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NOTES

TRUTH & BEAUTY, DECEPTION & DISFIGUREMENT: A FEMINIST ANALYSIS OF BREAST IMPLANT LITIGATION

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In her recent book, *The Beauty Myth*,¹ Naomi Wolf discusses the phenomenon in which a woman links her identity to her physical appearance. Wolf presents the beauty myth as a sequel to the feminine mystique² "discovered" by Betty Friedan.³ The feminine mystique depicts happy womanhood as a "modern" suburban housewife.⁴ The beauty myth, on the other hand, depicts the modern happy woman as physically perfect.⁵ "The beauty myth tells a story: the quality called 'beauty' objectively and universally exists. Women must want to embody it and men must want to possess women who embody it."⁶

This Note explores how the beauty myth affects a female plaintiff's recovery in a products liability action against manufacturers of products targeted toward women. Part I examines male bias in the area of products liability and explains the beauty myth, outlining the theoretical bases for the problem that impedes women plaintiffs. Part II recounts the breast implant story, including the marketing and testing of the devices, demonstrating how male bias and the beauty myth fueled the implant industry and contributed to the subsequent injuries and litigation. Part III illustrates how the beauty myth disadvantages breast implant plaintiffs on several levels. Part IV recommends a doctrinal method to compensate for the effects of the beauty myth on female plaintiffs who bring product liability actions, and identifies various policy reasons for doing so. More specifically, Part IV argues that courts should not apply the learned intermediary

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1. NAOMI WOLF, *THE BEAUTY MYTH: HOW IMAGES OF BEAUTY ARE USED AGAINST WOMEN* (1991).

2. BETTY FRIEDAN, *THE FEMININE MYSTIQUE* (1963).

3. WOLF, *supra* note 1, at 16, 18, 21, 64-67, 168-69.

4. FRIEDAN, *supra* note 2, at 33-68.

5. See WOLF, *supra* note 1, at 15-16.

6. *Id.* at 12.

doctrine in "failure to warn" claims against breast implant manufacturers.

I. MALE BIAS AND THE BEAUTY MYTH

A. *Women and Products Liability*

Female mass tort plaintiffs encounter male bias in both the legal and medical systems,⁷ and a recognition of systemic male bias is crucial if female mass tort victims are to recover fully for their injuries. That the Anglo-American legal system is male created, and therefore male biased to the extent it often ignores concerns and experiences traditionally labeled "female," is not a new concept and has received extensive treatment by legal scholars.⁸ Part of the problem with a system created exclusively by one sex is that the creators used their own concerns, bodies, and experiences as representative of the norm.⁹ Furthermore, this presumption that the male is the norm often goes unstated. For example, gender bias inheres in such ostensibly gender neutral language as "the reasonable person."¹⁰

To account for this underlying male bias, some courts have narrowly applied a reasonable woman standard in sexual harassment cases, as women are the usual victims in this area.¹¹ Outside

7. See *infra* notes 8-53 and accompanying text.

8. See CATHARINE A. MACKINNON, *FEMINISM UNMODIFIED: DISCOURSES ON LIFE AND LAW* (1987); see also Katherine T. Bartlett, *Feminist Legal Methods*, 103 HARV. L. REV. 829 (1990) (seeking a feminist legal methodology); Leslie Bender, *A Lawyer's Primer on Feminist Theory and Tort*, 38 J. LEGAL EDUC. 3 (1988) (exploring the influence of the patriarchy on the tort system); Carrie Menkel-Meadow, *Mainstreaming Feminist Legal Theory*, 23 PAC. L.J. 1493 (1992) (reviewing the history of feminist confrontation with law); Robin West, *Jurisprudence and Gender*, 55 U. CHI. L. REV. 1 (1988) (discussing the construction of human beings by masculine jurisprudence).

9. Lucinda Finley, "Feminist Jurisprudence"—*The 1990 Myra Bradwell Day Panel*, 1 COLUM. J. GENDER & L. 5, 17-18 (1991) (asserting that the dominant group is blind to its own characteristics of race, gender, and sexuality); see Bender, *supra* note 8, at 16-19 (arguing that women are described in terms of their differences from men).

10. Bender, *supra* note 8, at 20-25.

11. *Burns v. McGregor Elec. Indus.*, 989 F.2d 959, 962 n.3 (8th Cir. 1993) (noting and agreeing that the reasonable woman standard is appropriate in hostile environment litigation under Title VII); *Ellison v. Brady*, 924 F.2d 872, 879 (9th Cir. 1991) (holding that a female plaintiff states a *prima facie* case of hostile environment sexual harassment when she alleges conduct that a reasonable woman would consider creates an abusive working environment); *Yates v. AVCO Corp.*, 819 F.2d 630, 637 (6th Cir. 1987) (asserting that it is only reasonable that the person standing in the shoes of a female employee alleging sexual harassment should be a reasonable woman); *Rabidue v. Osceola Refining*

the narrow realm of sexual harassment claims, however, the unstated male norm remains pervasive.¹² For example, legal scholars have asserted that tort law focuses primarily on masculine goals¹³ and marginalizes certain types of harms typically suffered by women.¹⁴ More particularly, tort law has generally undervalued women and harms to their reproductive systems by not only limiting their grounds for recovery, but also by undercompensating them for such injuries.¹⁵ Mass torts involving DES¹⁶ and the Dalkon Shield¹⁷ exemplify how women's reproductive systems are often undervalued.¹⁸

Co., 805 F.2d 611, 626 (6th Cir. 1986) (Keith, J., dissenting) (concluding that the relevant inquiry for offensive environment actions is whether the conduct complained of is offensive to the reasonable woman), *aff'd*, 805 F.2d 611, *cert. denied*, 481 U.S. 1041 (1987), *abrogated on other grounds by* Harris v. Forklift Systems, Inc., 114 S. Ct. 367 (1993). *But see* Ellison, 924 F.2d at 884 (Stephens, J., dissenting) (asserting that "reasonable man" means an average adult person regardless of gender, and that the reasonable woman standard assumes men do not possess the same sensibilities as women); Robert Unikel, "Reasonable" Doubts: A Critique of the Reasonable Woman Standard in American Jurisprudence, 87 NW. U. L. REV. 326 (1992) (criticizing the workability of the reasonable woman standard in light of the inability of male judges and jurors to determine the qualities of a reasonable woman without resorting to gender stereotypes).

12. See Bender, *supra* note 8, at 20-25 (asserting that "reason" and "reasonableness" are themselves gendered concepts).

13. See generally Leslie Bender, *Feminist (Re)Torts: Thoughts on the Liability Crisis, Mass Torts, Power, and Responsibilities*, 1990 DUKE L.J. 848 (proposing a new meaning of legal responsibility grounded in feminist theory concepts of care, response, and interdependency).

14. Finley, *supra* note 9, at 22-25 (arguing that the tort system compensates injuries based on a market-referenced system, and thus undervalues women's reproductive capacity); Joan E. Steinman, *Women, Medical Care, and Mass Tort Litigation*, 68 CHI-KENT L. REV. 409 (1992) (suggesting that the attitudinal factors that disadvantage women in the corporate and scientific fields also perpetuate and exacerbate the disadvantage women face in the legal sphere); Stephanie M. Wildman, *Review Essay: The Power of Women*, 2 YALE J.L. & FEMINISM 435 (1990) (pointing out several landmark tort cases that exemplify the marginalization of abuse of women by men).

15. Finley, *supra* note 9, at 22-24; Lucinda M. Finley, *A Break in the Silence: Including Women's Issues in a Torts Course*, 1 YALE J.L. & FEMINISM 41, 68 (1989); Menkel-Meadow, *supra* note 8, at 1519-20; see SUSAN PERRY & JIM DAWSON, NIGHTMARE: WOMEN AND THE DALKON SHIELD 207-08 (1985) (quoting U.S. District Court Judge Miles Lord's statement to officials of A.H. Robins, manufacturer of the Dalkon Shield, "I dread to think what would have been the consequences if the victims [of the Dalkon Shield] had been men rather than women, women who seem through some strange quirk of our society's mores to be expected to suffer pain, shame and humiliation.").

16. DES litigation involved a drug (diethylstilbestrol) administered to pregnant women to prevent miscarriage. Thousands of women, daughters of the women who took the drug, developed various types of rare cancers decades later. See, e.g., Sindell v. Abbott Labs., 607 P.2d 924, 925 (Cal. 1980).

17. The Dalkon Shield is a contraceptive device inserted into a woman's uterus. Thousands of women who used the Dalkon Shield suffered an array of injuries ranging from pelvic inflammatory disease (PID) to infertility to death. See generally PERRY & DAWSON, *supra* note 15.

18. *Id.*

Male bias has traditionally influenced the characterization of a female plaintiff's injuries, as when courts have described women's physical injuries as psychological or hysterical.¹⁹ For example, judges frequently have classified women's fright-based physical injuries, such as miscarriages, as emotional harm.²⁰ Scholars assert that, historically, the medical system often dismissed women's complaints as emotional or hysterical, but commonly treated men's complaints of identical harm as serious physical injury.²¹ As the legal system is hesitant to compensate emotional harm, these women plaintiffs were often left uncompensated.²²

When women do recover for their injuries, they tend to recover significantly lower compensatory damage awards than do men.²³ Male bias in damage awards is especially evident when a woman's reproductive system is injured.²⁴ For example, the American Medical Association's *Guides to the Evaluation of Permanent Impairment*²⁵ lists a "whole person impairment" rating which is up to ten percent greater for injuries to male sex organs than for comparable injuries to female sex organs.²⁶ Scholars also note that damage awards are male biased in that they tend to under-compensate women for loss of future income. Not only are juries often swayed by gender stereotypes about employment, but in reality women are often paid significantly less than men because of employment discrimination.²⁷

19. Martha Chamallas & Linda K. Kerber, *Women, Mothers, and the Law of Fright: A History*, 88 MICH. L. REV. 814 (1990).

20. *Id.* at 814, 823, 826-55 (presenting a gendered history of the law's treatment of fright-based injuries); see, e.g., *Mitchell v. Rochester Ry. Co.*, 45 N.E. 354 (N.Y. 1896) (denying recovery to plaintiff who lost consciousness and suffered a miscarriage after a near miss by a horse car); *Maube v. Warrington*, 258 N.W. 497, 497 (Wis. 1935) (denying recovery to plaintiff who became "extremely hysterical, sick and prostrated" and died within one month of witnessing her daughter hit and killed by a negligent driver).

