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Julie M. Spanbauer

*John Marshall Law School, [jspanbau@uic.edu](mailto:jspanbau@uic.edu)*

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# BREAST IMPLANTS AS BEAUTY RITUAL: WOMAN'S SCEPTRE AND PRISON

By Julie M. Spanbauer<sup>†</sup>

*Taught from their infancy that beauty is woman's sceptre, the mind shapes itself to the body, and, roaming round its gilt cage, only seeks to adorn its prison.*<sup>††</sup>

## I. INTRODUCTION

In the past several years, various publications, including medical literature,<sup>1</sup> television reports,<sup>2</sup> newspaper articles,<sup>3</sup> and even a book written by a physician and editor of a prestigious medical journal,<sup>4</sup> have delivered roughly the same message to the public about silicone gel breast implants: they *do not* cause disease. According to these publications, the issue is all but closed.<sup>5</sup> They claim

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<sup>†</sup> Assistant Professor of Law, The John Marshall Law School. LL.M. 1992, Northwestern University School of Law; J.D. 1986, Valparaiso University School of Law. First, I would like to thank Lana Friedman who read between the lines and helped me find my voice for this piece. Next, I would like to thank my senior research assistant, Christopher Young, for his extraordinary efforts on my behalf. I would also like to thank Dr. Alice Stark for her feedback on the medical and scientific data. Finally, I would like to thank various members of The John Marshall Law School community for their support and feedback: Dean R. Gilbert Johnston, Associate Dean Susan Brody, Professor Jessie Grearson, and Professor Ardath Hamann.

<sup>††</sup> MARY WOLLSTONECRAFT, A VINDICATION OF THE RIGHTS OF WOMEN 44 (W.W. Norton & Co. 1975) (1792).

1. A recently released medical study allegedly demonstrating *no* increase in connective-tissue disease for women with breast implants involved 87,501 women, 1183 of whom had breast implants; 876 of this latter number had silicone gel implants. See J. Sanchez-Guerrero et al., *Silicone Breast Implants and the Risk of Connective-Tissue Diseases and Symptoms*, 332 NEW ENG. J. MED. 1666, 1666-67 (1995) [hereinafter *Nurses' Study*]. An earlier, smaller study of 2247 women in Olmsted County, Minnesota, 749 of whom had breast implants, found no increase in the targeted disease. See Sherine E. Gabriel et al., *Risk of Connective-Tissue Diseases and Other Disorders After Breast Implantation*, 330 NEW ENG. J. MED. 1697, 1698, 1702 (1994) [hereinafter *Mayo Clinic Study*].

2. The examples of television reports are so numerous as to make an exhaustive list impractical. For a report that casts doubt on safety problems with silicone implants in a manner that is neither sensational nor one-sided, see *The MacNeil Lehrer NewsHour* (PBS television broadcast, Sept. 13, 1995).

3. See Gina Kolata, *New Study Finds No Link Between Implants and Illness*, N.Y. TIMES, June 22, 1995, at A18; see also Joan Beck, *Hidden Agenda on Breast Implants*, CHI. TRIB., Feb. 29, 1996, at 23. Beck asserts that cause (breast implants) and effect (disease) have not been scientifically established. See *id.* She characterizes the arguments advanced to support a causal link as nothing more than a "folk tale," no more plausible than the following story:

When my son was 5 years old, he often played with a little boy who lived across the street. Whenever Roger got a small cut, his mother would gently lay the flat blade of a table knife on the wound and hold it in place for a few minutes. I asked her why. "It makes the cut heal," she said. "It always does."

*Id.*

4. See MARCIA ANGELL, SCIENCE ON TRIAL: THE CLASH OF MEDICAL EVIDENCE AND THE LAW IN THE BREAST IMPLANT CASE (1996). Dr. Angell is the executive editor of the *New England Journal of Medicine*. See *id.* at 9.

5. See *id.* at 102-10. Occasionally, the media presents an opposing view. See, e.g., John E. Swanson, *Exposing a Corporate Cover-up*, CHI. TRIB., Apr. 15, 1997, at 15.

that the earlier litigation documenting the dangers of silicone<sup>6</sup> and the misdeeds of surgeons,<sup>7</sup> as well as exposing greedy and fraudulent behavior of corporations such as Dow Corning,<sup>8</sup> was apparently either in error or was itself a fraud perpetrated upon the public by greedy, profit-seeking lawyers and physicians, and by the media, hungry for the latest sensational story.<sup>9</sup> Some of this literature

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6. See Alan A. Bridges & Frank B. Vasey, *Silicone Breast Implants: History, Safety, and Potential Complications*, 153 ARCHIVES OF INTERNAL MED. 2638, 2639-43 (1993); Judy Foreman, *Women & Silicone: A History of Risk*, BOSTON GLOBE, Jan. 19, 1992, at 1; Tamar Lewin, *As Silicone Issue Grows, Women Take Agony and Anger to Court*, N.Y. TIMES, Jan. 19, 1992, at 1.

7. One of the more dramatic claims of medical ineptitude involves a plastic surgeon who, in September of 1977 after surgically inserting silicone gel implants into a patient's breasts, "intentionally slit the envelope to allow the gel to escape" into the patient's breast tissue. *Henderson v. Heyer-Schulte Corp.*, 600 S.W.2d 844, 846 (Tex. Civ. App. 1980). Although this surgical technique was not a "recognized or accepted" method for breast augmentation at the time of the surgery, the jury found that the doctor had not committed malpractice. *Id.* The fact that the Food and Drug Administration banned direct injections of liquid silicone in 1963 makes the verdict in this case especially troubling. See Michele Simon, *The Silicone Gel Breast Implant Controversy: The Science Surrounding the Regulation and Litigation*, 17 J. PRODUCTS & TOXICS LIABILITY 141, 143 n.13 (1995). For a discussion of this case and others, see Stephen Lichtenstein, *A Discussion of the Silicone Gel-Filled Breast Implant Controversy*, 12 REV. LITIG. 205, 214 (1992). Another alarming medical charge involved a woman who had breast implant surgery after undergoing a double subcutaneous mastectomy for fibrocystic disease. See *Weinberg v. Bess*, 638 N.E.2d 841, 843 (Ind. Ct. App. 1994). The plaintiff alleged that after instructing the plastic surgeon to use saline implants, he instead inserted silicone gel implants into her breasts, and that on several occasions after the surgery misrepresented her implants as saline. See *id.* The court found that the plaintiff's claim of malpractice was barred by the applicable statute of limitations. See *id.* at 844.

8. Dow Corning's allegedly fraudulent behavior was summarized in *Hopkins v. Dow Corning Corp.*, 33 F.3d 1116, 1119 (9th Cir. 1994). The federal appellate court upheld the jury's finding of fraud based upon the following evidence:

The evidence presented at trial indicated that Dow rushed development of the silicone gel implants, failed to adequately test the implants, and ignored knowledge of adverse health consequences associated with the implants. Plaintiff presented evidence that Dow created a Mammary Task Force charged with getting the new gel implant to market in less than five months. Even after a task force member presented his concerns about "a possible gel bleed situation" Dow ignored proposed design modifications that would reduce the likelihood of leakage. The record indicates that Dow instructed salesmen to wash the implants with "soap and water" in the nearest restroom, and to "dry with hand towels as the implants become oily after being handled and [bleed] on the velvet in the showcase."

The evidence further indicated that in addition to the evidence of silicone leakage, Dow implants experienced a high rate of rupture. Despite proposals by one task force member to implement a "multiple dip" method as a means of ensuring greater uniformity in the envelope, and thereby less likelihood of rupture, Dow adopted the single dip method because it was "easier" and "cheaper." After an incident in which two of the new gel implants "broke during augmentation surgery for the TV taped demonstrations," Thomas Talcott, a Dow engineer, inquired of key Dow employees, "When will we learn at Dow Corning that making a product 'just good enough' almost always leads to products that are 'not quite good enough?'"

There was also evidence that no research concerning the long-term health effects had been conducted. The longest study to address possible adverse health effects of the implants took place over only 80 days and revealed evidence of inflammatory immune response caused by the gel. Dow continued to market these implants until 1987, without the benefit of a lifetime study to demonstrate the safety of its product.

Other evidence at trial indicated that Dow had knowledge of the harmful effects of silicone on the human body. Dow obtained results of a study in which four dogs received silicone gel implants that resembled the implants that Dow was then marketing. The results demonstrated that after six months, the implants appeared to be functioning properly, but that after two years, inflammation surrounding the implants demonstrated the existence of an immune reaction. Dow did not publicly release the results of this research for several years, and when it did ultimately release the results, Dow omitted the negative findings and implied that the implants were safe.

*Id.*

9. See ANGELL, *supra* note 4, at 133-76.

paints a picture of breast implant recipients as gullible, unwitting participants in this fraud, while other reports describe implant recipients as extortionists looking to exploit the deep pockets of manufacturers and surgeons.<sup>10</sup> Dr. Marcia Angell, who offers the single most comprehensive defense of breast implant safety, focuses upon a different concern:

The anti-science, anti-medicine strain in the feminist movement finds expression in the breast implant controversy. Many women see the controversy as a woman's issue in a political context, as well as a biological one. Some female plaintiffs' attorneys make much of the fact that they are women championing other women in a man's world. The epidemiologic studies that fail to find a connection between breast implants and disease are met with cynicism. To many feminists, the scientific studies seem irrelevant and distracting in the context of a perceived assault on women—first in subjecting them to implants, then in failing to respond promptly to the hazard. After all, implants are unnatural substances put in the body, and many women who have implants get sick. When scientific data are put up against their own "ways of knowing," some women ignore the science. Add to this anti-science bias the view of many women that breast implants are a manifestation of a discredited, masculine attitude that judges women primarily by their looks, and it is no wonder that some feminists believe that breast implants cause disease. They *want* to believe it.<sup>11</sup>

All of this recently disseminated literature touting the safety of breast implants has sent an important message to breast implant recipients—that the public will no longer believe, or even take seriously, their complaints about the negative impact that their implants have had on their health and on their lives. Yet these observations in the form of near definitive conclusions overstate the importance of the recently released studies to a number of the medical questions raised in breast implant litigation and, in particular, the Revised Breast Implant Settlement Program,<sup>12</sup> while simultaneously obscuring and glossing over the

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10. See Note, *Breast Implants: Choices Women Thought They Made*, 11 N.Y.L. SCH. J. HUM. RTS. 163, 201 & n.214 (1993) (arguing that plastic surgeons and manufacturers are engaged in a large-scale, joint "lobbying effort to convince both the public and the government that the health concerns surrounding silicone implants are a creation of hysterical women and the plaintiff's trial bar"). Some proponents of breast implants do not agree entirely with either perspective:

Women with breast implants are just as diverse as any other large population, and there is no reason to believe that they are all the same—either in their health or in their character. But it can be very difficult to distinguish the ill from the worried well and from the opportunists.

ANGELL, *supra* note 4, at 153.

11. ANGELL, *supra* note 4, at 182-83.

12. The Revised Breast Implant Settlement Program, which was officially approved on December 22, 1995 by Judge Sam C. Pointer, includes the following implant manufacturers: Bristol-Myers Squibb Company, Baxter International, Incorporated, Minnesota Mining and Manufacturing (3M), McGhan Medical Corporation, and Union Carbide. In *re* Silicone Gel Breast Implant Prod. Liab. Litig., 887 F. Supp. 1447 (N.D. Ala. 1995). This settlement arose after the original, global class action settlement, *In re* Silicone Gel Breast Implant Prod.

equally complicated legal and social issues involving breast implants. What is most troubling, however, is the fact that not so very long ago many of these same newspapers and television programs addressed the issues in an equally simple, all-or-nothing manner: breast implants were dangerous, defective products; the manufacturers and surgeons were culpable; and breast implant recipients were tragic victims.<sup>13</sup>

Indeed, even with the benefit of the recently released medical studies, we still know very little about the long-term effects of breast implants on women's bodies. This fact should not be surprising since no lifetime studies addressing the safety of breast implants were conducted before their introduction in the early 1960s,<sup>14</sup> and several studies are ongoing.<sup>15</sup> Even if every medical study presently underway fails to establish a definitive link between breast implants and particular diseases, the results will not compel the conclusion that breast implants are medically safe devices. It may well be that a gap exists between our current state of technology, which is advanced enough to produce this product, and our understanding of the effect that this product has on the human body, which itself is complex.<sup>16</sup>

Thus, this kind of all-or-nothing approach to the study of silicone breast implants is misguided because it is not conducive to further testing and to an open dialogue over time that questions the assumptions we make about disease and causation of disease. This narrow approach to the breast implant controversy is also disturbing because it does not leave room for research that is necessary to achieve a greater understanding of this women's health issue: it does not attempt to formulate more advanced methods of monitoring implants for rupture and leakage; it does not look for ways to accurately measure levels of silicone

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Liab. Litig., No. CV92-P-10000-S, 1994 U.S. Dist. LEXIS 12521 (N.D. Ala. 1994), fell apart due to the large number of claimants and Dow Corning's application for bankruptcy protection on May 15, 1995. In re Dow Corning Corp., 211 B.R. 545 (1997).

13. See Foreman, *supra* note 6; Lewin, *supra* note 6.

14. See Bridges & Vasey, *supra* note 6, at 2639 (stating that Dow implants were used in breast augmentation surgery beginning in 1962). Some reports state that Dow began to market the first silicone gel breast implants in 1963. See Stephen H. Osborn & Abby L. Hyman, *Damage to Breast Implants From Trauma*, 44 FICC Q. 417, 417 (1994). There is no dispute, however, that long-term premarket studies were not conducted. See *Hopkins v. Dow Corning Corp.*, 33 F.3d 1116, 1119 (9<sup>th</sup> Cir. 1994). In fact, Dow did not begin to plan such a safety study until 1989. See Douglas R. Shanklin, *Evidence for Immunological Disorders Due to Silicone*, 4 No. 2 MED. LEGAL ASPECTS BREAST IMPLANTS 5, 5 (1996).

15. One study currently underway is being conducted by the National Cancer Institute and is entirely funded by the federal government. See Janet Van Winkle, *Government Funds Implant Study, But There Are Some Pitfalls*, 3 No. 11 MED. LEGAL ASPECTS BREAST IMPLANTS 4, 4 (1995). "More than 20,000 women will be included in the study, with approximately 12,000 breast implant patients, limited to women who had plastic surgery before 1989, with health effects assessed for an average of 10-15 years." *Id.*

16. See Simon, *supra* note 7, at 160. The study of breast implants is also difficult because all of the medical research is, of necessity, retrospective rather than prospective. See *id.* For a discussion of the limits of the available scientific studies regarding breast implants, see Heidi Li Feldman, *Science and Uncertainty in Mass Exposure Litigation*, 74 TEX. L. REV. 1, 23-25 (1995). The article is dated in the sense that it was published before publication of several of the more recently released studies, but it discusses the limitations generally of animal studies, human case studies, and epidemiological studies. See *id.* It is also important to note that research may, as with breast implants, be a direct result of litigation and thus may develop "in parallel with legal proceedings" or may also "lag behind them." SHEILA JASANOFF, *SCIENCE AT THE BAR* 50 (1995).

migration throughout the body; and it fails to find new methods which, short of an invasive surgical procedure, effectively predict the remaining life span of implants.<sup>17</sup>

The goal of all medical research about breast implants should be to learn more about their effect on women's bodies and to help those women who currently have silicone implants stay healthy. Although medical research has not yet established silicone implants as a cause of particular diseases, there is no dispute that physical harm can and has been caused by such things as rupture, silicone migration, and capsular contracture, to name just a few of the medical complications.<sup>18</sup> Notwithstanding these serious side effects and complications, people remain camped out on either side of the issue, intent on reading the medical data to support the beliefs they held before the recent set of medical testing ever began.<sup>19</sup> This dichotomous approach to the issue of silicone breast implants has another negative effect: it necessarily results in the media disseminating sound-bytes of misleading, premature conclusions.

The message that never reaches the public is that the majority of women with breast implants, those who received their implants before approximately 1992,<sup>20</sup> have become nonconsenting, de facto participants in these and, unfortunately, in

17. As such, we want to ensure that women with implants do not relive the feelings of alienation and despair many Dalkon Shield recipients felt when they experienced medical complications:

For most of the years of illness, I lived in isolation with my problem. Doctors and the manufacturers of birth control technology never acknowledged it or its source. Neither did my family, friends, or colleagues. I continually met with such incomplete and uncompassionate responses as, "What's your problem? You look fine to me!," "But your blood test is normal," and "What are you trying to teach yourself by giving yourself this illness?" There are many sources for the ignorance and denial that surround technology-induced disease, but the ultimate result of such frames of mind is that they alienate sick people from the support and caring they deserve and they alienate all of us from addressing the collective problem of technology's dangers.

CHELLIS GLENDINNING, *WHEN TECHNOLOGY WOUNDS* 16 (1990).

This is not to say that research in this area is entirely lacking. For a recent development in monitoring implant integrity, see Leonard T. Yu et al., *In Vitro Measurement of Silicone Bleed from Breast Implants*, 97 *PLASTIC AND RECONSTRUCTIVE SURGERY* 756 (1996). The focus in this area, however, could be significantly stronger.

18. See *infra* notes 66-68, 73-75, 157, 174, 180 and accompanying text.

19. For example, Dr. Marcia Angell called for the FDA Commissioner, David Kessler, to lift the ban on silicone implants in 1992, long before the release of any long-term medical studies including the Mayo Clinic Study and the Nurses' Study. See Marcia Angell, *Breast Implants—Protection or Paternalism?* 326 *NEW ENG. J. MED.* 1695, 1696 (1992) (editorial); Gina Kolata, *Study Reports Small Risk, If Any, From Breast Implants*, *N.Y. TIMES*, Feb. 28, 1996, at A12.

20. This date is chosen because the FDA placed a moratorium on silicone gel breast implants in April of 1992. See Rebecca Weisman, *Reforms in Medical Device Regulation: An Examination of the Silicone Gel Breast Implant Debacle*, 23 *GOLDEN GATE U.L. REV.* 973, 973-74 (1993). Access to silicone implants is limited to those women who enroll in clinical studies and favors women who want the implants for reconstructive rather than for purely cosmetic reasons. See *id.*; see also Simon, *supra* note 7, at 149 & n.60; Note, *supra* note 10, at 190-91 & nn.149-51. It is likely, however, that many people learned about the potential dangers associated with breast implants a few months earlier on November 8, 1991, when Connie Chung delivered a television report on the topic. *Face to Face with Connie Chung: Breast Implants: Risky Business* (CBS television broadcast, Nov. 8, 1991). In this report, Chung interviewed several women whose lives became "a nightmare" after receiving silicone breast implants, as well as a physician who confessed that "We have done a large-scale clinical experiment on an unproven, probably unsafe, medical device" involving two million American women. *Id.*

future safety studies.<sup>21</sup> These women are living, breathing lifetime studies. In their case, to focus exclusively or even primarily upon the current research and safety data ignores the simple reality that these studies were not available when they made their decisions to undergo breast implant surgery. Instead, an analysis of their legal and medical situation should begin with what was known about breast implants at the time that they underwent breast augmentation surgery, what was not known, what the doctrine of informed consent means in our medical and legal systems, and what does or should constitute compensable, physical harm in our legal system.

In Part II of this article, in an attempt to provide a context for analysis of these issues, I present a brief history of western beauty rituals and practices unique to women. This history is followed by a discussion in Part III of the development of cosmetic surgery, which, because it is primarily performed upon women for aesthetic purposes, can be seen as an almost inevitable technological outgrowth of these earlier, more primitive beauty practices. There is, however, one important difference with cosmetic surgery: the beauty "practice," or more accurately, the physical change undertaken in the name of beauty, cannot be performed without the intervention of a third party, the surgeon. Thus, the development of surgery almost exclusively performed upon women is presented, focusing first on the earliest gynecological surgical procedures and then on cosmetic surgery.

After setting this stage, Part IV analyzes both existing law and the Revised Breast Implant Settlement Program. Specifically, Part IV analyzes the legal requirements for informed consent and the definitions of physical harm and disease under the Revised Breast Implant Settlement Program. In this section, the terms of the Revised Breast Implant Settlement Program are analyzed in conjunction with the conduct of the manufacturers (and physicians) so as to shed light on the complexities surrounding this medical device,<sup>22</sup> made of silicone, which, when broken down into silica, becomes toxic.<sup>23</sup> Experience with direct

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21. It is true that federal regulations mandate that participation in either federal studies or those studies subject to federal regulation be voluntary, 16 C.F.R. § 1028.116 (1996), and thus no woman with breast implants can be required to participate in a study if she truly wishes to be excluded. The reality is that in order to protect their future health, all women with silicone implants have very strong incentives to participate in any and all studies. Additionally, women who are neither asked nor consent to participate in a controlled study are in effect participating throughout the duration of their lives in a general study of breast implants because their physicians will be monitoring their health. Unfortunately, involuntary participation is nothing new in the case of silicone breast enhancement. During the 1960's, Dow Corning conducted experiments with liquid silicone on women who had not actually consented. See Lichtenstein, *supra* note 7, at 208 & nn.20-21; Foreman, *supra* note 6.

