5-1-1997

Keeping Women in the Dark: Lessons Not Learned and the Real Sins of the Breast Implant Manufacturers

Richard McCormick

Follow this and additional works at: http://lawdigitalcommons.bc.edu/twlj

Part of the Consumer Protection Law Commons, Health Law Commons, and the Women Commons

Recommended Citation
KEEPING WOMEN IN THE DARK: LESSONS NOT LEARNED AND THE REAL SINS OF THE BREAST IMPLANT MANUFACTURERS

RICHARD MCCORMICK*


The lengthy and erratic relationship between the Food and Drug Administration (FDA) and the silicone gel-filled breast implant manufacturers finally fractured on April 16, 1992, when FDA Commissioner David Kessler issued a ban1 on the sale of what had become a billion-dollar enterprise2 for Dow Corning and five other corporations.3 Kessler’s publicly stated reason for the ban was that the manufacturers had not

---

* Staff Writer, Boston College Third World Law Journal.

1 See MARCIA ANGELL, SCIENCE ON TRIAL 57 (1996). Although silicone breast implants had been on the market since 1964, they did not fall within the regulatory power of the FDA until 1976, when Congress passed the Medical Device Amendments to the Food, Drug, and Cosmetic Act. See id. at 51. Even then, the implant manufacturers were “grandfathered” and did not have to provide immediate evidence of the safety and effectiveness of their product. See id. In 1982, however, the FDA proposed a rule to classify implants as Type III Medical Devices, a move that would require the manufacturers to produce data showing that implants would not pose a health risk. See 47 Fed. Reg. 2,820 (1982) (to be codified at 21 C.F.R. § 878) (proposed Jan. 19, 1982). The FDA issued a final rule on the classification on June 24, 1988, giving the manufacturers 30 months to file their premarket approval applications. See 53 Fed. Reg. 23,872-74 (1988) (to be codified at 21 C.F.R. § 878). By April of 1991, the manufacturers had still not complied with the regulations, and the FDA issued an ultimatum: they must submit their applications within 90 days or suspend commercial distribution of the implants. See 56 Fed. Reg. 14,627 (1991) (to be codified at 21 C.F.R. § 878). The manufacturers responded unsatisfactorily, producing numerous but unhelpful studies. See Philip J. Hilts, Drug Agency Questions Companies’ Safety Data on Breast Implants, N.Y. TIMES, Sept. 17, 1991, at B6. Shortly thereafter, the FDA announced a temporary moratorium on the sale of implants, which, on the prompt of an advisory panel, evolved into the almost-complete ban of April, 1992. See ANGELL, supra, at 56-57. Only women who had undergone mastectomies could obtain silicone implants, and even then the conditions were closely controlled. See id. Saline-filled implant manufacturers were allowed to continue selling their product, but they too must eventually show data on safety. See id. at 60-61.

2 This estimate represents the peak years of implantation from 1979 to 1992. See ANGELL, supra note 1, at 34.

3 These smaller players were Bristol-Myers Squibb; Baxter International; Bioplasty, Inc.; Mentor Corporation; and McGhan Medical Corporation (now Inamed). See id.
positively demonstrated the implants' safety in accordance with FDA regulations. However, his decision was not made in a statutory and regulatory vacuum. He was likely also responding to breast implant recipients' complaints that implants were the cause of their connective tissue diseases (CTDs); to the pressures of an aggressive plaintiffs' bar that had everything to gain from an FDA ban and all that it implied about the safety of implants; to consumer groups' chastisement of the FDA for dragging its feet for so long; to the sensationalistic media coverage of the purported health hazard; and to the discovery of Dow Corning's internal documents suggesting their knowledge of unfavorable or non-existent safety data.

But the breast implant debate resounds beyond the political and public pressures that influenced Kessler's decision. The larger controversy revolves around women's claims that breast implants have caused their illnesses. The ensuing litigation of these claims has cost the implant manufacturers billions of dollars in jury verdicts and settlements, even though the plaintiffs' scientific evidence of causation was

---

4 See David Kessler, The Basis of the FDA's Decision on Implants, 326 NEW ENG. J. MED. 1713, 1713 (1992). As Kessler wrote: "The . . . standard is not that devices must be proved unsafe before the FDA can protect patients against their use. Rather, the law requires a positive demonstration of safety—and the burden of proof rests squarely with the manufacturer." Id.

5 See ANGELL, supra note 1, at 51–52. CTDs can be the manifestation of an autoimmune disease, where the person's immune system can no longer recognize and mounts an attack against the body's own cells. See id. at 21. Immune responses directed at connective tissue can result in CTDs such as lupus, rheumatoid arthritis, scleroderma, and polymyalgia. See id. Breast implants may also cause local complications of inflammation and formation of scar tissue around the implants, but most of the litigation concerned CTDs. See id.

6 See generally id. at 25–26.

7 See id. at 53.

8 See id. at 53–54.

9 See id. at 56; see also infra notes 112–19 and accompanying text (discussing the contents of the documents).

10 See ANGELL, supra note 1, at 21–24.

11 The first lawsuit was filed by Maria Stern against Dow Corning, alleging that implants caused her autoimmune disorder. See id. at 52. In 1984, a jury awarded her close to two million dollars. See id. In December, 1991, a jury awarded Mariann Hopkins $840,000 in compensatory damages and $6.5 million dollars in punitive damages for her mixed connective tissue disease. See Hopkins v. Dow Corning Corp., 33 F.3d 1116, 1119, 1126 (9th Cir. 1994), cert. denied, 115 S. Ct. 734 (1995). One year later, Pamela Johnson received a $25 million verdict against Bristol-Myers Squibb. See ANGELL, supra note 1, at 134–35. These are just a few of the cases decided in plaintiff's favor before a $4.25 billion class-action settlement was approved on April 1, 1994. See id. at 80. The settlement prospect had temporarily stalled when Dow Corning filed for bankruptcy protection on May 15, 1995. See id. at 192. The remaining corporations have since renegotiated a new settlement for two to three billion dollars. See Barnaby J. Feder, Dow Corning Offers Plan to End Suits, N.Y. TIMES, Dec. 3, 1996, at D1. Dow Corning has recently proposed a new plan that would
too tenuous to demonstrate a link between the implants and CTDs.12 Epidemiological studies13 published between 1994 and 1995 confirm that there is no clear connection between breast implants and CTDs.14

Marcia Angell recounts this element of the breast implant saga, its foundations and what it has wrought, in her book *Science on Trial: The Clash of Medical Evidence and the Law in the Breast Implant Case*.15 Part I of this Book Review will discuss Dr. Angell’s16 chief complaint about the basis and outcome of the breast implant litigation: verdicts for plaintiffs in the face of meager evidence of causation.

Because breast implants require a medical procedure to insert, it is important to view the controversy in light of the special physical and

end its credit woes, offering breast implant recipients $600 million initially, with an additional payment of $1.4 billion only if the results of a trial on causation show that implants can cause disease. See id. Dow Corning Corporation’s commercial creditors, however, have proposed a different settlement that would pay $1.75 billion into a Claims Trust set up to compensate women, regardless of any causation issues. See Thomas M. Burton, *Dow Corning Creditor Group Files Its Plan*, WALL ST. J., Jan. 13, 1997, at B6. Judge Arthur J. Spector of the U.S. Bankruptcy Court for the Eastern District of Michigan is expected to decide between the two proposals sometime in the first half of 1997. See id.

12 See *Angell*, supra note 1, at 27; see also Donald A. Lawson, Note, *Hopkins v. Dow Corning Corporation: Silicone and Science*, 37 Jurimetrics J. 53, 66-68 (1996) (stating that the “paucity” of the scientific evidence based on anecdotes and toxicological studies would not support an inference that breast implants cause CTDs).

Some of the evidence offered by the plaintiffs may have also been unreliable. See Gary Taubes, *Silicone in the System*, DISCOVER, Dec. 1995, at 64, 70. A frequent collaborator with plaintiff’s attorneys, Dr. Nir Kossovsky has supposedly developed a test able to detect autoimmune antibody reactions caused by silicone. See id. However, researchers at the Scripps Research Institute doubt the validity of his findings, as Kossovsky’s test has failed to distinguish autoimmunity in women with or without implants. See id. In addition, Kossovsky’s reported data is based on subject populations too small to yield statistically significant results. See id. at 71.