21. Finley, *supra* note 9, at 23; Finley, *supra* note 15, at 65; Steinman, *supra* note 14, at 424.

22. Chamallas & Kerber, *supra* note 19, at 827; Finley, *supra* note 9, at 23 (pointing to *Payton v. Abbott Labs.*, 437 N.E.2d 171 (Mass. 1982), in which the court dismissed claims of DES-exposed plaintiffs because their injuries were classified as trivial emotional harm).

23. NINTH CIRCUIT GENDER BIAS TASK FORCE, THE PRELIMINARY REPORT OF THE NINTH CIRCUIT GENDER BIAS TASK FORCE DISCUSSION DRAFT 175 (1992); Steinman, *supra* note 14, at 424.

24. See generally PERRY & DAWSON, *supra* note 15.

25. GUIDES TO THE EVALUATION OF PERMANENT IMPAIRMENT (A. Engelberg ed., 3d ed. 1988).

26. Steinman, *supra* note 14, at 425; Ellen S. Pryor, *Flawed Promises: A Critical Evaluation of the American Medical Association's Guides to Permanent Impairment*, 103 HARV. L. REV. 964 (1990) (book review).

27. Finley, *supra* note 15, at 51-52; Jane Goodman et al., *Money, Sex & Death: Gender*

The manner in which the tort system handles mass tort cases frequently limits the scope of a plaintiff's recovery.²⁸ Professor and feminist scholar Leslie Bender asserts that one function of the legal system is to permit injured parties to tell their stories and thus validate their experiences.²⁹ When mass torts are handled as class actions for purposes of judicial economy, such as in the Dalkon Shield litigation, women are denied an opportunity to tell their stories. Said one such Dalkon Shield victim, "I really wish I could tell [A.H. Robins officials] face to face what they did to me and my family. But they have such a wall around them ... legally."³⁰ Another woman recalls making an appointment with the doctor who had inserted her IUD years earlier, in order to confront him with her resulting injuries.³¹

In products liability litigation involving medical devices, women plaintiffs are doubly disadvantaged, because male bias in the legal system is reinforced and compounded by male bias that pervades the medical system. Legal scholars have pointed to male bias within the medical research community, such as the view that male physiology is the norm and female physiology is, therefore, deviant.³² As a result of this unstated male norm, the medical establishment commonly accepts research carried out exclusively on white men as scientifically valid.³³

The medical establishment has acknowledged that women are often excluded from testing procedures, resulting in the approval of drugs that were never tested on women.³⁴ Consequently, doctors do not know the appropriate dosages, effectiveness, or side effects of certain drugs on women patients, in effect making the

Bias in Wrongful Death Damage Awards, 25 LAW & SOC'Y REV. 263, 281-82 (1991); Steinman, *supra* note 14, at 424; see Finley, *supra* note 15, at 49-51 (asserting that, historically, rules limiting recovery for injury to children failed to value emotional relationships and did not recognize that a woman's sense of identity is often closely tied up in the well-being of her family because of her traditional role as primary caretaker).

28. See Bender, *supra* note 8, at 9-12.

29. *Id.* at 9-10.

30. PERRY & DAWSON, *supra* note 15, at ix.

31. *Id.* at 42. The opportunity for storytelling in breast implant litigation may be particularly important, due to the strong connection between the female plaintiff's sense of identity and self-worth and the injury to her physical appearance. See *infra* notes 195-208 and accompanying text.

32. Bender, *supra* note 8, at 17-18; Haley Gorenberg & Amanda White, *Off the Pedestal and into the Arena: Toward Including Women in Experimental Protocols*, 19 N.Y.U. REV. L. & SOC. CHANGE 205, 206 (1991-1992).

33. Gorenberg & White, *supra* note 32, at 206.

34. *Id.*; Marlene Cimon, *FDA to Change Drug Research Policy on Women*, L.A. TIMES, Mar. 25, 1993, at 1A; Malcolm Gladwell, *Women's Health Research to be New Priority at NIH*, WASH. POST, Sept. 11, 1990, at A17.

female patients "marketplace guinea pigs."³⁵ A 1989 memorandum from the National Institutes of Health reveals that underrepresentation of women in clinical studies has caused significant gaps in medical knowledge.³⁶ In June 1990 the General Accounting Office reported that medical research was carried out mainly on males, largely to the benefit of males only.³⁷

The Food and Drug Administration (FDA) has announced it will reverse a policy that forbids the participation of women of childbearing age in medical drug research.³⁸ The policy arose in response to a number of medical tragedies involving the use of drugs during pregnancy, for example, birth defects caused by thalidomide in the late 1950s.³⁹ Current reliable technologies are available, however, to prevent pregnancy during drug testing.⁴⁰

Feminist scholars have identified three rationales for excluding women from medical research. The "protectionist rationale" is based on a presumption of risk to the woman and/or her fetus, absent any evidence of such risk. This rationale ignores the reproductive risks men face in drug research and the risks that men will pass injuries along to their offspring.⁴¹ The "efficiency rationale" is based on the notion that the male physiology is simpler and that it is therefore easier for researchers to study men and generalize to women. The "efficiency rationale" accepts the belief that the white male population is the standard from which treatments for other groups should be extrapolated.⁴² The "unstated rationale" is that funding is driven by fear. This theory suggests that the medical establishment, largely male, funds those diseases it fears most. The lack of funding for research on osteoporosis, breast cancer, and AIDS in women is consistent with this claim.⁴³

Whereas women are often absent or underrepresented in general medical testing, male bias has the opposite effect in the area of contraceptive research. The scientific community places greater emphasis on developing and marketing contraception for women

35. Gorenberg & White, *supra* note 32, at 222.

36. Gladwell, *supra* note 34, at A17.

37. Shari Roan, *Working on a Cure for Unequal Medicine*, L.A. TIMES, June 9, 1992, at 1E.

38. Cimons, *supra* note 34, at 1A.

39. *Id.*

40. *Id.*

41. Gorenberg & White, *supra* note 32, at 209.

42. *Id.* at 215.

43. *Id.* at 216.

than for men.⁴⁴ At least one legal scholar has offered explanations for the focus on women in this context: men have traditionally been in the decision-making positions and would prefer to let women take pills and injections and install foreign objects inside their bodies.⁴⁵ Another explanation is that, once again, the male reproductive system is viewed as the norm and therefore need not be altered, but the female reproductive system is seen as deviant, and must be "fixed."⁴⁶

Products marketed for women, particularly those devices designed for women's reproductive systems, such as the Dalkon Shield, DES, Bendectin, Thalidomide, tampons, and breast implants, account for the majority of mass tort litigation.⁴⁷ Certain other products, most notably asbestos and agent orange, have caused injury predominantly to men, but the circumstances surrounding the men's exposure to these products differs significantly from the circumstances surrounding women's exposure to defective reproductive devices. The men were exposed to asbestos or agent orange as an incidence of the workplace or battlefield.⁴⁸ The women, however, were in some sense deliberately exposed, as the manufacturer marketed these products directly to female consumers precisely because of their sex.⁴⁹ The disparate impact of defective products on women has led at least one scholar to question whether manufacturers of these products are employing a sexually discriminatory standard of care.⁵⁰

For women to recover for injuries to their reproductive systems, they frequently must detail their use of the products and their sexual activities.⁵¹ However, the very discussion of sexual matters tends to discredit and devalue the women's claims.⁵² Furthermore, our market-referenced tort system is less likely to fully compensate reproductive harm than injuries that occur in the workplace or on the battlefield, because no direct economic loss results.⁵³

44. Steinman, *supra* note 14, at 412.

45. *Id.*

46. *See* Bender, *supra* note 8, at 16-18.

47. Steinman, *supra* note 14, at 409-13.

48. *See id.*

49. *See id.*

50. *Id.*

51. Steinman, *supra* note 14, at 423. *See generally* PERRY & DAWSON, *supra* note 15.

52. Steinman, *supra* note 14, at 423.

53. Finley, *supra* note 9, at 22-24 (arguing that the tort system is market-referenced, and thus undervalues harm to women's reproductive capacity).

Both the legal and medical research systems are male biased to the extent they have traditionally accepted the male historical experience and body as the norm. Thus, in mass tort litigation involving medical devices, female plaintiffs face systemic male bias on two fronts. For the reasons discussed above, women who use medical devices are more likely than men to be injured by the device, but less likely to be fully compensated through the legal system.

B. The Beauty Myth

In their book, *Face Value: The Politics of Beauty*,⁵⁴ Robin Tolmach Lakoff and Raquel Scherr explore a variety of myths and countermyths about beauty. The authors comment on "the problem of having one's self-esteem depend on a commodity . . . that is not in one's power to create, or determine, or choose, and which will certainly disappear, through aging or changes in the standards of the community, as time goes by."⁵⁵ This section outlines four underlying myths and assumptions about beauty that have affected female tort victims' recovery by influencing both the breast implant industry and breast implant litigation.

First, the beauty myth is a myth of happiness—it tells women that physical perfection is the key to self-fulfillment.⁵⁶ Although no logical connection exists between beauty and happiness,⁵⁷ a woman who links her self-worth to her appearance does so based not only upon her perceptions of others' reactions to her, but also upon reality. Data from numerous studies indicate that people are in fact treated differently from each other based upon their appearance.⁵⁸

Second, the beauty myth purports that beauty is an absolute, intrinsically recognizable and definable.⁵⁹ Beauty, however, is more akin to fashion.⁶⁰ It changes to meet specific needs at a

54. ROBIN TOLMACH LAKOFF & RAQUEL L. SCHERR, *FACE VALUE: THE POLITICS OF BEAUTY* (1984).

55. *Id.* at 277.

56. *See id.* at 126-55. *But see id.* at 32-33, 124 (relating conflicting myth that great beauty brings its possessor misery).

57. *Id.* at 33.

58. *Id.* at 126-55. *See generally* Gerald R. Adams, *Physical Attractiveness Research: Toward a Developmental Social Psychology of Beauty*, 20 HUM. DEV. 217 (1977) (compiling about 120 psychology studies performed between 1970 and 1977 that conclude there is indeed a link between physical attractiveness and the way people are treated).