22. In addition to breast implants, silicone has a number "of medical applications, including intravenous tubing, catheters, joint prostheses and penile" implants. Simon, *supra* note 7, at 142 & n.3. The FDA acquired the authority to regulate breast implants in 1976 with the Medical Device Amendments to the Food and Drug Cosmetic Act. 21 U.S.C. § 360(c) (1988). Breast implants, however, were not classified as a medical device by the FDA until 1988. See STAFF OF HOUSE COMM. ON GOVERNMENT OPERATIONS, 102D CONG., 2D SESS., THE FDA'S REGULATION OF SILICONE BREAST IMPLANTS 4 (Comm. Print 1992).

23. See Bridges & Vasey, *supra* note 6, at 2640 (stating that "silicone is not inert" and that "silicone can lead to marked tissue reactions"); Foreman, *supra* note 6.

silicone injections of medical grade silicone into women's breasts, the breast augmentation procedure utilized in this country prior to the introduction of the silicone gel implant, has, in fact, demonstrated that this medical device is also a toxic substance.<sup>24</sup> It is thus this author's hope that the story of silicone breast implants will provide important lessons about the need to assure individuals a meaningful opportunity to make choices about medical care, particularly elective, invasive medical procedures.<sup>25</sup>

## II. FEMININE BEAUTY RITUALS: A PAINFUL HISTORY

Breast augmentation is a drastic alteration of the body that has been undertaken by as many as two million women in the United States.<sup>26</sup> It is preceded by a virtually uninterrupted history of painful alteration of the female body in Western culture.<sup>27</sup> In fact, throughout recorded history, women have engaged in various beauty practices, many of which, in addition to being painful, were also dangerous.<sup>28</sup> Of course, not all feminine beauty practices are or have been harmful.<sup>29</sup> For instance, Neanderthal women who painted themselves with

24. Liquid silicone injections allegedly produced "severe tissue reactions." See Foreman, *supra* note 6.

25. Efforts are under way to improve the quality and safety of breast implants, and it appears that a replacement may have been found. The trilucet breast implant is available for women who qualify for a clinical study. See Sally Ogle Davis, *At Last—the Ideal Breast Implant?*, COSMOPOLITAN, Apr. 1997, at 140. The implant is like the silicone gel implant in that the shell is made of silicone, but it is filled with medical grade soybean oil, which is also used in intravenous feeding. See *Prime Time Live: Shape of the Future* (ABC television broadcast, May 14, 1997). Critics argue, however, that this product was introduced after only a six month study involving animals, and although soybean oil is not toxic if it is introduced into the body through a rupture of the implant shell, we do not know what will happen over time if, for instance, the oil becomes rancid and leaks into the woman's breast tissue and body. See *id.*

26. See Note, *supra* note 10, at 163; *Face to Face*, *supra* note 20. Other estimates place the number as low as one million. See Gayle L. Troutwine, *Beauty and the Beast, Breast Implants: A Beauty Fraud*, TRIAL, Aug. 1993, at 48, 49. FDA estimates support the latter, lower number. See Kerith Cohen, Note, *Truth & Beauty, Deception & Disfigurement: A Feminist Analysis of Breast Implant Litigation*, 1 WM. & MARY J. WOMEN & L. 149, 159-60 (1994). Although in rare instances men have undergone breast augmentation surgery, for example transsexuals, the surgical procedure is overwhelmingly performed on women. See Sarah Tankersley, Note, *Reproductive Freedom: Abortion Rights of Incarcerated and Non-Incarcerated Women*, 85 KY. L.J. 219, 226 (1997).

27. See SHARLENE HESSE-BIBER, *AM I THIN ENOUGH YET? THE CULT OF THINNESS AND THE COMMERCIALIZATION OF IDENTITY* 20-26 (1996). For an example of a very painful, bizarre practice, in which at least some women engaged in the name of beauty, see Eugenie Anne Gifford, "The Courage to Blaspheme": *Confronting Barriers to Resisting Female Genital Mutilation*, 4 U.C.L.A. WOMEN'S L.J. 329, 361-62 (1994) (arguing that the clitoridectomy "briefly reached fad proportions" in this country and was viewed by some women as a form of fashion).

28. See NANCY C. BAKER, *THE BEAUTY TRAP* 15 (1984). The author interviewed women from America, Latin America, Europe and the Middle East and found that all of these women were preoccupied with physical appearance and beauty. See *id.* at 8.

29. See Cohen, *supra* note 26, at 157 (describing such beauty products as eye shadow, nail polish, and lipstick); BAKER, *supra* note 28, at 14. Although men have also spent time on their appearance, their rituals and practices have not been as time consuming or as extreme. See *id.* at 18. "[W]hatever sartorial devices men have put on to bolster their body image—codpieces, elevated shoes, padded shoulders, a boxy jacket—these did not constrict or cause pain." SUSAN BROWNMILLER, *FEMININITY* 35 (1984).



ocher<sup>30</sup> and wore jewelry made of shells provide the earliest evidence of female adornment.<sup>31</sup>

In Western culture, the identification of beauty predominantly with the female gender can be traced to the Greeks, who ascribed different virtues to men and women, with beauty as a feminine virtue indicative of good character.<sup>32</sup> In non-Western cultures, both women and men believed deforming beauty rituals were a distinctive badge of moral correctness and evidence of a position of privilege and leisure within society.<sup>33</sup> Although the focus of this discussion is on Western practice, it is interesting that in the United States cosmetic surgery is an accepted practice and Chinese foot-binding, as described below, is viewed as an oppressive act of mutilation:

[T]he Chinese ... discovered that, by binding the feet of young girls, they could create a foot deformity resulting in a natural sort of "high heel." As the girl's foot grew, her toes became permanently twisted under the arch. The pain females must have endured in the name of beauty during the thousand years that foot-binding was customary in China can hardly be imagined. Yet some must have felt that the price was not too high. For the more petite her foot—the more tightly bound it was—the more beautiful the Chinese woman was considered to be.<sup>34</sup>

What remained of a woman's foot after undergoing this painful process for years was a deformed stub of approximately three to four inches.<sup>35</sup> Women were unable to stand without support or to walk without the use of a cane or the assistance of a servant or a man.<sup>36</sup> Such women were romanticized, even eroticized, within Chinese culture.<sup>37</sup> Ironically, not only was this a practice Chinese women endured, they were active participants as they imposed this same ritual upon their young daughters.<sup>38</sup> As will be seen in the discussion that

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30. Ocher is a "mineral oxide of iron" that is either "yellow, brown, or red" in color. See THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE 1251 (3d ed. 1992).

31. See BAKER, *supra* note 28, at 14.

32. See LOIS W. BANNER, AMERICAN BEAUTY 10 (1983). The word "beauty," which is of Latin derivation, means good. See *id.* It was initially "applied only to women and children; later it was used ironically to describe men." *Id.*

33. See BROWNMILLER, *supra* note 29, at 33.

34. BAKER, *supra* note 28, at 15.

35. See BROWNMILLER, *supra* note 29, at 33; HESSE-BIBER, *supra* note 27, at 20-21.

36. See BAKER, *supra* note 28, at 15 (stating that this practice provided "an obvious reward for men" in that "women with bound feet became virtual prisoners in the home, barely able to walk, much less run away from their men"); BROWNMILLER, *supra* note 29, at 33-34 (characterizing this practice as the "violent subjugation of women").

37. The lotus blossom, a revered flower in Chinese culture, became the metaphor for the woman's deformed, useless foot. See BROWNMILLER, *supra* note 29, at 33. "Making love to the lotus foot, an elaborate art of manipulation, postures and poses, was a dominant theme in Chinese pornography for eight hundred years while the custom of footbinding flourished." *Id.* at 34.

38. See *id.* Brownmiller observed that foot-binding:

demand[ed] the shared complicity of mother and daughter in the desperate work of beautification and the passing on of compliant, submissive feminine values, for the anxious mother was the agent of

follows, Western beauty practices were similarly thought to symbolize aristocratic stature; women actively engaged in these rituals, they imposed them on their daughters, and they believed them to be necessary components of feminine sexual appeal.<sup>39</sup> Eastern and Western beauty rituals share important facets of pain and disfigurement because many women believe that the natural shape of their bodies, or some aspect of their bodies, is inadequate, even defective.<sup>40</sup> Yet our cultural bias blinds us from seeing Western beauty practices in the same light that we see Eastern ritual—as torturous, mutilating, masochistic acts.

One little known beauty aid utilized by women in the United States at the end of the eighteenth century was ceruse, a type of make-up applied to the face in order to produce the appearance of a fair complexion.<sup>41</sup> This substance was, in fact, a toxic white paint that had a lead base.<sup>42</sup> Even though there were reports that women had damaged their skin by using this product and that, in some instances, women had “suffered slow deaths,” ceruse remained a popular beauty tool.<sup>43</sup> In the early nineteenth century, women also ingested “vinegar, chalk, or even arsenic to obtain a delicate complexion.”<sup>44</sup> During these periods, women’s hair styles were elaborate, taking hours to create and including hairpieces or wigs.<sup>45</sup> They wore heavy, large skirts with equally heavy undergarments that proved warm and inhibited movement.<sup>46</sup>

Another beauty device and probably the single most restrictive, painful part of a woman’s attire beginning in the sixteenth century and continuing through to the turn of the twentieth century was the corset.<sup>47</sup> It was originally made of

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will who crushed her suffering daughter’s foot as she calmed her rebellion by holding up the promise of the dainty shoe, teaching her child at an early age that the feminine mission in life, at the cost of tears and pain, was to alter her body and amend her ways in the supreme effort to attract and please a man.

*Id.*; see also HESSE-BIBER, *supra* note 27, at 20 (describing the story of a girl whose mother started binding her feet at age seven).

39. See BROWNMILLER, *supra* note 29, at 33-34.

40. See *id.* at 36-37. Brownmiller finds the homogenizing aspect of fashion and beauty troubling. She writes, “nearly every civilization has sought to impose a uniform shape upon the female body, a feminine aesthetic that usually denies solidity by rearranging, accentuating or drastically altering some portion of the female anatomy or some natural expression of flesh.” *Id.* at 33.

41. See BAKER, *supra* note 28, at 18.

42. See *id.*

43. See *id.*

44. BANNER, *supra* note 32, at 41. Arsenic ingestion can be traced to garbled scientific reports of an Austrian biologist, Johann Frederick Blumenbach, who asserted that “European stock” could be traced to the Caucasus (from which he coined the term “Caucasian”). *Id.* Circassian women who lived in the Caucasus were alleged to have beautiful complexions, and during the early nineteenth century, it was rumored and reported that these women ate arsenic to achieve their beautiful complexions. See *id.* In addition to oral ingestion, doctors prescribed topical creams and lotions that contained arsenic to battle adolescent acne. See *id.* The complexion of most men and women during this time in history was probably poor due to a diet high in fat. See *id.* Additionally, the desire for a translucent, clear complexion may have been inspired by a glorification of consumption, a disease that affected women disproportionately and was incurable. See *id.* at 51-52.

45. See BAKER, *supra* note 28, at 17-19.

46. See *id.*

47. See HESSE-BIBER, *supra* note 27, at 24-25. Not only was the purpose of wearing the corset to produce a small waist, but one author asserts that “[w]hether American women knew it or not, tightlacing was

wood, whalebone, or metal until the advent of the iron corset in the late sixteenth century.<sup>48</sup> Catherine de Medici, Queen of France, is credited with introducing the iron corset in accordance with her decree that the ideal waist measurement for a woman of her time was thirteen inches.<sup>49</sup> Throughout most of the seventeenth century, the ideal waist measurement was thought to be no more than eighteen inches.<sup>50</sup> Both of these measurements were unrealistic aspirations for women and were achieved at a high cost, including organ displacement, headaches, fainting, and breathing problems.<sup>51</sup> In the middle of the nineteenth century, many women began using padding to accentuate their breasts and hips.<sup>52</sup> Thus, fashion demanded the impossible of women, voluptuous breasts and hips with a child-like waist.<sup>53</sup>

Once again, women imposed this ritual, which required the exertion of as much as eighty pounds of pressure on the body and took as long as one-half hour to accomplish each day, on their daughters.<sup>54</sup> The following letter illustrates a young woman's indoctrination into this right of womanhood:

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designed to increase the size of the bosom and hips by reducing the size of the waist and pushing excess flesh upward and downward." BANNER, *supra* note 32, at 60.

48. See Baker, *supra* note 28, at 16.

49. See *id.* Queen Elizabeth I of England is also credited with popularizing the corset. See BROWNMILLER, *supra* note 29, at 35.

50. See BANNER, *supra* note 32, at 48. "Proper Victorians believed that a woman's frail body required the support of a corset." *Id.*

51. See BAKER, *supra* note 28, at 19-20. "The clergy spoke from their pulpits against the contraptions, noting that, when pregnant women laced themselves tightly in order to look socially respectable, abortions were frequently the result." *Id.* at 20. Doctors and reformers during this period also believed that corsets "may have been a primary cause of the uterine and spinal disorders wide-spread among nineteenth-century women." BANNER, *supra* note 32, at 48. In rare instances, death resulted. See HESSE-BIBER, *supra* note 27, at 25. A young woman, whose mother required that she wear a tightly-laced corset, died at the age of 20 because "her ribs had grown into her liver" and "her entrails were much hurt by being crushed together with her stays." *Id.*

52. See BANNER, *supra* note 32, at 60-61. One such inflatable device, the "gay deceiver," was made of rubber. *Id.* at 61.

53. During this time, "[m]any women embarked on what seems to be cross purposes: They went on crash diets to gain weight while simultaneously strapping themselves into smaller and smaller waistlines." BAKER, *supra* note 28, at 20. Some of these women are reported to have had ribs surgically removed. See *id.* As the nineteenth century progressed, different fashion trends that were built around the corset emerged. See BANNER, *supra* note 32, at 68-69. One such fashion of the late 1860's, the "S-shaped silhouette," involved an extremely accentuated "bulging" hips and buttocks with a very narrow waist. *Id.* at 68.

54. See BROWNMILLER, *supra* note 29, at 36-37. It is not surprising that women accepted and perpetuated this beauty ritual. They were surrounded by images reflecting an ideal body-type that mirrored the look the corset provided. One art historian has noted that many famous artists throughout history have depicted the nude female body not in its natural state, but instead in conformity with the illusion that the corset created. See ANNE HOLLANDER, *SEEING THROUGH CLOTHES* 128-34 (1978).

At any time the unadorned self has more kinship with its own usual *dressed* aspect than it has with any undressed human selves in other times and places, who have learned a different visual sense of the clothed body. It can be shown that the rendering of the nude in art usually derives from the current form in which the clothed figure is conceived.

*Id.* at xiii.

I was placed at the age of fifteen at a fashionable school in London, and there it was the custom for the waists of the pupils to be reduced one inch per month until they were what the lady principal considered small enough. When I left school at seventeen, my waist measured only thirteen inches, it having been formerly twenty-three inches in circumference. Every morning one of the maids used to come to assist us to dress, and a governess superintended to see that our corsets were drawn as tight as possible. After the first few minutes every morning I felt no pain, and the only ill effects apparently were occasional headaches and loss of appetite. I should be glad if you will inform me if it is possible for girls to have a waist of fashionable size and yet preserve their health. Very few of my fellow-pupils appeared to suffer, except the pain caused by the extreme tightness of the stays. In one case where the girl was stout and largely built, two strong maids were obliged to use their utmost force to make her waist the size ordered by the lady principal—viz., seventeen inches—and though she fainted twice while the stays were being made to meet, she wore them without seeming injury to her health, and before she left school she had a waist measuring fourteen inches, yet she never suffered a day's illness.<sup>55</sup>

As always with beauty, fashion changed and, when corsets were no longer in vogue, other painful, body-altering rituals emerged. In the 1920's, women with large breasts bound them to create the illusion of small breasts.<sup>56</sup> As will be discussed in the following section, shortly after this time, women began turning to surgery for enhancement of their breasts.<sup>57</sup> For the past twenty or more years, the ideal female has gotten thinner while her breasts have gotten larger.<sup>58</sup> A recent study revealed that the dimensions of the average department store mannequin would translate into a woman who would probably be too thin to menstruate.<sup>59</sup> While fashions change, one factor remains constant: the ever-changing fashion ideal is unattainable for the vast majority of women who,

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55. BAKER, *supra* note 28, at 19. This letter was printed in the May 1867 issue of *English Women's Magazine*. See *id.*

56. See BROWN MILLER, *supra* note 29, at 39.

57. See Lichtenstein, *supra* note 7, at 207-08.

58. See BAKER, *supra* note 28, at 25; see also HESSE-BIBER, *supra* note 27, at 3-6 (dating the trend toward an unnaturally thin beauty ideal to the 1960's).

59. See Cohen, *supra* note 26, at 158 & n.79. The author notes that while the ideal woman has become "taller and thinner," the average American woman has gotten heavier. *Id.* at 158. Recent studies of both men and women support this conclusion for the population as a whole. Hesse-Biber notes that "[i]n 1983, 58% of the adult population age 25 years and older weighed more than recommended for their height and frame size. In 1987, the figure rose slightly to 59%, climbing to 63% in 1992." HESSE-BIBER, *supra* note 27, at 37. In 1994, the obesity rate among American adults was reported to have increased from 25% to 33%. See *id.* Anorexia nervosa and bulimia, although seemingly modern afflictions, are not unique in the sense that frail, thin figures have been prized in American history. During much of the nineteenth century, a frail soma-type was the model for beauty. See BANNER, *supra* note 32, at 45-57. Many physicians from this era believed that the female diet should consist of only light fare, including "toast, tea, a bit of chicken or bouillon." *Id.* at 50. Cases of anorexia increased again in the 1920's, during the "Flapper Era." See HESSE-BIBER, *supra* note 27, at 27.

undeterred, hurt their bodies to achieve beauty.<sup>60</sup> When viewed in light of this history, the effects of foot-binding are only different from the restrictions imposed by the corset in terms of the degree of immobilization of the body. Unlike the foot-binding ritual, the corset did not directly impede walking, but instead made other routine acts of breathing and sitting difficult.<sup>61</sup>

Situated in this historical context, breast augmentation surgery appears to be a natural technological evolution in feminine beauty practices.<sup>62</sup> We accept it as part of our culture because women voluntarily engage in the practice and also because society at large is probably unaware of the level of pain, damage, and even deformity that can result from a "successful" augmentation surgery. Breast augmentation surgery takes from just under one hour to two hours to complete and usually results in a two or three inch scar beneath each breast.<sup>63</sup> Although many women immediately return home after the procedure, many also experience pain for days and even for a week or more following surgery.<sup>64</sup> The surgery is considered minor, but women are advised by their physicians to refrain from exercise and other physical exertion for a minimum of three weeks after a routine breast augmentation procedure so that their bodies can heal; they suffer from swelling and bruising on and near their breasts and over their rib cage.<sup>65</sup>

Thirty to fifty percent of all "successful" operations will result in side effects.<sup>66</sup> The most common of the adverse effects include partial or total loss of nipple sensation and numbing of the breasts due to nerve damage, painful hardening of the breasts, and breasts that are not symmetrical.<sup>67</sup> A somewhat less common but more deforming and painful side effect occurs when tissue surrounding the implanted breast "becomes doorknob-shaped, rock hard, and

60. See BAKER, *supra* note 28, at 14-26; see also Gifford, *supra* note 27, at 362-63 (discussing this issue in the specific context of breast augmentation surgery); FRANK B. VASEY & JOSH FELDSTEIN, *THE SILICONE BREAST IMPLANT CONTROVERSY: WHAT WOMEN NEED TO KNOW* 5 (1993) (citing statistics that show that the average woman is 9% shorter and 16% heavier than the female models she sees).

61. See BROWNMILLER, *supra* note 29 at 36.

62. See VASEY & FELDSTEIN, *supra* note 60, at 5 (comparing the corset to the "high-tech means" cosmetic surgery now provides for beautification).