13 Epidemiological studies are “scientific surveys of the incidence of disease in samples of different groups.” *Angell*, supra note 1, at 23. Essentially, these studies can determine if women with implants have a higher risk of developing CTDs than women without implants. See id. For a discussion of the value of epidemiological studies in the determination of disease causation, see infra notes 19-22 and accompanying text.

14 See *Angell*, supra note 1, at 100-03. These studies have not ruled out a very small link between implants and connective tissue disease. See id. at 102-03. However, such a risk is not in proportion to the 248,500 women (out of a total of one to two million) with implants who claim to have such illnesses. See id. at 80, 100-03. In a paper co-authored by David Kessler, researchers at the FDA came to a similar conclusion after reviewing all of the published studies: they do not indicate a large increase in CTDs among women with breast implants when compared to the general population of women, although a moderate risk may still exist. See Barbara G. Silverman et al., *Reported Complications of Silicone Gel Breast Implants: An Epidemiological Review*, 124 ANNALS OF INTERNAL MED. 744, 754-55 (1996).

15 *Angell*, supra note 1.

16 She is a physician and the executive editor of the New England Journal of Medicine. See id. at 9.
intangible harm women have suffered at the hands of doctors and the manufacturers of medical devices and pharmaceuticals; therefore, Part II of this Review will lay out women’s experiences with physicians and with pharmaceuticals and medical devices. Part III will focus on the manufacturers’ knowledge and conduct in testing and marketing the implants. Part IV will explore the element of causation in tort law, why it is required, and why the breast implant manufacturers should not be held liable for the physical systemic injuries of the plaintiffs. Finally, Part V will consider the idea of a dignitary tort to compensate breast implant recipients and deter manufacturers from risky marketing practices.

I. A Scientific Approach to Causation and the Proclaimed Innocence of the Breast Implant Manufacturers

The element of causation is the sturdy hook upon which Marcia Angell hangs both her outrage and her argument. She correctly bemoans the windfalls plaintiffs have received, because they were never able to prove that implants were the cause in fact of their illnesses. Dr. Angell’s input on this issue is informed by her medical training: she brings to the breast implant debate a classic scientist’s perspective on causation. First, she believes that causation in disease is best viewed in terms of “risk factors.” Second, and more importantly, she believes that epidemiological studies are the only way to determine whether a risk factor actually exists. When the plaintiff’s burden of production is viewed through the lens of science, then, it becomes evident that

---

17 See generally id. at 21–24.
18 See infra Part IV for a discussion about why a lack of causation will bar recovery.
19 See Troyen A. Brennan, Untangling Causation Issues in Law and Medicine: Hazardous Substance Litigation, 107 ANNALS OF INTERNAL MED. 741, 741–43 (1987) (discussing the divergent views of causation in the law and science: judges tend to rely on mechanistic corpuscularian-based models of causal chains, while scientists recognize that causal concepts are best represented by a probability of association).
20 See Angell, supra note 1, at 98. In eschewing the language of “cause” in favor of “contribution,” “risk factor,” “association,” and other probabilistic terms, she emphasizes the fact that many diseases do not have a single necessary and sufficient cause. See id. That is, breast implants may increase the “chances” of developing CTDs, but they are not required or sufficient to do so, as is evidenced by women without implants who develop CTDs and those with implants who do not. See id. at 97–98.
21 See id. at 100. Before it can be determined if breast implants caused CTDs in any particular plaintiff (i.e., proof of specific causation), it must first be settled if implants can cause CTDs at all (i.e., proof of general causation). See id. at 115. The only way to do this is through epidemiological studies. See id. If CTDs do not occur more often in women with implants than without them,
they failed to offer evidence to prove by a preponderance of the evidence that implants are associated with CTDs.22

Given the limited scientific evidence of causation, Dr. Angell muses upon the impetus behind frivolous litigation and the foundations of baseless jury verdicts, and asks “How could the law have been so far out in front of the scientific evidence . . . ?”23 She ultimately lays the blame on several culprits. First, she reproaches the greed of the plaintiffs’ lawyers24 and expert witnesses,25 and of the plaintiffs themselves.26 Second, she blames the hysteria of the American public, fomented by the media’s coverage of the “alarm of the day.”27 Third, she criticizes the use of lay juries in cases involving complex scientific or technical testimony; she fears that the jurors in the breast implant litigation may not have been up to the task of truly comprehending evidence of disease causation,28 and may have returned verdicts based more on sympathy for the clearly aggrieved plaintiffs than on sense.29 Finally, she casts doubt on the evidentiary rules of the legal system and their

22 See id. at 113–14.
23 Id. at 23.
24 See generally id. at 133–53.
25 See ANGELL, supra note 1, at 133–53.
26 See id.
27 See generally id. at 154–76.
28 See id. at 204. Dr. Angell similarly writes of an anti-science sentiment among the American public, see id. at 171–83, and how anecdote and surmise, tempered by political and social inclinations, have surpassed fact in a juror’s mind, see id. at 183–91. Juries therefore may be unsophisticated and incapable of separating the chaff of fringe science from the grain of the established scientific community. See, e.g., Brief for the American Association for the Advancement of Science and the National Academy of Sciences as Amici Curiae in Support of Respondents at 5, Daubert v. Merrell Dow Pharm., 113 S. Ct. 2786 (1993) (No. 92–102). But see Rochelle Cooper Dreyfuss, Is Science a Special Case? The Admissibility of Scientific Evidence After Daubert v. Merrell Dow, 73 Tex. L. Rev. 1779, 1796–1800 (1995) (arguing that juries are not overwhelmed by scientific evidence and do not allow it to take on an aura of mythic infallibility). To be fair to the juries in these cases, however, it should be understood that the scientific evidence they were evaluating was deemed admissible by the trial judges, and all of the verdicts came before the contrary epidemiological studies were published. See generally Lawson, supra note 12, at 68. The jury simply used the only evidence it had. See id.
29 See ANGELL, supra note 1, at 74–75. Many of the plaintiff’s lawyers commingled the elements of causation and damages in order to support the weakness of the former with the strength of the latter. See id. at 74.

Perhaps a more cogent way to reconcile the jury verdicts with lack of causation is to realize
ability to discern the conclusory opinions of expert witnesses from valid scientific analysis based on verifiable data.30

Dr. Angell has written a finely detailed and insightful book; the breast implant litigation juggernaut is laid bare by her penetrating analysis. In her rush to point a finger at the failures and foibles of the legal establishment, however, she elides the greed of the breast implant manufacturers. She claims that the “derelictions of the manufacturers paled in comparison” to the greed of the plaintiffs’ attorneys,31 but the manufacturers in the breast implant case surely had their own profit motives to satisfy—and they did so at the expense of women. Allowing that breast implants do not cause CTDs, the manufacturers still acted in bad faith by marketing a product without warnings when they had good reason to believe that it was unsafe.32 Their actions may not have caused physical injury, but they translated into an insult to the autonomy and dignity of women—an insult that has long existed in the healthcare industry.

that jurors are consumers of products. Even defense counsel in products liability cases admit as much. See Robert L. Haig & Stephen P. Caley, Successfully Defending Products Liability Cases, N.Y. St. B.J., Mar./Apr. 1996, at 16 (suggesting that defense lawyers “impress upon the jury that [their] client is . . . a manufacturer or distributor of useful products that are demanded by and benefit society, including, very often, consumers like . . . jurors”). Accordingly, they are also people who rely on the safety of products, and are just as likely to be affected by defective goods as the breast implant recipients seemed to be, so the misdeeds of a manufacturer could be believed by a juror to visit them in the form of grievous bodily injury. See Jack W. Snyder, Environmental (Toxic) Torts, 34 Duq. L. Rev. 899, 903-04 (1996). It is therefore possible that the jury was finding liability on the basis of outrage over the manufacturer’s deliberately risky conduct, and not only on the harm suffered by the plaintiffs. See id. This was probably a critical factor as the jurors became aware of the manufacturers’ inaction, misrepresentation, and nondisclosure of the possibility of risk of CTDs. See id.

