited Aug. 1, 2016).

36. *See* Annette L. Marthaler, *The FDA Defense: A Prescription for Easing the Pain of Punitive Damage Awards in Medical Products Liability Cases*, 19 HAMLINE L. REV. 451, 471 (1996).

37. *See, e.g.*, Jerome F. Strauss III & Michael Kafrissen, *Waiting For The Second Coming: Contraceptive Research Is Seriously in Need of Revitalization*, 432 NATURE 43, 43-44 (Nov. 4, 2004), http://www.nature.com/nature (arguing that liability hinders contraceptive researching, depriving 1.5 billion women of innovative products); Anna Birenbaum, *Shielding the Masses: How Litigation Changed the Face of Birth Control*, 10 S. Cal. Rev. L. & Women's Stud. 411, 423 (2001) (discussing Dalkon Shield and Norplant litigation, arguing that they had devastating impacts for the industry going forward).

products are simply no longer profitable.[38] The history is clear: in the past sixty-five years since the "pill" has been introduced,[39] the contraceptive arena has been plagued by successive, highly publicized product liability lawsuits.[40] The increase in product liability suits also closely corresponds to the rapid departure from the contraceptive market by drug and device manufacturers. For example, prior to the 1970s and 1980s, the United States led the world in contraceptive development.[41] However, today, there are only a few American manufacturers that continue to research and develop contraceptive products.[42] Any person who continues to believe that liability concerns are not heavily influencing pharmaceutical company business decisions should consider the examples below.

A. THE PILL

The pill is arguably the most socially and economically significant invention of the twentieth century. Introduced in the United States in 1960 by G.D. Searle & Co. as nearly 100-percent effective, "Envoid" quickly gained recognition as the most reliable way for women to control their own fertility.[43] However, almost immediately following the oral contraceptive's release, women began to report serious side effects including strokes, blood clots, cancers, birth defects, aneurysms, and heart attacks.[44] Gynecologists, who were often not informed or were simply unaware of the side effects of the pill, frequently dismissed their patients' complaints as exaggerations.[45] Others made the unilateral decision to not advise their patients as to the side effects of the pill, based on the common belief that "women, being very 'emotional,' might overreact. Not wanting to unduly alarm

38. Birenbaum, *supra* note 37, at 423.

39. *The Birth Control Pill: A History*, Planned Parenthood 1, 4 (last updated Mar. 2013), https://www.plannedparenthood.org/files/1213/9611/6329/pillhistory.pdf.

40. NAT'L RESEARCH COUNCIL INST. OF MED., DEVELOPING NEW CONTRACEPTIVES: OBSTACLES AND OPPORTUNITIES 121-22 (Luigi Mastroianni, Jr. et al. eds., 1990), http://www.nap.edu/catalog/1450.html.

41. *See* Birenbaum, *supra* note 37, at 423.

42. *See* Barot, *supra* note 14, at 7.

43. *People & Events: The Side Effects of the Pill*, PBS: Am. Experience, http://www.pbs.org/wgbh/amex/pill/peopleevents/e_effects.html (last visited Aug. 1, 2016).

44. William M. Brown, *Déjà vu All Over Again: The Exodus from Contraceptive Research and How to Reverse It*, 40 BRANDEIS L. J. 1, 26 (2002).

45. *See People & Events: The Side Effects of the Pill*, *supra* note 43.

women, doctors took the decision out of their patients' hands."[46]

It was not long before the product liability suits began to enter the courts. The first case that considered alleged defects in the Envoid pill was that of *Simonait v. Searle*.[47] There, the plaintiff alleged failure to warn and breach of implied warranty after she contracted thrombophlebitis, a blood clot disorder.[48] Following a lengthy jury trial, which included the expert testimony by G.D. Searle's lead investigatory doctors, the jury returned a verdict for the defense.[49] Another early case, *Black v. Searle*,[50] involved G.D. Searle's Envoid. The lawsuit was brought to trial in 1969 and involved a twenty-nine-year-old woman who died from a pulmonary embolism.[51] While the plaintiffs were able to show that, at the time of the woman's death, there were more than 600 reports of thromboembolic phenomena, they still encountered serious problems with respect to proving causation.[52] Ultimately, the jury again found for the defendant, but this time added a recommendation to their verdict, suggesting that G.D. Searle add more intensive warnings to their product.[53]

Motivated by the overwhelming reports from injured women, Barbara Seaman, a leading activist and journalist for the women's health movement, authored a book in 1969 that described the crisis and the urgent need for safer alternatives.[54] In her book, Seaman included testimony from world renowned physicians and researchers who questioned the safety of the pill.[55] The book, along with calls from similar activists,[56] soon prompted the

46. *People & Events: The Pill and The Doctor/Patient Relationship*, PBS: Am. Experience, http://www.pbs.org/wgbh/amex/pill/peopleevents/e_health.html (last visited Aug. 1, 2016).

47. Circuit Court for County of Kent, Grand Rapids, Michigan, Civil Case No. 1916, tried May 18-26, 1965; Joyce Barrett, *Product Liability and the Pill*, 19 CLEV. ST. L. REV. 468, 468 (1970).

48. *Id.*

49. Circuit Court for County of Kent, Grand Rapids, Michigan, Civil Case No. 1916, tried May 18-26, 1965; Barrett, *supra* note 47, at 469.

50. U.S. Dist. Ct. of Northern District of Indiana—South Bend Division, Civil Case No. 4082 (1969); Barrett, *supra* note 47, at 469.

51. *Id.*

52. Barrett, *supra* note 47, at 469.

53. *Id.* at 470.

54. Brown, *supra* note 44, at 26.

55. *See People & Events: The Side Effects of the Pill*, *supra* note 43.

56. *People & Events: The Senate Holds Hearings on the Pill (1970)*, PBS: American Experience, http://www.pbs.org/wgbh/amex/pill/peopleevents/e_hearings.html (last visited Aug. 1, 2016).

United States Senate to hold hearings in January 1970 to address the widespread adverse events.[57] Almost immediately after the hearings, hormone levels in the pill were decreased to a small fraction of what they were originally.[58] Despite the lower doses, product liability lawsuits continued through the 1970s and 1980s, but saw limited success as the pills became safer and the warnings more comprehensive.[59]

B. DALKON SHIELD

The Dalkon Shield, invented in 1968, was a device that was inserted into a woman's uterus that prevented the implantation of a fertilized egg.[60] The intrauterine device, commonly known as the "IUD," was engineered with spikes along its edges to prevent instances of natural expulsion from the body.[61] The IUD also contained a string that passed from the uterus into the vagina.[62] Based upon an impressive, year-long study in which the device purportedly achieved a 98.9-percent success rate,[63] the device was picked up by the A.H Robins Company in 1970.[64] From the device's inception, doctors, scientists, and sources within the company advised that the product could potentially cause pelvic infections, septic abortions, and higher-than-reported pregnancy rates.[65] Despite the ominous warnings, A.H. Robins Company

57. Michael J. Malinowski, *Doctors, Patients, and Pills—A System Popping Under Too Much Physician Discretion? A Law-Policy Prescription to Make Drug Approval More Meaningful in the Delivery of Health Care*, 33 CARDOZO L. REV. 1085, 1086 (2012).

58. *Id.* at 1087.

59. Sylvia A. Law, *Tort Liability and the Availability of Contraceptive Drugs and Devices in the United States*, 23 N.Y.U. REV. L. & SOC. CHANGE 339, 381 (1997).

60. *Id.* at 362-63.

61. Lucy Vernasco & Arikia Millikan, *The IUD's Long Path to Redemption*, MOTHERBOARD (Apr. 24, 2015), http://motherboard.vice.com/read/the-iuds-long-path-to-redemption.

62. Anna C., *"Instrument of Torture": The Dalkon Shield Disaster*, Planned Parenthood Advocates of Ariz. (Mar. 28, 2016), http://advocatesaz.org/2016/03/28/instrument-of-torture-the-dalkon-shield-disaster/.

63. Robert L. Shirley, *The Dalkon Shield in Private Practice: A Disappointment, in* 121 AM. J. OF OBSTETRICS & GYNECOLOGY 564 (1975).

64. Ron Wolf, *A.H. Robins' Struggle Is Over the End of a Dream – And of a Nightmare*, PHILLY.COM (July 5, 1987), http://articles.philly.com/1987-07-05/business/26198061_1_robins-board-robins-family-claiborne-robins.