63. See *id.* at 127-28. This type of incision is the most common and is known as an inframammary incision. See *id.* There are two other options, the axillary incision (the armpit) and the periareolar incision (the nipple). See *id.*

64. See *id.* at 125-27 (discussing possible side effects of surgery and stating that "[n]ormal activities can usually be resumed gradually after one week's time, with more strenuous activities avoided for approximately three weeks."). For a discussion of one woman's experience with breast augmentation, see JOHN A. BYRNE, *INFORMED CONSENT* 69-70 (1996).

65. See VASEY & FELDSTEIN, *supra* note 60, at 125-27.

The recovering patient will need to avoid reaching up or out for about three days; she should also sleep on her back with her head elevated for about seven days. Normal activities can usually be resumed gradually after one week's time, with more strenuous activities avoided for approximately three weeks post-op.

*Id.* at 127; see also KAREN J. CARLSON et al., *THE HARVARD GUIDE TO WOMEN'S HEALTH* 108-09 (1996).

66. See KATHY DAVIS, *RESHAPING THE FEMALE BODY: THE DILEMMA OF COSMETIC SURGERY* 27 (1995). The truth is that we do not know what percentage of women have complications after breast augmentation surgery. See ANGELL, *supra* note 4, at 40-41. The reason for our lack of knowledge may be due to physician self-interest: the physicians may not keep thorough records or report these problems to the FDA.

67. See DAVIS, *supra* note 66, at 27-28.

painful.”<sup>68</sup> When this side effect known as capsular contracture occurred in the past, a closed capsulotomy (external pressure applied to the breast by the surgeon)<sup>69</sup> was performed to release the hardened tissue. Now, surgical removal of the implants is the recommended procedure, and in the worst cases, the hardened implants must “be literally chiseled from the patient’s chest wall.”<sup>70</sup>

In such instances, the implant removal process can be a harrowing experience, especially when the surgeon has not prepared the woman in advance for the physical discomfort and pain likely to accompany the removal surgery. One woman who had her breast implants removed while under local anesthesia (she was awake during the surgery) experienced the following:

During the explantation, the surgeon cut through the original incisions to retrieve Ellen’s implants, which had been inserted submuscularly. “He had to cut through all that muscle to get them out,” she said. “And they didn’t pop right out. It was a tug-of-war game. He tugged and tugged and pulled to get them out. At times, he was lifting me off the table. I could feel my skin burning. I could feel him cutting. I could smell it, hear it sizzling, and I told him I could feel that. He didn’t . . . he didn’t acknowledge it.”<sup>71</sup>

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68. *Id.* Some estimates are that this side effect occurs in up to 35% of breast augmentation procedures. *See id.* Others estimate that the occurrence rate is as high as 50%. *See* ANGELL, *supra* note 4, at 41. One manufacturer, McGhan Medical Corporation, estimated the rate of capsular contracture to be as high as 74%. *See* VASEY & FELDSTEIN, *supra* note 60, at 96. The estimates of implant rupture also vary. *See id.* In 1992, one plastic surgeon reported a four to six percent rupture rate, while another plastic surgeon noted that implants which were removed that were more than ten years old were “almost always” ruptured. *Id.*; *see also* Donna L. de Camara et al., *Rupture and Aging of Silicone Gel Breast Implants*, 91 *PLASTIC RECONSTRUCTIVE SURGERY* 828, 829 (1993).

69. *See* VASEY & FELDSTEIN, *supra* note 60, at 102. This procedure is performed without the aid of anesthesia and has been described by women who have undergone it as excruciatingly painful. *See id.* Due to the high rate of implant rupture from this procedure, some manufacturers now provide package inserts that warn against this procedure. *See* ANGELL, *supra* note 4, at 42. It is not known how many surgeons still practice this painful and dangerous technique.

70. DAVIS, *supra* note 66, at 28; *see also* CARLSON, *supra* note 65, at 110 (stating that “[s]queezing the breast to rupture the capsule is not recommended, since this can actually damage the implant.”) Although it is not recommended by the manufacturers, closed capsulotomy is described as a viable procedure in plastic surgery textbooks, which were published as recently as 1995. A detailed discussion of the procedure taken from one textbook follows:

The technique of compression around the prosthesis [breast implant], building a force great enough to cause a fracture in the capsular wall, has proved highly successful in a majority of patients. The technique should be performed with the discomfort of the patient in mind, and the patient should be aware that damage to the prosthesis can result in this procedure. . . . The procedure is simple to perform in the office and usually causes only slight discomfort to the patient. Sedation or other means of diminishing pain response should not be administered. The patient’s discomfort should be the surgeon’s guide. . . . Hematoma that requires surgical intervention can occur from the closed capsulotomy. Incomplete rupture of the capsule wall can cause bizarre shapes caused by herniation of the prosthesis through the weakened defect in the capsule wall. This condition could require later surgical correction.

BERNARD M. BARRETT, JR., *PATIENT CARE IN PLASTIC SURGERY* 411-13 (2d ed. 1995).

71. VASEY & FELDSTEIN, *supra* note 60, at 47. Typically, implant removal is made difficult due to the calcifications that develop around ruptured or older implants. *See infra* notes 273-75 and accompanying text. Explantation procedures performed upon younger implants are generally not as traumatic because these implants are less likely to be ruptured. *See* de Camara, *supra* note 68, at 828-29; *see also* VASEY &

The fully numb or hardened misshapen breast, and the painful implant removal process begin to resemble the pain and mutilation caused by the corset or even the foot-binding practice.<sup>72</sup> It is true that a woman who suffers adverse consequences from breast implant surgery remains able to walk, sit, and breath; however, for some women, a basic function, breast feeding, is either lost or impaired.<sup>73</sup> This consequence has been virtually ignored by the manufacturers. In fact, Dow Corning performed only one study on four women who were breast feeding their babies by comparing the milk samples of the two who had implants with the two who did not.<sup>74</sup> Unfortunately, women with implants have been assured that it is safe for them to breast feed, despite the lack of supporting evidence.<sup>75</sup>

Moreover, eighty percent of the time breast augmentation surgery is performed for cosmetic reasons.<sup>76</sup> If severe deformity, pain, and disfigurement occur, the result is completely at odds with the initial goal of aesthetic "improvement." Any analysis of breast augmentation must also take into account the unique nature of breasts, their visibility and symbol of sexual maturity, femininity, and sexual appeal.<sup>77</sup> It is not a great inferential leap to conclude that if women were informed that one of every three implant operations would likely result in these consequences, many more would choose not to undergo this

FELDSTEIN, *supra* note 60, at 129 (discussing explantation procedures for implants that are not ruptured and noting that "[s]urgically related complications should in most cases be minor"). These procedures are, however, invasive surgical procedures and the pain and discomfort they cause should not be minimized. *See id.* at 129-30.

72. One author has argued that plastic surgery is a "barbaric" form of self-mutilation similar to foot-binding practices, dowry deaths, and even clitoridectomies. Ruth Rosen, *Perspective on Women's Health: Draw the Line at the Knife*, L.A. TIMES, Nov. 17, 1991, at M5; *see also* Karen Engle, *Female Subjects of Public International Law: Human Rights and the Exotic Other Female*, 26 NEW ENG. L. REV. 1509, 1511 (1992). Another writer, in the context of discussing cosmetic surgery, has commented that "the nineteenth century corset may have been unhealthy . . . but the twentieth century has produced an even more constraining corset—the woman's own skin." DAVIS, *supra* note 66, at 41. This latter author argues that "the amount of damage inflicted in the course of beautifying the body tends to be directly related to the development of technology." *Id.*

73. *See* VASEY & FELDSTEIN, *supra* note 60, at 40-41. FDA mandated warnings for patients state: "The surgical implantation of the device [breast implant] may interfere with a woman's ability to nurse her baby. . . . Although this is a known risk, the extent of the risk is unknown." Troutwine, *supra* note 26, at 50; *see also* Note, *supra* note 10, at 167 & n.23 (discussing claims for injury made by children who were breast fed). It is unknown whether silicone, which bleeds through the implant in all cases, can get into breast milk and be ingested by babies. *See* Terri D. Keville, *The Invisible Woman: Gender Bias in Medical Research*, 15 WOMEN'S RTS. L. REP. 123, 131 n.97 (1993-94).

74. *See id.*

75. *See id.* However, a study performed in 1994 "suggests that breast-fed infants of mothers with implants may develop diseases of the digestive tract with permanent effects." *Id.* (citing Jeremiah J. Levine & Norman T. Ilowite, *Sclerodermalike Esophageal Disease in Children Breast-Fed by Mothers with Silicone Implants*, 271 J. AM. MED. ASS'N 213 (1994)).

76. *See* Note, *supra* note 10, at 163. Between 1962-91, 80% of the breast augmentation surgeries performed were cosmetic. *See id.*

77. *See generally* DAPHNA AYALAH & ISAAC J. WEINSTOCK, *BREASTS: WOMEN SPEAK ABOUT THEIR BREASTS AND THEIR LIVES* (1979) (discussing women's ambivalence about their breasts).

elective surgical procedure for the simple reason that there is a real risk that their breasts will look worse rather than better after the surgery.<sup>78</sup>

A critical difference that separates silicone breast implants from the other more primitive beauty rituals is the addition of the surgeon in the beautification process and the relative permanence of the alteration to the body.<sup>79</sup> Thus, women's relationship with their physicians necessarily complicates any investigation of this issue, regardless of the investigative perspective.

### III. WOMEN AND SURGERY

Cosmetic or plastic surgery,<sup>80</sup> which has its roots in reconstructive surgery,<sup>81</sup> is nearly exclusively performed on women: physicians estimate that ninety to ninety-five percent of all such patients are women.<sup>82</sup> This is not to say that men never undertake cosmetic surgery, just that they do so in significantly smaller numbers.<sup>83</sup> The trend is changing, with an increase in the total number of cosmetic surgical procedures performed on men; however, the number of women

78. See Naomi Wolf, *Keep Them Implanted and Ignorant*, in *MINDING THE BODY: WOMEN WRITERS ON BODY AND SOUL* 187, 188 (Patricia Foster ed., 1994) (arguing that "even if a woman does full-time funded research for six months, she won't find facts she needs to make a genuinely informed choice"). *But see* DAVIS, *supra* note 66, at 142-47 (describing women who after experiencing many of the above mentioned side-effects stated that they did not regret their decision to have breast augmentation surgery). This anecdotal evidence does not resolve the issue of informed consent. Women may express satisfaction with breast augmentation surgery in the face of serious side-effects due to cognitive dissonance. See Solveig Beale, et al., *Augmentation Mammoplasty: The Surgical and Psychological Effects of the Operation and Prediction of the Result*, 13 ANN. PLAST. SURG. 279, 290, (Oct. 1984). They may have made a choice to have breast implants against the advice of family members or other important people in their lives, and they may not be able to admit dissatisfaction either to themselves or to others. *See id.* at 290.

79. Although many surgical procedures, face lifts and breast implant surgery, are not expected to last a lifetime, they are longer lasting than was the illusion created by the corset. Corsets actually had an opposite effect on the appearance of women's bodies in their natural state. See BROWNMILLER, *supra* note 29, at 36. A woman's muscles became "miserably atrophied from disuse and binding;" thus, the moment the corset was removed, a woman's waistline was larger and less defined than if she had never worn a corset. *Id.* It is estimated that a face lift should be repeated in five years while breast implants should be replaced within 15 years. *See* DAVIS, *supra* note 66, at 24-28.

80. The phrase "plastic surgery" comes from the Greek word "plassein," which is a word associated with art and sculpture. JOACHIM GABKA & EKKHARD VAUBEL, *PLASTIC SURGERY PAST AND PRESENT, ORIGIN AND HISTORY OF MODERN LINES OF INCISION* vii (1983). For purposes of this article, the terms "cosmetic" and "plastic" are used interchangeably to refer to the branch of this surgical specialty that is concerned with alteration of the body for aesthetic reasons.

81. Reconstructive surgery is generally "for restoring physical dysfunction or for minimizing disfigurement due to disease, congenital deformity, or accident." DAVIS, *supra* note 66, at 16. The first reports of reconstructive plastic surgery can be traced to 1000 B.C. in India when, after an individual was punished by having his nose cut off or an adulterous wife was punished by her husband who bit her nose off, the nose was surgically reattached. *See id.* at 14.

82. One author cites the figure as approximately 90%, *see id.* at 21, while another reports that the American Society of Plastic and Reconstructive Surgeons places the figure at 94%. *See* HESSE-BIBER, *supra* note 27, at 53. Until the middle of the twentieth century, however, cosmetic surgery was not a female province. Instead, its initial development in the United States, England, France, Germany, and Italy as a surgical specialty with an emphasis on reconstruction was spurred by the many casualties from war, particularly the Crimean War and the First and Second World War. *See* DAVIS, *supra* note 66, at 16; GABKA & VAUBEL, *supra* note 80, at 3-4.

83. *See* HESSE-BIBER, *supra* note 27, at 103-05.



who undergo some form of cosmetic surgery is still seven times greater than the corresponding number of men.<sup>84</sup>

The first recorded breast surgery, performed in 1560, involved neither reconstruction nor cosmetic alteration, but rather amputation to relieve extreme discomfort caused by excessive weight and proportion.<sup>85</sup> The amputation, or for that matter, any surgical procedure, was performed as a last resort for the simple reason that most invasive procedures proved fatal until after the introduction of general antiseptic agents in 1870.<sup>86</sup> In the late nineteenth century, breast reduction procedures became common.<sup>87</sup> As for breast augmentation, the first recorded procedure was performed in Germany in 1895.<sup>88</sup> The surgeon removed fat from a non-cancerous tumor located on a woman's back and surgically inserted it into her breasts.<sup>89</sup> Following this and other unsuccessful attempts (the fat was absorbed by the body), surgeons during the 1930's and 1940's experimented with various foreign agents including paraffin wax, petroleum jelly, bees wax, vegetable oils, and even sponges and glass balls.<sup>90</sup> The results were poor, producing infection, scar tissue, and lumps around the implanted substance.<sup>91</sup>

Direct liquid silicone injections into breasts followed. This was a technique developed in post-World War II Japan for prostitutes who wished to satisfy the American or Western male preference for large breasts and, subsequently, it was

84. *See id.* at 105. One doctor expressed his views regarding the increase in male consumption of plastic surgery, which continues to be outstripped by the female demand for cosmetic surgery:

We still don't view men and women as the same, and until our aesthetic demands on men equal the ones that continue to be placed on women, we will still see more women responding to those pressures through cosmetic surgery. However, I do see an increase in men having cosmetic surgery, and the most common reason that I'm encountering is economic. It's the male who is rising up the economic ladder and usually achieves his greatest economic success in his fifties and sixties. Now he needs a physical appearance that is consistent with his power and his place in society.

*Id.*

85. *See* GABKA & VAUBEL, *supra* note 80, at 95. The reason given for the amputation was that "both breasts had assumed such great proportions that she [a maidservant] could not support them, neither standing up nor being seated." *Id.*

86. Dr. Joseph L. Lister is credited with discovering the need for such antiseptic agents such as "alcohol, turpentine, carbolic acid" and other similar agents to prevent infection. *Id.* at 146. Prior to the introduction of antiseptics, amputations of the breast were reserved for situations in which tumors had grown to enormous proportions. *See id.* at 73. The procedure was performed by a barber surgeon who would pull the breast out and away from the body and then the breast would be quickly "cut off altogether close to the thorax, using a large amputation knife." *Id.* at 74. The procedure had to be performed quickly because anesthesia had not yet been developed. *See id.* at 92-93. The survival rate was as low as four out of every 60 surgical patients surviving for more than two years. *See id.* at 93. As one surgeon explained in 1773: "When the disease cannot be repelled by any other means, we have to turn to the operation as the best palliative means; dying of a slow fever is, after all, a gentler form of death than dying of the most hideous putrescence of cancer." *Id.*

87. *See* DAVIS, *supra* note 66, at 25.

88. *See* ANGELL, *supra* note 4, at 35.

89. *See id.*; *see also* Lichtenstein, *supra* note 7, at 207.

90. *See id.* at 207-08; *see also* ANGELL, *supra* note 4, at 35.

91. *See* DAVIS, *supra* note 66, at 25 (stating that these substances "often hardened, protruded or caused fluid to accumulate in the breasts, which then had to be drained"); *see also* ANGELL, *supra* note 4, at 38; Lichtenstein, *supra* note 7, at 208.

imported into this country.<sup>92</sup> The silicone often migrated to the soft tissue surrounding the breasts, the armpits, and to both regional and distant lymphnodes.<sup>93</sup> With the migration of the silicone came disfiguring lumps, but this was not all that happened; some women's breasts became infected with "gangrenous sores sometimes develop[ing] on the overlying skin or nipple."<sup>94</sup> As many as 50,000 American women received silicone injections before the practice was made illegal in this country.<sup>95</sup> In 1962, Dow Corning, apparently undeterred by the adverse effects of liquid silicone on the female breast and body, decided to encapsulate silicone gel in "a rubbery silicone envelope" for implantation into women's breasts.<sup>96</sup>

From 1962 or 1963 until 1992, when the FDA drastically curtailed the availability of silicone breast implants for cosmetic purposes, Dow Corning and other manufacturers successfully marketed breast implants.<sup>97</sup> Even in the face of the FDA moratorium and continuing restriction, breast implant surgery remains one of the most commonly performed cosmetic procedures, ranking second or third.<sup>98</sup> Not only is cosmetic surgery a medical specialty, it is also a big business in this country, generating five billion dollars in revenues annually, and this figure is increasing every year by ten percent.<sup>99</sup> The average annual income of a

92. See *id.* at 35-36. This type of silicone was not medical grade, but instead was "industrial strength transformer coolant stolen from barrels on the docks of Japanese cities." Foreman, *supra* note 6, at 1. This form of liquid silicone was the "forerunner of 'silly putty.'" Lichtenstein, *supra* note 7, at 208.

93. See Foreman, *supra* note 6, at 1. Because this silicone migrated, chemicals were added to cause the body to react by forming scar tissue around the silicone product and thereby keep it inert. See *id.* Some medical professionals assert that the reason for the adverse consequences was that the silicone was not pure, medical grade, and the adulteration of the silicone was responsible for the harm to the women in both Japan and in this country. See ANGELL, *supra* note 4, at 36-38. Other physicians agree that contaminated silicone was harmful; however, they point to studies of medical grade silicone that was directly injected into body tissue and that had similar adverse consequences. See Bridges & Vasey, *supra* note 6, at 2640. This latter group of physicians state that "[t]he mechanism of regional dissemination of silicone is unknown; however, uptake by inflammatory cells with migration to the reticuloendothelial system by way of the lymph channels or bloodstream is suspected." *Id.*

94. ANGELL, *supra* note 4, at 38.

95. See Foreman, *supra* note 6, at 1. This figure included approximately 10,000 showgirls and waitresses in Nevada. See *id.*; see also Lichtenstein, *supra* note 7, at 208. In 1963, the FDA banned the use of liquid silicone injections. In 1975, the Nevada legislature followed suit. See Simon, *supra*, note 7, at 143 & n.13.

96. ANGELL, *supra* note 4, at 39. This figure is disputed; some reports state that the date of the first implant by Dow Corning was 1963. See *supra* note 14 and accompanying text.

97. See ANGELL, *supra* note 4, at 34, 38-44.

98. See DAVIS, *supra* note 66, at 25 (stating that breast augmentation ranks second only to liposuction). *But see* ANGELL, *supra* note 4, at 34 (asserting that in 1994 breast augmentation surgery ranked third behind liposuction and eyelid surgery). In the same year, breast explantation (removal) surgery ranked fifth. See *id.* Since the availability of silicone breast implants for cosmetic surgery has been curtailed, the vast majority of these women are having saline-filled implants placed in their bodies. See *id.* These implants have historically had a higher rupture rate, and since they are filled with fluid, a rupture results in immediate deflation of the implant. See *id.* at 44. Due to their consistency, they are also thought to be less natural looking. See *id.* at 43-44.