30 See ANGELL, supra note 1, at 131–32. She does this while admitting that the United States Supreme Court opinion in Daubert v. Merrell Dow Pharmaceuticals, 113 S. Ct. 2786 (1993), could go a long way in keeping out unsubstantiated scientific theories. See ANGELL, supra note 1, at 130–32. Daubert held that expert testimony may only be admitted if its basis is scientifically valid and relevant to the issue at hand. See 113 S. Ct. at 2795–96. However, Dr. Angell reserved her final judgment on the ultimate effectiveness of the decision. See ANGELL, supra note 1, at 132. A recent breast implant case may put her fears to rest. In Hall v. Baxter Healthcare Corp., No. 92–182-JO, 1996 WL 730693 (D. Or. Dec. 18, 1996), Judge Robert E. Jones, presiding over a number of cases remanded to the U.S. District Court in Oregon, granted the defendants’ motion in limine to exclude evidence on causation presented by the plaintiffs’ expert witnesses. See id. at *17. Judge Jones ruled that their testimony was not admissible under the standard set forth in Daubert. See id.

31 ANGELL, supra note 1, at 202.

32 See infra Part III (discussing the scientific data available to the breast implant manufacturers before and during marketing).
II. Women’s Experiences as Consumers of Healthcare

Women’s reproductive systems and anatomies are under the constant assault of a society obsessed with perfection and convenience. Modern medical technology can assist in creating this culturally-defined image of the perfect woman, who is at once voluptuous and trim (think Barbie), with an easily manipulable fertility. Taking into account the normal intricacies of gynecological function as well, it should come as no surprise that two out of every three healthcare dollars in the United States are spent by women. As women are being “pushed” into becoming greater consumers of healthcare, they are

34 See id. at 248. Women who have succumbed to the allure of this image are driven to modify their bodies in accordance with it, through breast augmentation, liposuction, and other cosmetic surgery procedures. See id. at 231–32. Whether their decision is driven internally (boosting self-esteem) or externally (pleasing the opposite sex) is open to debate. See Angell, supra note 1, at 33–36 (briefly discussing the cultural vicissitudes and personal choices behind breast augmentation). The male medical and corporate establishment, however, have provided the means for the transformation. See Rebecca Weisman, Reforms in Medical Device Regulation: An Examination of the Silicone Gel Breast Implant Debacle, 23 Golden Gate U. L. Rev. 973, 991 (1993); Wolf, supra note 33, at 232–34, 268.
35 See Wolf, supra note 33, at 266–67.
36 See Elisabeth Beck-Gernsheim, From the Pill to Test-Tube Babies: New Options, New Pressures in Reproductive Behavior, in Healing Technology: Feminist Perspectives 23, 31–32 (Kathryn Strother Ratcliff et al. eds., 1989). Although women would appear to reap the greater benefit from increasingly effective contraception, men too can revel in the freedom: “[W]omen . . . become both more readily available and disposable, because the sexual relationship is ‘without consequences.’ Men . . . are relieved of even more responsibility than before.” Id. at 32. In addition, women alone bear the health risks of contraception. See id. Their onus has no match in the world of male-based contraception. See Kim Yanoshik & Judy Norsigian, Contraception, Control, and Choice: International Perspectives, in Healing Technology: Feminist Perspectives, supra, at 61, 70–72. Men have never had to expose themselves to the risk, discomfort, or invasiveness of modern contraception because “[a]s the majority of scientists, researchers, developers, physicians, drug company vendors and executives, and governmental officials, [they] control the way contraceptive research is developed and implemented.” Id. at 71. Only a small percentage of contraception research and development money is spent on male methods. See id. at 70.
38 See Charles Mann, Women’s Health Research Blossoms, 269 Science 766, 767 (1995). Women may also pay more than men because they are less likely to have jobs that provide health insurance, or they may not work at all. See Patricia Braus, Sex and the Single Spender, Am. Demographics, Nov. 1993, at 28, 32.
also, perversely, being pushed into a greater danger of medical malocurrence. Gender disparities in treatment and diagnosis of female and male patients adversely affect the quality of healthcare that women receive. 39 Women are also the victims of iatrogenic harm at the hands of inept cosmetic surgeons. 40

39 Studies have shown that a woman's gender-neutral symptoms are treated less seriously than identical male complaints. See Karen A. Armitage et al., Response of Physicians to Medical Complaints in Men and Women, 241 JAMA 2186 (1979); Council on Ethical and Judicial Affairs, American Medical Association, Gender Disparities in Clinical Decision Making, 266 JAMA 559, 561-62 (1991) [hereinafter Gender Disparities]. This difference in treatment may be due to bias in perceived gender roles. See Gender Disparities, supra, at 561. For example, men might receive more kidney transplants than women because their role as the "bread winner" of the family is awarded with the less cumbersome alternative of transplant instead of dialysis. See id. In other cases the bias is more discreet: although heart disease is the number one killer of women (in fact, it strikes both men and women equally), most doctors do not recognize the warning signs peculiar to women, possibly because of the common misconception that heart disease is solely a male concern. See For Women Sick at Heart, Tufts Univ. Diet & Nutrition NewsL., Nov. 1, 1995, at 2.

Another explanation for gender disparities may be that doctors attribute women's symptoms to an emotional and overanxious reaction to some perturbation in their health. See Gender Disparities, supra, at 561; Napoli, supra note 37, at 336. Women with test results indicating a cardiac abnormality were still twice as likely to have their symptoms attributed to a psychiatric or noncardiac etiology. See Gender Disparities, supra, at 560. History bears this out as, up until 1982, physicians still ascribed many of women's complaints to "hysteria." See George E. Murphy, The Clinical Management of Hystera, 247 JAMA 2559 (1982); see also Wolf, supra note 33, at 268 (stating that women have been regimented into compliancy through the over-prescription of tranquilizers); Patricia Peppin, Feminism, Law, and the Pharmaceutical Industry, in Corporate Crime: Contemporary Debates 87, 89 (Frank Pearce & Laureen Snider, eds. 1995) [hereinafter Peppin, Feminism] (stating that older women presenting gender-neutral symptoms are more likely than men to be prescribed mood-altering drugs). But see Angell, supra note 1, at 182 (stating that the medical profession, for the most part, no longer treats women's illnesses as being psychosomatic).

Some decisionmaking disparities are not due directly to gender bias on the part of the treating physician. See Gender Disparities, supra, at 560-61. Inaccurate diagnoses and insufficient therapies may be based on imperfect information about female physiology and the symptoms it manifests when diseased. See id. This bias is due in large part to the historical exclusion of women as subjects in clinical research and trials. See id. at 559; see also 1 Committee on the Ethical and Legal Issues Relating to the Inclusion of Women in Clinical Studies, Institute of Medicine, Women and Health Research: Ethical and Legal Issues of Including Women in Clinical Studies 27 (Anna C. Mastroianni et al. eds., 1994). This "male-model" of disease has created a gap in the knowledge that informs clinical decision making, and has resulted in poorer healthcare for women. See Gender Disparities, supra, at 559. But see Mann, supra note 38, at 767 (stating that more of the National Institute of Health's research budget is spent on female diseases than male diseases, and that clinical trials for gender-neutral diseases now include equal numbers of men and women).

Some of the most extreme trespasses against women are of an informational character, although the harm often extends into the physical. The first type of informational harm concerns unnecessary surgeries performed on women without disclosure of less invasive alternatives. The second type encompasses physical harm that flows directly from pharmaceutical and medical device manufacturers' failure to disclose risks associated with their products.