59. TOLMACH LAKOFF & SCHERR, *supra* note 54, at 29.

60. *Id.*

particular time and place. People in power define beauty, and as the possession of power shifts, the definition of beauty varies with it.⁶¹ Consequently, Wolf describes beauty as political and asserts that it has achieved a political purpose: compensating for the advances women have gained through the women's movement by tying a woman's self-esteem to her physical appearance.⁶²

Third, underlying the beauty myth is a close nexus between beauty and power, or the possession of a commodity someone else wants or needs.⁶³ For a man, that commodity can be wealth, influence, or knowledge, but for a woman, it has typically been beauty.⁶⁴ A woman's beauty, however, is of no intrinsic use to the woman; it is valuable only because it enables her to attract someone in possession of the commodities that will be useful or pleasurable to her, commodities that men typically possess.⁶⁵ In effect, beauty is a currency system like the gold standard,⁶⁶ and a woman's beauty is "for" the person she attracts.⁶⁷ By assigning value to women in a vertical hierarchy according to a culturally imposed physical attractiveness standard, beauty, Wolf argues, is an expression of power relations in which women compete for resources that men have appropriated for themselves.⁶⁸

"Artificial" beauty, in particular, is designed for the benefit of the onlooker.⁶⁹ Eyeshadow, high heels, colored nail polish, opalescent lipstick, and other unnatural looks are evidence of the effort and interest that went into a woman's appearance and send the message that the viewer is worth the time and effort

61. *Id.* This argument is bolstered by notions of "artificial" beauty in other cultures, such as bound feet, or long necks. The disfigurement that many cultures consider beautiful appalls outsiders. *Id.*

62. WOLF, *supra* note 1, at 18-19. But see TOLMACH LAKOFF & SCHERR, *supra* note 54, at 18 (pointing out that in one sense politics is the antithesis of beauty. Politics is active—politicians campaign, manipulate, make deals. Beauty, on the other hand, is appreciated, adorned).

63. TOLMACH LAKOFF & SCHERR, *supra* note 54, at 18; see also RITA FREEDMAN, BEAUTY BOUND 47 (1986) (asserting that although a woman may feel powerless in many ways, her body is an arena she can try to control).

64. TOLMACH LAKOFF & SCHERR, *supra* note 54, at 18.

65. *Id.* at 19, 136-38.

66. WOLF, *supra* note 1, at 12.

67. See *id.*; see also TOLMACH LAKOFF & SCHERR, *supra* note 54, at 18 (explaining that beauty is in the eye of the beholder).

68. WOLF, *supra* note 1, at 12. One example of how beauty functions as power is the stereotype of "catty," jealous women competing among each other. Another is the Greek myth of Paris and the golden apple. A more recent example is the annual Miss America Pageant. See TOLMACH LAKOFF & SCHERR, *supra* note 54, at 21-24.

69. TOLMACH LAKOFF & SCHERR, *supra* note 54, at 25.

necessary to create the look.⁷⁰ The more a woman is willing to sacrifice for the sake of someone else's pleasure, the more valuable the viewer feels.⁷¹ Artificial beauty is more than a statement about the beautiful woman (the object); it is a declaration of the importance of the viewer (the subject).⁷² Indeed, beauty is one example of how "[w]omen have served all these centuries as looking glasses possessing the magic and delicious power of reflecting the figure of man at twice its natural size."⁷³

Finally, the beauty myth encompasses a double standard: society puts a premium on beauty, yet considers the process of beautification a frivolous pursuit. Tolmach Lakoff and Scherr assert that women are often embarrassed to talk about or to display concern with their appearance, fearing others will perceive them as frivolous and, therefore, refuse to take them seriously.⁷⁴ Although beauty is the primary method women have of attaining power and influence,⁷⁵ society often dismisses beautiful women, treating them as if beauty were their only attribute. Beauty is an endless and exhausting, if not futile, process for which women receive little credit if they succeed, but much contempt if they do not.⁷⁶

The visual media expose women to the beauty myth by circulating millions of images of the current ideal. The message, delivered daily by the myriad images of beauty, is that women must look a certain way to be loved and admired—to be worth anything.⁷⁷ Images of the ideal female body have become taller and thinner while the majority of young American women has become heavier.⁷⁸ For example, one study has concluded that women as thin as the average modern mannequin would most likely be too thin to menstruate.⁷⁹

Numerous scholars and studies have recognized a link between physical attractiveness and the way people are treated.⁸⁰ For

70. *Id.* at 25-26; FREEDMAN, *supra* note 63, at 51.

71. *See* WOLF, *supra* note 1, at 12.

72. TOLMACH LAKOFF & SCHERR, *supra* note 54, at 282.

73. VIRGINIA WOLF, *A ROOM OF ONE'S OWN* 53 (1929).

74. TOLMACH LAKOFF & SCHERR, *supra* note 54, at 13-17; *see* FREEDMAN, *supra* note 63, at 54-55; *see also* WOLF, *supra* note 1, at 9, 61-62, 70-71.

75. TOLMACH LAKOFF & SCHERR, *supra* note 54, at 154.

76. *Id.*

77. *Id.* at 114.

78. *The New American Body*, U. CAL. BERKELEY WELLNESS LETTER (Health Letter Assocs.), Dec. 1993, at 1.

79. *Id.*

80. *See* Adams, *supra* note 58, at 223-26.

women in particular, beauty is often of foremost concern.⁸¹ Yet, in beauty, as in other aspects of life, the personal is political. Beauty, writes Wolf, is determined by politics. It is a belief system that preserves male dominance.⁸² This belief system, bolstered by the mass media, aids the marketing and sale of women's beauty products such as breast implants.⁸³ Thus, a feminist analysis of products liability requires a recognition that our patriarchal system itself promotes beauty devices such as breast implants, while systemic male bias within medicine and law adversely affects the products' safety and impedes the recovery of subsequent women plaintiffs.

II. THE IMPLANT INDUSTRY

Silicone breast implants and the resulting litigation are an excellent example of the interplay between the male biases in the medical and legal institutions and the beauty myth. Initially, manufacturers of silicone breast implants enjoyed enormous success from their products. The story of the marketing, testing, and sale of implants, however, reflects the general patterns of male bias present within the medical system as a whole.⁸⁴ Furthermore, the beauty myth has worked to the benefit of the implant industry and neither manufacturers nor surgeons have hesitated to allow the myth to bolster their sales. Part A of this section recounts the story of the breast implant controversy and Part B demonstrates how various myths and assumptions about beauty have benefited the implant industry.

A. *The Breast Implant Story*

Until media attention and the legal system exposed the potential dangers of silicone breast implants, implant surgery was one of the most popular cosmetic surgery procedures performed in the United States.⁸⁵ The FDA estimates that one million women

81. See WOLF, *supra* note 1, at 17 (pointing to the United States' \$20 billion cosmetics industry); see also Reena N. Glazer, *Women's Body Image and the Law*, 43 DUKE L.J. 113, 137 (1993) (reporting that the breast implant industry has grown into a \$500 million a year business).

82. WOLF, *supra* note 1, at 12.

83. See discussion *infra* part II.B.

84. See *supra* notes 32-53 and accompanying text.

85. Sarah Glazer, *Women's Health, Battle Over Breast Implants, Fewer Women are Seeking Enlargements, Plastic Surgeons Say*, WASH. POST, Jan. 14, 1992, at Z7.

in the United States have undergone breast implant surgery,⁸⁶ but other estimates place the number as high as two million.⁸⁷ According to the FDA, breast implant surgery for augmentation purposes accounts for eighty percent of the implant industry. Breast cancer patients seeking post-mastectomy⁸⁸ reconstruction account for the remaining twenty percent.⁸⁹

In 1992 the FDA received 21,968 complaints relating to breast implants.⁹⁰ As of December 1, 1993, the agency had received an additional 19,144 complaints.⁹¹ Package inserts included with manufacturer Dow Corning's implants acknowledge "reports of suspected immunological responses to silicone mammary implants."⁹² The information also lists the following side effects: difficulty in cancer detection, skin breakdown, pain, asymmetry, decreased breast sensation, gel bleed (seepage of silicone through the implant shell), and migration of implants.⁹³ Another complication associated with breast implants is "capsular contracture," a condition in which the breasts become as "hard and round as baseballs."⁹⁴ Capsular contracture requires either further surgery to remove the scar tissue or a procedure called a "closed capsulotomy" in which the surgeon breaks up the scar tissue by leaning heavily on the woman's breasts.⁹⁵ Surgeons disagree as to the rate of occurrence of capsular contracture, but estimates run as high as seventy-five percent.⁹⁶

Silicone implants have generated enormous amounts of litigation. In the United States, an estimated 12,000 lawsuits are

86. *Id.*

87. *Teich v. FDA*, 751 F. Supp. 243 (D.C. Cir. 1990); Tim Smart, *What Did the Industry Know, and When?*, BUS. WK., June 10, 1991, at 94.

88. Mastectomy is the excision of the breast. ILLUSTRATED STEADMAN'S MEDICAL DICTIONARY 837 (24th ed. 1982).

89. Glazer, *supra* note 85.

90. Christopher Connell, *AMA Urges No Ban on Silicone Gel Implants*, DETROIT FREE PRESS, Dec. 1, 1993, at 5A.

91. *Id.*

92. Dan C. Bolton, *The Evolution of Breast Implant Litigation*, in LITIGATING BREAST IMPLANT CASES: A SATELLITE PROGRAM 127, 162 (PLI Litig. & Admin. Practice Course Handbook Series No. H-451, 1992).

93. *Id.* at 158-62; see also Judy Foreman, *Before You Opt for a Breast Implant . . .*, BOSTON GLOBE, July 22, 1991, at 37 (discussing patients who ended up with implants in their abdomens or armpits).

94. Foreman, *supra* note 93, at 37.

95. *Id.*

96. *Id.* (interview with rheumatologist at the University of South Florida); see also WOLF, *supra* note 1, at 324-25 n.237 (70% rate of capsular contraction); Foreman, *supra* note 93 (25-40% for smooth surface implants, 4% for coated surface implants).

currently pending against implant manufacturers.⁹⁷ Some women are claiming immunological injuries associated with implants, such as lupus, connective tissue disorder, and chronic fatigue.⁹⁸ Others allege the devices cause mental confusion,⁹⁹ depression,¹⁰⁰ suicidal ideation,¹⁰¹ and reasonable fear of future damages.¹⁰² At least one claim alleges defective implants caused a death.¹⁰³ In *Fueuer v. McGahn Medical Corp.*,¹⁰⁴ seven children sued various manufacturers of silicone implants and requested a medical monitoring fund for all children born to and/or breast fed by women with implants.¹⁰⁵ The plaintiffs alleged that silicone tainted their mothers' breast milk, causing them to suffer physical injuries such as gastrointestinal problems, autoimmune symptoms, connective tissue disorder, and elevated liver enzymes.¹⁰⁶

Silicone implants were marketed in the United States for nearly twenty years without FDA approval.¹⁰⁷ When the devices first were put on the market, FDA approval was not required, as the agency had no jurisdiction over medical devices until the mid-1970s.¹⁰⁸ At that time, products currently on the market were

97. *Breast Implants: Three Major Producers to Pay \$3 Billion Toward \$4.75 Billion Global Settlement Fund*, Prod. Liab. Daily (BNA), Feb. 24, 1994, available in Westlaw, BNA-PLD database [hereinafter *Three Major Producers*].