99. See HESSE-BIBER, *supra* note 27, at 51. The amount of money spent on breast augmentation during its peak years (1979-92) would amount to \$ 300 million to \$ 450 million in present dollar values. See ANGELL, *supra* note 4, at 34; see also DAVIS, *supra* note 66, at 20.

plastic surgeon is nearly double that of pediatricians, internists, and general practitioners.<sup>100</sup>

Although cosmetic surgery patients are overwhelmingly female, cosmetic surgeons are predominately male.<sup>101</sup> The most recent statistics set the percentage of male plastic surgeons at approximately ninety-three percent.<sup>102</sup> Women are represented at drastically lower rates in all surgical specialties, but their numbers are markedly lower in the field of plastic surgery compared to numerous other surgical specialties.<sup>103</sup>

Strong parallels exist between cosmetic surgery and another field in which women are the patients, men are the physicians, and an emphasis is placed upon surgical intervention, a more aggressive form of treatment: gynecological surgery.<sup>104</sup> The history of this surgical specialty provides useful background information about the development of surgery generally and as a preferred form of treating women. This history is also necessary as a foundation for understanding the comparatively younger surgical specialty of cosmetic surgery.<sup>105</sup> Finally, this historical perspective offers insights into present-day medical/surgical beliefs and conventions regarding physician-patient relationships, including the surgeon's decisions about how much technical information he should provide to a woman who is contemplating surgery and whether he views the woman as an autonomous agent in the decision making process.<sup>106</sup>

At its inception, gynecology was not a separate specialty, but was instead a part of abdominal or pelvic surgery.<sup>107</sup> Innovations in surgical techniques for

100. *See id.* at 20.

101. *See* LILLIAN RANDOLPH, AM. MED. ASS'N, PHYSICIAN CHARACTERISTICS AND DISTRIBUTION IN THE US, Tables B-3 & B-4 (1997-98) [hereinafter PHYSICIAN CHARACTERISTICS]. In 1991, 8.9% of all surgeons were women. *See* Preeti N. Malani, *Surgery's Mighty 12,000: Increasingly, the Face Behind the Mask is a Woman's*, 34 AMERICAN MEDICAL NEWS No. 24, at 25 (June 24, 1991); *see also* Am. Med. Ass'n Council on Long Range Planning and Development, *The Future of General Surgery*, 262 J. AM. MED. ASS'N 3178, 3178-79 (1989).

102. In 1996, there were 503 female plastic surgeons and 5,395 male plastic surgeons. *See* PHYSICIAN CHARACTERISTICS, *supra* note 101, Tables B-3 & B-4.

103. *See* Malani, *supra* note 101, at 25.

104. *See* DIANA SCULLY, MEN WHO CONTROL WOMEN'S HEALTH 222-28 (Reissued with a New Introduction, Teachers College Press 1994) (1980) (discussing the techniques utilized by surgical residents to convince women to opt for gynecological surgery).

105. Cosmetic surgery for purely aesthetic purposes (separate from reconstructive cosmetic surgery) developed as surgical technologies were improved:

The emergence of cosmetic procedures in the mid-twentieth century dramatically altered the field of plastic surgery, marking a new phase in its history. Whereas nearly all plastic surgery in the first part of the century was done to alleviate deformities due to disease, birth, or mishap, in the second half of the century this was no longer the case. Plastic surgery began to be performed for the aesthetic improvement of otherwise healthy bodies and the number of operations increased dramatically.

DAVIS, *supra* note 66, at 16.

106. *See* SCULLY, *supra* note 104, at 91-93.

107. *See* ANN DALLY, WOMEN UNDER THE KNIFE 7 (1991). Due to its danger, surgery originated as a primarily external procedure; thus, the early surgeons specialized in skin problems. "Few, if any, dared to open an abdomen, chest, or skull, even though they knew a good deal about them and what needed to be done when trouble arose in them." *Id.* at 8. This was due to the extremely high mortality rate from shock, hemorrhage, or infection. *See id.* at 13.

problems exclusive to women resulted not only in the development of gynecology as a surgical specialty separate from pelvic surgery, but also in the development of modern surgery.<sup>108</sup> The key surgical innovations included the ovariectomy and surgical repair of vesico-vaginal fistula, the latter of which was a result of either protracted childbirth or inept use of instruments by the physician during childbirth.<sup>109</sup> Thereafter, nineteenth-century pelvic surgeons, as they were then called, began promoting surgery as the first option for physical and psychological problems experienced by women.<sup>110</sup>

Unfortunately, the pioneer surgeons of the nineteenth century who perfected these techniques did so at great expense to women, particularly to slaves and poor immigrants.<sup>111</sup> For instance, J. Marion Sims, heralded as “the father of gynecology,” perfected the procedure for closing vesico-vaginal fistula while working from 1845 through 1849 in his small, rural Alabama hospital where he engaged in medical and surgical experimentation on women.<sup>112</sup> During this four-year period, he acquired seven slaves from their plantation owners, brought them to his hospital, and performed repeated operations on them without any anesthesia.<sup>113</sup> He operated on one of these slaves, Anarcha, who was seventeen years-old when she first came to his hospital, thirty times before perfecting his surgical method.<sup>114</sup> The pain Anarcha and the other women endured was excruciating.<sup>115</sup>

108. *See id.* at 7.

109. *See id.* at 115-16. The ovariectomy, then referred to as “[e]xtirpation of the [o]varies,” involves the removal of both ovaries and the fallopian tubes. *Id.* at 16. Today, the procedure is referred to as a “salpingo-oophorectomy.” *Id.* The surgical repair of vesico-vaginal fistula involves closing “a tear in the wall between the vagina and bladder.” SCULLY, *supra* note 104, at 30. Before the surgery was developed, women with this affliction “suffered a continuous seepage of urine which caused severe discomfort, unpleasant odors, and often ended in social isolation for the victim.” *Id.* Childbirth was also a painful and dangerous experience for women due to “puerperal fever, or childbed fever,” which was a contagious disease “transmitted by hands, clothes, or instruments to women” in hospitals before the advent of simple antiseptic procedures. *Id.* at 31. Childbirth could also result in vesico-rectal fistula, which was a tear between the vagina and the rectum; some women experienced both the vaginal and rectal fistula. *See* DALLY, *supra* note 107, at 22.

110. *See* SCULLY, *supra* note 104, at 40.

111. *See id.* at 34, 42 (asserting that historically the disempowered poor have been “used for clinical observation, experimentation, and instruction”). The author argues that a motivating factor in the decision to open the first hospital specializing in medical problems exclusive to women in 1851, New York Women’s Hospital, was to “draw for its clientele the impoverished immigrant women who were flooding into New York City” and thereby ensure “a steady supply of subjects for surgical experimentation.” *Id.* at 45.

112. *Id.* at 42.

113. *See id.* Anesthesia came into general use sometime in 1860. *See id.* at 27.

114. *See id.* at 42-43.

115. *See id.* at 43. Not only did Sims believe that slaves were better equipped to endure the repeated pain he inflicted upon them than were Caucasian women, he stated that the pain would have been impossible for Caucasian women to bear. *See id.* The truth of the matter is that the slaves did not actually consent to the surgery, their owners did. *See id.* During their stay in Sims’ hospital, the slaves also became addicted to the opium that Sims admitted to administering to each of the women in “tremendous quantities.” *Id.* Before the advent of anesthesia, opium was used in surgery to help counteract the pain. *See id.* Addiction was not normally a problem, in the case of a single surgical procedure, but in the case of these women, the continued experimentation resulted in addiction. Finally, Sims fed, sheltered, and clothed these women, and they were in no position to resist him, a white man, especially since their owners had provided the necessary consent. *See id.*

Another surgeon, Ephraim McDowell, was the first to successfully perform the ovariectomy in his Kentucky home in 1809.<sup>116</sup> From 1860 until approximately the turn of the twentieth century, the ovariectomy was a popular method not only for removing tumors or cysts or for other types of ovarian disease, but also for alleged psychological disorders from which women were thought to suffer, including “nymphomania, and especially for nervous and psychological problems such as hysteria and ‘ovarian insanity.’”<sup>117</sup> This operation was sometimes performed upon women whose husbands procured the surgery as a cure for their wives’ “unruly behavior.”<sup>118</sup> Women who underwent the procedure to cure their psychiatric ills were allegedly miraculously transformed into docile, complacent wives and mothers.<sup>119</sup>

The ovariectomy as a tool for curing so-called insanity was finally found to violate the law in one jurisdiction when it was attempted to be used *en masse* in a psychiatric hospital:

At a state hospital for the insane in Pennsylvania a separate annex ward was established for women to have the operation. The surgeons began to operate and fifty more patients had been “marked for operation” when the committee on lunacy of the Pennsylvania State Board of Public Charities investigated. For the first time medico-legal considerations were taken into account. The committee stated, “The zeal of the gynaecologist is being carried to an unusual extent when it proposes to use a State Hospital for the Insane as an experimental station, where lunatic women are to be subject to doubtful operations for supposed cures.” It was felt that if the operation was permitted on forty or fifty patients, “it might be well to practice [sic] the experiment upon the entire lunatic population, so that the gynaecologist may have the large opportunity he doubtless craves to see just what would happen.” He could then “read his conclusions learnedly to his gynaecological brethren, with the resultant added forward movement up his ladder of fame.”<sup>120</sup>

It was not until the end of the nineteenth century that the operation when performed for psychiatric reasons fell into universal disrepute in this country.<sup>121</sup> Although the clitoridectomy<sup>122</sup> was a much more controversial procedure within the nineteenth-century medical community, it was another accepted surgical

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116. See DALLY, *supra* note 107, at 8-9, 16-17. The physician Robert Battey, however, is credited with popularizing the surgical process, also known as female castration. See SCULLY, *supra* note 104, at 48.

117. SCULLY, *supra* note 104, at 49.

118. BARBARA EHRENREICH & DEIRDRE ENGLISH, COMPLAINTS AND DISORDERS, THE SEXUAL POLITICS OF SICKNESS 35 (1973).

119. See *id.*

120. DALLY, *supra* note 107, at 154.

121. See *id.* at 155.

122. The term “clitoridectomy” actually describes several different surgical procedures:

An operation on the clitoris may be a true clitoridectomy, in which the entire organ is removed. This may even be part of a ‘vulvectomy’, [sic] in which the labia are excised. In Victorian times a popular word for this was ‘extirpation’ [sic]. Sometimes the operation done was actually circumcision, the

method and, like some uses to which the ovariectomy was put, was developed for correcting something other than disease, female masturbation.<sup>123</sup> This was true even though the “experts” believed that masturbation was more commonly practiced by men, and there was no corollary surgical procedure for men or any record of any man being subject to drastic surgical “correction” of masturbation.<sup>124</sup> There are no accurate records as to how many of these procedures were performed in this country, but Dr. W. Gill Wylie, J. Marion Sims’ associate, performed a number of these operations.<sup>125</sup> By 1920, the clitoridectomy was no longer performed by the vast majority of gynecological surgeons in the United States.<sup>126</sup>

This nineteenth-century surgical orientation and zealous intervention into otherwise healthy female reproductive organs were harshly criticized by some medical professionals:

What with burning and cauterizing, cutting and slashing, and gouging, and spitting, and skewering, and pessarying, the old-fashioned womb will cease to exist, except in history. The Transactions of the American Medical Association have figured 123 different kinds of pessaries, embracing every variety . . . . They look like the drawings of a turbine water-wheel, or a leaf from a work on entomology . . . . I do think that this filling of the vagina with traps, making a Chinese toy shop of it, is outrageous . . . . Nowadays, even our young women must have their wombs shored up, and if a baby accidentally gets in by the side of the machinery, and finds a lodgement in the uterus, it may, perchance, have a knitting needle stuck in its eyes before it has any.<sup>127</sup>

For the most part, however, the surgeons were lauded for their achievements, and the failed experiments and the women who endured them were largely forgotten.<sup>128</sup> The medical community has also demonstrated an unwillingness for

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removal of the hood of tissue that surrounds the organ, and sometimes it was infibulation, which is removal not only of the clitoris but also of the front parts of the labia, done to leave raw parts which are then sewn together.

*Id.* at 160. Very little is known about the procedure(s) utilized in this country. *See id.*

123. *See id.* at 162. Apparently attitudes toward masturbation have not changed drastically. A study conducted in 1959 revealed that “half of the medical students and a fifth of the faculty at five medical schools believed masturbation was a frequent cause of mental illness.” SCULLY, *supra* note 104, at 112.

124. *See* SCULLY, *supra* note 104, at 54. Men who masturbated were punished; they were sometimes required to “wear locked chastity belts by day, and spiked or toothed rings by night, the latter to awaken them in the case of a nocturnal erection.” *Id.* The only surgical procedure recommended by some physicians for the treatment of male masturbation was circumcision. *See id.* The obvious difference in the surgical “remedies” was that, for men, the procedure did not destroy or eliminate sexual response, and the procedure was less mutilating and presumably less painful.

125. *See id.*

126. *See id.* at 55. One author asserts that the last recorded clitoridectomy was performed in this country in approximately 1948 “on a child of five, as a cure for masturbation.” EHRENREICH & ENGLISH, *supra* note 118, at 34.

127. DALLY, *supra* note 107, at 130.

128. *See* SCULLY, *supra* note 104, at 38-56.

critical self-appraisal. Medical reference books from the early twentieth century to the present, including current gynecological textbooks, have either omitted any historical reference to the clitoridectomy and ovariectomy (for curing psychological disorders) or have included only a terse, passing notation of the procedures.<sup>129</sup> On rare occasions, physicians and other social scientists who have published books that cast a critical light on the history of the medical profession have been harshly rebuked by the medical community.<sup>130</sup> This inability to tolerate criticism is compounded by the fact that physicians and surgeons have been and continue to be subject to very limited outside regulation and weak internal review and disciplinary procedures.<sup>131</sup>

Many within the medical community downplay this history by arguing that the physicians of the nineteenth century must be viewed from the perspective of the social and legal system within which they operated: one in which slavery was accepted, views on morality and sexuality were vastly different from the present and one in which women were thought to assume a weak, subservient role in society.<sup>132</sup> It is true that the context within which these physicians pursued their craft must be understood and examined. It is striking, however, that present-day parallels exist. For instance, gynecology textbooks exhibit "a persistent paternalistic and sometimes condescending attitude on the part of the doctor toward his female patient,"<sup>133</sup> and surgery remains a first option in gynecology.<sup>134</sup>

One study that was conducted at two teaching hospitals in the mid-1970's<sup>135</sup> revealed that residents become skilled at selling the surgery when it is not required, but might prove a more efficient, not to mention profitable, option for

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129. See DALLY, *supra* note 107, at 155-56, 160. The available history has been characterized as "extremely sympathetic to physicians. The patient's role has been largely ignored, the issue of medical ethics has been vastly underplayed, and critical analyses are almost nonexistent . . . . [H]istorians and biographers of the early gynecologists, often themselves members of the medical profession, glorify these surgeons for their courage and daring use of the knife."

SCULLY, *supra* note 104, at 39.

130. See *id.* at 47-48.

131. See *id.* at 12-14.

132. See *id.* at 47.

133. *Id.* at 107.

134. See Keville, *supra* note 73, at 131. "'Gynecologists and surgeons remove our female organs with a lack of concern that is in marked contrast to the respect they display for men's private parts.' Alternatives to surgery (where some treatment is actually necessary) apparently have not been much explored." *Id.* (footnotes omitted) (quoting RUTH HUBBARD, *THE POLITICS OF WOMEN'S BIOLOGY* 17 (1990)); see also SCULLY, *supra* note 104, at 17 (citing government statistics that establish the hysterectomy as the most common operation performed in the United States, outranking the tonsillectomy and appendectomy, the former front runners). Scully explains the reason for all of the unnecessary surgery in both obstetrics and gynecology, including the prophylactic hysterectomy, based on the concept of organizational deviance: unnecessary surgery is a medical organizational norm. See *id.* at 234-36.

135. The study was conducted by a sociologist who spent three years at two medical centers observing their training programs in obstetrics and gynecology. See SCULLY, *supra* note 104, at 1-9. In her study, she observed the residents at these two medical centers "in labor and delivery rooms, surgical suites, clinics, classes, and informal gatherings." *Id.* at 1. Although the study is now more than twenty years old, in the *Introduction to the 1994 Edition*, Scully observes that many of the same problems and issues persist in women's health care. See *id.* at xv-xxvi.

the doctor.<sup>136</sup> The same study also revealed that the poor, minority women who came to these teaching hospitals were frequently treated with less respect, allowed to suffer more pain before being treated, and sometimes coerced into a surgical option when it was not necessary, but provided a learning opportunity to a resident who either had no experience or very little experience with the particular surgical procedure.<sup>137</sup> Thus, these women were used as teaching materials.<sup>138</sup> These residents in gynecology also exhibited a preference for female patients whom they labeled as “educated” and intelligent, but whom they then described as “‘happy,’ obedient, respectful and thankful patients.”<sup>139</sup> In reality, because the residents placed a premium on patient control, the residents preferred “malleable and submissive” patients.<sup>140</sup>

There is no reason to believe that these same residents leave behind their aggressive surgical attitudes and their desire for compliant patients when they begin practicing medicine. In fact, the continued emphasis on surgery in gynecology is supported by the evidence regarding hysterectomies and cesarean sections: they are performed at a much higher rate in this country than in other countries with comparable health care systems, and they are often performed unnecessarily.<sup>141</sup> In fact, cesarean sections, which “replaced the hysterectomy as the most frequently performed surgery in the United States” by 1981, “vary by

136. See SCULLY, *supra* note 104, at 191-96. Before residents could actually sell the idea of surgery to the patients, they had to become skilled at finding patients who fit the residents' training needs. See *id.* at 219-22. After locating patients, residents used the following tactics:

The sales pitch used by residents at both hospitals was remarkably similar; in some cases the very same words were used. The resident opened by moving from a general problem for which a number of solutions, including doing nothing, were possible, to the solution he was going to try to sell, usually a hysterectomy. The more supporting evidence that could be brought to bear on the problem, the more secure the resident was in his pitch. The pitch frequently began when a woman over the age of thirty-five requested birth control or permanent sterilization in the form of tubal ligation. If, in addition, the resident could locate evidence of some pathology, he would attempt to sell a hysterectomy. Essentially, the resident was substituting a hysterectomy (surgery he wanted to do) for a tubal ligation (surgical scut work). The tactic was similar to the “bait and switch” technique used in sales in which the advertised item is discredited and another, more expensive, product is substituted in its place.

*Id.* at 224-25.

137. See *id.* at 120-40.

138. See *id.* at 236-40.

139. *Id.* at 91-92.

140. *Id.* at 92.

141. See *id.* at 37-38, 140-49; see also Mary Anne Bobinski, *Autonomy and Privacy: Protecting Patients From Their Physicians*, 55 U. PITT. L. REV. 291, 302-03 & n.39 (1994). Groups, such as Hysterectomy Education and Resource Services (HERS), have formed to address concerns about these high rates of surgery. See KAREN M. HICKS, *SURVIVING THE DALKON SHIELD IUD: WOMEN V. THE PHARMACEUTICAL INDUSTRY* 81 (1994). In this country, surgery of every variety is on the rise and is increasing “four times faster than the population.” SCULLY, *supra* note 105, at 140. There is a positive correlation between the number of practicing surgeons and the amount of surgical procedures performed:

In the United States, where there are twice as many surgeons in proportion to the population as in England and Wales, there is also twice as much surgery. One study found that the rate of surgery in Kansas was dependent on the supply of surgeons and facilities in a region rather than on the incidence of disease. Other research has shown that so many physicians are performing surgery that the work loads of specialists are modest, thus making it difficult for them to maintain their surgical skills.

*Id.*



region of the country and by hospital within regions, and rates are higher in the United States than almost anywhere else in the world."<sup>142</sup> To a lesser extent, twentieth-century birth control devices, including Norplant,<sup>143</sup> the IUD,<sup>144</sup> and even birth control pills,<sup>145</sup> similarly require either surgical intervention and implantation, like the pessary devices of the nineteenth century, or physician oversight and monitoring, and, because they are products exclusively for women, their harms are visited solely upon women.<sup>146</sup>

Surgical attempts at breast augmentation beginning at the close of the nineteenth century and continuing to the present represent yet another example

142. SCULLY, *supra* note 104, at xx; *see also* Bobinski, *supra* note 141, at 302-03 & n.39 (citing "[n]umerous studies" that "have documented variations in the rate of cesarean section deliveries that seem unrelated to medical necessity"); Margaret M. Donohoe, *Our Epidemic of Unnecessary Cesarean Sections: The Role of the Law in Creating it, the Role of the Law in Stopping it*, 11 WIS. WOMEN'S L.J. 197, 197-98 (1996). While eleven other countries have lower rates of cesarean sections than the United States, "only one industrialized nation for which statistics are available has an infant mortality rate as high as our own." *Id.* Some authors argue that the rate at which cesarean sections are performed in this country "has reached epidemic proportions." Kelly F. Bates, Note, *Cesarean Section Epidemic: Defining the Problem—Approaching Solutions*, 4 B.U. PUB. INT'L L.J. 389, 390 (1995).