A. Unnecessary Surgery and the Expropriation of Women's Decisionmaking Capabilities

The doctor-patient relationship has always been one of inherent imbalance. The doctor's special knowledge and aura of breeding and education give him a larger share of power over the course and extent of treatment. The atmosphere of silence and authority established by the physician reduces the patient to a subsidiary participant in the quest to cure the disease, thus excluding the patient from a decision-making process that will ultimately affect him or her. This occurs at a time when the patient's body is in revolt—a time in which vulnerability creates an even greater need for the patient to have a voice in the search for a cure. This asymmetrical power distribution is magnified

around breast implants, the resultant misshapen breast can be forced back into shape in a simple but painful procedure called a "closed capsulotomy." See Angell, supra note 1, at 41. The physician forcefully squeezes the breast to dissipate the dense scar tissue and return the breast to its normal shape and consistency. See id. at 41-42. The result is often temporary, as scar tissue generally reforms. See id. at 42. What often attends this procedure is acute inflammation and trauma to the breast, and rupture of the implant itself, spreading silicone throughout the breast tissue where it may be transported to the lymph nodes. See id. at 41-42. Although the breast implant manufacturers warned of the possibility of rupture accompanying this procedure, some doctors persisted in its use. See id. at 135. The inherent brutality of this procedure also shows a lack of compassion for the female patient. See id.

Furthermore, women are more likely than men to be harmed by their physicians in ways that demand punitive damages. See Thomas Koenig & Michael Rustad, His and Her Tort Reform: Gender Injustice in Disguise, 70 Wash. L. Rev. 1, 58-59 (1995). Approximately two-thirds of all punitive damages verdicts for medical malpractice are awarded to women. See id. at 59-61. The spectrum of wrongdoing in these cases includes sexual misconduct, see id. at 64-66, injury due to gross incompetence, see id. at 71-75, and extreme failure of informed consent, see id. at 69-71.


43 See Katz, supra note 41, at 28-29; Patricia Peppin, Power and Disadvantage in Medical Relationships, 5 Tex. J. Women & L. 221, 222-23 (1994) [hereinafter Peppin, Power and Disadvantage].

44 See Peppin, Power and Disadvantage, supra note 43, at 222-23.
when the patient is female, because the profession has traditionally been male-dominated\(^{45}\) and has failed to appreciate the female perspective.\(^{46}\)

The combination of doctor-patient and male-female roles creates an environment ripe for the violation of women’s autonomy and bodily integrity.\(^{47}\) Although these interests may be protected by the doctrine of informed consent,\(^{48}\) they have nonetheless been abrogated in many cases of hysterectomies\(^{49}\) and cesarean sections.\(^{50}\) These procedures are the two most commonly performed surgeries in the United States, but they have been heavily criticized as being unnecessary in many instances.\(^{51}\)

Hysterectomies are frequently prescribed by physicians without full explanation of the risks and alternatives;\(^{52}\) this can be inferred from the fact that the procedure is not usually medically necessary.\(^{53}\) Prevalent attitudes toward female reproductive systems might be responsible

\(^{45}\) See J. Duncan Moore, Jr., *Ranks of Physicians Continue to Swell*, MODERN HEALTHCARE, Mar. 4, 1996, at 2. However, the population of female doctors has been steadily growing. See id. In 1970 they accounted for only 7.7% of all doctors; by 1994, the profession was 19.5% women. See id. This rising tide is expected to continue: in 1994, medical school enrollment of women was nearly 42%. See Andrea Peyser, *Gains: We’ve Come a Long Way, Baby!*, COSMOPOLITAN, May 1994, at 198.

\(^{46}\) See Fisher, *supra* note 42, at 30–31. As Western medicine expanded during the nineteenth century, women’s historical roles as healthcare providers for their gender were usurped by the larger male presence in the field. See id. Concepts of female health were altered by this new generation of doctors, and natural female processes were relegated to the status of “benign diseases.” See id. Familiarity with women’s health issues is still spotty today. See Betty Morris, *Women and Health: Medicine Begins Filling in the Gap*, FLA. TODAY, May 14, 1996, at 1D. Of 126 medical schools in the United States, only one integrates these issues into the required coursework; only four offer residencies in women’s health; and only one-fourth offer any classes at all on women’s health issues, and when they do, it is usually an elective. See id.


\(^{48}\) See Peppin, *Power and Disadvantage*, *supra* note 43, at 230; see also infra notes 136–38 and accompanying text (discussing the history of informed consent cases).

\(^{49}\) See Napoli, *supra* note 37, at 355–57 (discussing how the professional and reasonable person standards for disclosure are insufficient to protect a woman’s unique decision making process concerning reproductive organs, and suggesting a reasonable woman standard for disclosure and a subjective standard for causation).

\(^{50}\) See Caroline Forell, *Essentialism, Empathy, and the Reasonable Women*, 1994 U. ILL. L. REV. 769, 776 n.35 (also suggesting the same ineffectiveness of the doctrine in cases of mastectomies and episiotomies).


\(^{52}\) See id. at 345–48.

\(^{53}\) See id. at 340. The most common reason for the surgery is to relieve the discomfort of benign uterine fibroids. See id. Several studies say the total number of unnecessary or questionable hysterectomies is anywhere from 33% to 41% of all those performed. See id. at 340 n.26.
for the overuse of the procedure without adequate informed consent. The risks of the procedure may not be appreciated by the male-dominated medical establishment because they view the uterus and proximate organs as having only one function, reproduction. However, these women exhibit symptoms of “post-hysterectomy syndrome” that are unrelated to reproductive capacity. In addition, it may also interfere with a healthy sex life. Perhaps the most obvious outcome of the procedure is the future impossibility of bearing children. This outcome figures into damage awards in lawsuits—even though the procedure was flawlessly performed—when the patient is misled into believing that surgery is medically necessary. Physicians are also unlikely to discuss alternatives to hysterectomies because they may feel they are doing women a service by removing an organ they consider to be a repository for disease and inconvenience as women get older.

Unnecessary cesarean section rates are also high: in 1990, one study found that almost half were unwarranted. There are several reasons not related to gender-bias that may explain the high rate of cesarean sections, but gender does play some role in removing decisionmaking to the physician. Doctors do not inform women of the

54 See id. at 356–57. The overuse of these procedures may also represent the preference of “male-made” medical technology for more invasive procedures. See Kathryn Strother Ratcliff, Health Technologies for Women: Whose Health? Whose Technology?, in HEALING TECHNOLOGY: FEMINIST PERSPECTIVES, supra note 36, at 173, 174.

55 See Napoli, supra note 37, at 357.

56 See id. at 341. These women present symptoms including depression, hot flashes, urinary problems, fatigue, headaches, dizziness and insomnia. See id. These symptoms may indicate a reaction to losing a part of their female identity, a loss that may not be appreciated by male physicians. See id. at 355–56.

57 See id. at 341. Some studies also show that the uterus may protect premenopausal women from heart disease and other health problems. See id. at 341 n.40.

58 See Redford v. United States, No. 89-2324, 1992 U.S. Dist. LEXIS 4712, at *40–41 (D.D.C. Apr. 10, 1992). This is true notwithstanding the fact that infertility is a commonly understood consequence. See id. at *28.

59 See Napoli, supra note 37, at 357.

60 See Kelly F. Bates, Note, Cesarean Section Epidemic: Defining the Problem—Approaching Solutions, 4 B.U. PUB. INT. L.J. 389, 390 n.16 (1995). The mortality rate for the procedure is two to five times higher than that of vaginal birth. See id. at 391–92. The risk of harm other than death is 10 times higher. See Hilary E. Berkman, Note, A Discussion of Medical Malpractice and Cesarean Section, 70 OR. L. Rev. 629, 635 (1991).

61 Fear of medical malpractice liability is high on many doctors’ lists. See Bates, supra note 60, at 404–05. Financial gain is another reason, as cesareans costs at least twice as much as normal births. See Berkman, supra note 60, at 637. The procedure is also convenient for impatient physicians who do not want their work schedules dictated by the uncertainty and lengthiness of labor. See id. at 631 n.12. Women may also choose it for this reason. See id. at 631 n.13.

