



# From Regulation to Litigation: An Analysis of the Silicone Breast Implant Controversy

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From Regulation to Litigation:  
An Analysis of the Silicone Breast Implant  
Controversy

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Food and Drug Law  
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I.

I.

## Introduction

At the age of eighteen, Britney Spears has reached superstar status. She has

sold millions of albums, and her music videos are among MTV's most popular. Teenage boys idolize her, and teenage girls strive to look like her. Unfortunately, good genes alone may not account for Britney's sought after appearance. Recent reports allege that the teen idol underwent breast augmentation surgery last year, at the age of seventeen.<sup>1</sup> Although Britney denied the reports, other stars such as Pamela Anderson Lee owe much of their fame to well-publicized breast augmentation procedures. In fact, the American Society of Plastic and Reconstructive Surgeons (ASPRS) has reported a steady increase in the demand for all types of cosmetic surgery ranging from rhinoplasty to breast augmentation.<sup>2</sup> According to statistics compiled by the ASPRS, the number of procedures performed in the United States has increased 152 percent since 1992, to well over a million procedures a year. Twenty-five percent of those procedures are performed on patients under the age of 34.<sup>3</sup> As these statistics indicate, cosmetic surgery has become quite common, despite the disastrous history of what was once a highly popular cosmetic surgery procedure: silicone gel breast augmentation.

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<sup>1</sup>See Chrissy Illey, Britney is 18 but She's Already Had Breast Implants and There are Plenty of Other Young Americans Queuing to go Under the Knife, *The Scotsman*, Jan. 28, 2000, at 22; see also Alex Tresniowski et. al., Britney's Wild Ride, *People*, Feb. 14, 2000, at 98 (reporting on Britney's denial of the breast implant rumors).

<sup>2</sup>See Nancy Ryan, Cosmetic Surgery Jumps 50 Percent: Liposuction and Breast Augmentation Top Procedures (visited Mar. 1, 2000) <<http://www.plasticsurgery.org/mediactr/99stats.htm>>; see also Illey, *supra* note 1, at 22.

<sup>3</sup>See Illey, *supra* note 1, at 22.

### A. The Development of the Silicone Breast Implant

For over a century, women around the world have used various methods to enlarge their breast size. As Dr. Marcia Angell explains in her book, Science on Trial: The Clash of Medical Evidence and the Law in the Breast Implants Case, the first recorded breast augmentation procedure occurred in Germany in 1895 and involved transplanting fat from a benign tumor on a woman's back to her breasts.<sup>4</sup> Before turning to silicone, doctors tried injecting a variety of substances such as paraffin wax, petroleum jelly, beeswax and vegetable oils directly into the patient's breast.<sup>5</sup> The start of World War II, however, brought about increased innovation in many fields, including medicine. Scientists had stabilized silicone just prior to the start of the war, and silicone became quite valuable during the war because of its uses in lubrication, sealing, and insulation. Soon doctors began to investigate possible medical uses of silicone and discovered that the substance had many properties considered useful in the medical field. For example, silicone is inert when inserted into the human body, does not degrade, resists bacterial contamination and is easily tolerated by the human body.<sup>6</sup> These properties have made silicone one of the most widely used substances in medicine, and it is still a key component in important medical devices such as artificial joints, heart valves, needle lubrications and tubing.<sup>7</sup>

The first reported attempt to enlarge the breast using liquid silicone also oc-

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<sup>4</sup>See MARCIA ANGELL, M.D., *SCIENCE ON TRIAL: THE CLASH OF MEDICAL EVIDENCE AND THE LAW IN THE BREAST IMPLANT CASE* 35 (W.W. Norton & Co. 1997) (1996).

<sup>5</sup>See *id.*

<sup>6</sup>See *id.* at 36.

<sup>7</sup>See *id.*

curred during World War II when Japanese women had the substance injected directly into their breasts in an attempt to please American servicemen stationed in Japan. The women believed that the American men preferred bigger breasts and took drastic measures to satisfy this preference.<sup>8</sup> As Judy Foreman explains in her article, “Women and Silicone: A History of Risk,” those performing the augmentation procedures for the Japanese women usually injected the women with a type of silicone commonly used as an industrial strength transformer coolant and stolen from barrels kept on the docks of Japanese cities.<sup>9</sup> Unfortunately, this type of silicone also contained contaminants that would irritate the breast tissue and tended to ooze into the rest of the body.<sup>10</sup>

Despite these problems, the idea of using silicone injections to enlarge women’s breasts gained popularity and by the 1960s had spread to the United States, as Daniel Q. Posin discusses in his article, “Silicone Breast Implant Litigation and My Father-in-Law: A Neo-Coasean Analysis.”<sup>11</sup> The procedure gained particular popularity among Las Vegas showgirls and waitresses who believed that larger breasts would increase their popularity with the male customers.<sup>12</sup> In fact, silicone injections became such a popular method of breast augmentation that in the space of a few short years approximately 50,000 American women had undergone the procedure.<sup>13</sup> Unfortunately, these women did not escape the problems experienced by the Japanese women who first used the silicone

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<sup>8</sup>See *id.* at 35.