65. Russell Mokhiber, *The Dalkon Shield: A Deadly Product from A.H. Robins*, 8 MULTINATIONAL MONITOR: CORP. CRIME & VIOLENCE 1, 2-3 (1987), http://multinationalmonitor.org/hyper/issues/1987/04/ahrobins.html (An internal A.H. Robins memo informed almost 40 A.H. Robins executives, just before the Shield entered the market, of the dangerous, wicking properties of the string.).

marketed the product to the public as "[t]he modern superior I.U.D. [providing] safe, sure, sensible contraception."[66] By 1973, over three million women were using the new contraceptive product.[67]

Almost immediately, women began reporting adverse effects associated with the shield, including pain and bleeding, uterus perforation, and infections that led to miscarriages, stillbirths, and death.[68] Once again, A.H. Robins Company became aware of the reports, but did little to warn doctors about the risks.[69] The company also failed to investigate the reports.[70] Finally, in 1974, the American Journal of Obstetrics and Gynecology, along with the FDA, pressured A.H. Robins Company to suspend the manufacture and sale of the Dalkon Shield in the United States until the product's dangers could be more thoroughly investigated.[71] However, it was not until 1980 that the company sent letters to women, urging that they have their Dalkon Shields removed, and telling them that A.H. Robins Company would cover all associated expenses.[72]

The first wave of lawsuits against A.H. Robins Company commenced in 1974.[73] Known for insinuating that the injured woman's hygiene and sexual misconduct was the impetus for the injury, A.H. Robins Company won a number of successive defense verdicts.[74] In fact, in the 1970s, the company was only required to pay out an average of $11,000 per claim.[75] However, in 1983, the tide turned for plaintiffs when the small firm handling a

66. Palmer v. A.H. Robins Co., 684 P.2d 187, 195-96 (Colo. 1984).

67. *See* Law, *supra* note 59, at 364.

68. *See* Mokhiber, *supra* note 65, at 2.

69. *Id.*

70. *Id.*

71. *See* Law, *supra* note 59, at 365.

72. David Ranii, *First Public Federal Disciple Hearing*, 6 Jud. Conduct Rep. 1, 5 (1984) ("Robins took the Dalkon Shield off the market in 1974 and, in 1980, mailed a letter to 200,000 physicians and government agencies recommending the removal of the device from any women still using it. But the product has never been recalled, and critics of the shield believe an untold number of women are still wearing it today.").

73. Charles A. Homsy, *How FDA Regulations and Injury Litigation Cripple the Medical Device Industry*, USA TODAY (July 2003), http://www.questia.com/magazine/1G1-104971300/how-fda-regulations-and-injury-litigation-cripple.

74. *See* Mokhiber, *supra* note 65, at 3-4 ("At trial, the company has, in some instances, sought to defend itself by shifting the blame to the victims. A.H. Robins' attorneys have argued that frequent sexual intercourse with multiple partners could cause injuries currently being blamed on the shield.").

75. *See* Law, *supra* note 60, at 366.

majority of the cases was forced to pass the cases to a large and experienced Minneapolis-based firm Robins, Zelle, Larson and Kaplan.[76] Led by high-powered attorneys, Dale Larson and Michael Ciresi, the plaintiffs managed to consolidate a number of their cases and secured successive multi-million dollar verdicts based on defective design and willful negligence claims.[77] News of Ciresi's and Larson's victories soon emboldened other plaintiffs' attorneys to pursue Dalkon Shield cases.[78] Faced with billions of dollars in liability exposure and damaging press, A.H. Robins Company filed for bankruptcy in 1986.[79]

Kirsten Thompson, researcher at the University of California, San Francisco, noted the effect that A.H. Robins Company's bankruptcy had on the industry: "The idea that a company could go bankrupt because of a contraceptive product was pretty horrifying."[80] Indeed, Dalkon Shield litigation and the resulting bankruptcy cast a shadow over IUD development for the past thirty years.[81] From 1983 to 1988, not a single IUD was marketed in the United States, as the horror stories still lingered in women's consciences.[82] In 1988, a newer type of IUD, "Paragarud," was introduced but achieved limited success.[83] It took another eleven years until "Mirena," a modern version of the hormonal IUD was developed.[84] Mirena has seen more success than previous IUDs,[85] but manufacturers, still tentative about future liability, have consistently charged astronomical prices for these devices at approximately $500 to $800 per device.[86]

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76. Richard B. Sobol, Bending the Law: THE STORY OF THE DALKON SHIELD BANKRUPTCY 16 (1991).

77. *Guide to the Dalkon Shield Claimants Trust Collection*, VIRGINIA HERITAGE (2002), http://ead.lib.virginia.edu/vivaxtf/view?docId=uva-law/viu00041.xml.

78. *Robins, Kaplan, Miller & Ciresi L.L.P.*, ENCYCLOPEDIA.COM (2006), http://www.encyclopedia.com/doc/1G2-2690500085.html.

79. Ultimately, over $3 billion was paid to Dalkon Shield victims. *See* THOMAS H. KOENIG & MICHAEL L. RUSTAD, IN DEFENSE OF TORT LAW 119 (2001).

80. *See* Schwartz, *supra* note 19, at 3.

81. *Id.* at 2.

82. Clare L. Roepke & Eric A. Schaff, *Long Tail Strings: Impact of the Dalkon Shield 40 Years Later*, OPEN J. OBSTETRICS & GYNECOLOGY 996, 1001 (2014).

83. Martha Kempner, *FDA Approves New IUD Designed to Be More Affordable*, RH Reality Check (Mar. 13, 2015), http://rhrealitycheck.org/article/2015/03/13/fda-approves-new-iud-designed-affordable/.

84. *See* Roepke & Schaff, *supra* note 82, at 1001-02.

85. *See The IUD Is Getting More Popular in America. Here's Why*, HUFFINGTON POST (Mar. 10, 2015), http://www.huffingtonpost.com/2015/02/24/iud-birth-control_n_6736218.html.

86. *More US Women Choosing IUDs for Birth Control*, FOX NEWS (Aug. 2, 2012), http://www.foxnews.com/health/2012/08/02/more-us-women-choosing-iuds-for-birth-

Moreover, thirty-percent of health providers continue to be unconvinced of the safety of IUDs for women who have never given birth.[87] This is despite the fact that the newest IUD devices have proven to be extraordinarily safe and are no endorsed by the American College of Obstetricians and Gynecologists.[88]

C. NORPLANT

Norplant was the first implant contraceptive marketed in the United States.[89] The drug consisted of six hormone-releasing, silicone coated rods implanted under the skin in the arm.[90] The drug was essentially a new delivery method for levonorgestrel, a manufactured hormone previously used in the pill forms of birth control.[91] The drug, which cost upwards of $114 million to develop,[92] boasted an effectiveness period of five years.[93] First introduced by the New York based non-profit, "Population Council,"[94] and eventually brought to market by Wyeth-Ayerst in 1991,[95] Norplant became one of the most popular contraceptives in the United States.[96] As of 1995, nearly one million United States women, and 2.5 million women worldwide, used the Norplant device.[97] In sharp contrast to the Dalkon Shield, Norplant underwent comprehensive studies before being

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control.html.

87. *Id.*

88. *Id.*

89. *The Single-Rod Contraceptive Implant*, ASS'N OF REPROD. HEALTH PROF'LS (July 2008), http://www.arhp.org/publications-and-resources/clinical-proceedings/Single-Rod/History.

90. *Drug Company Draws Criticism for Norplant Pricing*, ORLANDO SENTINEL (Sept. 7, 1993), http://articles.orlandosentinel.com/1993-09-07/business/9309030724_1_norplant-ayres-planning-clinic.

91. *See* Brown, *supra* note 44, at 30.

92. Christopher Connell, *Norplant Developer Accused Of Making Excessive Profits*, SEATTLE TIMES (Nov. 11, 1993), http://community.seattletimes.nwsource.com/archive/?date=19931111&slug=1731089.

93. *Id.*

94. *See The Single-Rod Contraceptive Implant*, *supra* note 89.

95. *See Drug Company Draws Criticism for Norplant Pricing*, *supra* note 90.

96. CONTRACEPTIVE RESEARCH, INTRODUCTION, AND USE: LESSONS FROM NORPLANT 110 (Polly F. Harrison & Allan Rosenfield eds., 1998).

97. Sharon Cohen, *Norplant Lawsuits Flourish Along With Women's Reports of Problems: Medicine: Some Who Have Used the Implanted Contraceptive Have Reported Serious Side Effects. The Drug Company Defends its Product and Blames Predatory Lawyers for the Furor.*, L.A. TIMES (Oct. 8, 1995), http://articles.latimes.com/1995-10-08/news/mn-54703_1_side-effects/2.

introduced to the market.[98] Additionally, Norplant was much more straightforward with respect to listing potential side effects in its marketing campaign than was Dalkon Shield.[99]

Inspired by the large verdicts in the Dalkon Shield lawsuits of the 1980s,[100] plaintiffs attorneys boasted thousands of claimants that complained of "the now-discredited shifting constellation of symptoms . . . [of] . . . an ill-defined array of auto-immune disorders."[101] Initially attributed to the silicone casting on the implant,[102] and eventually to the hormones within the implant itself,[103] symptoms were almost always reversible and dissipated once the device was removed from the patient.[104] Despite the comparatively benign nature of the product and the comprehensiveness of the warnings on the device,[105] there were soon several class action suits pending against the manufacturer of Norplant.[106] By 1995, as many as 50,000 women alleged serious personal injury lawsuits against the manufacturer, with the claims being consolidated in federal court.[107]

Finally, in 2002, after a tumultuous decade of litigation and faltering sales of the device, Wyeth suspended sales of Norplant in the United States.[108] While Norplant had managed to achieve significant legal victories and favorable settlement

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98. *See Research, Introduction, and Use: Advancing From Norplant*, NAT'L CTR. FOR BIOTECHNOLOGY INFO. (Dec. 1998), http://www.ncbi.nlm.nih.gov/pubmed/10095968.