143. The Norplant birth control device is:

a long-acting method of reversible contraception for women. It consists of six flexible tubes, surgically implanted beneath the skin of the upper arm, which deliver a sustained low dose of levonorgestrel, a synthetic progestin. Once absorbed and systemically distributed, the levonorgestrel dosage works to impede fertility by inhibiting the midcycle hormonal surge necessary for ovulation, suppressing the cyclic maturation of the inner layer of the uterus, and thickening the cervical mucus which acts as a barrier to the entry of sperm. Effectiveness begins immediately upon insertion and continues for five years or until the device is surgically removed. While implanted the failure rate is approximately equivalent to that of sterilization.

Rachel Stephanie Arnow, *The Implantation of Rights: An Argument for Unconditionally Funded Norplant Removal*, 11 BERKELEY WOMEN'S L.J. 19, 20 (1996). A number of side-effects have been found, the most common of which is "erratic menstrual bleeding." *Id.* Some of the less common side-effects that have been documented include "weight gain and increase in appetite, headaches, breast tenderness, ovarian cyst formation, hair loss or hairiness, dermatitis, acne, and hyperpigmentation or scarring over the implantation site." *Id.* For general discussions about the alleged social and legal adverse effects the Norplant device has on women, particularly poor women and women of color, *see* Catherine Albiston, *The Social Meaning of the Norplant Condition: Constitutional Considerations of Race, Class, and Gender*, 9 BERKELEY WOMEN'S L.J. 9 (1994); Jeanne L. Vance, *Womb for Rent: Norplant and the Undoing of Poor Women*, 21 HASTINGS CONST. L.Q. 827 (1994).

144. *See* HICKS, *supra* note 141, at 3-4. An IUD is:

inserted into the uterus via the vagina. The cervix (which connects the vagina to the uterus) must be stretched with a special instrument during insertion and removal. Most IUD models have tailstrings attached, which hang down into the vagina and are used to check for proper placement and for removal. The medical literature is inconclusive on the precise mechanism of IUD action. The IUD may prevent fertilization of the egg (if it contains copper or hormones), but, more often, it interferes with implantation of an embryo. Therefore it can be categorized both as a contraceptive and as a contragestive device.

*Id.* IUD devices were originally introduced in the late nineteenth century, but were later abandoned when "many women died of massive infections." *Id.* at 3.

145. *See id.* at 158.

146. *See id.* at 19. Sexism is identified by some scholars as the reason for these types of contraceptive products:

(1) The contraceptive world is sexist—leaders and researchers are predominately male, and female methods are their overwhelming focus; (2) the preference is for systemic and surgical methods, as opposed to barrier methods, which receive 2.2% of funds; and (3) greater concern is shown for efficacy than for safety, as less than 10% of total expenditures for contraceptive development since 1965 have been devoted to safety.

*Id.*

of the development of a surgical procedure and the corresponding creation and use of a medical device through medical experimentation on women.<sup>147</sup> Plastic surgeons concur in describing the method by which breast augmentation technology has developed and also admit that “[e]xperiments go on unendingly . . .”<sup>148</sup> The idea for breast implants was generated in 1959, when a medical resident, who was holding a plastic bag used to store blood, realized that the blood-filled bag had the consistency of a breast.<sup>149</sup> The first silicone gel-filled implant surgery was performed in March, 1962, in Houston.<sup>150</sup> The implants were the creation of Dow Corning product developers who worked in conjunction with two plastic surgeons.<sup>151</sup> These implants were larger than the implants of today, and they were also more firm because the capsule or shell was thicker and the silicone gel, which was “milky-colored,” was also more viscous than the later-developed implants.<sup>152</sup> Although the procedure was uneventful, no safety tests involving humans were performed prior to the surgical procedure, and only limited animal testing had been done.<sup>153</sup> Thus, the woman in Houston was the human guinea pig.

Other women quickly joined her in the experiment, and during the early 1970’s several competing manufacturers entered the breast implant market.<sup>154</sup> Each of these competitors was attempting to manufacture and market more natural looking implants. Development of a thinner implant shell filled with “more watery silicone gel” was rushed by Dow Corning.<sup>155</sup> Another implant coated with polyurethane foam and sold by several companies was developed to prevent the formation of scar tissue and capsular contracture.<sup>156</sup> Both of these products created problems. Increased rates of rupture and significant gel bleed occurred with the thinner implants.<sup>157</sup> The polyurethane-coated implants created another hazard: the foam coating broke down in the breast, producing 2-toluenediamine (TDA), a substance known to cause cancer in animals.<sup>158</sup> The

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147. See KURT WAGNER & HELEN GOULD, *A PLASTIC SURGEON ANSWERS YOUR QUESTIONS: A PERSONAL CONSULTATION IN BOOK FORM* 80-81 (1972); see also *supra* notes 88-96 and accompanying text.

148. WAGNER & GOULD, *supra* note 147, at 80.

149. See RUDOLPH H. GUTHRIE, *THE TRUTH ABOUT BREAST IMPLANTS* 7 (1994).

150. See BYRNE, *supra* note 64, at 48.

151. See *id.* at 47.

152. *Id.* at 48. The implants came equipped with “small Dacron mesh patches,” which were designed so that the implants “would adhere to the chest muscles to secure the implant without sutures.” *Id.*

153. See *id.* at 48-49. The animal study involved six dogs, only two of which were monitored for a period of 18 months. *Id.* at 46-47.

154. See *id.* at 71-76. By 1975, the Dow Corning monopoly on the breast implant market had fallen to approximately 35 % of the breast implant market. See *id.* at 72.

155. *Id.* at 73.

156. See GUTHRIE, *supra* note 149, at 14.

157. See *id.* at 62-64; BYRNE, *supra* note 64, at 76-79.

158. See NANCY BRUNING, *BREAST IMPLANTS, EVERYTHING YOU NEED TO KNOW* 91 (2d ed. 1995). TDA was banned from use in hair dyes in 1971 because of its carcinogenicity. See *id.* One surgeon who used polyurethane implants for implantation into more than 250 women’s breasts observed the following: “[W]ithin days after surgery about ten percent of the patients developed a fiery, red rash and severe itching that lasted about two weeks.” GUTHRIE, *supra* note 149, at 15. The surgeon found this to be an allergic reaction. See *id.* The polyurethane implant also produced a severe capsular contracture and sometimes the contracture caused the implant envelopes to break open or rupture at the seams. See *id.* at 16.

implants were used by plastic surgeons even though the manufacturers had performed only limited testing, and some surgeons continued using them after problems began to surface.<sup>159</sup>

Another innovation in breast implant technology occurred in the early 1970's when plastic surgeons began performing breast augmentation surgery under local anesthesia on an outpatient basis.<sup>160</sup> Prior to this time, the surgery was performed in a hospital under general anesthesia; patients remained hospitalized for approximately five days with their arms restrained or bound so they could not move.<sup>161</sup> The new outpatient procedure proved to be very profitable for the surgeon, allowing for as many as six breast augmentation procedures to be performed in a single day.<sup>162</sup> In order to develop the outpatient technique, some surgeons retained patients for their experiments by offering the surgery free of charge.<sup>163</sup>

Plastic surgeons have also become highly skilled at selling the surgery. In 1983, the American Society of Plastic and Reconstructive Surgeons (ASPRS), whose membership includes 90% of plastic surgeons in the United States, initiated a \$4 million public relations campaign promoting breast implants by stating that they were "essential to women's mental health" and that flat-chestedness caused a "total lack of well being."<sup>164</sup> Earlier in 1982, the ASPRS had petitioned the FDA to deregulate implants, arguing that

there is a common misconception that the enlargement of the female breast is not necessary for maintenance of health or treatment of disease. There is a substantial and enlarging body of medical information and opinion, however, to the effect that these deformities [small breasts] are really a disease which in most patients result in feelings of inadequacy, lack of self-confidence, distortion of body image and a total lack of well-being due to a lack of self-perceived femininity. The enlargement of the female breast, is, therefore, often very necessary to insure an improved quality of life for the patient.<sup>165</sup>

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159. *See id.* at 16-17.

160. *See* BYRNE, *supra* note 64, at 64.

161. *See id.* at 64-65.

162. *See id.* at 67.

163. *See id.* at 65. More recently, entrepreneurs who are not doctors have purchased clinics and have hired surgeons to perform the cosmetic procedures. *See* HESSE-BIBER, *supra* note 27, at 52-53. The emphasis for these business owners is high volume, cost efficiency, and high profit. *See id.*

164. Weisman, *supra* note 20, at 990 & n.138. As recently as 1991, the ASPRS marketed a pamphlet entitled "Straight Talk About Breast Implants," which is no longer distributed, claiming that "breast implants are among the safest surgically implanted devices in use today. For the vast majority of women, the implant will come to feel like part of their bodies, occasionally subject to their own special 'illnesses' and injuries." VASEY & FELDSTEIN, *supra* note 60, at 97. Not only does this brochure overstate the safety of breast implants, it also implies somehow that women's bodies may be the cause of any problems associated with the implants.

165. Troutwine, *supra* note 26, at 49.

Around the same time, plastic surgeons invoked the official-sounding medical term “micromastia”<sup>166</sup> to describe this newly discovered physical and psychological malady afflicting women with small breasts. This promotional tactic was not limited to the ASPRS’ strategic attempts to obtain deregulation of the breast implant market, but was utilized by plastic surgeons who authored books directed to the consuming public.<sup>167</sup> Plastic surgeons appear to have internalized the theory that small breasts are a physical deformity, as evidenced by even a cursory review of medical reference books and textbooks published before 1992 which are replete with the label “micromastia” and other similar terminology.<sup>168</sup>

The “before” photographs that are offered in these medical texts as proof that these women are, in fact, diseased reveal that they are simply very thin women with small frames and correspondingly small breasts.<sup>169</sup> Thus, like the pelvic surgeons of the nineteenth century, twentieth-century plastic surgeons created a psychological ailment peculiar to women that they have linked to a uniquely feminine body part requiring surgical “correction.”<sup>170</sup>

The books written by plastic surgeons for plastic surgery patients before 1992 are also patronizing, condescending, and, above all else, misleading.<sup>171</sup> Women are told that they should expect the implant to become a “permanent *natural* part of their body and therefore of the breast structure,” that the implants create breasts which are “not only for real, they’re permanent and forever.”<sup>172</sup> Yet, estimates regarding the life span of silicone gel implants range from only five to fifteen years.<sup>173</sup> This kind of inaccuracy is compounded by the

166. Cohen, *supra* note 26, at 169 & n.181. The term appeared as early as 1973 and is defined as follows:

This condition, also called *micromastia*, is believed due to a failure of the breast to respond to hormonal stimulation during the normal maturation phase. Estrogen administration will not significantly alter the size. There may be gradations in size and shape from the male configuration to one of juvenile female characteristics with apparently normal nipple development.

PLASTIC SURGERY, A CONCISE GUIDE TO CLINICAL PRACTICE 987 (WILLIAM C. GRABB & JAMES W. SMITH eds., 2d ed. 1973) [hereinafter GRABB & SMITH].

167. See JOHN MCCABE, PLASTIC SURGERY HOPSCOTCH 57 (Miriam Ingersoll ed., 1995).

168. See GABKA & VAUBEL, *supra* note 80, at 98-99 (referring to a photograph allegedly demonstrating a “[c]linical view of an extensive hypotrophy of the mamma which was excellently repaired by means of an augmentation plasty using Dow-Corning epithesis”); GRABB & SMITH, *supra* note 166, at 987; Another term utilized to denote small breasts as diseased is “hypomastia,” and this term is defined in medical dictionaries as “atrophy or congenital smallness of the breasts.” STEDMAN’S MEDICAL DICTIONARY 836 (26th ed. 1995). Another apparent synonym utilized to characterize this alleged disease is “hypoplasia,” BARRETT, *supra* note 70, at 388, which is defined as “[u]nderdevelopment of a tissue or organ, usually due to a decrease in the number of cells,” or “[a]trophy due to destruction of some of the elements and not merely to their general reduction in size.” STEDMAN’S MEDICAL DICTIONARY, *supra*, at 838.

169. See GABKA & VAUBEL, *supra* note 80, at 99; GRABB & SMITH, *supra* note 166, at 988; WAGNER & GOULD, *supra* note 147, at 86.

170. See *supra* notes 117-126 and accompanying text.

171. See WAGNER & GOULD, *supra* note 147, at 80-83.

172. *Id.* at 81, 83; see also ELIZABETH MORGAN, THE COMPLETE BOOK OF COSMETIC SURGERY, A CANDID GUIDE FOR MEN, WOMEN & TEENS 348 (1988). Although the title of the book promises honesty, the author unequivocally states that a breast augmentation procedure will last “[p]ermanently.” *Id.*

173. See Note, *supra* note 10, at 187-88 & n.130 (citing estimates as low as five to seven years); see also DAVIS, *supra* note 66, at 28 (stating that “silicone breast implants need to be replaced after fifteen

minimization of side effects and the complete omission in many of these books of silicone-gel bleed and migration as a potential complication.<sup>174</sup> Gel bleed and migration have been discussed in medical journals since the 1970's; thus, this omission appears to be a strategic promotional tactic.<sup>175</sup> These omissions and misstatements are problematic because this kind of information about breast implants, which has not been readily available to consumers, is the type of information patients generally rely upon physicians to supply. Moreover, in the books written for and relied upon by the public, plastic surgeons purport to be providing accurate and complete information.<sup>176</sup>

These same books stress that a woman can achieve "normal" breasts through augmentation surgery, once again sending the message to women with small breasts that there is something wrong with their bodies, and they equate the implanted breast with poetry: "[The implanted breast] must have been what Keats had in mind when he said that a thing of beauty is a joy forever."<sup>177</sup> They glamorize the recovery process and patronize women with their reassurance that during the two weeks after breast augmentation surgery patients can "read, sleep, get used to the idea of [their] *new* body image and enjoy being a Sybarite generally."<sup>178</sup>

Since potential problems with breast implants became public in 1992, medical publications have, for the most part, stopped describing small breasts as

years."). One study revealed that all implants studied that were more than ten years old at the time of removal were ruptured. See VASEY & FELDSTEIN, *supra* note 60, at 96; de Camara, *supra* note 68, at 829. The former FDA Commissioner, David Kessler candidly admitted that "[w]e know more about the life span of automobile tires than we do about the longevity of breast implants." See Note, *supra* note 10, at 187-88 & n.130.

174. See WAGNER & GOULD, *supra* note 147, at 80-81 (discussing only capsular contracture as a possible complication and stressing that "the operation is now so well perfected that there is no reason to wait on any future improvements"); see also KURT J. WAGNER & GERALD IMBER, *BEAUTY BY DESIGN: A COMPLETE LOOK AT COSMETIC SURGERY* 93-96 (1979). In texts that actually mention leakage or gel bleed, it is treated as a minor clean-up issue: "the result is not harmful to you . . . . Treatment for this complication is simple—removal of the gel (it sticks to itself and is pulled out like a string of taffy)." MORGAN, *supra* note 172, at 361. This last statement is simply not true. "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.'" Cohen, *supra* note 26, at 162. It is impossible to remove all of the silicone during an explantation procedure. MCCABE, *supra* note 167, at 65. Residual silicone will remain "in the breast area and throughout the body." *Id.*

175. See MCCABE, *supra* note 167, at 57.

176. See *id.* Prior to 1992, breast implant patients were not provided with the information regarding many potential side-effects, and this information was not a matter of media attention. See *supra* note 20. Both men and women, of necessity rely on their physicians for information regarding medical risks:

As more of daily life becomes medicalized, supposedly morally neutral and objective physicians are able to make, in the name of health and illness, final judgments that pertain to an ever-increasing part of human existence. Their unquestioned status as experts has resulted in their almost unprecedented power over people's lives.

SCULLY *supra* note 104, at 20.

The very titles of the books written by these surgeons for consumers suggest complete and full disclosure regarding the surgical procedures. See MORGAN, *supra* note 172 (*The Complete Book of Cosmetic Surgery, A Candid Guide for Men, Women, & Teens*); WAGNER & IMBER, *supra* note 174 (*Beauty By Design: A Complete Look at Cosmetic Surgery*).

177. WAGNER & GOULD, *supra* note 147, at 81.

178. *Id.* at 82.

a disease and have ceased to exaggerate the safety of silicone implants.<sup>179</sup> These texts, however, fail to thoroughly catalogue potential side effects and complications and mention silicone gel bleed only in passing, usually making no reference to silicone migration.<sup>180</sup> Some of these texts also assume physician dominance or actual control over an important aspect of the decision-making process: the size of the implants.<sup>181</sup> These surgeons apparently are not concerned with their patients' desired results and are instead confident in their ability to make these very personal decisions for their patients.<sup>182</sup>

In one plastic surgery textbook, a rheumatologist devoted a part of his discussion to the legal system, labeling the Revised Breast Implant Settlement Program a "giveaway program."<sup>183</sup> This physician also downplayed the generalized complaints of fatigue and pain made by many women with breast implants, attributing their problems to a "hyperirritable state in which fear predominates."<sup>184</sup> Consistent with their use of psychology to create a market for breast implants, it now appears that at least some physicians are utilizing psychology to explain away problems that women associate with their breast implants.<sup>185</sup> Like their nineteenth-century counterparts, twentieth-century

179. See Jack Waxman, *Silicone Fears—How Real Are They?*, in 12 *ADVANCES IN PLASTIC AND RECONSTRUCTIVE SURGERY* 1-10 (Mutaz B. Habel et al. eds., 1996); CARLSON, *supra* note 65, at 107-10. But see BARRETT, *supra* note 70, at 388 (discussing the psychological benefits of breast augmentation for women who suffer from low self-esteem due to breast "hypoplasia").

180. See Waxman, *supra* note 179, at 1-10; see also CARLSON, *supra* note 65, at 109-10. One author advocates warning potential breast implant recipients about many possible side effects, including gel bleed or leakage, but does not include in this list of side effects the potential for silicone gel that has leaked into breast tissue to migrate from the breast to other parts of the body. BARRETT, *supra* note 70, at 395-401. Instead, he simply advocates warning a patient that "[s]mall microscopic droplets of silicone gel may leak or bleed through the silicone shell of a breast implant," and that "[t]he long term effects of silicone gel in the body are unknown." *Id.* at 398. This warning is insufficient given the fact that silicone gel has been found to migrate to lymph nodes. See ANGELL, *supra* note 4, at 41.

181. One text clearly makes the decision the surgeon's:

Implant size is decided upon, and a note is made on the chart. The patient's expectations are evaluated, and volumes are discussed with the patient. Templates are available showing base diameter and sizes, and the implant base may be related to these templates to aid the surgeon in choosing the right implant.

BARRETT, *supra* note 70, at 395. Women who were interviewed about their experience with breast implant surgery have confirmed that they were frequently not given a choice as to what their breasts would look like after the surgery. DAVIS, *supra* note 66, at 129-30.

182. See *id.*

183. Waxman, *supra* note 179, at 2.

184. *Id.* at 5. This same physician stated that when women complain of pain and fatigue, "If the implants are intact in these women, reassurance along with careful examination, proper diagnosis, and appropriate therapy is needed—not explantation." *Id.* Apparently, this physician believes that the surgeon should also control the decision regarding implant removal.

185. See *id.* Plastic surgery texts often devote sections to discussions of patient selection and how to spot the potential problem patient. See BARRETT, *supra* note 70, at xxi-xxv. One plastic surgeon published a list of twenty different types of problem patients, including a "patient in psychotherapy." *Id.* at xxiii. This physician, when discussing another type of problem patient, "the patient whom you dislike," stated:

Unlike psychiatrists—whose work is to deal with many unpleasant emotions, such as hostility—we, as plastic surgeons, do not need and should not wish to become therapists. Avoid the temptation to nurture your masochism or megalomania—to want to become an Osler or Freud (they did not operate on such patients!).

ROBERT GOLDWYN, *THE PATIENT AND THE PLASTIC SURGEON* 49 (1981). Nowhere in this statement does the surgeon admit that psychiatry and psychology are outside his field of expertise. Instead, this statement

physicians and surgeons are not only experts in their respective medical fields, but are also experts in psychology, and some are apparently well versed in the law.<sup>186</sup>

Situated in the proper historical context, breast implants become simply another in a long line of painful, body-altering beauty rituals, one which is also a technologically advanced medical product and surgical procedure. When the focus broadens to the American public and US laws governing women, a larger lens emerges for this story. An examination of the law in the next section reveals that the narrative of public opinion, which changed over time by sympathizing first with the women and then with the manufacturers and surgeons, plays a crucial part in this story. The doctrine of informed consent and the terms of the Revised Breast Implant Settlement Program illustrate how the law may in fact diverge from public understanding about its meaning and how the law reflects and reacts to public opinion.