98. Bolton, *supra* note 92, at 165.

99. *Breast Implants: Class Action Filed in Ohio Court Seeking Damages for Past, Future Injuries*, Prod. Liab. Daily (BNA), Feb. 19, 1992, available in Westlaw, BNA-PLD database (discussing *Dante v. Dow Corning Corp.*).

100. *Breast Implants: Three Georgia Women Sue Manufacturers, Alleging Devices Caused Various Ailments*, Prod. Liab. Daily (BNA), Jan. 29, 1992, available in Westlaw, BNA-PLD database (discussing *Martin v. Dow Corning Corp.*) [hereinafter *Three Georgia Women*].

101. *Breast Implants: Suit Filed in Federal Court in Tennessee Alleges Devices Lead to 'Suicidal Ideation'*, Prod. Liab. Daily (BNA), Feb. 19, 1992, available in Westlaw, BNA-PLD database (discussing *Pool v. Surgitek, Inc.*).

102. *Breast Implants: Woman Files Suit Seeking Damages for Fear of Future Injury*, Prod. Liab. Daily (BNA), Feb. 5, 1992, available in Westlaw, BNA-PLD database (discussing *Moe v. Dow Corning Wright*).

103. *Breast Implants: Widower Sues Dow Corning, Physician, Alleging Devices Caused Wife's Death*, Prod. Liab. Daily (BNA), Apr. 22, 1992, available in Westlaw, BNA-PLD database.

104. *Breast Implants: Children of Nursing Mothers Sue Makers, Seek Monitoring for Silicone Related Harm*, Prod. Liab. Daily (BNA), Mar. 4, 1993, available in Westlaw, BNA-PLD database (discussing *Feuer v. McGhan Medical Corp.*).

105. *Id.*

106. *Id.*

107. Michael Castleman, *The Enemy Within*, 13 CAL. LAW. 44, 47 (Mar. 1993); Smart, *supra* note 87.

108. Breast implants are governed by the Medical Device Amendments of 1976, 21 U.S.C. § 360(c) (1988).

"grandfathered" in, pending later review by an advisory panel.¹⁰⁹

In 1982, amid growing concerns about gel migration and unknown long-term toxic effects of silicone, the FDA proposed a classification for silicone implants that would require manufacturers to prove their safety.¹¹⁰ The proposal did not become law, however, until April 1991.¹¹¹ By that time, the FDA had received some five thousand complaints about silicone implants.¹¹²

One reason for the FDA's delay in requiring proof of breast implant safety may be that cosmetic surgeons dominated the advisory panel.¹¹³ As a profession, cosmetic surgeons faced substantial economic losses if the FDA banned breast implants. According to the American Society for Plastic and Reconstructive Surgeons (ASPRS), breast augmentation was one of the top three cosmetic surgery procedures in 1990.¹¹⁴ Breast augmentation accounted for fourteen percent¹¹⁵ of procedures in the \$300 million per year industry.¹¹⁶ Such an apparent conflict of interest calls into question the motives of the FDA advisory panel.

Once aware of the risk implants pose, women have had difficulty getting them removed. A breast implant operation takes twenty minutes to two hours, but surgical removal can take three to six hours, especially if the implant's coating has disintegrated or the implant has ruptured.¹¹⁷ One specialist described the process of removing the silicone that escapes after an implant ruptures as being "like picking wet bread from a basin of water."¹¹⁸ Surgeons are often reluctant or unwilling to perform the operation,¹¹⁹ and insurance companies often refuse to pay for it.¹²⁰

109. STAFF OF HOUSE COMM. ON GOVERNMENT OPERATIONS, 102D CONG., 2D SESS., FDA'S REGULATION OF SILICONE BREAST IMPLANTS 4 (Comm. Print 1992); Castleman, *supra* note 107, at 47.

110. Smart, *supra* note 87, at 94.

111. 21 C.F.R. § 878.3540(c) (1994).

112. Teresa Moran Schwartz, *Punitive Damages and Regulated Products*, 42 AM. U. L. REV. 1335 (1993); see also Stuart A. Schlesinger, *Breast Implants and the Law*, N.Y. L.J., Jan. 1992, at col. 1 (asserting that the number of lawsuits against implant manufacturers should have alerted the FDA years before they took action of the possibility that Dow's claims of safety were unsupported. "The silicone breast implant controversy supports the position that having the FDA approve a drug or product may be proof of nothing.").

113. Smart, *supra* note 87, at 94.

114. Glazer, *supra* note 85, at Z7.

115. *Id.*

116. WOLF, *supra* note 1, at 17. The cosmetic surgery industry is the fastest growing medical specialty. *Id.* at 10.

117. Foreman, *supra* note 93, at 37.

118. *Id.*

119. Emily C. Aschinger, *The Selling of the Perfect Breast: Silicone, Surgeons, and Strict*

Procrastination by the FDA and uncooperativeness on the part of surgeons and insurance companies are not the only factors that led to the breast implant controversy. Perhaps one of the greatest causes of the uproar was the revelation that manufacturers were aware of dangers years before the FDA took any action.¹²¹ For at least a decade prior to an FDA study linking implants to a cancer-causing agent, manufacturers knew of animal studies that linked implants to cancer and other illnesses.¹²² Internal company memos reveal that researchers at Dow Corning questioned the safety of silicone implants as early as the 1970s.¹²³ By 1974 Dow had warnings on file from researchers reporting possible side effects as well as complaints from recipients with medical problems.¹²⁴ In November 1992 Dow Corning admitted that some of its employees had altered data from tests of silicone gel implants.¹²⁵ If indeed "[b]eauty is truth, truth beauty,"¹²⁶ then perhaps it is no surprise that Dow Corning's deception led to the disfigurement of so many women.

If Dow's own test results and researchers' warnings did not alert Dow to the possibility that breast implants were unsafe, the litigation should have. As early as 1981, Dow defended a lawsuit in which the plaintiff alleged that silicone breast implants caused injury when they ruptured.¹²⁷ Dow did not contest that the rupture caused the plaintiff's injury.¹²⁸ Rather, Dow argued

Liability, 61 UMKC L. REV. 399, 413 (1992) (proposing that plastic surgeons be classified as "sellers" of breast implants and be subject to strict liability for implanting defective products).

120. Sandra G. Boodman, *Breast Implants: Now Women are Having a Hard Time Getting Them Out*, WASH. POST, June 23, 1992, at Z10, 27; Barbara A. Serrano, *Women Seek Help for Implant Removal: Insurance Often Won't Pay, Legislators Told*, SEATTLE TIMES, Apr. 21, 1992, at D1.

121. Schlesinger, *supra* note 112, at col. 1; *see also* *Teich v. FDA*, 751 F. Supp. 243 (D.C. Cir. 1990).

122. Smart, *supra* note 87, at 94.

123. Bolton, *supra* note 92, at 187-93; *Chronology Silicone Breast Implants*, STAR TRIB., Oct. 17, 1993, at 15A.

124. Michele Weldon, *Her-Say: Score One for Legal Scare Tactics*, CHI. TRIB., July 4, 1993, at 9C.

125. Castleman, *supra* note 107, at 106.

126. John Keats, *Ode on a Grecian Urn*, line 49.

127. *Klein v. Dow Corning Corp.*, 661 F.2d 998 (2d Cir. 1981) (holding that the statute of limitations did not start to run on plaintiff's claim until the implants ruptured); *see also Breast Implants: Minneapolis Woman Files Class Action Suit Seeking Damages for Fear of Future Injury*, Prod. Liab. Daily (BNA), Feb. 5, 1992, available in Westlaw, BNA-PLD database (discussing *Moe v. Dow Corning Wright*) (alleging Dow Corning knew as early as 1975 that implants were only minimally tested and that silicone gel could escape).

128. *Klein*, 661 F.2d at 998.

that the tort claims were barred by the statute of limitations. In holding that the plaintiff's cause of action accrued from the time of implant rupture, not of implantation, the court compared a ruptured implant injury to the damage caused by a "toxic chemical"¹²⁹ in *Thornton v. Roosevelt Hospital*.¹³⁰ "[I]n *Thornton*, injection and injury were concurrent. The chemical began its damage immediately. Here damage occurred only when the prostheses burst."¹³¹ The willingness of the court to compare silicone to a "toxic chemical" should have put Dow on notice of the likelihood of other breast implant claims.

Three years earlier, in 1978, another breast implant manufacturer had faced similar litigation. The litigant claimed that silicone adversely affected the body after escaping from implants.¹³² In *V. Mueller & Co. v. Corley*,¹³³ the plaintiff received breast implants after undergoing a mastectomy.¹³⁴ When the plaintiff's incision failed to heal properly, her doctor removed the implants and observed a tear in the implant "shell."¹³⁵ The doctor detected the presence of silastic fluid in the plaintiff's wound, and blamed this for the failure of the wound to heal properly.¹³⁶

Dow could have responded to these early cases by conducting more safety studies or notifying consumers of reported injuries. Instead, Dow attempted to conceal its prior knowledge of safety concerns. In *Teich v. FDA*,¹³⁷ both Dow and the FDA contended that animal studies constituted "'confidential' commercial information" under exemption four of the Freedom of Information Act.¹³⁸ Holding that "[t]his is the very type of case for which the Freedom of Information Act was designed,"¹³⁹ the court chastised Dow for creating "unnecessary roadblocks" and preventing informed decisions.¹⁴⁰

Dow's stonewalling has led to at least two claims based on this conduct alone. In Los Angeles Dow is the subject of a criminal

129. *Id.* at 999.

130. 391 N.E.2d 1002 (N.Y. 1979).

131. *Klein*, 661 F.2d at 999.

132. *V. Mueller & Co. v. Corley*, 570 S.W.2d 140 (Tex. Ct. App. 1978).

133. *Id.*

134. *Id.* at 141.

135. *Id.*

136. *Id.*

137. 732 F. Supp. 17 (D.C. Cir. 1990).

138. *Id.* at 17.

139. *Id.* at 20.