99. Birenbaum, *supra* note 37, at 430. Birenbaum provides a compelling case that Norplant is a safe, convenient, and effective contraceptive product that was destroyed by plaintiffs' attorneys and poor publicity.

100. Jennifer Mesko, *Mirena IUD Litigation Revives Memories of Dalkon Shield Injuries*, DRUGWATCH (June 28, 2013), http://drugwatch.com/2013/06/28/mirena-litigation-dalkon-shield-injuries/.

101. Mark Arkin, *Products Liability and the Threat to Contraception*, MANHATTAN INST. 1, 8-9 (Feb. 1, 1999), http://www.manhattan-institute.org/html/cjm_36.html.

102. *See* Brown, *supra* note 44, at 33.

103. *Id.* at 33-34.

104. *Id.*

105. *Id.*

106. L. Stuart Ditzen, *How A Promising Contraceptive Fell Victim To Lawsuits Norplant's Pa. Maker Has Spent Millions Defending It. Those Who Have Sued Have Yet to Win A Cent, Or A Major Court Ruling*, PHILLY.COM (Dec. 30, 1998), http://articles.philly.com/1998-12-30/news/25722492_1_norplant-lawsuits-side-effects-wyeth-ayerst-laboratories.

107. Steven Garber, ECONOMIC EFFECTS OF PRODUCT LIABILITY AND OTHER LITIGATION INVOLVING THE SAFETY AND EFFECTIVENESS OF PHARMACEUTICALS, RAND INST. FOR CIVIL JUSTICE 38 (2013).

108. *See* Garber, *supra* note 107, at 38-39.

negotiations,[109] the Norplant device was simply unable to recover from the negative publicity.[110] Such publicity caused sales of the drug to plunge dramatically, from 800 units per day in 1993, to sixty units per day in 1995.[111] Sadly, Norplant has since been shown to be one of the most highly efficacious contraceptives ever marketed, with failure rates just under one-percent.[112] Most significantly, it has been shown that some of the worst side effects tend to peter out by the end of the first year of use.[113] Anna Birnbaum, a notable female health scholar, notes that the real loser of the Norplant litigation was women, who no longer have access to an otherwise safe and effective birth control method.[114]

D. RECENT LAWSUITS

Following the Norplant litigation, a few other contraceptive-related personal injury lawsuits have grabbed headlines. "Yasmin" and "Yaz" were contraceptive pills brought to the United States market by Bayer in 2001 and 2006, respectively.[115] Both products contain a blend of synthetic hormones known as drospirenone and ethinyl estradiol,[116] although Yaz contains a lower level of ethinyl estradiol than Yasmin.[117] These two hormones are meant to control ovulation and vaginal fluid levels to prevent egg fertilization.[118] Both products initially showed

109. David J. Morrow, *Maker of Norplant Offers a Settlement in Suit Over Effects*, N.Y. TIMES (Aug. 27, 1999), http://www.nytimes.com/1999/08/27/us/maker-of-norplant-offers-a-settlement-in-suit-over-effects.html.

110. *Id.*

111. Shari Roan, *The Chill in Birth Control Research*, L.A. TIMES (Mar. 23, 1998), http://articles.latimes.com/1998/mar/23/news/mn-31897.

112. *See* CONTRACEPTIVE RESEARCH, INTRODUCTION, AND USE: LESSONS FROM NORPLANT, *supra* note 96, at 38.

113. *Id.* at 12.

114. *See* Birenbaum, *supra* note 37, at 412-13.

115. Gordon Gibb, *10,000 Yaz and Yasmin Lawsuits Just a Cost of Doing Business?*, LAWYERSANDSETTLEMENTS.COM (Feb. 28, 2014), https://www.lawyersandsettlements.com/articles/yasmin-side-effects-yaz-blood/yasmin-birth-control-lawsuit-side-50-19560.html.

116. *Drospirenone And Ethinyl Estradiol (Oral Route)*, MAYO CLINIC (Jan. 1, 2016), http://www.mayoclinic.org/drugs-supplements/drospirenone-and-ethinyl-estradiol-oral-route/description/drg-20061917.

117. A.D.A.M., Inc., *Birth Control and Family Planning*, N.Y. TIMES (Dec. 18, 2013), http://www.nytimes.com/health/guides/specialtopic/birth-control-and-family-planning/oral-contraception-and-combination-hormonal-methods.html.

118. *Zarah: Ethinyl Estradiol/Drospirenone*, WEBMD, http://www.webmd.com/drugs/2/drug-154621-5115/zarah-oral/ethinylestradiol-drospirenone-oral/details (last visited Aug. 1, 2016).

great promise in preventing pregnancy and having convenient off-label uses, including the treatment of hormone-related acne.[119] By 2009, however, the love affair with the new blend was over, with these "fourth generation" contraceptive pills becoming involved in high-profile product liability lawsuits.[120] Otherwise healthy patients were dying or sustained injuries from pulmonary embolisms, deep vein thrombosis, and other blood clothing conditions.[121] As of April 2014, Bayer had negotiated Yaz and Yasmin lawsuit settlements with about 8,560 claimants in the United States.[122] To date, Bayer has paid $2 billion to settle Yasmin and Yaz litigation.[123]

The German pharmaceutical giant is also facing a new wave of lawsuits concerning complications caused by its "Mirena" IUS birth control devices and its "Essure" permanent birth control devices.[124] Mirena is the first IUD marketed since Dalkon Shield,[125] and has been the subject of large-scale lawsuits over allegations that its warning label inadequately cautioned against the risk of side effects such as uterine perforation and migration.[126] To date, 1,163 claims have been filed against Bayer for injuries resulting from its device.[127] Many commentators have drawn comparisons to Dalkon Shield litigation, suggesting that the Mirena litigation is eerily reminiscent of that era.[128] "Essure,"

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119. *Yaz*, DRUGS.COM, http://www.drugs.com/yaz.html (last visited Aug. 1, 2016).

120. *Yaz/Yasmin Products Liability Litigation: February 2014 Bayer Information About the Number of Claims, Lawsuits, and Settlements*, DRUG INJURY WATCH (Mar. 12, 2014) (posted by Tom Lamb), http://www.drug-injury.com/druginjurycom/2014/03/yaz-beyaz-yasmin-safyral-lawsuits-filed-claims-unfiled-total-settlements-bayer-litigation-report-february-2014-information.html.

121. *Id.*

122. *Yaz Lawsuit Settlements*, DRUG REP. (Apr. 23, 2015), http://drugreporter.com/yaz/lawsuit-settlements/.

123. Austin Kirk, *Bayer Still Faces 4,000 Yaz and Yasmin Lawsuits, Even After $2B in Settlements*, ABOUTLAWSUITS.COM (July 21, 2015), http://aboutlawsuits.com/yaz-yasmin-lawsuits-after-settlements-85394/.

124. Laura Woods, *Essure Lawsuits Cite Issues Similar to Mirena IUD Complications*, Surgical Watch (June 4, 2015), http://surgicalwatch.com/2015/06/essure-lawsuits-cite-issues-similar-mirena-iud-compliactions/.

125. Jennifer Mesko, *Mirena IUD Litigation Revives Memories of Dalkon Shield Injuries*, Drugwatch (June 28, 2013), http://drugwatch.com/2013/06/28/mirena-litigation-dalkon-shield-injuries/.

126. Eleanor Smith, *Mirena IUD's Harmful Side Effects Lead to Multidistrict Litigation*, Nat'l Trial Lawyers (Sept. 2, 2015), http://www.thenationaltriallawyers.org/2015/09/mirena-iud-harming-women/.

127. *Id.*

128. *See* Mesko, *supra* note 125.

on the other hand, involves the insertion of two metal coils inside the fallopian tube and is meant to instigate a natural tissue inflammation response to block sperm.[129] Litigation on Essure has just started to get off the ground, with the first lawsuit being filed in 2014.[130] While the precise implications of the Mirena and Essure litigation is still unclear, these lawsuits suggest that Bayer will approach with caution its investments in additional cutting-edge products.

IV. THE RISE OF FEDERAL PREEMPTION

The mass tort litigation that has plagued the pharmaceutical and medical device industry over the past thirty years has spurred greater interest from commentators, scholars, and politicians in offering manufacturers immunity from product liability lawsuits.[131] In support of immunity, legal commentators and defense attorneys have pointed to the strong basis "that product liability has been a major factor in discouraging efforts to develop new contraceptives."[132] Simply speaking, the threat of liability and subsequent negative publicity has lessened the economic incentives to become involved in "high risk" medical products. Over the past ten years, supporters of immunity have successfully advocated for judicial recognition of the affirmative defense of federal preemption to shield manufacturers from burdensome liability.[133]

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129. *How Does the Essure® Procedure Work?*, Essure: Permanent Birth Control (Mar. 2016), http://www.essure.com/what-is-essure/how-essure-works.

130. Lauren Gilger, *Federal Judge to Decide on Lawsuits Challenging Protected Status of Essure Birth Control*, ABC 15 (June 8, 2015), http://www.abc15.com/news/local-news/investigations/federal-judge-to-rule-on-lawsuits-challenging-protected-status-of-essure-birth-control.