62 See Berkman, supra note 60, at 631. A male predilection for invasive procedures may also explain its use disproportionate to necessity. See Ratcliff, supra note 54, at 174.
alternative of natural birth because they may believe that women are not anatomically structured to easily pass the baby from the uterus to vagina.63 Even in the absence of medical indications, doctors prefer cesarean sections because vaginal births are inherently complex.64 These doctors may believe that the difficulty attending vaginal birth outweighs the risks of cesarean sections, but they do not appreciate some of the more subtle, gender-specific risks of cesarean surgery, even when it is successfully performed. Women who undergo cesarean sections are less likely to become pregnant in the future.65 Furthermore, these women relate that they feel deceived by their bodies, that it "doesn't work the way it should."66 They may also have a general dissatisfaction with the entire birthing experience.67 Such risks would surely be material to a woman considering her options,68 but her decision is frequently preempted because of the doctor's ignorance of these risks,69 or through his self-serving assurances that a cesarean section is medically necessary.70

B. The Unhappy Marriage of the Female Body with Medical Devices and Pharmaceuticals

Corporate America has a male face.71 Since such a small percentage of women occupy prime managerial and decisionmaking positions in corporations, these corporations may not appreciate female perspec-

63 See Berkman, supra note 60, at 631. "One physician . . . stated that, '... since women have been walking on two legs, their pelves are not in line for vaginal delivery. . . . You might say we're helping women do what nature hasn't evolved her to do for herself.'" Id. (quoting H. Marieskind, An Evaluation of Caesarean Section in the United States 177-78 (June 1979) (final report submitted to the Department of Health, Education, and Welfare)).
64 See id.
65 See id. at 635–36. This might be due to an aversion to the emotional trauma of major surgery connected with future births, or to a decreased biological ability to conceive. See id.
66 Id. at 635–36 n.32 (quoting N.W. COHEN & L.J. ESTNER, SILENT KNIFE 63–64 (1983)).
67 See id. at 636 n.34.
68 See Berkman, supra note 60, at 648.
69 See id. at 635–37.
70 See supra notes 61, 64 and accompanying text.
71 See Diane Kunde, Floor to Ceiling: Commission Aims to Eliminate Barriers on All Corporate Levels, DALLAS MORNING NEWS, Dec. 9, 1993, at 1D (discussing a Department of Labor survey finding that only 6.6% of executives in 94 large corporations were women); David Benjamin Oppenheimer, Understanding Affirmative Action, 23 HASTINGS CONST. L.Q. 921, 967 (1996) (stating that women occupied only 3% of top management positions in Fortune 1500 companies (citing FEDERAL GLASS CEILING COMM’N, GOOD FOR BUSINESS: MAKING FULL USE OF THE NATION’S HUMAN CAPITAL 10–11 (1995))).
tives and needs, except as they relate to sales. While it is not clear if numerically women are disproportionately harmed by medical products, roughly half of all the punitive damages verdicts for women in products liability cases concern medical products; for men, the number is around ten percent.

The following products were marketed even though the manufacturers knew or had reason to believe that they were harmful. These products did in fact cause harm, killing or injuring thousands of women. They exemplify the magnitude and totality of gender-specific harm that can be avoided when warnings are given or when the product is not marketed in the first place. They show how important it is for manufacturers to be honest in the appraisal of their products, to warn women of inherent risks, and allow them to make thoughtful, informed decisions about their purchases.

1. The Dalkon Shield

A.H. Robins first marketed the Dalkon Shield intrauterine contraceptive device (IUD) in 1971, and enjoyed revenues of eleven million dollars until it was forced to abandon the domestic market in 1974 after an FDA study linked the Shield to Pelvic Inflammatory Disease (PID) and spontaneous septic abortions. Through its own research, Robins knew that the Shield's design would lead to a greater risk of infection, but chose to suppress this information, thus exposing 2.2

73 See id. However, some studies indicate that women may experience more adverse drug reactions than men. See Peppin, Feminism, supra note 39, at 88–89.
74 See Koenig & Rustad, supra note 40, at 34–38.
75 The manufacturer's duty to warn encompasses two distinct species: risk reduction warnings and informed choice warnings. See James A. Henderson, Jr. & Aaron D. Twerski, Doctrinal Collapse in Products Liability: The Empty Shell of Failure to Warn, 65 N.Y.U. L. REV. 265, 285 (1990). Risk reduction warnings are instructional: they tell the consumer how to reduce the risks associated with the use of the product. See id. Informed choice warnings, on the other hand, inform the consumer that there is a nonreducible risk associated with the product; the warning exists so that the consumer may exercise his or her autonomy and decide whether the benefits of the product outweigh its risks. See id.
76 See Deborah R. Hensler & Mark A. Peterson, Understanding Mass Personal Injury Litigation: A Socio-Legal Analysis, 59 BROOK. L. REV. 961, 983–84 (1993). The FDA's request to suspend domestic sales did little to affect marketing in foreign countries. See id. at 984. Robins continued foreign sales for another year, even selling unsterilized IUDs in underdeveloped countries, where poor health facilities would certainly contribute to greater mortality and injury rates. See Yanoshik & Norsigian, supra note 36, at 74–75.
77 See Hensler & Peterson, supra note 76, at 984.
million American women (and roughly another two million worldwide) to potentially fatal risks. In the end, its decision to withhold information was responsible for at least twenty deaths and 300,000 injuries (as assumed from the total number of claims) of women in over fifty countries.

2. Copper 7 IUD

The Copper 7 IUD was manufactured by G.D. Searle & Co., and marketed specifically for women who had not yet had children. Unfortunately for this particular group of women, Copper 7’s use was accompanied by a risk of infertility, PID, ectopic pregnancy, and perforation of the uterus. Searle had a domestic and foreign market, and sold over eight million IUDs worldwide. Although it had won many of the early lawsuits, in 1988 a federal judge unsealed hundreds of the company’s internal documents showing Searle’s premarketing knowledge of the product’s inappropriateness for women who had not previously had children. The following trial ended with an $8.75 million jury verdict for the plaintiff, which in turn spawned a rush to settle the remaining claims. Searle was ultimately able to avoid litigating 350 other claims by winning its argument against consolidation.

3. Super-Absorbent Tampon

When the United States Centers for Disease Control and Prevention (CDC) first suspected in 1980 that super absorbent tampons may play a role in toxic shock syndrome (TSS), it came as no surprise to the manufacturers: they had known of a possible link since 1975, when anecdotal evidence started to accumulate. A CDC request for data from the manufacturers about the suspected link yielded little infor-

---

78 See id. at 983. In addition, Robins originally touted the device as having a pregnancy rate of 1.1% (they later lowered that number to .05% to boost lagging sales), when they knew the rate was greater than 5%. See id. at 983–84.
79 See Yanoshik & Norsigian, supra note 36, at 73–74.
80 See Koenig & Rustad, supra note 40, at 40–41.
81 See Hensler & Peterson, supra note 76, at 987.
82 See id.
83 See id. Of the 775 claims filed by 1986, ten went to trial. See id. Searle prevailed in eight of those suits. See id.
84 See id.
85 See id. at 988.
86 See Hensler & Peterson, supra note 76, at 988.
87 See Koenig & Rustad, supra note 40, at 41–42.
The manufacturers had collectively sat on their hands for five years, conducting no research on TSS and high-absorbency tampons. As the first cases came to trial, it was discovered that Playtex was aware of the connection between unnecessary absorption capacity of tampons and increased rates of TSS. The company had knowingly produced and advertised a product that was “far more absorbent than necessary for its intended effectiveness.” Johnson & Johnson, another tampon manufacturer, had to pay punitive damages because a court held that the company knew of a possible link between TSS and super-absorbent tampons, but did no further research, even in light of repeated consumer complaints.