<sup>9</sup>See Judy Foreman, *Women and Silicone: A History of Risk*, THE BOSTON GLOBE, Jan. 19, 1992, at 1.

<sup>10</sup>See *id.*

<sup>11</sup>See Daniel Q. Posin, *Silicone Breast Implant Litigation and My Father-in-Law: A Neo-Coasean Analysis*, 70 TUL. L. REV. 2565, \*2567-68 (1996).

<sup>12</sup>See *id.*

<sup>13</sup>See Foreman, *supra* note 9, at 1.

injections. As the silicone used in early breast enlargement procedures, like that used in Japan during World War II, often came from unregulated sources, women desiring larger breasts ran the risk of receiving injections of bacteria-contaminated silicone. Furthermore, those performing the procedure often used contaminated needles, which increased the woman's risk of contracting infections.<sup>14</sup> These infections could cause gangrenous sores to develop on the skin around the breast.<sup>15</sup> Moreover, it became common practice to purposely add contaminants such as olive oil to the silicone in order to cause the formation of scar tissue around the injection and minimize oozing. This practice converted the silicone from a substance that ordinarily produced only a mild inflammatory reaction to one that could produce inflammation so severe as to cause tumor-like lumps to develop around the breast.<sup>16</sup> These lumps not only disfigured the breast, but also caused the woman enormous pain. Even if the augmentation procedure did not cause inflammation or infection, it produced other side effects such as hardening of the breasts, connective tissue pain, and interference with the detection of cancer.<sup>17</sup> In fact, as Mary White Stewart describes in her book, Silicone Spills: Breast Implants on Trial, in 1965 the problems with silicone injections led the U.S. Food and Drug Administration (FDA) to classify these injections as a drug under §201 of the Food, Drug, and Cosmetic Act (FDCA).<sup>18</sup> This classification allowed the FDA to regulate silicone injections,

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<sup>14</sup>See ANGELL, *supra* note 4, at 38.

<sup>15</sup>See *id.*

<sup>16</sup>See *id.*

<sup>17</sup>See Posin, *supra* note 11, at \*2568.

<sup>18</sup>See MARY WHITE STEWART, SILICONE SPILLS: BREAST IMPLANTS ON TRIAL 17 (Praeger 1998); see also Federal Food, Drug, & Cosmetic Act, 21 U.S.C. § 321 (1998).

and based on the serious problems with the injections, the agency quickly acted to ban their use.<sup>19</sup> Thus, even at this early stage in the development of silicone breast augmentation, it became apparent that artificial methods to increase the size of the breast were not risk-free.

Despite the early problems with breast augmentation procedures, doctors continued to try to provide women with a permanent way to achieve their desired breast size. In 1961, Dr. Thomas Cronin and Dr. Frank Gerow, plastic surgeons practicing in Texas, began to develop what has become the most famous type of breast implant: the silicone gel breast implant.<sup>20</sup> This implant consisted of silicone gel encased in a malleable silicone bag, and its developers touted the new implant as an improvement on the silicone injection method.<sup>21</sup> For example, the silicone bags, for the most part, ensured that the liquid silicone remained in the proper place in the body and reduced the irritation associated with injections of large amounts of unpurified liquid silicone directly into the patient's body. The silicone implants felt more natural than the alternatives, and plastic surgeons could easily customize their size to give the woman the desired increase in breast size.<sup>22</sup> In addition, the simplicity of the procedure used to insert the implants into the body contributed to their popularity. Silicone breast augmentation procedures, even by modern standards, were quite simple. They required only two small incisions, which the surgeon usually made

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<sup>19</sup> See STEWART, *supra* note 18, at 17.

<sup>20</sup> See ANGELL, *supra* note 4, at 39.