140. *Id.* Many aspects of the testing and early litigation of breast implants parallel those of the Dalkon Shield. For an excellent account of the Dalkon Shield story, see MORTON MINTZ, *AT ANY COST* (1985).

investigation under the California Corporate Criminal Liability Act.¹⁴¹ The law provides for criminal sanctions against corporate managers who possess actual knowledge of a product's serious concealed danger, but fail to notify government safety agencies.¹⁴² A second claim alleges conspiracy among several manufacturers to mislead the medical profession and the public about implant safety.¹⁴³

In January 1992, after ordering Dow to turn over its research documents, the FDA imposed a moratorium on the sale of silicone implants. In April 1992 the agency allowed the use of silicone implants for reconstructive surgery as part of a clinical study.¹⁴⁴ The FDA has also insisted it must be able to notify current implant users quickly if new problems arise.¹⁴⁵ Implant manufacturers contend that this type of record keeping will increase the cost of business.¹⁴⁶ Indeed, Keith McKennon, corporate chair of Dow Corning, has announced that the company, whose market share represented ten to fifteen percent of the silicone gel implant market prior to the moratorium, will not re-enter the market if the FDA moratorium is lifted.¹⁴⁷

The FDA is not alone in its reaction to breast implant litigation; courts and manufacturers have also responded. In June 1992 the federal courts consolidated all federal breast implant cases to the Northern District of Alabama under Judge Sam C. Pointer, Jr.¹⁴⁸ In addition, Dow proposed a \$4.25 billion class action settlement to cover worldwide claims which was approved by Judge Pointer on September 1, 1994.¹⁴⁹ In February 1994 Dow Corning agreed

141. CAL. PENAL CODE § 387 (West 1993); *Breast Implants: Los Angeles Investigates Dow Corning Under California Criminal Liability Law*, Prod. Liab. Daily (BNA), Feb. 19, 1992, available in Westlaw, BNA-PLD database.

142. *Id.*

143. *Breast Implants: Seven Tennessee Plaintiffs Sue Dow Corning Alleging Conspiracy to Conceal Risks*, Prod. Liab. Daily (BNA), Sept. 24, 1992, available in Westlaw, BNA-PLD database (discussing *Rachel v. Dow Corning Corp.*).

144. John Schwartz, *Breast Implant Settlement Enters Notification Period*, WASH. POST, Apr. 5, 1994, at A3.

145. James M. Gomez, *Makers Must Track All Implants*, L.A. TIMES, Sept. 1, 1993, at 1D.

146. *Id.*

147. *Product Safety: Dow Corning Announces Withdrawal from Silicone Gel Breast Implant Market*, Prod. Liab. Daily (BNA), Mar. 20, 1992, available in Westlaw, BNA-PLD database [hereinafter *Withdrawal*]. Dow has maintained that the decision is not an admission that silicone implants are unsafe. *Id.*

148. *In re Silicone Gel Breast Implants* Prod. Liab. Litig., 793 F. Supp. 1098 (J.P.M.L. 1992).

149. *Three Major Producers, supra* note 97; *\$4.2 Billion Implant Settlement Is Approved*, N.Y. TIMES, Sept. 2, 1994, at A20 [hereinafter *Settlement Is Approved*].

to pay \$2 billion to the settlement fund.¹⁵⁰ Bristol-Myers Squibb Company and Baxter Healthcare Corporation provided more than \$1 billion.¹⁵¹ This is the largest personal injury settlement in history.¹⁵² Plaintiffs' steering committee co-chair Stanley Chesley estimates the class could be as large as 1.4 million women.¹⁵³ More than 90,500 women have already filed claims.¹⁵⁴

One of the most advantageous features of the settlement is that it opens up a thirty year recovery opportunity for women whose diseases develop or worsen after the statute of limitations has run.¹⁵⁵ Furthermore, under the settlement, women who suffer from one of the specified conditions will receive payments of \$200,000 to \$2 million without proving the implants caused the injury.¹⁵⁶ In addition, most of the women who have filed individual claims cannot identify which of the 1500 kinds of implants they received; the settlement will permit recovery in this situation.¹⁵⁷ The settlement will also compensate plaintiffs in significantly less time than would conventional litigation.¹⁵⁸

Critics of the settlement argue that it will not adequately compensate those plaintiffs with severe injuries.¹⁵⁹ Mike Hugo, a member of the settlement advisory committee, estimates the fund will accommodate only about 3000 women, although an estimated 12,000 cases are currently pending nationwide.¹⁶⁰ If the \$4.25 billion is insufficient to compensate all claimants, plaintiffs may receive smaller payments than their claims warrant.¹⁶¹ Hugo argues that if manufacturers and suppliers want to conceal documents, "they should be willing to fund a settlement of at least \$10 billion."¹⁶² Another critic argues that the settlement unfairly limits recovery of women outside the United States.¹⁶³ Claims by nonresidents are restricted to three percent of the amount United

150. Schwartz, *supra* note 144, at A3.

151. *Id.*

152. *Settlement Is Approved*, *supra* note 149, at A20.

153. *Three Major Producers*, *supra* note 97.

154. *Settlement Is Approved*, *supra* note 149, at A20.

155. *Three Major Producers*, *supra* note 97.

156. *Id.*

157. *See id.*

158. *See id.*

159. *Id.*

160. *Id.*

161. *Settlement Is Approved*, *supra* note 149, at A20.

162. *Three Major Producers*, *supra* note 97.

163. *Id.* (interviewing Mark Steven of the law firm Connell, Lightbody in Vancouver, Canada).

States citizens receive.¹⁶⁴ The approved settlement sets aside \$96.6 million for women outside the United States.¹⁶⁵

Dow has also announced it intends to create a \$10 million research fund, and pay up to \$1200 to women who will need implants removed, or have had implants removed, for "medical reasons."¹⁶⁶ The woman and her doctor will determine what constitutes medical need.¹⁶⁷ Critics argue that the \$1200 would cover only reimbursement for the device itself, as surgical fees can reach several thousand dollars.¹⁶⁸

B. How the Beauty Myth Benefits Industry

The breast implant and cosmetic surgery industries have allowed the myths and underlying assumptions about beauty to sell their products and services. Amid conflicting, frequently deprecating messages women receive from society, one message is clear—women are supposed to be sexy, which translates into breastiness.¹⁶⁹ Boston health advocate Esther Rome calls breast augmentation "a medical solution to a social problem. A lot of women grow up with a poor body image in this culture, but nobody can be the ideal because it's so narrow."¹⁷⁰ These myths and assumptions about beauty have helped manufacturers to sell breast implants, and have helped surgeons to sell augmentation surgery, by shaping a woman's assessment of the product's utility. Thus, these myths and assumptions must be considered in breast implant litigation.

Dow capitalizes on the beauty myth in its informational patient brochure: "If you are thinking about having breast implants, then join the hundreds of thousands of modern women who already have them. And hundreds of thousands more who will soon. Of course, you can look the way you wish. And be a totally happier woman."¹⁷¹ In this brochure, Dow appeals directly to the female consumer's desire to attain happiness through beauty.

164. *Id.*

165. *Settlement Is Approved*, *supra* note 149, at A20.

166. *Withdrawal*, *supra* note 147.

167. *Id.*

168. *Id.*

169. Jan Gehorsam, *Women Feeling Pressured to Sculpt a Perfect Body, Implants a Response to Cultural Message*, ATLANTA J. & CONST., Mar. 29, 1992, at A1 (interviewing Georgia State University sociologist Jackie Boles).

170. Foreman, *supra* note 93, at 37.

171. Bolton, *supra* note 92, at 149.

In separate information provided only to doctors, however, Dow warns against using implants for a patient who "[d]emonstrates psychological instability . . . or inappropriate motivation or attitude."¹⁷² The information does not indicate what might be an "inappropriate motivation" for implant surgery. Dow's patient brochure, however, implies that the pursuit of happiness, as opposed to beauty, is not an inappropriate motive for wanting larger breasts. Thus, Dow's sales literature implicitly relies upon the myth that beauty brings its possessor happiness.¹⁷³

Manufacturers relied upon the changing nature of beauty and its political function¹⁷⁴ to sell breast implants. The popularity of breast size has changed with fashion. The '20s, '40s, and '60s celebrated boyish figures, reflecting growing opportunities for women as they entered the male arena of work.¹⁷⁵ In the '80s, big breasts came back into style, possibly due to media images which sold sex more than ever before. Newspapers, magazines, cable, and video all constantly displayed images of cleavage, much of it artificially enhanced.¹⁷⁶

As the woman-targeted media portrayed women with bigger and bigger breasts, the standard of the normal body image changed.¹⁷⁷ According to one survey, the number of American women dissatisfied with their breast size rose from one-quarter in 1973 to one-third in 1986.¹⁷⁸ Although the number of men surveyed who were dissatisfied with their own chest size also rose over this same period,¹⁷⁹ it was the women, not the men, whom implant manufacturers targeted as consumers. Thus, for women, "fixing the problem" with breast implants became so simple that many felt they were losing out on an opportunity if they declined to do it.¹⁸⁰

172. *Id.* at 155.

173. See *supra* notes 56-58 and accompanying text.

174. See *supra* notes 59-62 and accompanying text.

175. Gehorsam, *supra* note 169, at A1. Katherine Hepburn and Marlene Dietrich are examples of this changing beauty fashion. *Id.*

176. *Id.* Perhaps big breasts regained popularity in the '80s as a reaction to too many women entering male dominated jobs. Big breasts emphasize one of the physical differences between men and women, and women who do not have boyish figures do not fit in with the boys.

177. Linda R. Hirshman, *Reply: Big Breasts and Bengali Beggars: A Reply to Richard Posner and Martha Nussbaum*, 70 TEX. L. REV. 1029, 1032 (1992).

178. Thomas F. Cash et al., *The Great American Shape Up*, PSYCHOL. TODAY, Apr. 1986, at 30, 33.

179. *Id.* The number of dissatisfied men increased from 18% in 1973 to 28% in 1986. *Id.*

180. Gehorsam, *supra* note 169, at A1.

The changing nature and political function of beauty has helped plastic surgeons sell breast augmentation surgery. In the early '80s, the American Society of Plastic and Reconstructive Surgeons (ASPRS) coined a new disease called micromastia, or "small breasts."¹⁸¹ Petitioning the FDA that this was a bona fide medical problem, surgeons claimed that breast implants were often necessary to fix what they termed a "deformity."¹⁸² At least one critic has charged that "micromastia" is nothing more than a "PR blitzkrieg" designed to bolster demand for ASPRS' services.¹⁸³ Although the "ideal" breast size, like other aspects of fashion, has changed over time in the United States,¹⁸⁴ the ASPRS has used medical terminology to reinforce one particular trend. This is a classic example of how those with power reinforce the power structure through naming and labeling.¹⁸⁵

Another writer has argued that such conduct on the part of plastic surgeons, in addition to their active participation in advertising and selling the devices, justifies classifying plastic surgeons as "sellers" of breast implants.¹⁸⁶ This classification would eliminate the immunity from strict liability in tort that plastic surgeons, as providers of a service, currently enjoy.¹⁸⁷

Just as beauty is in the eye of the beholder, often the primary value of breast augmentation is the sexual admiration of others.¹⁸⁸ Although manufacturers claim silicone gel "feels natural,"¹⁸⁹ breast implants frequently cause reduced sensation in the breasts.¹⁹⁰ When this complication occurs, it is unlikely the patient considers her breasts to "feel natural." Moreover, up to seventy-five percent of women with implants experience capsular contracture, which gives their breasts the consistency of hard plastic.¹⁹¹ Iron-

181. *Id.*; Aschinger, *supra* note 119, at 407. MERRIAM WEBSTER'S MEDICAL DESK DICTIONARY 436 (1993) defines micromastia as "postpubertal immaturity and abnormal smallness of the breasts."