131. *See, e.g.*, Joseph F. Petros III, *The Other War on Drugs: Federal Preemption, the FDA, and Prescription Drugs After Wyeth v. Levine*, 25 NOTRE DAME J. L. ETHICS & PUB. POL'Y 637, 661 (2012) ("[D]enying federal preemption in prescription drug regulation will deter innovation in the pharmaceutical industry."); Lisa M. Mottes, *The Need for Federal Preemption of State Tort Claims in the Context of "New Drugs" and Premarket-Approved Medical Devices*, 41 SETON HALL L. REV. 723, 726 (2011) (arguing the FDCA should be amended to include express preemption provision for new drugs); *and* RICHARD EPSTEIN, OVERDOSE: HOW EXCESSIVE GOVERNMENT REGULATION STIFLES PHARMACEUTICAL INNOVATION 201 (2006) (arguing federal preemption is preferable to product liability litigation).

132. *See* Garber, *supra* note 107, at xiv.

133. Eric Lindenfeld & Jasper L. Tran, *Beyond Preemption of Generic Drug Claims*, 45 Sw. L. Rev. 101, 104 (2016) ("While the Supreme Court has historically abided by a strong presumption against implied preemption, the Court has displayed a growing willingness to reverse their traditional preemption doctrine. This is especially true in their decisions relating to the FDCA and the preemption of claims

A. FEDERAL IMPOSSIBILITY PREEMPTION

The doctrine of preemption originates from the Supremacy Clause of the United States Constitution, which states that federal law "shall be the supreme law of the land. . . . [A]ny Thing in the Constitution or Laws of any State to the contrary notwithstanding."[134] The Supreme Court has since recognized that State laws that conflict with federal law are "without effect."[135] There are two ways that a federal law and a state law can "conflict," either expressly or impliedly.[136] The doctrine of "express preemption" is self-explanatory, applied when federal legislation or regulation includes language expressly preempting state law.[137] Implied preemption is applied in three scenarios: (1) "where state law creates an *obstacle* for compliance with federal law"; (2) where federal law "occupies an entire *field* so as to create an 'inference of federal exclusivity'"; or (3) "where it is *impossible* for one to comply with both federal and state law."[138] Over the past six years, pharmaceutical companies have been arguing in favor of the third option, also known as "impossibility preemption."[139] As this argument goes, it is impossible to comply with state law tort standards while simultaneously complying with its duties under the federal, Food Drug and Cosmetic Act (FDCA).[140] Therefore, companies argue that state law tort standards should be preempted and plaintiffs should be barred from bringing state tort lawsuits relating to the drug or device in

made against manufacturers of generic drugs.").

134. U.S. CONST. art. VI, cl. 2.

135. Maryland v. Louisiana, 451 U.S. 725, 746 (1981); McCulloch v. Maryland, 17 U.S. 316, 427 (1819); *See also* Gade v. Nat'l Solid Wastes Mgmt. Ass'n, 505 U.S. 88, 108 (1992) (internal quotation omitted) ("[U]nder the Supremacy Clause, from which our pre-emption doctrine is derived. 'any state law, however clearly within a State's acknowledged power, which interferes with or is contrary to federal law, must yield.'"); Felder v. Case, 487 U.S. 131, 138 (1988).

136. Tyler W. Olson, *The Supreme Court's Overreaching Preemption Interpretation and Its Consequences: Granting Generic Drug Manufacturers Legal Immunity Through "The Duty of Sameness" in* Mutual Pharmaceutical Co. v. Bartlett *and* PLIVA v. Mensing, 12 Ind. Health L. Rev. 769, 783 (2015) (citing Jennifer S. Hendricks, *Preemption of Common Law Claims and the Prospects for FIFRA: Justice Stevens Puts the Genie Back in the Bottle*, 15 Duke Envtl. L. & Pol'y F 65, 69 (2004)).

137. *Id.*

138. *Id.* at 784 (quoting Hendricks, *supra* note 136, at 70).

139. *See* Lindenfeld & Tran, *supra* note 133, at 105 ("Over the past five years, the Supreme Court has addressed whether the ANDA approval process and its corresponding federal 'sameness' requirement, conflicts with duties imposed by state tort law.").

140. *Id.* at 106.

question.[141]

B. PHARMACEUTICAL PREEMPTION

The FDCA requires FDA approval for a new drug through its "New Drug Approval" (NDA) process.[142] Understanding that the NDA process is often prohibitively expensive, and recognizing the need to stimulate the market for generic drugs, Congress eventually implemented the less-arduous Abbreviated New Drug Application (ANDA) approval process.[143] The ANDA approval process, which is meant to be a less demanding standard than the NDA, only requires that a generic manufacturer show that the drug it seeks to have approved is bioequivalent to an already approved NDA-approved drug.[144] Additionally, the generic manufacturer applying for ANDA approval must ensure that the generic drug's label always matches its brand-name counterpart.[145] Any dissimilarity between the two labels will cause the generic drug's ANDA application to be denied.[146] These requirements have been dubbed as the "duty of sameness."[147] Over the past six years, large generic manufactures have successfully argued that they were unable to comply with state law tort standards because of the ANDA regulations that require "sameness" in bio-content and warnings of the generic and brand name drug.[148]

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141. *Id.* at 108.

142. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355).

143. Colleen Kelly, *The Balance Between Innovation and Competition: The Hatch-Waxman Act, the 2003 Amendments, and Beyond*, 66 FOOD & DRUG L. J. 417, 426 (2011) ("This shorter, less-expensive ANDA mechanism for receiving drug approval has created a boom in the generic drug industry.").

144. 21 U.S.C.A. § 355(j)(2)(A)(iv) (West 2013); *see also* Kelly, *supra* note 143, at 417 ("Instead of having to submit lengthy preclinical and clinical data demonstrating the drug's safety and efficacy to FDA, like that required in an innovator's New Drug Application ('NDA'), the only scientific data that a generic manufacturer must submit to FDA is data that the drug is 'bioequivalent' to the pioneer drug.").

145. 21 U.S.C. § 355(j)(2)(A)(i) (2012). Certain exceptions to this requirement may apply.

146. 21 U.S.C. §§ 355(d)(7), (j)(2)(A)(i) (2012).

147. Danielle L. Steele, *The "Duty of Sameness" as a Shield—Generic Drug Manufacturers' Tort Liability and the Need for Label Independence After PLIVA, Inc. v. Mensing*, 43 SETON HALL L. REV. 441, 483-84, 487 (2013) (citing PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2574-75, 2593 (2011)).

148. Caitlin Sawyer, *Duty of "Sameness"?:* Bartlett *Preserves Generic Drug Consumers' Design Defect Claims*, 54 B.C. L. REV. 1, 10 (Jan. 31, 2013), http://lawdigitalcommons.bc.edu/cgi/viewcontent/cgi?article=3281&context=bclr.

For example, in 2009, in *PLIVA v. Mensing*,[149] the United States Supreme Court ruled that the plaintiff's state law, failure-to-warn claims were preempted because it was impossible for the generic manufacturer to create more robust, and inclusive, warnings without violating the federal rules regarding "sameness."[150] Similarly, in 2013, in *Mutual Pharmaceutical Co. v. Bartlett*,[151] the Supreme Court applied the same reasoning to preempt design defect claims made against the manufacturer of the generic drug, Clinoril.[152] Relying heavily upon the reasoning in *Mensing*, the Court ruled that New Hampshire's common law duty to ensure that a product's design is adequate was preempted by the federal law that forbids a generic manufacturer from making any unilateral changes to a drug's design that would cause it to differ from the brand name.[153]

Recently, courts have begun to extend the reasoning in *Mensing* and *Bartlett* beyond claims against generic manufacturers to apply to brand name manufacturers.[154] For example, in 2015, in *Yates v. Ortho-McNeil-Janssen Pharmaceuticals, Inc.*,[155] the Sixth Circuit became the first appellate authority to extend the *Bartlett* design-defect preemption rationale to a brand name drug.[156] In *Yates*, a woman suffered a severe stroke one week after beginning the Ortho Evra contraceptive patch.[157] The court ruled that, because the pharmaceutical company could not make major, unilateral changes to the composition of a drug post-approval, it was impossible for the company to comply with the New York tort standards relating to defectively designed products.[158] James Beck, leading medical device and pharmaceutical product liability scholar, has tallied five other lower-court decisions that have applied impossibility preemption to brand name drug products—a notable shift in the preemption landscape to an even more

149. 131 S. Ct. 2567 (2011).

150. *Id.* at 2570, 2578 (2011); *see also id.* at 2582 (Sotomayor, J., dissenting).

151. 133 S. Ct. 2466 (2013).

152. *Id.* at 2477-78.

153. *Id.* at 2470, 2477.

154. James M. Beck, *Another Decision Applying Bartlett Preemption to All Drugs*, DRUG & DEVICE L. BLOG (Oct. 5, 2015), http://druganddevicelaw.blogspot.com/2015/10/another-decision-applying-bartlett.html; *see also Bartlett*, 133 S. Ct. at 2471.

155. 808 F.3d 281 (6th Cir. 2015).

156. *Id.* at 293

157. *Id.* at 288.