#### IV. BREAST IMPLANTS AND THE LAW

The doctrine of informed consent looms large in any legal discussion of breast implants, whether involving individual lawsuits or the terms of the Revised Breast Implant Settlement Program.<sup>187</sup> An understanding of this legal doctrine is crucial to assessing the current split and shift in public opinion from a consumer protective viewpoint to a perspective favoring the manufacturers and surgeons.<sup>188</sup> Although individuals in this latter group, most of whom are physicians, often argue that it is paternalistic and even sexist to allow women to recover money from manufacturers or surgeons after they have made a choice to have breast augmentation surgery,<sup>189</sup> implicit in this assertion is the assumption that these women were given the information necessary to make an informed choice. This assertion must be examined in light of the requirements of informed consent.

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illustrates how he implicitly assumes he is able to engage in therapeutic activities, including diagnosis and counseling.

186. This is not to say that psychological concepts have no place in a discussion about breast implants. For a brief discussion of psychoanalytic theory, social psychology, sociology, and feminist theories regarding women and their relationships to their bodies, in particular regarding plastic surgery as a feminine beauty ritual, see DAVIS, *supra* note 66, at 42-56.

187. In the context of breast augmentation surgery, lack of informed consent, medical malpractice, and product defect are the most frequently litigated legal theories. See Kathy A. King-Cameron, Comment, *Carving Another Exception to the Learned Intermediary Doctrine: Application of the Learned Intermediary Doctrine in Silicone Breast Implant Litigation*, 68 TUL. L. REV. 937, 963 (1994). The doctrine of informed consent arises in both the traditional medical treatment situation and in medical research settings. See Sharon Nan Perley, Note, *From Control Over One's Body To Control Over One's Body Parts: Extending The Doctrine Of Informed Consent*, 67 N.Y.U.L. REV. 335, 338-45 (1992). Different patient interests are at stake in these two situations. In the medical research or experimentation situation, "informed consent serves a primarily prophylactic function; through a system of rules and regulations, the doctrine attempts to prevent harms before they occur." *Id.* at 342.

188. See *supra* notes 1-11 and accompanying text.

189. See *supra* note 19.

Before examining the doctrine of informed consent, which found its way into the law as recently as 1957,<sup>190</sup> an historical overview of physician attitudes and practices regarding patient consent is in order. Warnings against disclosing risks to patients can be traced to Hippocrates:

Perform [these duties] calmly and adroitly, concealing most things from the patient while you are attending to him. Give necessary orders with cheerfulness and serenity, turning his attention away from what is being done to him; sometimes reprove sharply and emphatically, and sometimes comfort with solicitude and attention revealing nothing of the patient's future or present condition.<sup>191</sup>

This attitude, which found foreign the concept of mutual decision making, was carried through in Western medical history to the American Medical Association's (AMA) first ethical Code.<sup>192</sup> Although the provisions of the AMA Code warning against disclosure of medical risks to patients were later eliminated, the AMA did not explicitly address informed consent requirements until 1981, and then it created two general exceptions to disclosure: when the patient was "unconscious or otherwise incapable of consenting" and harm without treatment was "imminent;" and when disclosure created "such a serious psychological threat of detriment to the patient as to be medically contraindicated."<sup>193</sup> The AMA, however, did not set forth what kinds of disclosure were required for patient consent, and explicitly limited disclosure requirements to "the nature and purpose of the treatment undertaken or prescribed."<sup>194</sup>

From the perspective of physicians (as evidenced by AMA pronouncements), the legal requirements of disclosure and patient consent involve only disclosing risks and benefits of recommended procedures, not disclosing the available alternatives, and definitely not disclosing "the certainties and uncertainties inherent in most treatment options."<sup>195</sup> Thus, informed consent appears to be nothing more than "an unwitting attempt by physicians to shape the disclosure

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190. See JAY KATZ, *THE SILENT WORLD OF DOCTOR AND PATIENT* 49 (1984); Peter H. Schuck, *Rethinking Informed Consent*, 103 *YALE L.J.* 899, 900 (1994).

191. See KATZ, *supra* note 190, at 4 (quoting 2 HIPPOCRATES, *DECORUM* 297 (W. Jones trans., Harvard Univ. Press, 1967)). Hippocrates, author of the Hippocratic Oath, made this statement in the fifth century, B.C. See *id.* at 4 & 240 n.5.

192. See *id.* at 21. The Code, drafted in 1847, admonished doctors to "unite tenderness with firmness, and condescension with authority, [so] as to inspire the minds of their patients with gratitude, respect and confidence." *Id.* The Code also explicitly spoke of the role of the patient: "obedience . . . should be prompt and implicit." *Id.*

193. *Id.* at 22-23. The earlier statements regarding physician-patient relationships were eliminated in 1903. See *id.* at 22. The explicit discussion of patient consent in 1981 was contained in *The Current Opinions of the Judicial Council*, published by the American Medical Association. See *id.* at 23 & 242 n.43; see also Anthony Szczygiel, *Beyond Informed Consent*, 21 *OHIO N.U.L. REV.* 171, 176 (1994).

194. KATZ, *supra* note 190, at 23-24.

195. *Id.* at 26.



process so that patients will comply with their recommendations.”<sup>196</sup> The reasons offered for this approach to patient consent are that the patient is often incapable of understanding the complex medical information regarding treatment, that disclosure of such information will likely confuse and possibly frighten the patient into inaction when treatment is necessary, and that the physician acts to convince patients of the proper treatment options with the patient’s best interest in mind.<sup>197</sup> Regardless of whether the physicians’ motives are benign and even protective, their understanding of the requirements of patient consent and actual practice must be compared with the legal requirements.

The legal doctrine requiring informed consent is premised upon “an individual’s interest in bodily integrity and her concomitant right to self-determination” and thus mandates that a doctor “disclose all information material to an individual’s decision regarding whether to submit to a particular medical procedure.”<sup>198</sup> The case law, which has been less than successful in effectuating this purpose, has developed along two different lines. The first and majority approach is physician-centered and finds a duty to inform the patient if physicians in the medical community “customarily inform their patients about the type of risk involved,” or if “a reasonable physician would make the disclosure in [similar] circumstances.”<sup>199</sup> This approach is consistent with the actual, albeit paternalistic, practice of physicians.<sup>200</sup> The second approach to informed consent is a patient-centered approach, one in which the standard applied is that of the “reasonable patient in the plaintiff’s position.”<sup>201</sup> A physician is, therefore, required to disclose information that would be material to the reasonable patient’s decision.<sup>202</sup>

Under either approach, the plaintiff generally must also establish causation, that is, the plaintiff must prove that had the information been disclosed, the plaintiff would not have undertaken the medical procedure.<sup>203</sup> Again, the answer to this latter question is generally based upon an objective standard—whether a reasonable person in the plaintiff’s situation would have declined treatment.<sup>204</sup> Although the reasonable patient test provides more protection than does the physician-centered approach, it is not a subjective test, and it does not allow the individual consumer to determine what is relevant to her decision and thus may

196. *Id.* Some physicians have labeled the informed consent requirements “quaint” because of their belief that “they could always guide the patients to accept the treatment they had selected for them.” *Id.*

197. *See id.* at 16, 26-27.

198. Perley, *supra* note 187, at 338.

199. *Id.* at 341 & n.34 (quoting W. Page Keeton et al., PROSSER & KEETON ON THE LAW OF TORTS § 32, at 191 (5th ed. 1984)).

200. *See supra* notes 194-97 and accompanying text; *see also* Bobinski, *supra* note 141, at 347 (asserting that the disclosure of provider-associated risks, risks associated with the nature of the physician, “are unlikely in jurisdictions which have adopted the physician-centered standard”).

201. Perley, *supra* note 187, at 341; *see also* Schuck, *supra* note 190, at 916.

202. *See* Perley, *supra* note 187, at 341.

203. *See id.*; *see also* Schuck, *supra* note 190, at 918-19.

204. *See* Perley, *supra* note 187, at 341-42. Only a minority of jurisdictions have adopted a subjective test for the causation requirement. *See* Bobinski, *supra* note 141, at 346-47.

deny her a meaningful right of self-determination regarding her own bodily integrity.<sup>205</sup>

Manufacturers of medical devices are, in turn, insulated from liability via the learned intermediary doctrine.<sup>206</sup> This legal theory requires that a manufacturer of a medical device pass along product warnings to the physician, the learned intermediary, and not directly to the patient.<sup>207</sup> If the manufacturer adequately warns the physician, the manufacturer generally cannot be held liable for the physician's failure to warn the ultimate consumer of any dangers or risks.<sup>208</sup> The cumulative legal effect of informed consent and the learned intermediary doctrine prior to 1992 was that neither the physician nor the manufacturer were required to pass along package inserts to prospective silicone breast implant recipients that described the product's potential dangers.<sup>209</sup>

These legal doctrines can be very harmful to the breast implant recipient, given the fact that breast augmentation surgery has never fit the traditional medical treatment scenario in which a patient receives information about a medical procedure or treatment from the physician alone.<sup>210</sup> Instead, many women who have undergone breast augmentation have done so after reading advertising literature provided by the manufacturer, which assures the patient of product safety directly and fails to mention any harms or side effects.<sup>211</sup>

Like the manufacturer, the surgeon's relationship to the patient is also very different from the traditional medical treatment model, with many plastic surgeons advertising their services and having a strong economic interest in the

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205. See KATZ, *supra* note 190, at 82-84. The author eloquently and succinctly summarizes the current status of the legal doctrine:

[T]he law of informed consent is substantially mythic and fairy tale-like as far as advancing patients' rights to self-decisionmaking is concerned. It conveys in its dicta about such rights a fairy tale-like optimism about human capacities for "intelligent" choice and for being respectful of other persons' choices; yet in its implementation of dicta, it conveys a mythic pessimism of human capacities to be choice-makers. The resulting tensions have had a significant impact on the law of informed consent which only has made a bow toward a commitment to patients' self-determination, perhaps in an attempt to resolve these tensions by a belief that it is "less important that this commitment be total than that we believe it to be there."

*Id.* (quoting Jay Katz, *Informed Consent—A Fairy Tale? Law's Vision*, 39 U. PITT. L. REV. 137, 174 (1977)).

206. See King-Cameron, *supra* note 187, at 942-43; Susan A. Casey, Comment, *Laying an Old Doctrine to Rest: Challenging the Wisdom of the Learned Intermediary Doctrine*, 19 WM. MITCHELL L. REV. 931, 936 (1993).

207. See King-Cameron, *supra* note 187, at 942.

208. See *id.* at 943.

209. See *id.* at 963-69. One author asserts that during this time-frame, less than one-third of the doctors surveyed by researchers mentioned the complications contained in package inserts to their patients. See Note, *supra* note 10, at 188. The manufacturers of breast implants have since agreed to provide a "Breast Implant Information Package" to women considering breast augmentation surgery that includes the following information: "implant availability, current clinical data, potential medical risks, answers to frequently asked questions, reimbursement policy, notice of FDA meetings on breast implants, and an extensive bibliography of related publications compiled by the National Library of Medicine." King-Cameron, *supra* note 187, at 969-70.

210. See Casey, *supra* note 206, at 952-54 (comparing breast implants to vaccines and contraceptive drugs).

211. See *id.* at 954-57.

patient's decision regarding this elective procedure.<sup>212</sup> In assessing patient consent requirements, it must be remembered that these doctrines were created for situations involving the treatment of disease and medical conditions, not for elective surgery upon healthy bodies.<sup>213</sup> The law of patient consent in the case of purely elective, cosmetic surgery must account for the fact that women choose this type of surgery for subjective, personal reasons and that this choice is a choice between surgery and no surgery, not a choice between competing medical treatments.<sup>214</sup> Even the patient-centered approach to informed consent becomes questionable under these circumstances.

Since different motives operate for the patient in purely elective surgery and different incentives exist for both the physician and manufacturer in the provision of warnings, informed consent requirements and the learned intermediary exception to warn may prove inadequate protection for consumers of breast implants.<sup>215</sup> The public needs to know what exactly is meant in the law by patient consent requirements.<sup>216</sup> Public awareness about the differences that distinguish breast implants from other medical devices and how these differences interact with the law may very likely influence public opinion regarding whether these women have been legally wronged.<sup>217</sup>

The wholesale adoption of these doctrines from other medical device situations to breast implant litigation may reflect the general lack of public, not to mention judicial,<sup>218</sup> awareness about what information the medical community considers to be shielded from laws requiring patient warning.<sup>219</sup> Public assumptions regarding disclosure and warning requirements may also be at odds with the current state of the law regarding these doctrines, which has internalized a great deal of paternalism. This may be especially true, given the cumulative effect of the physician-centered theory of informed consent and the learned intermediary doctrine.<sup>220</sup>

The current prevailing public opinion that breast implants do not cause "harm" may additionally reflect public ignorance, due to lack of knowledge about just how much information both physicians and manufacturers consciously failed to supply to women considering breast implant surgery and

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212. See King-Cameron, *supra* note 187, at 970-71; see also Emily C. Aschinger, Note, *The Selling of the Perfect Breast: Silicone, Surgeons, and Strict Liability*, 61 UMKC L. REV. 399, 407-11 (1992).

213. See Casey, *supra* note 206, at 952.

214. See *id.*

215. See *id.* at 952-57.

216. See KATZ, *supra* note 190, at 82-84. "The legal vision of informed consent, based on *self-determination*, is still largely a mirage. Yet a mirage, since it not only deceives but also can sustain hope, is better than no vision at all." *Id.* at 84.

217. See Cohen, *supra* note 26, at 180-82 (discussing the duty to warn in the context of the learned intermediary doctrine).

218. See Jay Katz, *Duty and Caring in the Age of Informed Consent and Medical Science: Unlocking Peabody's Secret*, 8 HUMANE MED. 187, 188 (1992). The author asserts that the doctrine of informed consent was created by judges who incorrectly "assumed that customary medical practice already encompassed shared decision making." *Id.* at 188.

219. See KATZ, *supra* note 190, at 26.

220. See *supra* notes 199-202, 206-09 and accompanying text.

the misrepresentations made to women who consulted them personally or read their literature, prior to 1992.<sup>221</sup> Certainly, for those women who have suffered tangible physical injury after having been under-informed, or even deceived, as to safety issues, the fact that limited medical testing involving a small number of specific medical conditions has thus far established no link to breast implants becomes less important and not entirely relevant to their situations.<sup>222</sup>

Moreover, the most frequently articulated arguments against increased disclosure requirements in medicine are simply not persuasive in the context of silicone gel breast implants. A general argument made against disclosure of medical risks is that the average person is incapable of understanding the complexities involved with medical treatment, medical products, and medical devices.<sup>223</sup> A second argument frequently articulated by scientists and physicians is that the successful breast implant litigation and the compensation provided by the Revised Breast Implant Settlement Program, all without hard data of causation, have a spill-over effect of chilling development of all medical products for medical treatment contexts, situations in which treatment is necessary for disease.<sup>224</sup> As applied to increased patient warning requirements, the argument is slightly modified: as a result of all of the warning requirements, product development will be drastically inhibited and slowed so that manufacturers and developers can carefully document every conceivable occurrence and thereby fend off litigation.<sup>225</sup>

A final argument against increased warnings involves reconstructive surgery after mastectomy. The argument is premised on a view of breast reconstruction as not a truly elective procedure.<sup>226</sup> There is ample evidence to support the assertion that many women who have undergone breast reconstruction with silicone gel implants after losing a breast due to cancer enjoy increased levels of self-esteem.<sup>227</sup> It is argued that the unfounded scare created with silicone breast implants and increased warning requirements has and will continue to dissuade

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221. See *supra* notes 8, 164-80, 209 and accompanying text.

222. See *supra* note 1. The studies assessed the risk for connective-tissue diseases, including rheumatoid arthritis, systemic lupus erythematosus, Sjogren's syndrome, dermatomyositis, polymyalgia rheumatica, vasculitis, arthritis associated with inflammatory bowel disease, and polychondritis. See *Mayo Clinic Study*, *supra* note 1, at 1698-99.

223. See *supra* note 197 and accompanying text.

224. See ANGELL, *supra* note 4, at 82-86; Catherine Baase, *Breast Implant Cases More Than Just Health Issue: The Conflict Between Science and Lawyers Has Far-Reaching Implications*, ORLANDO SENT., Mar. 16, 1997, at G1.

225. See Baase, *supra* note 224.

226. In fact, the FDA ban on silicone gel implants reflects this view. Then Commissioner David Kessler agreed to allow more ready access to silicone gel implants for women seeking reconstructive breast surgery than for those seeking cosmetic augmentation, stating that "it makes little sense for the FDA to consider breast augmentation of equivalent importance with an accepted component of cancer therapy." ANGELL, *supra* note 4, at 63.

227. Women who had undergone reconstructive surgery provided vigorous testimony against restricting or banning silicone implants at the FDA hearings. See *id.*

many women who would otherwise have chosen breast reconstruction and will adversely affect their quality of life.<sup>228</sup>

None of these arguments are persuasive. The lack of pre-market testing and the potential side effects previously mentioned, coupled with probable occurrence rates, to the extent such information is available, is not conceptually difficult information.<sup>229</sup> There is no reason to believe that women who are considering breast augmentation surgery are incapable of understanding this data. As to the argument that advances in medicine will be hindered, the real problem with silicone breast implants involved gross inadequacies—a complete failure to test the product on humans before marketing and the additional failure to warn of known risks with relatively high occurrence rates.<sup>230</sup> The types of product harms, such as rupture, capsular contracture, gel bleed, calcification formation in breast tissue, to name just a few, are not minor nuisances from this invasive surgical procedure, but are the very kinds of harms that should be investigated as a part of product development. It is true that medical experimentation is a necessary component of technological growth in medicine; however, the manner of experimentation should be through controlled clinical trials.<sup>231</sup>

As to the different interests involved in elective and reconstructive breast augmentation, the argument against increased disclosure is similar to the argument involving patient abilities to understand warnings: they are both premised on paternalism in the sense that a woman is deemed to need protection from technical, medical information because of the belief that she cannot critically assess the information and make the decision to undergo treatment that is in her best medical interest. In reality, these assumptions about medical care are not protective; instead, they deny the woman the right to make her own decision. If a certain percentage of women who would otherwise elect to undergo reconstructive breast implant surgery with silicone gel implants now decide, due to the information regarding both known risks and uncertainties of some risks, to forego surgery, they have made a more informed decision. In fact, many potential reconstructive surgery patients object to the continued restriction on silicone breast implants.<sup>232</sup> If these women have been provided with appropriate warnings, and if the product has undergone sufficient testing and study, breast reconstruction with silicone implants should be an option.

It is likely, however, that after being warned, a number of women will choose to forego reconstructive surgery. It is also likely that a number of women, both those considering elective breast augmentation and reconstructive breast surgery,

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228. As one woman stated, "Having my body restored eased away much of the trauma of breast cancer." *Id*; see also *Is the FDA Protecting Patients From the Dangers of Silicone Breast Implants?: Hearing Before the Human Resources and Intergovernmental Subcomm. of the Comm. on Gov't Operations*, 101st Cong. 11-12 (1990) (statement of Rosemary A. Locke, Director, My Image After Breast Cancer).

229. See *supra* notes 8, 14, 164-80, 209 and accompanying text.

230. See *supra* notes 66-77, 153 and accompanying text.

231. See *supra* notes 21, 25.

232. See *supra* notes 227-28.

will fail to carefully review the warnings. They should thereafter be held responsible for their negligent decision making. For those women who decide not to have the surgery due to fear of even slight risk, so long as the potential risk is accurately communicated, this result is not bad. It is, in fact, a reflection of risk-aversion, which varies with the individual.

To use these facts about human nature to require less disclosure is paternalistic.<sup>233</sup> In other contexts protective, paternalistic laws have long since been abolished.<sup>234</sup> The law presumes that people of a certain age in this society are adults and are responsible for assessing risks and benefits and making decisions.<sup>235</sup> An exception should not be made in this medical context. Certainly, the manufacturers and surgeons who misled women about breast implant safety should not be allowed to hold this paternalistic argument up as a shield.

It bears repeating that in the case of breast implants, not only have manufacturers advertised directly to women, but in the written warnings provided with their product prior to 1992, they failed to indicate that long-term studies had never been conducted on humans before the product was marketed.<sup>236</sup> Under the learned intermediary doctrine, manufacturers in a very real sense have been rewarded for their lack of sensitivity to safety issues. At a minimum, women who were contemplating surgery should have been told what kind of testing had, or in this case, had not been done, so that they could have made a meaningful choice about whether to assume the long-term risks and uncertainties of breast implants.