4. High Dosage Estrogen Oral Contraceptives

In the end of the 1960s and beginning of the 1970s, the scientific and medical literature on adverse reactions to high doses of estrogen in birth control pills began to accumulate. Among the increased risks women were exposed to were acute renal failure, malignant hypertension, blood vessel wall lesions, and anemia, all of which are the symptoms of hemolytic uremic syndrome (HUS). The high dosage pill was also linked to thromboembolism (vessel obstructions caused by blood clots). Before 1976, twenty-one cases of HUS were reported in women using the pill, a number which later rose to thirty-nine. In Great Britain, the high dosage pill’s “very decisive” association with thromboembolism was enough to quash its use almost entirely. Despite these indications, Ortho Pharmaceuticals persisted in aggressively mar-

88 See id. at 41.
89 See id. at 42.
90 See id. One court stated, “Our review of the record reveals abundant evidence that Playtex deliberately disregarded studies and medical reports linking high-absorbency tampon[s] . . . with . . . toxic shock at a time when other tampon manufacturers were responding . . . by modifying or withdrawing their high-absorbency products.” O’Gilvie v. Int’l Playtex, Inc., 821 F.2d 1438, 1446 (10th Cir. 1987).
91 O’Gilvie, 821 F.2d at 1446.
94 See id. at 1046–47.
95 See id. at 1062.
96 See id. at 1043, 1048. The symptoms abated in at least two of those women when they were taken off the oral contraception, but recurred when it was re-prescribed. See id.
97 See Brochu v. Ortho Pharm. Corp., 642 F.2d 652, 658 (1st Cir. 1981). The British Committee on Safety of Drugs stated that it “did not feel that it could delay for months for a detailed analysis of the individual [dosage] preparations, since during each month several women would die unnecessarily and many others would suffer from avoidable hazard.” Id.
keting the high dosage pill\textsuperscript{98} without adequate warnings.\textsuperscript{99} Ortho’s salesmen were directed to “urge” Ortho-Novum 1/80 on practitioners, and mitigate the British studies by way of Ortho’s own “analysis” of the data.\textsuperscript{100} The reason for these tactics was the competitive market for birth control pills at the time: while many manufacturers made a lower dose pill, Ortho wanted to remain the leader in the high dose market which appeared to be dwindling in light of the scientific literature.\textsuperscript{101}

III. THE SINS OF THE BREAST IMPLANT MANUFACTURERS

Although Dr. Angell alludes to the implants’ apparent safety because of their thirty-year track record,\textsuperscript{102} she concedes that the manufacturer’s claims of safety were misleading because there was no scientific evidence in either direction.\textsuperscript{103} While this is true, enough evidence had accumulated to suggest to the manufacturers that implants might be causing some immune system disorders in addition to the known local complications.

Since 1982, following the publication of the first article attempting to link CTDs to breast implants,\textsuperscript{104} researchers and physicians began to believe that silicone might have an effect on the immune system.\textsuperscript{105} Although the patient sample size in the early studies was too small to extrapolate to the general population,\textsuperscript{106} they at least provided

\textsuperscript{98} Ortho manufactured two doses of pill: a high-dose Ortho-Novum 1/80 (containing 80 micrograms of estrogen) and a lower dose Ortho-Novum 1/50 (containing 50 micrograms). See Wooderson, 681 P.2d at 1063. Low-estrogen pills are just as effective as their high-estrogen counterparts. See Brochu, 642 F.2d at 654.

\textsuperscript{99} See Wooderson, 681 P.2d. at 1063. Before 1977, Ortho’s package inserts did not mention any possible harm to renal systems. See id. at 1061. Subsequent inserts warned only of impaired renal function, not complete renal failure and the other symptoms suggested by the scientific literature. See id.

\textsuperscript{100} See id. at 1063.

\textsuperscript{101} See id. High dosage pills were eventually taken off of the market at the advice of the FDA. See High-Estrogen Oral Contraceptives To Be Discontinued, PR Newswire, Apr. 14, 1988, available in WESTLAW, Trade and Industry File.

\textsuperscript{102} See Angell, supra note 1, at 62.

\textsuperscript{103} See id. at 23.

\textsuperscript{104} See id. at 52. Several articles had already been published by Japanese physicians indicating such a link, but the exposure to silicone in those cases was through direct injection of liquid silicone into the breast. See id. at 103-04.

\textsuperscript{105} See id. at 105-08; see also Hearings Before the House Comm. on Government Reform and Oversight Subcomm. on Human Resources and Intergovernmental Relations and Subcomm. on Government Management, Information and Technology, Aug. 1, 1995, available in 1995 WESTLAW 10382296 (testimony of John S. Sergent, M.D.) (stating that, like most rheumatologists, he thought the early scientific literature linking breast implants to immune disorders was cogent).

\textsuperscript{106} See Angell, supra note 1, at 100.
manufacturers with a signal that something may be awry. When this is viewed in light of the nearly 5000 implant-related complaints the FDA received between 1983 and 1991, the resulting conclusion is that there were questions of safety that needed to be addressed by the manufacturers.

Dow Corning had been doing its own research into the toxicity of liquid silicone in animals as early as the 1950s. Rats and dogs in these in-house studies proved sensitive to silicone-induced tumors and immune reactions. They also conducted several experiments that showed liquid silicone being transported throughout the bodies of these animals, and depositing in their lymph nodes, adrenal glands, and kidneys.

Several internal memoranda existed proving that Dow Corning at least had a subjective belief that implants may be harmful. One memorandum discussed the gradual silicone gel "bleeding" through the implant envelope. Sales representatives were directed to wipe the oily slick from the outside of the implant before showing it to prospective buyers. This memorandum presents two issues. First, it is very susceptible to an interpretation that Dow Corning believed there were systemic dangers of silicone outside of the envelope as it migrated to the lymph nodes, and acted to conceal this. Second, it raises the possibility of a battery claim, as women had not consented to the direct contact of the liquid silicon with their bodies.

108 The importance of reacting to anecdotal evidence is seen most clearly in smoking-related illnesses. For centuries, doctors had suspected a link between smoking and certain diseases. See Surgeon Gen., U.S. Dep't of Health and Human Servs., Reducing the Health Consequences of Smoking: 25 Years of Progress 5 (1989). At the turn of this century, many doctors believed that smoking increased the risk of getting lung cancer. See id. Despite this evidence, warning labels were not required on cigarette packs until 1965. See Federal Cigarette Labeling and Advertising Act, Pub. L. No. 89-92, 79 Stat. 282 (1965).
110 See Angell, supra note 1, at 57–58.
111 See id. Other structural defects in the envelope were diminished by Dow. Their reported asymptomatic rupture rates were between .2 and 1.1%; the FDA advisory panel later determined the real rate was from four to six percent. See Kessler, supra note 4, at 1713.
112 See Angell, supra note 1, at 58–59.
113 See id. Of course, it is also possible that the manufacturers were concerned with aesthetics and just wanted to sell an attractive product.
There were other memoranda that imply Dow Corning’s knowledge of the questionable safety of implants. One from 1976 urges members of Dow’s Mammary Task Force to start research on long-term toxicological effects “over and above what [was then] underway.”\(^{116}\) Another memorandum from 1977 recounts a Dow representative’s meeting with plastic surgeons at an international conference.\(^{117}\) When asked if Dow Corning was conducting studies into the gel leakage and migration away from the breasts to other organs, the representative replied that he “assured them, with crossed fingers, that Dow Corning too had an active ‘contracture/gel migration’ study under way.”\(^ {118}\) A memo from 1990 relates how a Dow Corning attorney asked the medical director to destroy his analysis of data of complication rates attending breast implants.\(^ {119}\)

Warnings about the possibility of immune system-related disease were not put on the package inserts until 1985,\(^ {120}\) roughly twenty-one years after the implants went on the market,\(^ {121}\) thirty years after the initial animal studies,\(^ {122}\) and three years after the first scientific paper was published suggesting such a link.\(^ {123}\) What we find then is that in relentless pursuit of their marketing goals, the manufacturers withheld material risks, which they could have reasonably believed existed, from consumers.\(^ {124}\)

IV. LIABILITY AND CAUSATION

The sine qua non of any successful tort action is causation in fact: if the defendant’s negligent conduct was not the cause in fact of the

\(^{116}\) ANGELL, supra note 1, at 60.

\(^{117}\) See Robert J. Gordon, Letters to the Editor: Dow Corning Created the Tort Monster, WALL ST. J., June 8, 1995, at A12.