158. *Id.* at 300.

inclusive regime.[159]

C. MEDICAL DEVICE PREEMPTION

Like pharmaceutical products, certain classes of medical devices are required to undergo significant FDA testing before approval.[160] And, also like pharmaceutical products, courts have authoritatively construed the Medical Device Amendments (MDA) to the FDCA to preempt any claims made against certain classes of medical device products.[161] For example, in 2008, in *Riegel v. Medtronic*,[162] the Supreme Court denied a design defect claim made against a device manufacturer on the grounds that state law claims were expressly preempted by the MDA.[163] Justice Scalia, writing for the majority, was rather forthright with respect to the growing skepticism of excessive liability for medical device and drug manufacturers when he stated that tort liability under negligence or strict liability is "less deserving of preservation" in the face of federal regulations.[164] Many scholars have attributed this skepticism to preemption's rise and have noted that "[e]ven when courts are using the language of preemption doctrine, they may to some extent be seeking to reform products liability litigation."[165]

Interestingly, there has been a recent push to apply impossibility preemption to 510(k) approved products by utilizing the same theories developed in *Mensing*.[166] The 510(k) approval is the medical device equivalent to the generic drug, ANDA

159. *See* Beck, *supra* note 154 ("Just last month we collected all the favorable precedent applying impossibility preemption under [Bartlett] to innovator drugs – although the precise subject of that post was preemption of design defect claims involving § 510(k) medical devices. We were aware of four such rulings, all in the last year or so: [Yates]; Shah v. Forest Laboratories, Inc.; Booker v. Johnson & Johnson; [and] Amos v. Biogen Idec, Inc.") (internal citations omitted).

160. *See* Robin Helmick Turner, *Preemption of State Product Liability Claims Involving Medical Devices: Premarket Approval as a Shield Against Liability*, 72 WASH. L. REV. 963, 965-68 (1997).

161. *Id.* at 963, 973-74, 976, 990, 994.

162. 552 U.S. 312.

163. *Id.* at 316, 321

164. *Id.* at 325.

165. Richard L. Cupp Jr., *Preemption's Rise (and Bit of a Fall) as Products Liability Reform:* Wyeth, Riegel, Altria, *and the* Restatement (Third)*'s Prescription Product Design Defect Standard*, 74 BROOK. L. REV. 727, 729 (2009).

166. James M. Beck, *In Case of Good Judge, Break Glass – Implied Impossibility Preemption in Cases Involving § 510(k) Cleared Medical Devices*, LEXOLOGY (Sept. 24, 2015), http://www.lexology.com/library/detail/aspx?g=c2c67d65-2032-4bca-a382-0550cd82de10.

approval process.[167] 510(k) products have not traditionally been subject to the protections offered by the MDA express preemption.[168] As a result, this category of devices has been the prime target of a litany of state tort law claims over the past five years.[169] James Beck touches on these recent developments in a recent article, arguing that the 510(k) "substantial equivalence" process is amenable to a "duty of sameness" type of argument as used in the *Mensing* and *Bartlett* decisions.[170] While no known cases have yet to utilize such an argument, we should expect to see defendants test the boundaries of the MDA's precise preemptive scope.

D. FEDERAL PREEMPTION IS A POOR SOLUTION TO THE GROWING CRISIS

Despite data suggesting that manufacturers may respond positively to a decrease in potential liability,[171] federal preemption is an unnecessarily broad, and draconian approach, with concerning implications for those injured by medical and pharmaceutical products.[172] Under a federal preemption regime, all users of medical and pharmaceutical products are barred from bringing any claims under either strict liability or negligence theories.[173] This problem is particularly troublesome for women, who have historically suffered more severe, physically grotesque and personal injures than the typical consumer, and are now at an even greater risk of being barred from any form of compensation.[174] This is especially true for low-income women, who are more likely to opt for the generic substitute of any oral contraceptive product—liability for which has already been

167. *Id.*

168. *Id.*

169. *See id.*

170. *See id.* Beck cautions defense attorneys that such an approach should only be taken "[i]n cases where you believe this novel defense-side argument will receive fair consideration and bears a colorable chance of success."

171. Lindsey K. Peterson, *Evading Preemption: The State's Search for Recovery for the Masses*, 9 CHARLESTON L. REV. 403, 424 (2015).

172. *Id.* at 404.

173. *See* Lindenfeld & Tran, *supra* note 133, at 103, 108, 110, 112-13; *see also* Jesse Morris, *Third Circuit Confirms Preemption Scope of Mensing and Bartlett*, PRODUCT LIAB. MONITOR (May 6, 2014), http://product-liability.weil.com/preemption/third-circuit-confirms-preemption-scope-of-mensing-and-bartlett/.

174. Thomas Koenig & Michael Rustad, *His and Her Tort Reform: Gender Injustice in Disguise*, 70 WASH. L. REV. 1, 24, 29, 48, 53-54 (1995).

foreclosed by the holdings in *Mensing* and *Bartlett*.[175]

Federal preemption may even contribute to a decrease in the use of contraceptive products, and, thus, to an increase in the unwanted pregnancy rate.[176] Women, who will have inevitably heard of the succession of contraceptive failures and injuries, will also be aware that they are now at risk for a lack of compensation should they be injured. These women will increasingly turn to more benign, and less effective, modes of birth control.[177] Similarly, doctors will turn to prescribing lower risk, and less effective, contraceptive products to insulate themselves from potential liability arising from the use of contraceptive products.[178] In this sense, federal preemption will also have a cooling effect on the market for contraceptive products that offsets any benefits that might be achieved through insulation of liability.

Most importantly, proponents of federal preemption place too much faith upon the FDA regulatory process in ensuring that a product is dispenses at its maximum safety levels.[179] The threat of liability has been determined to be one of the most significant motivators in ensuring that manufacturers engage in thorough pre- and post-market testing of their products.[180] Indeed, the FDA sets only a minimum threshold of safety and does not require or encourage vigorous aftermarket studies.[181] Furthermore, pre-

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175. *See* Lindenfeld & Tran, *supra* note 133, at 109 ("This void in pre-market and post-market safety for generic drugs is particularly troubling considering that the market for generic drugs increases exponentially every year, and that the primary consumers of generic drugs are low income." (citing Daniel Perrone, *Crafting an Exception to the* Mensing *Ruling*, JURIST (Apr. 11, 2013), http://jurist.org/dateline/2013/04/daniel-perrone-generic-drugs.php.)).

176. Marie Boyd, *Unequal Protection Under the Law: Why FDA Should Use Negotiated Rulemaking to Reform the Regulation of Generic Drugs*, 35 CARDOZO L. REV. 1525, 1577 (2014).

177. *See id.* ("Consumers concerned about the different potential legal remedies for brand-name and generic drugs may request brand-name drugs.").

178. *See* Daniel Kazhdan, Wyeth *and* PLIVA: *The Law of Inadequate Drug Labeling*, 27 BERKELEY TECH. L. J. 893, 894, 914-16 (2012) (Arguing federal preemption will create public pressure on states, doctors, and pharmacists to avoid prescribing medications of which private causes of action have been foreclosed by preemption).

179. Elissa Levy, *The Health Act's FDA Defense to Punitive Damages: A Gift to Drug Makers or to the Public?*, 74 FORDHAM L. REV. 2425, 2448-49, 2451-52 (2006).

180. *See generally* James M. Beck, *Federal Preemption in FDA-Regulated Product-Liability Litigation: Where We Are and Where We Might Be Headed*, 32 HAMLINE L. REV. 657, 659 (2009) (quoting Cipollone v. Liggett Group, Inc., 505 U.S. 504, 521 (1992)).

181. Brittany Croom, *Buyer Beware:* Mutual Pharmaceutical Co. v. Bartlett *Continues to Alter the True Costs and Risks of Generic Drugs*, 15 N.C. J. L. & TECH.

marketing clinical trials are necessarily limited, as they cannot take into account all the long-term effects of a drug at the time of approval.[182] As Justice Sotomayor aptly noted in her dissent in *Mensing*, "'[s]tate tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly.' Thus, we recognized, 'state law offers an additional, and important, layer of consumer protection that complements FDA regulation.'"[183]

Lastly, judicial recognition of federal impossibility preemption as a viable affirmative defense in the pharmaceutical and medical device arena will contribute to a volatile, and unpredictable, preemption regime. A judicially-originated process of reform is an unavoidably haphazard, inconsistent process as jurisdictions begin to implement the general rule of law. Recently, in *Reckis v. Johnson & Johnson*,[184] the Massachusetts Supreme Court exemplified this phenomenon when they refused to comply with over six years worth of federal case law precedent, holding that a claim against a drug manufacturer was not preempted because the defendant failed to show that the FDA did not approve a change in a drug's label.[185] As *Reckis* demonstrates, judicial standards will necessarily become increasingly dissimilar and muddled as more jurisdictions increasingly grapple with federal preemption principles.[186]

V. NO-FAULT FIX TO THE CONTRACEPTIVE AND UNINTENDED PREGNANCY CRISIS

In light of the decreased research and development of contraceptive products, as well as the misguided application of

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ON. 1, 24, 29 (2014) (quoting Stacey B. Lee, PLIVA v. Mensing: *Generic Consumers' Unfortunate Hand*, 12 YALE J. HEALTH POL'Y L. & ETHICS 209, 245 (2012)), http://ncjolt.org/buyer-beware-mutual-pharmaceutical-co-v-bartlett-continues-to-alter-thetrue-costs-and-risks-of-generic-drugs/.