As previously documented, there is also ample evidence that before 1992, many women were not given either accurate or complete information regarding

233. See *supra* notes 200, 205 and accompanying text.

234. Courts began striking down protective legislation for working women between 1897 and 1923. Julie Novkov, *Liberty, Protection, and Women's Work: Investigating the Boundaries Between Public and Private*, 21 L. & SOC. INQUIRY 857, 857 (1996). In a 1907 decision, the New York Court of Appeals struck a state law that limited women's work during night hours, prohibiting their employment between nine in the evening and six in the morning. See *People v. Williams*, 189 N.Y. 131, 134 (1907). In doing so, the court expressed its objections in terms of women's rights. The law went "far beyond" a mere limitation on the number of hours that women could work to interfere with their liberty to select those hours: "It attempts to take away the right of a woman to labor before six o'clock in the morning, or after nine o'clock in the evening, without any reference to other considerations." Novkov, *supra* note 234, at 869 (quoting *People v. Williams*, 189 N.Y. 131, 134 (1907)). Although the same court "reversed itself when confronted with a nearly identical law in 1915," *id.*, the last vestiges of such protective legislation were eliminated by the Civil Rights Act of 1964. See e.g., *Rosenfield v. Southern Pacific Co.*, 444 F.2d 1219, 1225 (9th Cir. 1971); *Ridinger v. General Motors Corp.*, 325 F. Supp. 1089, 1096 (S.D. Ohio 1971).

235. This reasoning was also the basis for the decision of the Williams court in 1907:

The court believed that this limitation infringed women's status as full human beings. "If this enactment is to be sustained, then an adult woman, although a citizen and entitled as such to all the rights of citizenship under our laws, may not be employed, nor contract to work, in any factory for any period of time, no matter how short, if it is within the prohibited hours."

*Novkov, supra* note 234, at 869 (quoting *Williams*, 189 N.Y. at 135). These same reasons apply to medical situations involving disclosure of risk and patient consent. Dieter Gieson, *Vindicating the Patient's Rights: A Comparative Perspective*, 9 J. CONTEMP. HEALTH L. & POL'Y 273, 305-06 (1993) (asserting that "the rights of the patient and not any medical assessment as to his best interests must be the preeminent consideration in the mind of the treating doctor" and warning that "[t]he days of paternalistic medicine are numbered").

236. See Weisman, *supra* note 20, at 987-92.

known risks of breast implant surgery.<sup>237</sup> Presumably, the greater the omission in terms of potential for physical pain or repeated medical treatment, the more likely it is that a reasonable person would have declined the procedure had she been informed of the potential side effect or danger. For instance, a woman who was not warned of the potential for rupture, and was, in fact, actively misled by physician statements to the effect that her implants would survive if she were "run over" by "a Mack truck"<sup>238</sup> or that she would have "the breasts of an 18-year-old for the rest of her life,"<sup>239</sup> would likely fare well under the objective standard. A physician who neglects to warn his patient of the more physically deforming side effects, such as extreme cases of capsular contracture accompanied by difficult, painful removal procedures, should also more readily fail this test of informed consent for the simple reason that cosmetic surgery is designed to enhance physical appearance.<sup>240</sup>

In the context of cosmetic breast augmentation, the need to provide the patient with complete risk information, thereby placing the entire decision in the patient's hands, is critical for the simple reason that these women are choosing an elective medical procedure to achieve aesthetic change to their bodies. Even if these women have severe self-esteem issues about the size or shape of their breasts, indecision or a decision not to undergo breast augmentation surgery will not cause them adverse health consequences. This is simply not a situation in which a learned intermediary, such as a physician, provides or withholds information to induce the patient to receive necessary medical care. An adverse decision will only mean that the manufacturers and surgeons will lose a sale of their product and their service.

Regardless of the level of protection actually afforded, or assumed by the public to be afforded, to breast implant recipients by legal mandate, the Revised Breast Implant Settlement Program (Settlement Program), a private settlement,<sup>241</sup>

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237. See *supra* notes 167-180, 209 and accompanying text.

238. Note, *supra* note 10, at 187 & n.130.

239. VASEY & FELDSTEIN, *supra* note 60, at 62.

240. In terms of lawsuits against manufacturers, the case law does not always bear this out. In fact, according to Dow Chemical Company, over the past 12 years, implant manufacturers have won 69% of all cases that went to trial. Mark Hansen, *Tougher Than the Best, Oregon Judge Refuses to Allow Evidence that Implants Cause Disease*, 83 A.B.A. J. 22, 22 (1997). These negative verdicts may be due in part to a public perception that women who choose breast implants for cosmetic reasons are making "frivolous," "unreasonable, even stupid decision[s]." See Cohen, *supra* note 26, at 173. The number of lawsuits against doctors is significantly lower, and doctors are not included in the Settlement Program. Richard L. Cupp, Jr., *Sharing Accountability for Breast Implants: Strict Products Liability and Medical Professionals Engaged in Hybrid Sales / Service Cosmetic Products Transactions*, 21 FLA. ST. L. REV. 873, 888-89 (1994). The total number of pending breast implant lawsuits in both federal and state court was estimated in January 1996 to be approximately 20,000. *In Context With Arthur Miller* (Court TV broadcast, Jan. 24, 1996).

241. Unlike the Global Settlement, the Settlement Program is not a settlement agreed to by the defendants and plaintiffs. Mark Curriden, *Lawyers Advise Implant Clients to Reject Offer*, 82 A.B.A. J. 18, 18 (1996). The "Plaintiff's Settlement Class Counsel" did not approve the terms of the Settlement Program because they believed "that the settling defendants should have been willing to offer greater benefits, and to more members of the Lindsey [Settlement Program] class." *In re Silicone Breast Implant Prod. Liab., MDL 926, Breast Implant Litigation Notice*, 2 (mailed to potential class members in January, 1996) [hereinafter *Settlement Litigation Notice*]. Thus, the Settlement Program is a revised settlement offer made by some of the

provides a certain measure of protection to women with implants.<sup>242</sup> It tells yet another story about the effect of shifting public opinion and possibly the lack of public awareness of the actual harm suffered by many women with breast implants, some of whose implants the medical community labeled as intact and whose breasts the medical community declared healthy.

Under the terms of the Settlement Program, claimants who qualify as “current claimants”<sup>243</sup> are not required to establish causation, which means that they are not required to prove that silicone breast implants caused the diseases from which they suffer.<sup>244</sup> Instead, they are required to establish “that the qualifying symptoms [for their medical conditions] did not exist before the date of first implantation.”<sup>245</sup> This aspect of the Settlement Program (and its predecessor, the Global Settlement Agreement) has been harshly criticized and is the basis for its characterization as a “giveaway program.”<sup>246</sup> These criticisms, which have been widespread and have taken center stage in the media’s presentation of the breast implant controversy over the past several years, could not help but influence public opinion.<sup>247</sup>

Yet once again, if this information were accompanied by information revealing the manufacturers’ failure to conduct any lifetime tests prior to the introduction of the product and during the thirty years before safety questions became highly publicized, public opinion might be more moderate.<sup>248</sup> If the current media coverage of the issues involved in silicone breast implants included the fact that the manufacturers made deliberate decisions to market these devices without thoroughly studying their long-term effects, a different story would emerge. If the public were also apprised of the manufacturers’ failure to adequately test this product while simultaneously utilizing aggressive marketing tactics and misleading product literature targeted directly at women,

original defendants from the Global Settlement, which women may choose to accept or reject. *See In Context With Arthur Miller*, *supra* note 240.

242. *See supra* note 12. It was estimated that due to the more than 100,000 projected “current claimants,” substantial “ratcheting” or reduction in projected benefits would be necessary “to perhaps less than 5% of the amounts shown in the original” disease compensation schedule of the Global Settlement. *Settlement Litigation Notice*, *supra* note 241, at 1-2. This “led the Court to conclude not only that thousands of additional class members would opt out of the class [Global Settlement], but also that the defendants would withdraw from the settlement as a result of these opt-outs.” *Id.* at 2.

243. *Settlement Litigation Notice*, *supra* note 241, at 4-5. These are individuals who qualified under either the Global Settlement or the Settlement Program as having currently recognized compensable diseases such as lupus or scleroderma.

244. *See id.* at 10. The Global Settlement contained a similar provision regarding causation. In re Silicone Breast Implant Prod. Liab., MDL 926, *Breast Implant Litigation Settlement Notice*, 5 (mailed to potential class members in May 1994) [hereinafter *Global Litigation Notice*]. Although a discussion of causation in science and law is beyond the parameters of this article, for a discussion of the social construction of science, see JASANOFF, *supra* note 16, at 52-53.

245. *Settlement Litigation Notice*, *supra* note 241, at Exhibit E1(I)(B).

246. *See supra* note 189 and accompanying text. This view of the Settlement Program as a “giveaway program” has also been fueled by the recently released studies finding no causation between silicone breast implants and connective-tissue disease. *See supra* note 1.

247. *See supra* notes 2-3.

248. *See supra* notes 14, 153 and accompanying text.



perhaps the public would be more sympathetic to these women.<sup>249</sup> Perhaps the general public would view the no-causation requirement as a trade-off for the unknown, a trade-off for these women having become, without consent, the de facto lifetime studies for silicone gel breast implants.<sup>250</sup>

Even if public opinion were not entirely sympathetic to these women, if media coverage were more balanced, or at least more thorough, the public might very well reserve judgment on this medical and legal situation involving at present hundreds of thousands of women and potentially many more.<sup>251</sup> A very recent example of the media's unbalanced coverage involves the release of a medical study in the February 1997 edition of a widely cited international medical journal, *The Lancet*.<sup>252</sup> The researchers involved in this study assert that it provides the first medical evidence linking silicone gel breast implants to non-specific autoimmune conditions that many women claim to experience.<sup>253</sup> In comparison to the widespread multimedia coverage of other recently released medical studies finding no link between breast implants and various connective-tissue diseases, this study received limited, one-time newspaper coverage.<sup>254</sup>

What is most interesting about this disparity in coverage is that the study that received significantly less media attention involved the physical complaints many physicians downplay and characterize as either complaints by hysterical women, or by women who are malleable and easily subject to suggestion, or even by women who are motivated by fraud.<sup>255</sup> Although this type of victim-

249. See *supra* notes 209-11 and accompanying text.

250. See *supra* notes 20-21 and accompanying text.

251. It was estimated that more than 440,000 women registered for disease compensation under the Global Settlement. Mark Curriden, *Implant Global Settlement in Jeopardy*, 81 A.B.A. J. 34, 34 (1995). Because the Settlement Program allows women to make claims for disease compensation over the next 15 years (until December 15, 2010), the number of women claiming injuries associated with their implants could exceed this original number under the prior settlement agreement. See *Settlement Litigation Notice*, *supra* note 241, at 5.

252. Scott A. Tenenbaum et al., *Use of Antipolymer Antibody Assay in Recipients of Silicone Breast Implants*, 349 LANCET 449, 450-51 (Feb. 15, 1997)

253. Researchers developed a blood test to measure antibodies that they believe may be "markers" for silicone-related problems. *Id.* The researchers concluded that, "Our findings suggest that some individuals may mount a specific antipolymer immune response after exposure to silicone from SBI [silicone breast implants]." Tenenbaum, *supra* note 252, at 453. This study has been criticized as being "methodologically flawed." Stanley A. Edlavitch, *Antipolymer Antibodies, Silicone Breast Implants, and Fibromyalgia*, 349 LANCET 1170 (April 19, 1997). "The Nurses" Study, see Sanchez-Guerrero, *supra* note 1, which found no increase in connective-tissue disease for women with silicone breast implants, was also criticized for other reasons, including a possible conflict of interest of one of the physicians involved in the research. *Today* (NBC television broadcast, reported by Matt Lauer, interviewing Dr. Marcia Angell, June 22, 1995).

254. Terence Monmaney, *Study Claims to Link Disease, Breast Implants*, L.A. Times, Feb. 15, 1997, at A1. For the multi-media coverage of the earlier studies, see *supra* notes 2-3 and accompanying text. For the newspaper coverage of the current study, see *Study Links Illness to Breast Implants, Tests Must Undergo Scientific Scrutiny*, ARIZ. REPUBLIC, Feb. 15, 1997, at A8; *New Study May Correlate Breast Implants to Illness*, HOUS. CHRON., Feb. 15, 1997, at 1; *Study: Implants May Cause Problems*, SUN-SENT. FT. LAUD., Feb. 15, 1997, at 11A.

255. See *supra* notes 9-10, 190 and accompanying text. These physical complaints that the researchers studied "include diffuse muscle pain, fever, unremitting fatigue, . . . rashes, alopecia, and neuropathy." Tenenbaum, *supra* note 252, at 449; see also Cohen, *supra* note 26, at 174 (stating that "the legal and medical systems have often marginalized women's injuries by calling them hysterical rather than physical" (footnote omitted)).

blaming is nothing new to women's medical issues, if the media provided more balanced coverage, the public could decide for itself whether the medical testing was indeed as conclusive, as so many medical scientists and physicians claim.<sup>256</sup>

The details of the Settlement Program have also garnered much less media interest than had either the Global Settlement or Dow Corning's application for bankruptcy protection. Pursuant to the terms of the Settlement Program, current claimants may assert claims according to the "disability/severity levels specified in the Disease Schedule of the [G]lobal [S]ettlement," but they do so at greatly reduced rates of recovery.<sup>257</sup> If a current claimant chooses instead to make a claim for the higher level of benefits provided under the Settlement Program, she must meet more stringent medical criteria.<sup>258</sup> Even under the Settlement Program, the dollar amounts remain significantly lower than they were under the Global Settlement.<sup>259</sup>

An obvious reason for this drastic reduction in benefits is the withdrawal of a key manufacturer, Dow Corning, who was obligated to contribute nearly half of the total \$4,225,070,000 for the Global Settlement.<sup>260</sup> Another pragmatic consideration for women who have the right to participate in the Settlement Program is the great cost involved in the alternative in terms of money, emotional investment, and time; it is estimated that litigation costs for a breast implant claim range between \$100,000 and \$200,000 and take between two and five years, depending upon whether the verdict is appealed.<sup>261</sup>

256. The authors of one article found historical support for this type of victim-blaming in a nineteenth-century medical condition, "hysteria":

Despite these new understandings, the older perception that hysteria was a disorder traceable to the uterus and was therefore peculiar to women continued to persist both inside and outside the medical community. Medical definition of hysteria as an authentic illness was undercut by physicians' simultaneous suspicion that, as Carroll Smith-Rosenberg has argued, the hysterical woman was likely to be guilty of conscious malingering, "self-indulgence," and "moral delinquency." Even S. Weir Mitchell, famous for his treatment of hysterical women, described them as "the pests of many households, who constitute the despair of physicians, and who furnish those annoying examples of despotic selfishness, which wreck the constitutions of nurses and devoted relatives, and in unconscious or half-conscious self-indulgence destroy the comfort of everyone about them." Therapy for hysteria reflected this distrust: it involved isolating the patient from all except the doctor, who then dominated the patient emotionally. In short, treatment could be punitive.

Martha Chamallas & Linda K. Kerber, *Women, Mothers, and the Law of Fright: A History*, 88 MICH. L. REV. 814, 825 (1990) (footnotes omitted). A more recent example of a victim-blaming defense tactic involves the early lawsuits against A. H. Robins, the manufacturer of the Dalkon Shield intrauterine birth control device (IUD). HICKS, *supra* note 141, at 1,8 (for an explanation and definition of the IUD, see *supra* note 139). Not only did A. H. Robins officials deny wrongdoing and withhold information, they also alleged that the "women's injuries from the Dalkon Shield were caused by promiscuity and poor personal hygiene, thereby shifting attention away from themselves and perpetuating a 'blame-the-victim' posture." *Id.* at 8, 16.

257. *Settlement Litigation Notice*, *supra* note 241, at 5-6; see also *Global Litigation Notice*, *supra* note 244, at 6 (these benefits were only estimates or projections).

258. See *Settlement Litigation Notice*, *supra* note 241, at 5-8 & Exhibit E1.

259. The projected dollar values of the Global Settlement ranged from \$105,000 to \$1,400,000 for domestic claimants, depending upon the type of disease and its level of severity. *Id.* at 1. In contrast, the maximum benefits payable under the Settlement Program are \$253,000. *Id.* at 3.

260. *In Context with Arthur Miller*, *supra* note 240 (estimating Dow's contribution to comprise three-eighths of the total settlement).

261. These estimates are for the cases that would come to trial first. *Id.* As more of these cases are tried, it is expected that the cost of litigation will come down slightly. *Id.*

The role of the media and its influence upon public opinion, however, cannot be underestimated in its ultimate ability to shape the terms of the Settlement Program. As public opinion has shifted over time, the legal pendulum has swung to favor the manufacturers, and for that matter, the physicians.<sup>262</sup> This shift occurred long before any of the recently released studies were concluded.<sup>263</sup> Such a drastic shift in public opinion would likely give any woman contemplating her alternatives pause for the simple reason that the general public comprises a civil jury, and public opinion is a general barometer for a jury's opinion in the form of its verdict.<sup>264</sup>

Another change wrought by the Settlement Program involves the redefining of diseases, physical harms, and symptoms associated with breast implants, which are the result of the more stringent qualifying medical criteria.<sup>265</sup> Probably the most significant change involves the heightened level of proof for what were referred to as "atypical" syndromes or diseases and "non-specific autoimmune conditions"<sup>266</sup> under the Global Settlement and what are referred to as "general connective tissue symptoms"<sup>267</sup> under the Settlement Program.

What may be of greater interest are those diseases and symptoms excluded from the Settlement Program. For instance, cancer is not a disease for which breast implant recipients may receive compensation.<sup>268</sup> This is true even though some studies have found a correlation between direct liquid silicone injections into the breast and cancer.<sup>269</sup> These studies are relevant to silicone gel breast implants because all implants experience gel bleed into the surrounding breast tissue.<sup>270</sup> Thus, even so-called healthy implants release some silicone into women's bodies.<sup>271</sup> Animal studies have also demonstrated a risk of cancer from the chemical created by polyurethane-coated implants when they are in direct

262. See *supra* notes 1-13 and accompanying text.

263. The studies were released in 1994 and 1995. See *supra* note 1; Angell, *supra* note 19, at 1696 (calling for the FDA Commissioner, David Kessler, to lift the ban on silicone gel implants in 1992).

264. It is true that historically, "jury verdicts were deemed legitimate precisely because they were rendered by an independent body and not subject to the influence of popular opinion." Kenneth B. Nunn, *When Juries Meet the Press: Rethinking the Jury's Representative Function in Highly Publicized Cases*, 22 HASTINGS CONST. L.Q. 405, 435 (1995). However, "[j]ury verdicts must . . . be in accord with popular notions of fairness and justice in order for them to be successfully defended in the arena of public opinion." *Id.* at 436.

265. See *Settlement Litigation Notice*, *supra* note 241, at 5.

266. *Global Litigation Notice*, *supra* note 244, at Exhibit D, Disease Schedule.

267. *Settlement Litigation Notice*, *supra* note 241, at Exhibit E1.

268. See *id.* It was also not covered under the Global Settlement apparently for its "high incidence rate in the general population." *In re Silicone Gel Breast Implant Prod. Liab. Litig.*, 1994 WL 578353, at \*27-28 n.9.

269. See T.H. Chen, *Silicone Injection Granulomas of the Breast: Treatment by Subcutaneous Mastectomy and Immediate Subpectoral Breast Implant*, 48 BRIT. J. PLASTIC RECONST. SURG. 71, 71 (1995) (stating that "silicone leakage from silicone breast prosthesis with or without rupture of the prosthesis is of great concern"). "Silicone injection for breast augmentation is still common in Asia, even though silicone injection induced granulomas and associated malignancy have been reported." *Id.*; see also Melvin A. Shiffman, *Silicone Breast Implant Litigation*, 13 MED. LAW 681, 685-88 (1994) (listing study results and arguing that "[t]he occurrence of breast cancer in patients and the fact that they have had silicone injections or implanted silicone prostheses do not necessarily have a cause and effect relationship").

270. See Marian Segal, *Silicone Breast Implants: Available Under Tight Controls*, FDA Consumer 6, 7-8 (June 1992).

271. See *id.*

contact with breast tissue. These implants were utilized beginning in the 1970's and continued until April, 1991.<sup>272</sup>

When silicone leaks from the implant into the breast tissue, calcifications develop.<sup>273</sup> The greater the silicone leakage, the more prevalent the calcifications become.<sup>274</sup> Even if a woman has her implants removed, this trapped silicone will remain in her body for the rest of her life.<sup>275</sup> The manufacturers who did not warn women that all implants bleed or leak silicone or of the potential for rupture or leakage as an implant ages, are not compensating these women for this very real, permanent alteration and harm to their breast tissue.<sup>276</sup> These calcifications create, at the very least, uncertainty for women and may result in lifetime mammography problems.