\(^{118}\) Id.

\(^{119}\) See Dow Memo Alleges Ethics Breach, Data Destruction Request, MEALEY’S LITIG. REP.: BREAST IMPLANTS, Nov. 12, 1993, available in WESTLAW, MLRBI File. The other breast implant manufacturers were also aware of the potential problems with the implants. See, e.g., Texas Jury Awards Three Women $33 Million, MEALEY’S LITIG. REP.: BREAST IMPLANTS, Mar. 3, 1994, available in WESTLAW, MLRBI File (McGhan admitting that they knew about gel bleed through the implant envelope); Valentine Trial Begins in San Fransico, MEALEY’S LITIG. REP.: BREAST IMPLANTS, Feb. 29, 1995, available in WESTLAW, MLRBI File (plaintiff’s attorney implicating Baxter in ignoring the data from early animal studies and relying on plastic surgeons to relate adverse reactions after implantation).

\(^{120}\) See Dow CORNING CORP., BREAST IMPLANT PACKAGE INSERT (1985).

\(^{121}\) See supra note 1.

\(^{122}\) See supra notes 109–11 and accompanying text.

\(^{123}\) See supra note 104 and accompanying text.

\(^{124}\) See ANGELL, supra note 1, at 60.
plaintiff's damages, then liability will not lie with the defendant. The reason behind the requirement of causation is generally considered to be one of fairness in accountability. Defendants should only be liable if, by "intervening in the world, [they] have changed the course of events for the worse." Another compelling reason is society's desire for "moral space" in freedom of action. We treasure this freedom because we want to be able to evaluate our own conduct and assess the possible consequences. Risk-taking or negligence that does not produce harm is therefore immune to civil liability because of the value we place on freedom of action.

Under this theory, the breast implant manufacturers should not be held liable, because their negligence—marketing breast implants without providing warnings about risks they could have reasonably believed existed—was not the cause in fact of women's illnesses. Freedom of action would therefore support the breast implant manufacturers' decision to act negligently and sell a potentially dangerous product, because they determined that the risk of harm was outweighed by the implants' benefits, and because the risk never materi-

125 See Keeton, supra note 115, § 41, at 263–66. It is a necessary element procedurally because the plaintiff's claim generally cannot advance without it. See id. It is also a necessary element in that but for the cause, the harm would not exist. See id. Dr. Angell states it in application perhaps more succinctly when she writes, "The manufacturer cannot be held negligent if the implants didn't cause the harm, and the implants cannot be blamed if there is no harm." Angell, supra note 1, at 112.


127 Id.


129 See id.

130 An illustration of this concept is found in Professor Thomson's depiction of Alfred and Bert, two homeowners backing their cars out of their respective driveways. See Judith Jarvis Thomson, The Decline of Cause, 76 Geo. L.J. 137, 139–40 (1987). Neither man looks for pedestrians as he approaches the street, but only Bert runs over someone. See id. Both men are negligent, and we can chastise them for their shoddy driving, but we heap additional legal blame on Bert because he caused tortious harm. See id. Alfred's conduct, however, will not have legal blame attached: freedom of action supports his choice to drive negligently because he evaluated his situation, decided that he had a (presumably) good reason for driving negligently, and, most importantly, injured no one through his negligence. See id. However, society does not respect all freedoms. Certain conduct is criminalized even when it does not cause harm, on the theory that if allowed to continue, harm will eventually occur. See Wayne R. LaFave & Austin W. Scott, Jr., Criminal Law § 1.3, at 12–13 (2d ed. 1986). Therefore, some non-injurious conduct will require legal sanctions in the form of criminal penalties. See id.

131 See supra notes 13–14, 21 and accompanying text (discussing the scientific evidence that implants are not associated with increased risks of CTDs).
alized. Essentially, the breast implant manufacturers have committed no legal wrong (notwithstanding the jury verdicts against them), at least based on the current scientific evidence, despite their inaction, misrepresentation, and nondisclosure.

Although any future litigation over breast implants would probably be decided in the manufacturers' favor, this still does not seem like a fair result. What makes this outcome unsatisfying and discom­forting is that the manufacturers would be found not liable only because they were lucky enough to have produced a safe product. The fact that they potentially exposed women to a degree of harm on the order of what was seen in the IUD cases is of no consequence; nor is it of any consequence that they perpetuated the historic mistreatment of women in healthcare, where women's own risk-benefit analyses have been substituted by analyses based on bias, ignorance, or greed.

V. REDEFINING THE HARM: A CAUSE OF ACTION FOUND IN A DIGNITARY TORT OF INFORMED CONSENT

What would a fair outcome entail in the breast implant case? The issues of concern are compensating women for the insult to their dignity and restituting them for their submission to an expensive procedure they otherwise might not have undergone if they knew the possible risks; deterring the dishonest and potentially dangerous corporate practices in the marketing of products; and being fair to the manufacturers, at least in the fact that they caused no tangible physical harm. It is difficult to reconcile these issues without first discerning the real harm that the manufacturers caused the individual plaintiffs.

The problem presented by the lack of physical harm can be circumvented if we redefine the type of harm the plaintiffs suffered. Although historically tort law has compensated only physical or eco-

---

132 See Thomson, Remarks on Causation, supra note 128, at 108.

In the eyes of the public, however, marketing a product with the subjective belief that it may cause harm is most certainly a criminal act. A study of people's attitudes about the seriousness of crime found that "[a] drug company executive [who allowed] his company to market a drug 'knowing that it may produce harmful side-effects for most individuals' was rated in the United States as committing a crime more serious than all of the FBI index offenses except murder and rape." John Braithwaite, Corporate Crime in the Pharmaceutical Industry 6–7 (1984).
nomadic injury, the move has been to increase the scope of harm that tort law will redress.134 Among these newly recognized harms is failure to obtain informed consent.135

The doctrine of informed consent is familiarly applied to physician conduct.136 Although actions under informed consent were originally brought under a theory of battery,137 they now sound in negligence, and the plaintiff must prove that the doctor's nondisclosure of risks fell below the standard of care.138 The concept and dignitary protections of medical informed consent are also present in a manufacturer's duty to warn consumers of the nonreducible risks of their

---


135 See id. at 150–52.

136 The doctrine of informed consent requires doctors to inform patients of "the nature of the pertinent ailment or condition, the risks of the proposed treatment or procedure, and the [availability and] risks of any alternative methods of treatment, including the risks of failing to undergo any treatment at all." KEETON, *supra* note 115, § 32, at 190. If this information is not disclosed, the patient's otherwise valid consent to a procedure is vitiated, and the doctor may be held liable for adverse consequences that should have been disclosed—even those arising from non-negligently performed procedures. See id. The physician need not disclose risks "commonly understood, obvious, or already known to the patient." Id. §32, at 192. The standard of disclosure in some states is a professional one: the risks and alternatives that a reasonable doctor in the medical community would divulge. See, e.g., Rush v. Miller, 648 F.2d 1075, 1076 (6th Cir. 1981). In other jurisdictions, what must be disclosed is measured by what information would be material to a reasonable person in the plaintiff's position. See, e.g., Canterbury v. Spence, 464 F.2d 772, 786–87 (D.C. Cir. 1972). The latter standard is probably more in line with protecting the patient's autonomy because it does not allow a physician to substitute his medical judgment for the patient's personal cost-benefit analysis in deciding to undergo a medical procedure. See id.

The standard of causation in a majority of states is whether a reasonable patient would have refused the proposed treatment if they were informed of the risks or alternatives. See, e.g., id. at 790–91. Other courts, believing that an objective standard impairs the right to self-determination, hold that decision-causation should be determined under a subjective standard: whether disclosure would have affected the decision of this patient, the plaintiff. See, e.g., Scott v. Bradford, 606 P.2d 554, 559 (Okla. 1979).

All states agree that the plaintiff's claim fails in the absence of bodily injury caused by the nondisclosure. See Alan Meisel, *"Dignitary Tort" as a Bridge Between the Idea of Informed Consent and the Law of Informed Consent*, 16 LAW, MED. & HEALTH CARE 210, 211 (1988) [hereinafter Meisel, *Dignitary Tort*]. If the undisclosed risk does not materialize, the nondisclosure “however unpardonable, is legally without consequence.” Canterbury, 464 F.2d at 790.