182. *See* Cupp, *supra* note 165, at 752 ("The [*Wyeth*] Court emphasized that the FDA has only limited resources to monitor the thousands of drugs on the market, and that the tort system may be especially helpful in regulating new risks that may emerge in drugs' postmarketing phase.").

183. PLIVA, Inc., 131 S. Ct. at 2592 (Sotomayor, J., dissenting) (quoting Wyeth v. Levine, 129 S. Ct. 1187, 1202-03 (2009) (internal citation omitted)).

184. 28 N.E.3d 445, 458 (Mass. 2015).

185. This is despite the fact that the Supreme Court in *Wyeth v. Levine* was clear that a defendant was only required to show "clear evidence that the FDA *would not have approved* a change [in labeling]." *See Wyeth*, 129 S. Ct. at 1198 (emphasis added).

186. *See generally Reckis*, 28 N.E.3d at 455-61 (Mass. 2015).

federal preemption in response to such issues,[187] lawmakers should be urged to investigate alternatives to the existing state law compensation schemes for injured consumers of contraceptive products. The most plausible alternative to the existing scheme is a no-fault compensation plan for those injured by contraceptive products. Such a scheme could be modeled around the National Childhood Vaccine Injury Act of 1986 (NCVIA).[188]

A. THE NATIONAL CHILDHOOD VACCINE INJURY ACT OF 1986

The NCVIA[189] was passed in response to shortages of vaccines in the 1970s and 1980s.[190] Such shortages were a direct result of product liability lawsuits brought by consumers gravely injured by vaccine products.[191] These lawsuits generated a greater perceived risk of exposure to vaccine manufacturers and caused them to effectively vacate the industry.[192] The Act, intended to relieve much of the liability burden on manufacturers of these products,[193] instituted a no-fault compensation plan for those injured by vaccines and related products.[194] The Act authorizes the Vaccine Injury Compensation Program (VICP) to issue pre-determined awards contingent upon a number of factors, including whether an alleged injury has is found to be "vaccine related."[195] However, no inquiry is made into whether the manufacturer had breached any duty of safety, and as such, it is truly a "strict liability" process.[196]

Although those plaintiffs who disagree with the award can petition for redress of their claims in federal court under state-law product liability standards,[197] they are explicitly barred from bringing design defect and failure-to-warn claims, as well as from

187. *See* discussion *supra*, Parts III.D. & IV.D.

188. 42 U.S.C.A. § 300aa-1 (West 2015).

189. 42 U.S.C.A. § 300aa-1 (West 2015).

190. Kapil Kumar Bhanot, *What Defense a Public Health Emergency? An Analysis of the Strategic National Stockpile and the National Childhood Vaccine Injury Act: The Need for Prevention of Nonterror National Medical Emergencies*, 21 J. CONTEMP. HEALTH L. & POL'Y 137, 141 (2005).

191. *Id.* ("The government's initial response to vaccine shortages was to protect the vaccine industry from lawsuits.").

192. *See* Brown, *supra* note 44, at 1.

193. 42 U.S.C.A. § 300aa-1 (West 2015).

194. *See* Garber, *supra* note 107, at 40.

195. *Id.*

196. *Id.* at 18.

197. 42 U.S.C.A. § 300aa-12(e)(1) (West 2015).

receiving punitive damages absent "fraud," "intentional and wrongful withholding of information," or "other criminal or illegal activity."[198] The program is intended to be self-funded, and is financed by a seventy-five-cent excise tax on each sale of a vaccine.[199] A claimant may recover lifelong medical expenses, lost earnings, attorney fees and up to $250,000 for pain and suffering.[200]

B. SUCCESS OF THE NCVIA

The NCVIA has proven to be successful at insulating manufacturers from volatile and unpredictable liability from defective products.[201] This is evidenced by a number of manufacturers returning to the vaccine market after the passage of the act, and the development new and useful products.[202] Indeed, only four years after passage of the act,[203] the New York Times noted "a major revival in vaccine research by private pharmaceutical companies."[204] In the 1990s, the revival was even more dramatic—prices of vaccines had decreased dramatically, and more people were getting vaccinated than at any other time in history.[205]

Most importantly, manufacturers have developed many vaccines that did not exist before the crisis,[206] and have also

198. Bruesewitz v. Wyeth LLC, 562 U.S. 223, 229, 243 (2011); 42 U.S.C.A. § 300aa-23(d)(2)(A)-(C) (West 2015).

199. *About the National Vaccine Injury Compensation Program: Vaccine Injury Compensation Trust Fund*, U.S. DEP'T HEALTH & HUM. SERVS. ADMIN. (HRSA), http://www.hrsa.gov/vaccinecompensation/about/index.html (last visited Aug. 21, 2016) (The Trust Fund is "[f]unded by a $.75 excise tax . . . on each dose (i.e., disease that is prevented) of a vaccine.").

200. 42 U.S.C.A. § 300aa-15 (West 2015); *see also* Nora Freeman Engstrom, *A Dose of Reality for Specialized Courts: Lessons From the VICP*, 163 U. PA. L. REV. 1631, 1661 (2015).

201. Mary Holland, Louis Conte, & Robert Krakow, *Unanswered Questions from the Vaccine Injury Compensation Program: A Review of Compensated Cases of Vaccine-Induced Brain Injury*, 28 PACE ENVTL. L. REV. 480, 480, 486 (2011).

202. Steve P. Calandrillo, *Vanishing Vaccinations: Why Are So Many Americans Opting out of Vaccinating Their Children?*, 37 U. MICH. J. L. REFORM 353, 408, 410 (2004).

203. *See generally* National Childhood Vaccine Injury Act of 1986, 42 U.S.C.A. § 300aa-1 (West 2015).

204. *See* Arkin, *supra* note 101, at 17.

205. *See* Elizabeth C. Scott, *The National Childhood Vaccine Injury Act Turns Fifteen*, 56 FOOD & DRUG L. J. 351, 357 (2001).

206. *See* Sara Wexler, Bruesewitz v. Wyeth: *The "Unavoidable" Vaccine Problem*, 6 DUKE J. CONST. L. & PUB. POL'Y SIDEBAR 93, 104 (2011) ("Since the 1986 enactment of the Vaccine Act, manufacturers have brought over twenty new vaccines to market.").

improved significantly on existing vaccines.[207] For example, in 1986, children were immunized against seven diseases.[208] Today, children are regularly immunized against eight additional diseases: haemophilus influenza type B, hepatitis A, hepatitis, B, influenza, meningococcal disease, pneumococcal disease, rotavirus, and varicella.[209] Another notable example includes the recently developed HPV vaccine,[210] which, in 2014, was FDA approved for administration to protect against nine strains of HPV, a cancer-causing virus.[211] Other vaccines developed since the initiation of the Act now protect against two types of viruses that cause seventy-percent of cervical cancers.[212] Drug manufacturers are also rushing to develop new, genetically-engineered vaccines for diseases such as HIV, heroine addiction, cocaine addiction, and gonorrhea.[213] And, while cancer vaccines have been pursued for years, dozens of potential vaccines are finally in the late stages of clinical trials.[214]

Fascinating new techniques and delivery method have also been developed since the initiation of the Act.[215] For decades,

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207. Scott, *supra* note 205, at 357.

208. Brief Amici Curiae of the American Academy of Pediatrics and 21 Other Physician and Public Health Organizations in Support of Respondent at 27, Bruesewitz v. Wyeth, Inc., 562 U.S. 223 (2011) (No. 09-152, 2010 WL 3017751, at *27.

209. *Id.*

210. *See FDA Approves Gardasil 9 for Prevention of Certain Cancers Caused by Five Additional Types of HPV*, U.S. FOOD & DRUG ADMIN.: FDA NEWS RELEASE (Dec. 10, 2014), http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm426485.htm.

211. *Id.*

212. Ctrs. for Disease Control & Prevention, *Recommended Immunization Schedules for Persons Aged 0 Through 18 Years —- United States, 2010*, 58 MMWR 1-4 (Jan. 8, 2010), http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5851a6.htm; Ctrs. for Disease Control & Prevention, *Quadrivalent Human Papillomavirus Vaccine: Recommendations of the Advisory Committee on Immunization Practices (ACIP)*, 56 MMWR 1-24 (Mar. 12, 2007).

213. *See* Barbara Loe Fisher, *The Vaccine Culture War in America: Are You Ready?*, NAT'L VACCINE INFO. CTR. (Mar. 8, 2015), http://www.nvic.org/nvic-vaccine-news/march-2015/the-vaccine-culture-war-in-america-are-you-ready.aspx ("Drug Companies . . . are rushing to licens[e] . . . vaccines for syphilis, gonorrhea, herpes, HIV/AIDS, tuberculosis, chlamydia, hepatitis C, e-coli, cytomegalovirus, ebola, salmonella, norovirus, adenovirus, enterovirus, asthma, diabetes, obesity, high blood pressure, anti-smoking, anti-cocaine and anti-heroin use, and many more.").