182. Aschinger, *supra* note 119, at 407; Gehorsam, *supra* note 169.

183. SUSAN FALUDI, BACKLASH: THE UNDECLARED WAR AGAINST AMERICAN WOMEN 217 (1991).

184. *See supra* notes 175-76 and accompanying text.

185. *See* Bender, *supra* note 8, at 16-25; Martha Minow, *Forward: Justice Engendered*, 101 HARV. L. REV. 10, 61 (1987).

186. Aschinger, *supra* note 119, at 406-15.

187. *See* RESTATEMENT (SECOND) OF TORTS § 402A (1965); *Margine v. Krasnica*, 227 A.2d 539 (N.J. Super. Ct. Law Div. 1967).

188. Hirshman, *supra* note 177, at 1033.

189. WOLF, *supra* note 1, at 248 (describing an advertisement in a surgical journal which shows a man squeezing a silicone gel implant, remarking that it "feels natural").

190. Hirshman, *supra* note 177, at 1033; Bolton, *supra* note 92, at 158-59, 162.

191. WOLF, *supra* note 1, at 248; *see supra* notes 94-96 and accompanying text.

ically, capsular contracture, a purely unintended complication, is merely one step closer (or perhaps one step too far) towards the complete objectification of a woman's body; a transformation into the barbie-doll-like ideal figure, which can be admired and touched, but which has no sensation itself.

III. THE BEAUTY MYTH AND COMPENSATION OF BREAST IMPLANT PLAINTIFFS

Breast implant users are likely to underestimate the risks posed by the product for two reasons: (1) industry misconduct ranging from inadequate testing to outright deception in test results,¹⁹² and (2) the lack of adequate warnings provided to the user.¹⁹³ Furthermore, the beauty myth may influence the user's expectations about beauty products, and thus color her appreciation of their benefits and utility. Because such factors as risk, benefit, and utility are central to a products liability analysis, the beauty myth's influence necessarily has legal consequences in breast implant litigation.

The beauty myth may hinder a breast implant user's recovery by encompassing a double standard. Beauty is promoted as essential to self-worth, and at the same time, characterized as a frivolous pursuit.¹⁹⁴ Such characterizations of a woman's actions further hinder her tort recovery by inviting inappropriate considerations of her conduct. Such considerations may include inquiries into her reasons for choosing the product (for reconstruction or augmentation) and her lifestyle. The following section illustrates how the beauty myth affects silicone breast implant litigation on several levels.

*Livshits v. Natural Y Surgical Specialties*¹⁹⁵ demonstrates how the beauty myth affects an implant user's expectations about breast implants and informs her view of the injuries caused by the implants. In *Livshits*, plaintiff alleged defendant's polyurethane foam-covered silicone gel implants accelerated the development of breast cancer in her right breast, ultimately forcing her to undergo a mastectomy rather than a lumpectomy.¹⁹⁶ Plain-

192. See *supra* notes 121-25 and accompanying text.

193. Under the learned intermediary doctrine, breast implant manufacturers are required to warn the surgeon, rather than the patients, of known risks. See discussion *infra* part IV.

194. See *supra* notes 74-76 and accompanying text.

195. 35 Fed. R. Evid. Serv. (Callaghan) 433 (S.D.N.Y. 1991).

196. *Id.* at *5.

tiff further alleged that the polyurethane foam degraded into a toxic byproduct that caused her to develop cancer in her ovaries and uterus.¹⁹⁷ In addition, plaintiff alleged the silicone and foam residue in her remaining breast made it impossible to monitor for cancer and therefore a mastectomy for this breast was also likely.¹⁹⁸

Plaintiff testified that since early adolescence she had been "acutely concerned" about the appearance of her breasts, and that this concern led her to decide to undergo breast augmentation surgery.¹⁹⁹ In the weeks immediately following surgery, plaintiff experienced an infection.²⁰⁰ Surgeons removed the implants, but the implants ruptured during the procedure, leaving remnants of polyurethane foam and silicone in plaintiff's breast tissue.²⁰¹ Plaintiff stated that when she was later diagnosed with breast cancer, the importance of her physical appearance led her to reject a mastectomy and instead undergo a lumpectomy.²⁰² She experienced continued excruciating pain and observed green liquid seeping from her breasts.²⁰³ Doctors believed that these symptoms were linked to the presence of silicone and polyurethane residue in her breast tissue, which necessitated a mastectomy.²⁰⁴

The beauty myth influenced the plaintiff's decision to undergo breast implant surgery in the first place, and it persuaded her to choose a lumpectomy rather than a mastectomy when she developed breast cancer. In addition, the beauty myth affected her own conceptualization of her injury. She testified, "I don't feel like a woman at all. I feel—I can't look at a mirror of myself, I try not to think about it, I have scars all over, one breast. I have nothing else, I don't know who I am."²⁰⁵

The court held that the expert who testified as to the link between the implants and the acceleration of plaintiff's cancer was not qualified.²⁰⁶ The court therefore set aside a jury verdict for plaintiff of \$2.5 million for pain and suffering, and \$450,000

197. *Id.* at *5-*6.

198. *Id.* at *6.

199. *Id.* at *26-*27.

200. *Id.* at *2-*3.

201. *Id.* at *3.

202. *Id.* at *27.

203. *Id.* at *5.

204. *Id.*

205. *Id.* at *27.

206. *Id.* at *23-*24.

for lost wages, but affirmed an award of \$1.5 million for future damages.²⁰⁷ In order to compensate plaintiff as fairly as possible, however, the court should have considered her injury in its proper context.

Plaintiff's injury occurred in a society that privileges female beauty, in which one's physical attractiveness influences how one is treated and in which a woman's self-esteem is often caught up in her appearance.²⁰⁸ These factors all promote a favorable market atmosphere for the implant industry. To the extent these societal factors aid the manufacturers' sales, courts should consider them when compensating the resulting injuries. Courts should hold manufacturers to a standard of care that recognizes that the same assumptions about beauty that create a demand for implants also inform plaintiffs' perception of their injuries.

In a products liability action, the double standard of the beauty myth²⁰⁹ can lead to inappropriate considerations of the plaintiff's conduct. A good example of such a case is *Turner v. Dow Corning Corp.*²¹⁰ Turner McCartney (McCartney) was a former topless dancer who had augmentation surgery in 1987 and has since undergone six operations to correct problems from implant rupture.²¹¹ McCartney lost a \$7 million lawsuit that alleged that the ruptured implants caused immune dysfunction, chronic fatigue, joint and muscle pain, and short term memory loss. The verdict against McCartney, which came after only one hour of deliberation,²¹² was the first victory for Dow since the FDA moratorium in January 1992.²¹³

Lawyers for Dow focused on McCartney's lifestyle, which influenced at least two of the six jurors.²¹⁴ In a post-trial interview, one juror said, "[Plaintiff] gave her baby up for adoption, she had abortions, she was a dancer for seven years, and all at once she wanted (damages for alleged faulty) breast implants."²¹⁵ An-

207. *Id.* at *33.

208. See discussion *supra* part II.B.

209. See *supra* notes 74-76 and accompanying text.

210. Jennifer Mears, *Dancer Loses Implant Lawsuit: Dow Corning Says Damage Unproven*, DETROIT FREE PRESS, June 12, 1993, at 6A; *Breast Implants: Colorado Jury Returns Defense Verdict in Lawsuit by Former Topless Dancer*, Prod. Liab. Daily (BNA), June 29, 1993, available in Westlaw, BNA-PLD database (discussing *Turner v. Dow Corning Corp.*) [hereinafter *Colorado Jury*].

211. *Colorado Jury*, *supra* note 210.

212. *Id.*

213. Mears, *supra* note 210, at 6A.

214. *Id.*

215. *Colorado Jury*, *supra* note 210 (quoting a videotaped interview recorded by Dow

other juror, however, said that the plaintiff simply failed to link her immune system injuries to the breast implants.²¹⁶ Ironically, a few days after the verdict, a University of Wisconsin Hospital study revealed that women with silicone implants showed signs of abnormal immune system reactions similar to those McCartney alleged.²¹⁷

Plaintiff's attorney, Jo Stone, has suggested that Dow took this case to trial as a part of an overall strategy to dissuade women from coming forward in the future.²¹⁸ In addition, Stone claims Dow hired private investigators to look into plaintiff's past, and the past of her associates.²¹⁹ Stone also alleges that one defense expert was paid \$1 million to testify.²²⁰

Regardless of whether Dow's alleged trial strategies influenced the jury, the jurors' statements make it clear that the beauty myth affected the outcome of the trial. If a breast implant is defective, it is defective even if the plaintiff has given up her baby for adoption, had abortions, or worked as a dancer. These lifestyle choices are irrelevant to the plaintiff's claim. Perhaps the evidence somehow seems less objectionable if the plaintiff claims her alleged injuries resulted from another lifestyle choice on her part—the choice to surgically enlarge her breasts. Moreover, if this choice is considered “frivolous,” the jury may be more likely to dismiss the plaintiff's injuries as just another consequence of her “bad” lifestyle.

Breast augmentation is not merely seen as frivolous, but as an unreasonable, even stupid decision. The injuries from the implants prove the stupidity. Anyone who would have their healthy breasts sliced open and sacs of silicone gel shoved in, merely to look more beautiful, must be stupid.²²¹ Furthermore, this line of thinking is borne out by recurrent stereotypes linking beauty with stupidity, the classic example being the dumb blond.²²²

after the trial. Another juror called the lawsuit a scam. “We thought not only that, we think most (breast implant cases) are going to be scams” (alteration in original) (second alteration in original).

216. *Id.*

217. Mears, *supra* note 210, at 6A.

218. *Colorado Jury*, *supra* note 210. Attorneys for Dow, however, denied having such a legal strategy. *Id.*

219. *Id.*

220. *Id.*

221. See FREEDMAN, *supra* note 63, at 54-55 (setting forth the idea that beautification rituals have been used as proof that women are inferior and stupid).