137 See KEETON, *supra* note 115, § 18, at 120. The idea was that if the patient consented to a medical procedure without being fully informed of the risks, his consent was vitiated and the doctor's contact was constructively unwanted and offensive. See generally id.

138 See id. § 32, at 190. Claims in battery are now reserved for cases where the patient has not consented at all to a procedure, Scott, 606 P.2d at 557, or where the procedure or nature of the touching is significantly different from the one for which consent was given, Cornfeldt v. Tongen, 262 N.W.2d 684, 699 (Minn. 1977).
products, where it is more accurately called informed choice. 139 The standard of disclosure of risks in the physician-patient context can be similar to that in a products liability case. 140

In either context, the plaintiff must show that the risk that should have been disclosed actually materialized. 141 Among medical informed consent scholars, this requirement has been criticized as being antithetical to the autonomy rights the doctrine purports to protect. 142 The fact that the harm from the undisclosed risk did not arise is irrelevant—the violation of the person’s right to self-determination is itself the harm. 143 If the doctrine of informed consent is truly freighted with concerns for autonomy, bodily integrity, dignity, and the decisionmak-

---


140 Compare Canterbury, 464 F.2d at 786–87 (“[T]he test for determining whether a particular peril must be divulged is its materiality to the patient’s decision: all risks potentially affecting the decision must be unmasked.”) with Borel v. Fibreboard Paper Prods. Corp., 493 F.2d 1076, 1089 (5th Cir. 1973) (“[A] consumer is entitled to make his own choice as to whether the product’s utility or benefits justify exposing himself to the risk of harm. Thus, a true choice situation arises, and a duty to warn attaches, whenever a reasonable man would want to be informed of the risk in order to decide whether to expose himself to it.”) and Moran v. Johns-Manville Sales Corp., 691 F.2d 811, 814 (6th Cir. 1982) (same) and Johns-Manville Sales Corp. v. Janssens, 463 So. 2d 242, 251 (Fla. Dist. Ct. App. 1984) (same).

In addition, a manufacturer’s duty to warn is not limited to risks that are known with certainty. See Seley v. G.D. Searle & Co., 423 N.E. 2d 831, 837 (Ohio 1981) (“[W]here scientific or medical evidence exists tending to show that a certain danger is associated with use of the [product], the manufacturer may not ignore or discount that information in drafting its warning solely because it finds it to be unconvincing.”).


142 See KATZ, supra note 41, at 79 (“This [requirement], however pertinent to negligence law, demonstrates strikingly how far the court had strayed from its root premise.”); Meisel, Dignitary Tort, supra note 139, at 211 (“[T]he rules by which the doctrine is administered in the courts . . . inadequately protect the fundamental right of individuals as patients . . . .”)

143 See KATZ, supra note 41, at 79; see also Meisel, Informed Consent, supra note 139, at 204 (“If the doctrine’s avowed individualistic purposes . . . are to be honored, then the failure to disclose information deserves these purposes. It makes no difference that the patient incurred no bodily harm; the failure to disclose is [itself] a harm . . . .”); Joseph Goldstein, For Harold Lasswell: Some Reflections on Human Dignity, Entrapment, Informed Consent, and the Plea Bargain, 84 YALE L. J. 683, 691 (1975) (“The materialized risk requisite demonstrates the extent to which the concept has departed from its purpose. It does not recognize that a citizen can be wronged
ing process, then it should be flexible enough to remedy wrongs unrelated to physical harm.144 This could be accomplished in several ways. The requirement of materialized risk in a negligence-based informed consent claim could be abandoned, or a return to a theory based on battery could be implemented.145 Either basis for the action would create a dignitary tort of informed consent.146

Application of such a dignitary tort in the breast implant case would be the fairest way to compensate women and encourage full disclosure by the manufacturers. Although it is possible to extrapolate from a dignitary tort of informed consent to one of informed choice (i.e., the manufacturer’s failure to warn without causing physical harm is itself a compensable tort),147 it is wiser to keep any claims in a medical context.148 The application of a dignitary tort of informed consent to manufacturers of medical products would be premised on the overlapping roles of the manufacturer and physician. The distinction between these roles is blurred for breast implants because of the necessity of surgery for implantation. In the case of most pharmaceuticals and medical devices, the duty to warn the patient is satisfied when the manufacturer warns the physician because the physician must, by law, pass this information on to the patient—the so-called learned intermediary doctrine.149 Despite the disjunction of the relevant parties, the

without being ‘harmed,’ that his dignity as a human being has been violated . . . the moment the deceiving authority commences therapy . . . .”).


145 The law of battery would work because injurious contact is not a prerequisite; offensive touching alone will support a claim. See Meisel, Dignitary Tort, supra note 136, at 211.


147 See supra notes 139–40 and accompanying text (discussing the similar policy goals each doctrine advances).

148 The problem with keeping it as a failure to warn claim is that this theory may eventually be preempted by federal regulation. See Desmarais v. Dow Corning Corp., 712 F. Supp. 13, 16 (D. Conn. 1989) (holding that the Medical Device Amendments of 1976 to the Food, Drug, and Cosmetic Act would preempt some failure to warn cases if the implants were received after enactment).

manufacturer is still directly liable to the patient for harm that arises if the manufacturer breaches its duty to warn.\textsuperscript{150} In the breast implant cases, the manufacturers did not divulge all of the risks that may have been material to a woman's decision, including the ones they reasonably believed could be true (the effects on immune systems) and those they knew were true (the silicone leakage through the implant envelope). It is therefore possible to view the breast implant manufacturers' nondisclosure and misrepresentation as an interference with a woman's ability to gain full understanding of the risks of breast implants, and thus their failure to warn may be collapsed into a failure to obtain medical informed consent.\textsuperscript{151} Since the potential harm never developed, they should not be held liable for the plaintiffs' diseases, but they should still have to answer for their interference with a woman's right to make an informed choice in a medical procedure. Under a dignitary tort of informed consent, the compensation might be nominal, but the egregious conduct of the breast implant manufacturers would warrant punitive damages.\textsuperscript{152} This would deter other manufacturers from testing their luck by marketing products without knowing if they are truly safe and without providing adequate and meaningful warnings.

VI. Conclusion

Women have not received the pure benefits and proper treatment one would expect in this medically and technologically advanced age. This has often been due to the ignorance and bias of the medical profession, but the greater harms perpetrated against women have their roots in the greed of pharmaceutical and medical device manufacturers. These manufacturers have harmed women in visible ways, but the affront to their dignity has often gone unnoticed, either because the physical injury was so overwhelming or because the courts

\textsuperscript{150} See McEwen v. Ortho Pharm. Corp., 528 P.2d 522, 529 (Or. 1974). Although the physician is merely the conduit through which the information flows from manufacturer to patient, the patient's informed consent will ultimately be based on his or her own analysis of the risks disclosed by the physician. \textit{See id.}

\textsuperscript{151} A conflation of the two concepts is not chimerical. Throughout the breast implant debate, physicians and ethicists referred to a lack of informed consent as being its central ethical dilemma. \textit{See generally} Judy Foreman, \textit{Implants: Is Uninformed Consent a Woman's Right?}, \textit{Boston Globe}, Jan. 13, 1992, at 25.

\textsuperscript{152} Punitive damage awards are not completely alien to cases where informed consent is lacking, \textit{See Koenig & Rustad, supra} note 40, at 69–71.
had not yet recognized the primacy of a person’s right to choose what shall be done with his or her body. The breast implant controversy brings this dignitary right to the forefront. Only when the courts appreciate this right for what it is—an inviolable right protecting bodily integrity and autonomy, one which is already recognized in other areas of tort law—will they begin to restore women’s decisionmaking capabilities.

153 For example, the tort of battery is generally understood to protect a person’s interest in bodily integrity. See Keeton, supra note 115, § 9, at 40.