214. *The Future of Vaccines*, VACCINES TODAY: THE BLOG (Mar. 27, 2014), http://www.vaccinestoday.eu/diseases/the-future-of-vaccines-2/ ("In the past, plenty of vaccines have fallen at the last hurdle but vaccines for prostate cancer, colorectal cancer, brain tumours, and melanoma (amongst others) continue to look promising. Indeed, a prostate cancer vaccine has recently been given the thumbs up by regulators in the US.").

215. *See A Report of the National Vaccine Advisory Committee: Strengthening the*

vaccines have strictly depended upon the "attenuation" technique, which relies on weakened or killed viruses to provoke an immune response.[216] However, since the Vaccine Act, new and other cutting-edge techniques have been employed with high degrees of success.[217] The first recombinant vaccine was licensed and approved in 1986 for use in the United States, first offering an effective method at preventing the Hepatitis B virus.[218] Today, much of the new research depends on the "live recombinant vaccine" technique, which utilizes attenuated viruses or bacterial strains as delivery devices for genes intended to provoke an immune response.[219] This technique has been touted as the most promising for development of an HIV vaccine.[220] Another technique that shows great promise is the "DNA Vaccine," which

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Supply of Routinely Recommended Vaccines in the United States, U.S. DEP'T HEALTH & HUM. SERVS., THE NAT'L VACCINE ADVISORY COMM. (NVAC), http://www.hhs.gov/nvpo/nvac/nvac-vsr.html ("The VICP has assisted in stimulating the availability of new vaccines since its inception in 1988.").

216. *Louis Pasteur*, CHEMICAL HERITAGE FOUND., http://www.chemheritage.org/discover/online-resources/chemistry-in-history/themes/pharmaceuticals/preventing-and-treating-infectious-diseases/Pasteur.aspx (last visited Aug. 1, 2016) (Discussing how Louis Pasteur's research "led to his discovery of how to make vaccines by attenuating, or weakening, the microbe involved.").

217. Lisa Winter, *Cutting-Edge Technology Aiding Development of Novel Synthetic Polio Vaccine*, IFLSCIENCE (Feb. 17, 2015), http://www.iflscience.com/health-and-medicine/cutting-edge-technology-aiding-development-novel-synthetic-polio-vaccine. For a discussion on emerging technology, *see generally* Jasper L. Tran, *To Bioprint or Not to Bioprint*, 17 N.C. J. L. & TECH. 123, 133 (2015) (discussing bioprinting); Jasper L. Tran, *The Law and 3D Printing*, 31 J. MARSHALL J. INFO. TECH. & PRIVACY L. 505, 505-07 (2015) (discussing 3D printing); Jasper L. Tran & Derek Tri Tran, *(De)Regulating Neuroenhancement*, 37 U. LA. VERNE. L. REV. 179, 183-91 (2015) (discussing neuroenhancement); Jasper L. Tran, *A Primer on Digital Rights Management Technologies, in* DIGITAL RIGHTS MANAGEMENT: A LIBRARIAN'S GUIDE (Catherine A. Lemmer & Carla P. Wale eds., 2016) (discussing digital rights management technologies); *and* Jasper L. Tran, *Press Clause and 3D Printing*, 14 NW. J. TECH. & INTELL. PROP. 75, 77 (2016) ("Technology is progressing at an extraordinary speed.").

218. *See Types of Vaccines*, VACCINES.GOV (July 23, 2013), http://www.vaccines.gov/more_info/types/ ("A recombinant subunit vaccine has been made for the hepatitis B virus. Scientists inserted hepatitis B genes that code for important antigens into common baker's yeast. The yeast then produced the antigens, which the scientists collected and purified for use in the vaccine."); *Hepatitis B Vaccine History*, HEPATITIS B FOUND. (Oct. 21, 2009), http://www.hepb.org/professionals/hepatitis_b_vaccine.htm.

219. *See Types of Vaccines*, *supra* note 218.

220. This is because HIV cannot be attenuated enough to be given to humans, and could cause AIDS. *See Types of HIV Vaccines*, NAM: Aidsmap, http://www.aidsmap.com/types-of-hiv-vaccines/page/1065633/ (last visited Aug. 1, 2016).

involves the injection of the DNA coding for an antigen directly into the muscle.[221] This technique has been noted as a potentially potent weapon against diseases such as malaria.[222]

C. NCVIA AS A MODEL FOR THE CONTRACEPTIVE CRISIS

The staggering costs of unwanted pregnancies, the increased dissatisfaction with existing contraceptive methods, and the lack of innovation in contraceptive products indicates a clear need for immediate congressional action.[223] Given the tremendous growth and diversification of the vaccine industry following the passing of the NCVIA, it is suggested that an identical, no-fault approach be adopted for contraceptive products marketed in the United States.[224] A no-fault system based on the NCVIA would strike an ideal balance of product safety and product innovation. With threat of liability under the no-fault act, as well as through state law tort remedies, if a claimant is not satisfied with his no-fault act award, device manufacturers will still be motivated to prevent injury. However, the no-fault system will not impose excessive liability upon manufacturers, as it will disallow punitive damages against manufacturers except in situations involving criminal conduct, fraud, or non-compliance with the FDCA.[225]

With each manufacturer being required to "pay into" the system on a per-contraceptive-sold basis,[226] device manufacturers will better be able to predict costs associated with producing a contraceptive product. No longer will contraceptive manufacturing executives be leery of huge Dalkon-like awards, or

221. Robert G. Whalen, *DNA Vaccines for Emerging Infectious Diseases: What If?*, 2 Emerging Infectious Diseases 168, 168 (Sept. 1996), http://wwwnc.cdc.gov/eid/pdfs/vol2no3_pdf-version.pdf.

222. *Malaria: SynCon® Vaccines Targeting Malaria*, INOVIO (2014), http://www.inovio.com/products/infectious-disease-vaccines/malaria/ (last visited Aug. 1, 2016).

223. *See* discussion *supra*, Parts III & IV.

224. Janet Benshoof, *Protecting Consumers, Prodding Companies, and Preventing Conception: Toward a Model Act for No Fault Liability for Contraceptives*, 23 N.Y.U. REV. L. & SOC. CHANGE 403, 430-31 (1997).

225. *See* Mark Geistfeld, *The Political Economy of Neocontractual Proposals for Products Liability Reform*, 72 TEX. L. REV. 803, 808-09 n.25 (1994); *Bruesewitz*, 562 U.S. at 229-30; 42 U.S.C.A. § 300aa-23(d)(2)(A)-(C) (West 2015); Katherine M. Glaser, *A Step Toward Preemption: The Effect of the FDA's 2006 Preamble*, 80 TEMP. L. REV. 871, 887 (2007).

226. *See, e.g.*, *About the National Vaccine Injury Compensation Program: Vaccine Injury Compensation Trust Fund*, *supra* note 195.

Norplant-like publicity.[227] The claims will be quietly and efficiently settled through the no-fault program, offering adequate compensation for women injured by contraceptive products and, at the same time, avoiding huge windfalls for plaintiffs' attorneys. It is conceded that significant questions remain in determining the precise dollar amount of the tax per contraceptive that manufacturers would be required to pay out. It is also conceded that this amount would necessarily require constant modifications as dangers of particular products become more known and widespread. However, the scheme clearly offers a significantly more balanced approach than what is currently in place.

Of course, many women who have suffered non-economic damages exceeding the $250,000 cap may appear to be ill-served by the scheme.[228] However, these claimants will still have the ability to pursue strict liability and negligence causes of action against a manufacturer should they be dissatisfied with their no-fault award.[229] Moreover, like the NCVIA, a no-fault program for contraceptive products would relieve a claimant from much of their burden of proving causation.[230] This is because claimants would only be require to show by a preponderance of the evidence an injury suffered that is listed on a pre-determined table.[231] Most critically, women's interest as a whole will increasingly be advanced as research and development into newer and safer

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227. *See* discussion *supra*, Part III (discussing the tremendous impact Norplant publicity and Dalkon Shield jury awards had upon the profitability of those devices).

228. This problem is particularly troubling given that women have traditionally suffered more grotesque and life-altering injuries as a result of defective products. A contraceptive device is likely to cause similar catastrophic injuries that far exceed the mandated cap. *See generally* Koenig & Rustad, *supra* note 174, at 23, 80, 85, 87.

229. Under a no-fault scheme, a woman dissatisfied with her award will have even more litigation options than a consumer of a vaccine product that is dissatisfied with his or her award. This is because, under Restatement (Second) of Torts, Section 402A, comment k, strict liability claims against vaccine manufacturers are precluded. However, no such preclusion categorically applies to contraceptive products. *See* RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (AM. L. INST. 1965)

230. Michael Regan, *Health Care Law-Resolving Disputed Diagnoses Prior to Applying the* Althen *Test in Claims Brought Pursuant to the National Childhood Vaccine Act*—Lombardi v. Sec'y of Health & Human Services, *656 F.3d 1343 (Fed. Cir. 2011)*, 8 J. HEALTH & BIOMEDICAL L. 315, 320 (2013).