One woman's experience may best illustrate the harms caused by silicone leakage and calcifications. This woman, who had breast implant surgery in February of 1983, underwent diagnostic testing in 1995 to determine if her implants were intact.<sup>277</sup> After being told that the state-of-the-art technology for

272. See *id.* It has been estimated that approximately 10% of women with implants have the polyurethane-coated implants. *Id.* "It is not known whether women with this type of implant have an increased risk of cancer." *Id.*

273. Calcifications in breast tissue consist of either microcalcifications or macrocalcifications. Z. Urbanowicz et al., *Calcifications Visible in Mammographic Examination as a Diagnostic Problem*, 67 GINEKOL POL 366 (1996) (written in Polish, WL Medline Abstract written in English). "Differentiation between microcalcifications and macrocalcifications is based on variations in size, shape and radiological changes which they accompany." *Id.* (quoting Abstract). Microcalcifications can and do occur in breast tissue of women who have not had either silicone injections or silicone breast implants, *id.*, and "may be indicative of a cancerous process." *Davis v. Caldwell*, 429 N.E.2d 741, 743 n.5 (N.Y. 1981); see also R.A. Ersek et al., *A New Biologically, Osmotically, and Oncologically Balanced Gel that Shows Calcifications Blocked by Silicone*, 17 AESTHETIC PLAST. SURG. 331, 334 (1993). In the case of silicone breast implants, the calcifications often occur in the breast tissue (pocket) surrounding the implant shell. Shiffman, *supra* note 269, at 691. The incidence of calcification is higher with direct liquid silicone injections than with silicone gel breast implants, and its exact cause for both types of procedures "remains poorly elucidated." Walter Peters and Dennis Smith, *Calcification of Breast Implant Capsules: Incidence, Diagnosis, and Contributing Factors*, 34 ANN. PLAST. SURG. 8, 10, 11 (Jan. 1995). These calcifications are commonly composed of "calcium carbonate-hydroxyapatite." *Id.* at 10. Sometimes the calcifications "consist of hydrated zinc-calcium phosphate" which "has never been reported in any other mineralization process related to human disease" and its source "is thought to be the room-temperature vulcanizing glue that is used in the final sealing process in the manufacture of these implants." *Id.* The term "granuloma" is sometimes used to describe noncancerous calcifications when they consist of "lumps or nodules of inflammatory cells—formed where silicone [has] leaked into [a woman's body] and combined with tissue." BYRNE, *supra* note 64, at 93. The term "siliconoma," a synonym for granuloma, is also occasionally used to denote these calcifications or "tissue reaction[s] to silicone gel particles." *Study: Women with Ruptures have no Greater Incidence of Immune Disease, Cancer*, 19 Mealey's Litiq. Rep. 28 (1994). Because calcification is a broader term, used to include granuloma and siliconoma, for purposes of this article, the term calcification will be utilized throughout.

274. See Bridges & Vasey, *supra* note 6, at 2641 (comparing gel bleed with gel leakage from a rupture or defect in the silicone implant and stating that a leak will be "accompanied by a more profound inflammatory reaction"); see also de Camara, *supra* note 68, at 831, in which the authors observed that:

The capsules of leaking implants showed inflammation and foreign-body tissue reaction. In the ruptured group, the response was more intense, with histiocytes, giant cells, and calcification of the capsule. Masses adjacent to the ruptured implants all showed a similar pattern of foreign-body reaction with histiocytes. Some of them contained silicone and were calcified.

275. See MCCABE, *supra* note 167, at 65.

276. See *supra* notes 8, 14, 153-58, 173, 209, 236 and accompanying text.

277. See *Northwestern Memorial Hospital Diagnostic Radiology Report*, June 24, 1994 [hereinafter *Ultrasound Report*]; *Northwestern Memorial Hospital Diagnostic Radiology Report*, July 13, 1994

documenting implant rupture was a breast sonogram or ultrasound test and magnetic resonance imaging (MRI) of the breast, she underwent both tests and was told that her implants were not ruptured.<sup>278</sup> Even though the test results were favorable, she decided to have her implants removed and not replaced.<sup>279</sup> The operative report from the explant surgery told a more vivid story than had either test:

An incision was made in the inframammary incisions bilaterally and with the Bovie dissection, carried down to the pocket on the right. This was opened. The implant was removed. The capsule [implant shell] appeared intact but there was free silicone around the outside of this, some calcifications in the pockets but not enough to do a capsulectomy. The capsule on the pectoral portion was very thin. The pocket [surrounding breast tissue] on the subglandular portion was thick and had the calcifications in a milky like material mixed with the silicone . . . . Similar procedure was carried out on the opposite side [the other breast] where similar findings were found. The implant broke on removing it and it was not broken internally but there was free silicone around it.<sup>280</sup>

The significance of this operative report is that it describes the damaged condition of the breast pocket or tissue surrounding the implants, which prior testing had found to be intact. Because women were never told about silicone gel bleed and leakage and implant life span, they were never informed that as their implants deteriorated over time, they would leave thick calcifications containing silicone in breast tissue.<sup>281</sup> Women were also never told that these calcifications, which can also be indicative of a cancerous process, might interfere with mammography.<sup>282</sup>

This particular woman's subsequent mammography report revealed the following:

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[hereinafter *MRI Report*]. This woman does not wish to reveal her identity, but copies of these and other reports are available from the author of this article with the woman's name redacted.

278. *Id.*; see also M.K. Dobke, M.S. Middleton, *Clinical Impact of Breast Implant Magnetic Resonance Imaging*, 33 ANN. PLAST. SURG. 241, 241 (1994) (stating that MRI is the state-of-the-art technique for diagnosing implant rupture); *Ultrasound Useful in Detecting Breast Implant Ruptures*, *Cancer Researcher Weekly*, May 23, 1994, at 12 (asserting ultrasound as 94% accurate in detecting implant rupture).

279. To be precise, the first test, the ultrasound, revealed a "possible intracapsular rupture" of the left breast implant. *Ultrasound Report*, *supra* note 277, at 1. An MRI was recommended to determine if the implant was ruptured. *Id.* at 2. The subsequent MRI test revealed no evidence of rupture. *MRI Report*, *supra* note 277.

280. *Northwestern Memorial Hospital Procedure Report*, June 14, 1995 [hereinafter *Procedure Report*].

281. See *supra* notes 171-175, 209, 238-39 and accompanying text.

282. Ersek, *supra* note 273, at 331.

There are large collections of bizarre macrocalcifications and benign-appearing, tightly grouped microcalcifications within the central posterior aspects of both breasts that are consistent with residual capsular calcifications from the patient's previous bilateral likely subglandular breast implants. There is no obvious free silicone identified. However, evaluation for residual silicone . . . is made difficult given these extensive bilateral calcifications. . . . Elsewhere throughout both breasts are scattered and occasionally groups [of] benign appearing punctate microcalcifications. Given the fact that there are multiple randomly distributed similar appearing groups of this calcification throughout both breasts, supports a benign etiology . . . .

No specific radiographic features of malignancy are identified. Changes are noted consistent with a history of status post bilateral breast implant removal. There are numerous chunky calcifications within the posterior aspects of both breasts that are consistent with residual benign capsular calcifications, status post breast implant removal . . . .

It is strongly recommended that the patient's previous outside mammograms . . . be obtained for comparison to insure the stability of these findings.<sup>283</sup>

After compared to previous mammogram testing, the radiologist concluded, that the comparison was "not particularly useful given the presence of pre-pectoral silicone implants at the time of the 1989 [mammogram] study."<sup>284</sup> The radiologist also stated that one reason for a failure of the calcifications to appear on the 1989 mammogram screening could "in part be due to previous obscuration by the implants."<sup>285</sup> The radiologist's final recommendation was for yearly "mammographic follow-up, scheduled as a diagnostic examination."<sup>286</sup>

Prior to 1992, women were not told that even after implant removal, their breasts and bodies would forever contain silicone and these calcifications.<sup>287</sup> At the very least, every woman contemplating breast augmentation surgery has a right to know that these calcifications, when viewed by a radiologist reading a mammogram, often look like cancerous tumors and that the silicone implant can "block or distort mammograms, causing a lump to go undetected at the early stage of cancer when it is still small."<sup>288</sup> "According to some studies, early detection through mammography reduces the rate of death from breast cancer by

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283. *University of Chicago Hospitals Radiology Consultation Report*, November 8, 1996 [hereinafter *Mammogram Report*].

284. *University of Chicago Hospitals Radiology Consultation*, January 7, 1997, at 1.

285. *Id.*

286. *Id.* at 2.

287. MCCABE, *supra* note 167, at 65.

288. Cupp, *supra* note 240, at 886 & n.106; *see also* Shiffman, *supra* note 269, at 691.

30 percent to 50 percent.”<sup>289</sup> These harms are not discussed by either the medical profession or the media when scientists, physicians, and surgeons unequivocally state that breast implants do not cause disease. Neither is this physical damage to breast tissue or the resulting difficulty with mammography compensated under the Settlement Program.<sup>290</sup>

Increased benefits for implant rupture are only available under the Settlement Program if women who claim to be suffering from a disease currently recognized under either the Settlement Program or its predecessor, the Global Settlement, can also establish that at least one of their implants was ruptured at the time of removal.<sup>291</sup> There are, thus, no available benefits for proof of rupture without a documented disease.<sup>292</sup> Thus, rupture itself is not a recognized compensable harm under the Settlement Program.<sup>293</sup> This fact is especially unfortunate for those women whose breast tissue immediately surrounding the implant, the capsule, has become “heavily calcified.”<sup>294</sup> For some of these women, not only must their ruptured implants be removed, the surgeon must also excise nearly all of the remaining breast tissue.<sup>295</sup> In order to retrieve as much silicone as possible, surgeons have sometimes been required to go “deep into the rib cage and scrape it out.”<sup>296</sup> The pain accompanying these procedures is much more intense than with the original implantation surgery.<sup>297</sup>

Women are also not compensated under this Settlement Program for other physical damage, including severe, deforming capsular contracture.<sup>298</sup> Instead, a small amount of money is provided for removal of the implants.<sup>299</sup> This amount may not cover the entire cost of removal and does not include compensation for the additional scarring and pain associated with another surgical procedure.<sup>300</sup>

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289. Caroline W. Jacobus, *Legislative Responses to Discrimination in Women's Health Care: A Report Prepared for the Commission to Study Sex Discrimination in the Statutes*, 16 Women's Rts. L. Rep. 153, 300 (1995).

Mammography is presently the best method of detecting breast cancer at its earliest stages—before the cancer has spread and often before the tumor can be felt. Detecting the cancer this early means a higher chance of survival and perhaps less drastic surgery. One study estimates that for women 50 and over, physical examination alone has reduced deaths due to breast cancer by 18[%], but physical exam combined with annual mammography screening reduced breast cancer mortality by 56[%].

Peter J. Thill, Note, *Insurers' and Courts' Response to High Dose Chemotherapy with Autologous Bone Marrow Transplant in the Treatment of Breast Cancer: A Tragedy or Necessity?*, 43 DRAKE L. REV. 863, 865 n.9 (1995) (quoting Judith Willis, *Why Women Don't Get Mammograms (And Why They Should)*, FDA CONSUMER, May 1987, at 5).

290. See *Settlement Litigation Notice*, *supra* note 241, at 4-12.

291. See *id.* at 6.

292. See *id.* at 5.

293. See *id.*

294. BYRNE, *supra* note 64, at 159.

295. See *id.*

296. *Id.* at 158.

297. See *id.* at 158-59.

298. For an explanation of capsular contracture, see *supra* notes 68-70 and accompanying text.

299. The Settlement Program provides women with \$3,000.00 as a one-time explanation fee upon documentation that they have had their implants removed. *Settlement Litigation Notice*, *supra* note 241, at 4.

300. For some women, the estimate of implant removal costs is as high as \$25,000.00. See Curriden, *supra* note 241, at 18.

For those women who were not informed that capsular contracture might occur or that their implants would deteriorate over time and eventually require replacement, the Settlement Program is inadequate in this respect.

The Settlement Program does not compensate for another side effect that can result from repeat surgical procedures—nerve damage and numbness to the nipples and breast tissue.<sup>301</sup> This is a very real and significant harm to a woman who has lost in part her potential for sexual arousal and whose joy in her own body has been diminished. If the legal system generally provides compensation for emotional pain and suffering and for loss of sexual enjoyment due to personal injury, why were women not provided even modest sums under the Settlement Program for these harms to their bodies?<sup>302</sup> A similar argument can be made for another very real physical harm to women's breasts: some women lose the ability to breast feed their babies.<sup>303</sup> Again, many women were not warned of this potential side effect which causes tangible, physical harm and emotional pain.<sup>304</sup>

The harm resulting for these women is three-fold. First, they have been harmed by the misleading, inaccurate information provided by both manufacturers and physicians when they made their decisions to undergo breast augmentation surgery. Next, they have been harmed because their significant physical injuries have not been recognized by even minimal compensation under the Settlement Program. Finally, they have been harmed by the one-sided presentation of the issues by the media, which has never focused on these types of injuries, their rate of occurrence, the failure to warn, and the failure to compensate under the Settlement Program.

The failure to acknowledge these harms through balanced media coverage and even modest monetary settlement benefits amounts to sanctioning "medical violence" against women.<sup>305</sup> The message to these women and to society is that

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301. See DAVIS, *supra* note 66, at 27-28; *Settlement Litigation Notice*, *supra* note 241, at 4-12. It is true that this harm is a direct result of surgery, but if the repeat surgical procedure is due to a failure to warn about the nature of the product in terms of rupture or lifespan, there is a strong basis for manufacturer responsibility.

302. See generally David W. Leeborn, *Final Moments: Damages for Pain and Suffering Prior to Death*, 64 N.Y.L. Rev. 256, 263 (1989) (discussing damages for "possible loss of sexual function" in action involving "partial or complete paralysis of a victim"); Joy Lazo, Comment, *True or False: Expert Testimony on Repressed Memory*, 28 LOY. L.A.L. REV. 1345, 1355 & n.55 (1995) (discussing damages for sexual dysfunction in repressed memory, childhood sexual abuse claim); Linda Jorgenson, et al., *The Furor Over Psychotherapist-Patient Sexual Contact: New Solutions to an Old Problem*, 32 WM. & MARY L. REV. 645, 712-13 (1991) (reviewing implications of claim involving allegations of emotional harm resulting in sexual dysfunction). Damage awards for loss of sexual functioning or enjoyment are also made based upon a derivative claim of a spouse or partner—loss of consortium claims. See Katharine Silbaugh, *Turning Labor into Love: Housework and the Law*, 91 NW. U.L. REV. 1, 42-43 (1996) (discussing generally the evolution of the claim of loss of consortium from an exclusively male right to one including women).

303. See *supra* notes 73-75 and accompanying text.

304. *Id.*

305. This phrase is borrowed from Karen Hicks in her discussion of the Dalkon Shield controversy and A.H. Robins' treatment of the women who were injured by its product. See HICKS, *supra* note 141, at 15. She defines medical violence as "all needless operations, misdiagnoses, and failed medical interventions performed on victims with less social power than medical professionals. Medical violence reflects and reinforces patriarchal values and social structures. It also results in an enormous profit to the medical elites and in great cost, both physical and financial, to the victims." *Id.* In the context of this discussion, medical violence refers to the negligent, deceptive marketing of this product and the surgery accompanying its use and the resulting



these are not harms, but rather acceptable occurrences.<sup>306</sup> When the media oversimplifies such issues into black and white sound-bites while currently transmitting the message that silicone breast implants are medically safe devices, not only are many women harmed, but the public also loses something—its ability to make informed judgments about these issues of disease and physical harm.

## V. CONCLUSION

Somewhere along the way, the story of silicone gel breast implants has lost its focus, has become skewed. The current focus has narrowed to a limited number of connective-tissue diseases that thus far have not been scientifically linked to breast implants. Women claiming symptoms of these and other diseases are being sent very clear messages. If they suffer from a recognized condition such as lupus, they are being told that even though the Settlement Program will compensate them for their condition, their implants were not the cause of that condition. If they suffer from generalized complaints of fatigue, muscle and joint pain, memory loss, and other symptoms,<sup>307</sup> they are told their condition is psychosomatic or even non-existent and fraudulently motivated.

Women, who are valued for their physical beauty,<sup>308</sup> and who were aggressively, not to mention deceptively, targeted for this cosmetic surgical procedure, are now being condemned after undergoing this beautification ritual. Consequently, in a very real way, silicone gel breast implants have become “woman’s sceptre and prison.”<sup>309</sup> Both the breast implant recipients and the

physical and emotional harm suffered by women, most of which has not been compensated by the Settlement Program. While it is understandable that the resources provided under the Settlement Program are limited, it is astonishing that these harms are not recognized through even nominal settlement amounts.

306. In fact, there is evidence that members of the medical community treat these very real harms in this manner. For example, in her book, Dr. Angell states, “Difficulty in performing mammography is a fourth problem. It is not exactly a complication, but a necessary concomitant of having breast implants.” ANGELL, *supra* note 4, at 42. If women were not warned of this “necessary concomitant,” and if they would have not chosen breast implants had they been provided with this information, then they have been harmed.

307. See Mark Ballard, *Class Action Implant Trial Opens in Big Easy*, NAT’L L.J., Mar. 31, 1997, at A10 (discussing these symptoms and allegations of silicone migration to the “liver, spleen and brain stem” in the context of the class action trial currently underway against Dow Chemical Corporation in New Orleans).

308. See generally Toby Mark Miller et al., *Survey on Body Image, Weight, and Diet of College Students*, 77 J. AM. DIETETIC ASS’N 561, 561 (1980) (discussing “the overwhelming emphasis on beauty in our society, and our preoccupation with appearance” in the context of weight issues).

309. One study of jury verdicts in breast implant cases may provide an explanation:

A total of 17 product liability verdicts in silicone and saline breast implant cases were awarded between January, 1970 and March, 1994. Plaintiffs prevailed in 11 of these cases, for an overall success rate of 65 percent. Twelve of the seventeen decided cases were brought by plaintiffs who used the implants for cosmetic breast augmentation. Of these, only six (fifty-five percent) of the cases resulted in plaintiff victories. In contrast, plaintiffs prevailed in four out of the five (eighty percent) cases filed by women whose implants were inserted as part of breast reconstruction surgery. This suggests that gender stereotypes of the “good” and “bad” woman play a role in the outcome of the cases.

Thomas Koenig & Michael Rustad, *His and Her Tort Reform: Gender Injustice in Disguise*, 70 WASH. L. REV. 1, 43-44 (1995) (footnotes omitted). For another statistical study of breast implant verdicts in more recently tried cases, see Hansen, *supra* note 240, at 22.

general public deserve more complete, accurate information about important medical questions: Are breast implants safe enough? And who should bear the burden of proving harm, or, for that matter safety, when, for instance, state-of-the-art medical technology demonstrates no rupture, but upon removal it becomes apparent that the implants have leaked silicone into the woman's breast tissue that will forever remain in her breasts making mammography and cancer detection difficult?<sup>310</sup>

One answer likely to be provided by the manufacturers who have agreed to the terms of the Settlement Program is that they did so not as an admission of liability or wrongdoing but to avoid paying multimillion dollar jury verdicts.<sup>311</sup> Certainly, the studies showing no link between connective-tissue diseases and breast implants are relevant to lawsuits in which liability was premised upon the breast implants causing these diseases.<sup>312</sup> This refrain that the recently released studies conclusively establish no wrongdoing is, however, misleading because these manufacturers and surgeons have committed numerous other wrongs resulting in physical harm for which hundreds of thousands of women will never be compensated.

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310. See *supra* notes 287-89 and accompanying text. Current technology for measuring the integrity of the silicone gel breast implant shell includes in vitro measurement. See Yu, *supra* note 17, at 762.

311. See *Settlement Litigation Notice*, *supra* note 241, at 11, in which it is clearly stated that "the settling defendants continue to deny any wrongdoing or any legal liability of any kind."

312. For a discussion of one of these cases, see *Hopkins v. Dow Corning Corp.* 33 F.3d 1116 (9th Cir. 1994). In this case, the plaintiff alleged that she suffered from mixed connective-tissue disease, "a rheumatological disorder which includes symptoms such as extreme fatigue, weakness, muscle aches and pains, arthralgia, myalgia, and arthritis." *Id.* at 1118. The plaintiff was awarded \$840,000.00 in compensatory damages and \$6.5 million in punitive damages, and this award was upheld on appeal. *Id.* at 1119-20, 1128.