222. TOLMACH LAKOFF & SCHERR, *supra* note 54, at 35.

The myth that beauty brings its possessor misery²²³ also prejudices the plaintiff. Disfigurement, illnesses, and injuries are part of the price of beauty. No one ever said being beautiful was easy. Furthermore, women's injuries from implants are seen as punishment for deception. The women were trying to "get away" with something, tricking men into believing they were more beautiful, and thus more valuable, than they actually were.²²⁴

Lucinda Finley and others have asserted that the legal and medical systems have often marginalized women's injuries by calling them hysterical, rather than physical.²²⁵ Now implant manufacturers are utilizing this tactic. In *Johnson v. Bristol-Myers Squibb*,²²⁶ the plaintiff suffered a variety of flu-like symptoms, including fatigue, joint pain, chronic infections, and headaches, for two years following the rupture of her left implant during a closed capsulotomy.²²⁷ Defense attorneys unsuccessfully maintained that Johnson was a victim of mass media hysteria, not defective implants.²²⁸ The manufacturer was more successful in *Turner v. Dow Corning Corp.*²²⁹ An attorney for Dow Corning called the victory against McCartney precedent setting because it was based on science, not hysteria.²³⁰

The medical community has responded similarly to implant injuries. In *Martin v. Dow Corning Corp.*,²³¹ the plaintiff also experienced flu-like symptoms, in addition to panic attacks, insomnia, forgetfulness, and confusion. Doctors diagnosed Martin with depression and prescribed an anti-depressant. Later, Martin was hospitalized for two weeks and treated with Prozac, another anti-depressant, for fourteen months. Doctors later discovered that her implants had ruptured.

In addition to diagnosing women's implant-related injuries as hysterical, doctors have maintained that women with small breasts will suffer emotional harm *without* implants. The ASPRS has stated that flat chestedness causes a "total lack of well-being."²³²

223. *Id.* at 32-33.

224. See FREEDMAN, *supra* note 63, at 54-55.

225. See *supra* notes 19-22 and accompanying text.

226. *Breast Implants: Texas Jury Awards \$25 Million to Woman Who Alleged Devices Caused Silicone Disease*, Prod. Liab. Daily (BNA), Jan. 12, 1993, available in Westlaw, BNA-PLD database (discussing *Johnson v. Bristol-Myers Squibb*).

227. *Id.*

228. *Id.*

229. *Colorado Jury*, *supra* note 210.

230. Mears, *supra* note 210, at 6A.

231. *Three Georgia Women*, *supra* note 100 (discussing *Martin v. Dow Corning Corp.*).

232. FALUDI, *supra* note 183, at 217; see *supra* notes 181-87 and accompanying text.

Once again, the beauty myth poses a no-win situation for implant users—without augmentation surgery, women with small breasts will lack emotional well-being, but women who allege implant injuries are called victims of mass media hysteria.

When women choose to have their implants removed, often their surgeons are reluctant or unwilling to perform the surgery.²³³ At the same time, however, many doctors oppose the FDA moratorium and assert that women should have the “right to choose” to undergo breast implant surgery.²³⁴ The American Medical Association (AMA) has voiced support for women’s right to choose silicone or saline implants for augmentation or reconstruction purposes after being fully informed of the risks and benefits.²³⁵ While this language of “choice” implies that doctors are concerned about women’s autonomy, the doctors’ other arguments against the moratorium belie their asserted confidence in women’s decision making ability. The ASPRS has speculated that if silicone implants are not available, women will be afraid to go to doctors when they find a lump in their breasts.²³⁶ Apparently, the ASPRS believes that women are at once capable of deciding to undergo elective breast augmentation surgery, and incapable of deciding to go to a doctor for medical need.

The AMA’s “freedom of choice” argument for breast implant surgery parallels that same organization’s argument against President Clinton’s health care reform plan. Although critics such as the AMA and the insurance industry worry that the plan would limit patients’ choice of hospitals and doctors, at least half of all Americans are already in plans that limit their choice.²³⁷ Analysts say the choice issue is more a “hot button” than a meaningful point of debate.²³⁸

When doctors speak of the “right to choose” breast implant surgery, it is often unclear whose choice they mean. Dr. Jack Fisher, Assistant Clinical Professor of Plastic Surgery at Van-

233. See *supra* notes 117-20 and accompanying text.

234. Aschinger, *supra* note 119, at 411; Dianne Klein, *Breast Implants: Taking Risky Road to Higher Self-Esteem*, L.A. TIMES, Nov. 24, 1991, at E1.

235. John Schwartz, *FDA and AMA Clash on Breast Implants, Kessler Berates Doctors' Group for Taking 'Right to Choose' Stance*, WASH. POST, Feb. 1, 1993, at A4; *Breast Implants: AMA Backs Continued Use of Devices*, PROD. LIAB. DAILY (BNA), Dec. 31, 1992, available in Westlaw, BNA-PLD database.

236. STAFF OF HOUSE COMM. ON GOV'T OPERATIONS, 102D CONG., 2D SESS., *FDA'S REGULATION OF SILICONE BREAST IMPLANTS* 26 (Comm. Print 1992).

237. Joan M. Mazzolini, *What's to Choose? Health Care Already Limited*, PLAIN DEALER, Oct. 4, 1993, at 1B.

238. See *id.*

derbilt University, argues that women should be able to choose silicone implants because the current alternatives are inadequate.

I should use the device that has the best shape, the best contour. The only people who can judge that are my patients and myself. What they (the FDA) are doing is preventing me from giving my patients the best result I can. It's almost like a bureaucrat coming in and saying to a sculptor, "This is how you're going to make your sculpture."²³⁹

Clearly, the FDA's restrictions on the sale of breast implants are based on concerns of safety, not aesthetics. Yet, Dr. Fisher's Pygmalion-esque metaphor of the plastic surgeon as sculptor unintentionally demonstrates the inherent assumptions and implications of the beauty myth. If Dr. Fisher is the sculptor, then the woman who is receiving the implant must be the stone. Carrying the objectification of women to its literal extreme, Dr. Fisher fails to acknowledge the critical difference between surgeon and sculptor: if the sculptor uses defective tools, no living, breathing human being suffers.

IV. RECOMMENDATION AND POLICY

In order to account for the impact of male bias and the beauty myth on the legal and medical systems,²⁴⁰ the breast implant industry,²⁴¹ and subsequent plaintiffs,²⁴² courts should find that manufacturers of breast implants have a duty to warn users directly of dangers associated with their product. Some courts hold manufacturers of oral contraceptives or IUDs²⁴³ to a duty to warn users directly. The same policy rationales that support a duty to warn oral contraceptive or IUD users directly exist in the context of breast implants. Accordingly, courts should extend this duty to breast implant manufacturers, and hold them liable for failure to warn women users directly of a dangerous condition.

239. Glazer, *supra* note 85, at 27 (alteration in original); see also FALUDI, *supra* note 183, at 215-16 (quoting Dr. Robert "the breast man of San Francisco" Harvey: "cosmetic surgeons are sculptors").

240. See discussion *supra* part I.A.

241. See discussion *supra* part II.B.

242. See discussion *supra* part III.

243. N. Kathleen Strickland & John P. Katerndahl, *Current Applications and Limitations on the Learned Intermediary Rule*, in TOXIC TORT CASE ESSENTIALS: STRATEGIES, EXPERTS, MOTIONS, AND ADR 259, 267-71 (PLI Litig. & Admin. Practice Course Handbook Series No. H446, 1992).

A. The Learned Intermediary Doctrine and Its Exceptions

Ordinarily, "a manufacturer of a product, which the manufacturer knows or should know is dangerous by nature or is in a dangerous condition" is under a duty to give warning of those dangers to "persons who it is foreseeable will come in contact with, and consequently be endangered by, that product."²⁴⁴ If, however, the manufacturer reasonably may rely upon an intermediary to warn the user, the learned intermediary doctrine absolves the manufacturer of its duty to warn the user directly.²⁴⁵

The learned intermediary doctrine applies to products classified as prescription drugs or medical devices. The manufacturer's only duty is to warn the prescribing physician. In prescription drug cases, the prescribing physician acts as a "learned intermediary" between the manufacturer and the patient, and "the duty of the ethical drug manufacturer is to warn the doctor, rather than the patient, [although] the manufacturer is directly liable to the patient for a breach of such duty."²⁴⁶ Courts have analogized medical devices to prescription drugs, and held the learned intermediary doctrine also applies to devices such as a heart catheter²⁴⁷ and a cardiac pacemaker.²⁴⁸

Courts have expressed several interrelated reasons for the learned intermediary doctrine:

- (1) physicians, not patients, make the decisions as to whether prescription drugs should be taken—hence patients have little need for information about the risks and benefits of the drugs;
- (2) to the extent patients are involved in such decisions, it is the responsibility of the physician, not the drug company, to provide patients with the necessary information under the doctrine of "informed consent;"
- (3) if manufacturers provide warnings directly to consumers, they could interfere with doctor-patient relationships and deter patients from taking their prescribed medications; and
- (4) it is too difficult to provide warnings to consumers because the risks and benefits . . . are so varied, and so much depends on . . . individual patients that

244. *H.P. Hood & Sons v. Ford Motor Co.*, 345 N.E.2d 683, 688 (Mass. 1976).

245. *Carter v. Yardley & Co.*, 64 N.E.2d 693, 697 (Mass. 1946); see *RESTATEMENT (SECOND) OF TORTS* § 388 cmt. n (1965).

246. *McEwen v. Ortho Pharmaceutical Corp.*, 528 P.2d 522, 529 (Or. 1974) (footnote omitted).

247. *Phelps v. Sherwood Medical Indus.*, 836 F.2d 296 (7th Cir. 1987).

248. *Brooks v. Medtronic, Inc.*, 750 F.2d 1227 (4th Cir. 1984).

the information cannot be meaningfully conveyed via a drug label or package insert.²⁴⁹

Some courts do not apply the learned intermediary rule in cases involving oral contraceptives²⁵⁰ or IUDs.²⁵¹ Manufacturers of these products must warn the patient directly of known dangers.²⁵² In *MacDonald v. Ortho Pharmaceutical Corp.*,²⁵³ plaintiff sued for damages from a stroke caused by defendant's birth control pills. The court reasoned that the nature of "the pill" warranted its exception from the learned intermediary rule:

in light of the heightened participation of patients in decisions relating to use of "the pill"; the substantial risks affiliated with the product's use; the feasibility of direct warnings by the manufacturer to the user; the limited participation of the physician ... and the possibility that oral communications between physicians and consumers may be insufficient ... to apprise consumers of the product's dangers.²⁵⁴

In *Hill v. Searle Laboratories*,²⁵⁵ the court extended the exception for oral contraceptives, a prescription drug, to the IUD, a medical device. The court applied the same reasoning to IUDs that other courts had applied to oral contraceptives: that the patient, rather than the physician, decides to use an IUD; that the product is marketed directly to consumers; that continuing patient-doctor contact is infrequent; and that existing FDA regulations require manufacturers to provide direct warnings to patients.²⁵⁶

B. Current Application in Breast Implant Litigation

So far, courts have applied the learned intermediary doctrine to breast implant litigation. The doctrine requires manufacturers to warn the prescribing physician, rather than the medical pro-

249. Theresa Moran Schwartz, Esq., *Consumer-Directed Prescription Drug Advertising and the Learned Intermediary Rule*, 46 FOOD DRUG COSM. L.J. 829, 830 (1991) (citations omitted).