231. William Dobreff, *The National Vaccine Compensation Act No-Fault for Vaccine Injuries*, 69 MICH. B. J. 806, 807 (1990) ("For certain types of injuries occurring within the time frame set forth on the table after administration of the vaccine there is a presumption of causation. The burden of proof for proving a Table case is a preponderance of the evidence.").

contraceptives becomes reinvigorated as a result of the scheme.[232]

D. MODIFICATIONS AND COMPLIMENTS TO A NCVIA-TYPE SYSTEM

As discussed in Section C., the NCVIA does not explicitly foreclose private actions against a vaccine manufacturer so long as the claimant has exhausted all his avenues through the Act.[233] The Act does, however, explicitly prohibit claimants from ever alleging failure to warn claims in the private suit.[234] In 2011, vaccine manufacturers were further insulated from private suits when the Supreme Court, in *Bruesewitz v. Wyeth LLC*,[235] held that claimants are also forever prohibited from bringing design defect claims against a manufacturer of a vaccine. Justice Scalia, writing for the majority, was characteristic in his assault on state tort liability when he held that design defect claims are "[t]he most speculative and difficult type of products liability claim to litigate,"[236] and leaving them available to plaintiffs would "hardly coax manufacturers back into the market."[237] In this respect, and in the face of the Supreme Court's long-held presumption against preemption,[238] the Supreme Court held almost all avenues of private redress against vaccine manufacturers as completely foreclosed.[239] The impact of the decision will have enormous rippling effects on product safety and claimant recovery for those injured for vaccine products.[240]

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232. *See* discussion *supra*, Parts III & V.

233. *See* discussion *supra*, Part V.B.

234. *Id.*

235. *Bruesewitz*, 562 U.S. at 243.

236. *Id.* at 240.

237. *Id.*

238. Kendra D. Hanson, *The End of Design-Defect Claims: The Supreme Court's Immunization of Vaccine Manufacturers in* Bruesewitz v. Wyeth LLC [*131 S. Ct. 1068 (2011)*], 51 WASHBURN L. J. 737, 746 (2012) ("Because preemption has such significant effects, the Supreme Court has established what has come to be known as a presumption against preemption.").

239. *Bruesewitz*, 562 U.S. at 243.

240. *See, e.g.*, Hanson, *supra* note 238, at 765 (arguing that state design-defect claims should be allowed to proceed because of their powerful role in supplementing federal regulations regarding vaccine safety: "such a system is better not only for the individual plaintiffs but for public safety as a whole."); Eva B. Stensvad, *Immunity for Vaccine Manufacturers: The Vaccine Act and Preemption of Design Defect Claims*, 95 Minn. L. Rev. 315, 318 (2011) (Arguing that the *Bruesewitz* Court put a sizeable portion of consumers at unnecessary risk); *and* Mary J. Davis, *The Case Against Preemption: Vaccines & Uncertainty*, 8 Ind. Health L. Rev. 293, 316 (2011) (discussing the disastrous effects of foreclosing design defect claims against vaccine

Considering the recent decision in *Bruesewitz*, when drafting a no-fault act for contraceptives, Congress should be explicit and unambiguous in allowing design defect and failure to warn claims to proceed if a claimant has exhausted all remedies under the act. A no-fault system that shield contraceptive manufacturers from large-scale liability is necessary to reinvigorate the contraceptive market. However, this system should be carefully balanced against a claimant's ability to be made whole.[241] In the future, there will invariably be women severely injured from contraceptive products who cannot with precision prove placement on any pre-determined, injury/compensation table, and who require alternative, civil remedies.[242] As discussed in previous sections, wholesale preemption of any class of injury is an unnecessarily draconian approach that can cause manufacturers to purposely disregard information about deficiencies in their warnings or design.[243]

In adopting a no-fault act for contraceptives, Congress should also be aware that drug manufacturers may not immediately be receptive to a decrease in liability, especially with a new tax imposed upon them by the no-fault act.[244] In the event that the market is not immediately responsive, Congress should consider adopting an Orphan Drug Act[245]-type of approach to complement the no-fault system, and to jump start investment by private manufacturers.[246] The Orphan Drug Act, passed in 1983, was created to attract manufacturers to design products for a market that would otherwise be too small to be profitably by giving them monopoly rights over the market.[247] The Act has proven successful in facilitating the research or development of drugs for rare diseases, such as ALS, Huntington's disease, and Myoclonus,

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manufacturers).

241. *See* Daniel A. Cantor, *Striking a Balance Between Product Availability and Product Safety: Lessons from the Vaccine Act*, 44 AM. U. L. REV. 1853, 1856, 1902 (1995) (Arguing that no-fault scheme generally serves its purpose, but must take into account policy considerations including product safety and ability of injured claimant to be made whole).

242. Benshoof, *supra* note 224, at 425.

243. *See* discussion *supra*, Part IV.C.

244. Veronica Henry, *Problems with Pharmaceutical Regulation in the United States: Drug Lag and Orphan Drugs*, 14 J. LEGAL MED. 617, 636 (1993).

245. Orphan Drug Act of 1983, Pub. L. No. 97-414, 96 Stat. 2049 (codified as amended at 21 U.S.C. §§ 301, 360aa).

246. *See* Gary A. Pulsinelli, *The Orphan Drug Act: What's Right With It*, 15 SANTA CLARA COMPUTER & TECH. L. J. 299, 304, 325-26, 344 (1999) (discussing the incredible promise of an orphan drug-oriented scheme).

247. *See id.* at 301, 310.

which all affect small numbers of people residing in the United States.[248] Under an Orphan Drug Act approach, a limited number of contraceptive manufacturers could be given exclusive market control for a set period of time, contingent upon their development of new and cutting-edge contraceptive technologies.[249]

VI. CONCLUSION

In the United States, there is an ongoing public health problem relating to unintended pregnancies. The unintended pregnancy rate is particularly concerning, given that childbirths that result from unintended or closely-spaced pregnancies are correlated with negative outcomes for the parent and child. While it is true that two-thirds of women in the United States are on some form of contraception,[250] almost half of all unintended pregnancies result from women who use their contraception inconsistently or incorrectly.[251] The most widely reported reason for contraceptive nonuse or gaps in use is dissatisfaction with available contraception methods and concerns about side effects of alternatives.[252]

Despite the fact that women consistently express dissatisfaction with existing contraception methods,[253] the availability of the newer, safer, and more comfortable contraceptive methods remains stagnant.[254] The threat of excessive liability, as evidenced from the Dalkon Shield and

248. Orphan Drug Act of 1983, Pub. L. No. 97-414, § 1(b)(1), 96 Stat. 2049 (codified as amended at 21 U.S.C. §§ 301, 360aa) ("[T]here are many diseases and conditions, such as Huntington's disease, myoclonus, ALS (Lou Gehrig's disease), Tourette syndrome, and muscular dystrophy which affect such small number of individuals residing in the United States that the diseases and conditions are considered rare in the United States.").

249. Benshoof, *supra* note 224, at 430.

250. *See Unintended Pregnancy in the United States*, GUTTMACHER INST. 1, 3 (Mar. 2016), https://www.guttmacher.org/sites/default/files/pdfs/pubs/FB-Unintended-Pregnancy-US.pdf.

251. *Id.*

252. *CDC Report Shows Women Highly Likely to Discontinue Use of Hormonal Contraceptive Methods*, CYCLEBEADS (July 15, 2013), https://www.cyclebeads.com/blog/801/cdc-report-shows-women-highly-likely-to-discontinue-use-of-hormonal-contraceptive-methods.

253. *See id.*

254. *See generally The Stagnant Contraceptives Industry: Birth Control: Lawsuits, Red Tape and The Religious Lobby Have Slowed Innovations, Drug Firms Say. The Pill Remains the Most Trusted Method.*, L.A. TIMES (May 17, 1995), http://articles.latimes.com/1995-05-17/business/fi-2897_1_birth-control-methods.

Norplant litigation,[255] has caused contraceptive manufacturers to abandon the market in droves.[256] Only a few contraceptive manufacturers continue to invest in contraceptive research.[257] Over the past ten years, critics of liability have successfully advocated for judicially imposed federal preemption of drug and device claims as the primary vehicle to shield manufacturers from burdensome liability.[258] However, despite the data that suggests that manufacturers may respond positively to a decrease in potential liability,[259] federal preemption is an unnecessarily broad and radical approach to implications for those injured by medical and pharmaceutical products.[260]

Lawmakers should be urged to investigate alternatives to the existing state law compensation schemes and wholesale preemption of contraceptive products. The most plausible alternative to the existing scheme is a no-fault compensation plan for those injured by contraceptive products.[261] Such a scheme could be modeled around the National Childhood Vaccine Injury Act of 1986, which has proven to be successful at insulating manufacturers from volatile and unpredictable liability from defective products. Most importantly, a no-fault system based on the NCVIA might strike an ideal balance of contraceptive product safety and product innovation.

255. *See supra* notes 68-79, 100-07, and accompanying text.
256. *See supra* notes 37-42, and accompanying text.
257. *See supra* note 42, and accompanying text.
258. *See supra* note 133, and accompanying text.
259. *See supra* note 171, and accompanying text.
260. *See supra* note 172, and accompanying text.
261. *See supra* Part V.