250. *MacDonald v. Ortho Pharmaceutical Corp.*, 475 N.E.2d 65 (Mass.), cert. denied, 474 U.S. 920 (1985).

251. *Hill v. Searle Labs.*, 884 F.2d 1064 (8th Cir. 1989).

252. *MacDonald*, 475 N.E.2d at 70; Schwartz, *supra* note 249, at 833.

253. 475 N.E.2d 65 (Mass.), cert. denied, 474 U.S. 920 (1985).

254. *Id.* at 70.

255. 2884 F.2d 1064 (8th Cir. 1989).

256. Schwartz, *supra* note 249, at 833-34.

fession generally.²⁵⁷ In *Desmarais v. Dow Corning Corp.*,²⁵⁸ the plaintiff sued the manufacturer of her silicone implants after both implants leaked into her breast tissue.²⁵⁹ Defendant contended that its duty under the learned intermediary doctrine was simply to warn the medical profession as a whole.²⁶⁰ The court held that the manufacturer had a duty to warn the plaintiff's physician, not merely the medical profession, about known dangers of its breast implants.²⁶¹

At least one court has applied the learned intermediary doctrine to breast implant litigation brought under the theory of inadequate warning.²⁶² In *Toole v. McClintock*,²⁶³ the plaintiff had breast augmentation surgery and subsequently suffered from capsular contracture.²⁶⁴ Her surgeon performed a closed capsulotomy that caused the implant to rupture.²⁶⁵ In assessing the plaintiff's claim that defendant's warning to her doctor was inadequate, the court held that "[u]nder the 'learned intermediary doctrine,' the adequacy of [the manufacturer's] message is measured by its effect on the *physician*, ... not by its effect on [the plaintiff]." ²⁶⁶

Courts have classified breast implants as medical devices and applied the learned intermediary doctrine. In *Lee v. Baxter Healthcare Corp.*,²⁶⁷ the plaintiff sued under theories of negligence, strict liability, and breach of warranty after her breast implants ruptured.²⁶⁸ Plaintiff testified that "had she been warned of the possibility of any complications, she would not have proceeded" with the augmentation surgery.²⁶⁹ The court held that the manufacturer had no duty to warn the plaintiff directly of the risks associated with breast prostheses.²⁷⁰ Rather, its only legal duty was to warn the surgeon.²⁷¹ The court reasoned that an implant, like a heart catheter and a cardiac pacemaker, was properly

257. *Desmarais v. Dow Corning Corp.*, 712 F. Supp. 13, 17 (D. Conn. 1989).

258. *Id.*

259. *Id.* at 13-14.

260. *Id.* at 17.

261. *Id.* at 18.

262. *Toole v. McClintock*, 999 F.2d 1430 (11th Cir. 1993).

263. *Id.*

264. *Id.* at 1431.

265. *Id.*

266. *Id.* at 1433.

267. 721 F. Supp. 89 (D. Md. 1989), *aff'd*, 898 F.2d 146 (4th Cir. 1990).

268. *Id.* at 90.

269. *Id.* at 91.

270. *Id.* at 94.

271. *Id.*

classified as a medical device and subject to the learned intermediary doctrine.²⁷²

Like other medical devices to which the learned intermediary doctrine applies, breast implants may be sold only to a licensed physician. In *Perfetti v. McGhan Medical*,²⁷³ plaintiff sued the manufacturer of her saline solution and silicone gel implants after the saline solution leaked from the left implant and the breast deflated.²⁷⁴ On the plaintiff's claim for failure to warn, the court reasoned that because the sale of implants was restricted to doctors only, the learned intermediary doctrine should apply to breast implants. "[A] manufacturer of a product ... which is obtainable only through the services of a physician fulfills its duty if it warns the physician of the dangers attendant upon its use, and need not warn the patient as well."²⁷⁵

Perfetti and *Lee* can be distinguished. In *Perfetti*, the plaintiff had previously undergone a mastectomy and her doctor recommended the implants for medical reasons.²⁷⁶ In *Lee*, however, the plaintiff had implants for augmentation purposes.²⁷⁷ Thus, the plaintiff in *Perfetti* was in a similar circumstance to a patient who receives a heart catheter or a cardiac pacemaker. On the other hand, *Lee* was healthy at the time of her decision, and thus more similar to the typical oral contraceptive user.

C. Why Courts Should Modify the Learned Intermediary Rule for Breast Implant Litigation

Breast implants for augmentation purposes are more analogous to birth control than to heart catheters or cardiac pacemakers. Implants, like contraceptives, are chosen actively by the user. Direct warnings to the user are not only feasible, but have been required by the FDA since 1991.²⁷⁸ Once the surgery is performed, contact between patient and plastic surgeon is even more sporadic than contact between patient and gynecologist.²⁷⁹ Also, implants

272. *Id.* at 95.

273. 662 P.2d 646 (N.M. Ct. App. 1983), *cert. denied*, 662 P.2d 645 (N.M. 1983).

274. *Id.* at 648.

275. *Id.* at 650 (quoting *Terhune v. A.H. Robins Co.*, 577 P.2d 975, 979 (Wash. 1978)).

276. *Id.* at 648.

277. *Lee v. Baxter Healthcare Corp.*, 721 F. Supp. 89, 91 (D. Md. 1989).

278. *Breast Implants: FDA Orders Makers to Give Doctors Information on Risks to Pass on to Patients*, Prod. Liab. Daily (BNA), Oct. 15, 1991, available in Westlaw, BNA-PLD database.

279. *MacDonald v. Ortho Pharmaceutical Corp.*, 475 N.E.2d 65, 69 (Mass.), *cert. denied*, 474 U.S. 920 (1985) (citing to J. WILLSON ET AL., *OBSTETRICS AND GYNECOLOGY* 184 (7th ed. 1983); D. DANFORTH, *OBSTETRICS AND GYNECOLOGY* 267 (4th ed. 1982); T. GREEN, *GYNECOLOGY: ESSENTIALS OF CLINICAL PRACTICE* 593 (3d ed. 1977)).

and contraceptives are less therapeutic in nature than heart catheters or cardiac pacemakers. Thus, the exception to the learned intermediary rule created in *MacDonald* should extend to breast implants chosen for cosmetic purposes.

*Phillips v. Baxter Healthcare Corp.*²⁸⁰ is a good case example of why and how courts should extend the exception to the learned intermediary doctrine to breast implant cases. In *Phillips*, the plaintiff underwent breast augmentation surgery with defendant's silicone implants and subsequently experienced three successive capsular contractures.²⁸¹ Her doctor performed a closed capsulotomy to correct the second capsular contracture. Later her right implant ruptured while she was reading a book and "rolled over onto her stomach and felt a 'popping' in her chest."²⁸² Plaintiff claimed, *inter alia*, that defendant breached its duty to warn of implant rupture and that the silicone used had a low viscosity which made it more likely to migrate to other parts of her body.²⁸³ The court held that breast implants did not present a "special circumstance" which would warrant an exception to the learned intermediary doctrine.²⁸⁴ Furthermore, the court did not "accept that breast augmentation patients are more actively involved in the use of the medical device than patients who 'passively' ingest pharmaceuticals."²⁸⁵ Finally, the court held that "[t]he physician is in the superior position to evaluate product risks and side effects, not the patient. The licensed physician is, in effect, the consumer."²⁸⁶

What the court did not discuss is at least as interesting as what it did. The court, for example, did not distinguish between a healthy woman who elects breast augmentation surgery for nonmedical reasons and a prescription drug user for whom a physician prescribes the drug specifically for medical reasons. In effect the court did not examine whether a warning to the plaintiff would have affected her decision to undergo surgery in the first place, but focused on whether a warning would have changed her use of the product. Thus, the court could not "accept that breast augmentation patients are more actively involved in

280. No. B061926, 1993 WL 524688 (Cal. Ct. App. Nov. 9, 1993).

281. *Id.* at *1.

282. *Id.*

283. *Id.* at *2.

284. *Id.* at *6.*7.

285. *Id.* at *7.

286. *Id.* (citing *Rosburg v. Minnesota Mining & Mfg. Co.*, 226 Cal. Rptr. 299, 303 (Ct. App. 1986)).

*the use of the medical device than patients who 'passively' ingest pharmaceuticals."*²⁸⁷

Arguing for direct warnings to the user, the plaintiff raised the issue that breast implant users may be treated by different doctors who are not aware of the brand of implant or specific warnings accompanying that particular brand. The court stated that it "seem[ed] obvious that it would be inappropriate for the manufacturer to warn the patient and then rely on the patient to deliver those warnings to the subsequent physician."²⁸⁸ The court, however, did not consider that an adequate warning to the intended user could influence her decision to use the product in the first place. Moreover, the court did not address why the manufacturer could not warn both the physician and the user. In situations in which the court chooses to characterize the consumer and the user as two different parties, perhaps two warnings are the most "obvious" solution.

V. CONCLUSION

Male bias within the legal and medical systems disadvantages women mass tort plaintiffs by increasing the probability of harm and decreasing the probability of full recovery. When the litigation involves a beauty product, such as silicone breast implants, the beauty myth further impedes recovery by influencing the plaintiff's assessment of the product's utility, and by inviting the fact finder to make inappropriate considerations of the plaintiff's conduct. Regardless of whether the breast implant industry actively or intentionally used the beauty myth to increase profits, both manufacturers and surgeons benefitted from the beauty myth, and, at the same time, perpetuated it. To this extent, the legal system should consider the role of the beauty myth in the resulting breast implant litigation.

Given the predictions that the settlement offer by the major manufacturers will cover only about one-fourth of current claims, a substantial amount of breast implant litigation will remain in the courts. Thus, courts still have an opportunity to find a just result. To this end, they should hold manufacturers to a duty to warn implant users directly and allow plaintiffs to bypass the learned intermediary doctrine in failure to warn claims.

²⁸⁷ *Id.* (emphasis added).

²⁸⁸ *Id.*