<sup>21</sup> See *id.*

<sup>22</sup> See *id.*

under the crease of the breast. The surgeon then formed a pocket behind the breast and in front of the pectoral muscle where the implant would sit and push forward the woman's own breast tissue.<sup>23</sup> In cases of post-mastectomy breast reconstruction, the procedure was only slightly more complicated because the surgeon had to place the implant behind the pectoral muscle, against the ribs, or between muscles. Also, the surgeon had to reconstruct a nipple, usually using skin taken from other areas of the woman's body.<sup>24</sup> Even considering the additional complications posed by the case of breast reconstruction, silicone implant surgery, as explained by the ASPRS, only took around two hours to complete, and the average patient could resume most activities within 48 hours.<sup>25</sup> As a result, the new silicone implants quickly became the preferred method of breast augmentation for millions of women.<sup>26</sup>

The silicone breast implants developed by Dr. Cronin and Dr. Gerow remained the most popular form of breast implants until the FDA, citing potentially serious health risks, severely limited their availability in April 1992. Among the problems noted early on with the use of silicone breast implants were contractures, leakage, rupture, and difficulties with mammography. First, contractures resulted from the formation of scar tissue around the point of insertion of the implant. This scar tissue formed a capsule that surrounded the implant and then contracted. This capsular contracture squeezed the implant and resulted

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<sup>23</sup> See *id.* at 39-40.

<sup>24</sup> See *id.*

<sup>25</sup> See American Society of Plastic Surgeons, *Breast Augmentation* (visited Mar. 10, 2000) <<http://www.plasticsurgery.org/surgery/brstaugm.htm#7>>.

<sup>26</sup> See ANGELL, *supra* note 4, at 40.



in a hardening of the breast tissue around the implant.<sup>27</sup> In addition, as the scar tissue contracted, it often caused the implant to bulge. This bulging was noticeable and extremely painful. Surgeons quickly developed a procedure called a “closed capsulotomy” to deal with the capsular contracture problem. This procedure involved forcibly rupturing the scar tissue by hand but unfortunately, often also ruptured the implant itself. In addition, it was rarely completely successful because the scar tissue that caused the original problem simply reformed over time.<sup>28</sup>

The second problem noticed early on in the development of silicone implants was leakage. Doctors discovered in the 1970s that the implants tended to “bleed,” resulting in the release of small amounts of silicone into the body.<sup>29</sup> Although the capsule of scar tissue limited most of the leakage, doctors examining patients suffering from leakage had discovered silicone particles in lymph glands surrounding the breast.<sup>30</sup> The implants also leaked silicone into the surrounding tissue when they ruptured. Rupture was a more serious problem because it caused the breast to lose its shape. Finally, the implants made the detection of cancer through mammography more difficult. They interfered with the passage of x-rays through the breast, and in order to get an accurate image the technicians needed to take great care to maneuver the x-ray around the implant.<sup>31</sup> Although these early problems ranged from inconvenient to painful,

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<sup>27</sup> See *id.*

<sup>28</sup> See *id.* at 41.

<sup>29</sup> See *id.*

<sup>30</sup> See *id.*

<sup>31</sup> See *id.* at 42.

as discussed in later sections of this paper, they paled in comparison to the multitude of symptoms including lupus, rheumatoid arthritis, memory loss, chronic fatigue syndrome, and insomnia cited by the thousands of women involved in the breast implant litigation of the 1990s.<sup>32</sup>

## **B.**

### **The Choice to Undergo Breast Augmentation Surgery**

As the above discussion demonstrates, even before the start of the

silicone breast implant litigation, the decision to increase the size of a healthy breast by inserting a silicone gel filled implant into the body should have at least caused women to give serious consideration the potential downsides of the procedure. However, as the statistics compiled by the ASPRS demonstrate, breast augmentation has always been one of the most popular forms of plastic surgery. In 1998 alone, plastic surgeons performed over 132,000 breast augmentation procedures, 10,000 more procedures than in the previous year.<sup>33</sup> In addition, even in the aftermath of the silicone breast implant litigation, breast augmentation surgery for cosmetic purposes (using saline filled implants) continues to make up the vast majority of augmentation procedures with post mastectomy breast reconstruction accounting for only twenty percent of implant procedures.<sup>34</sup> This statistic is amazing considering the panic created by the litigation and the news

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<sup>32</sup>See Posin, *supra* note 11, at \*2568.

<sup>33</sup>See American Society of Plastic Surgeons, *National Clearinghouse of Plastic Surgery Statistics* (visited Mar. 5, 2000) <<http://www.plasticsurgery.org/mediactr/trends92-98.htm>>.

<sup>34</sup>See STEWART, *supra* note 18, at 56.

coverage of the silicone breast implant controversy and prompts a look at the reasoning behind the decision to receive breast implants.

As Julie M. Spanbauer explains in her article, “Breast Implants as Beauty Ritual: Woman’s Sceptre and Prison,” throughout history and across cultures, women have taken measures of varying extremes to meet the societal view of beauty.<sup>35</sup> In the 1800s, women wore corsets to achieve the ideal waist size despite the fact that achieving the tiny waist in fashion at the time often required allocating over 30 minutes to tighten the strings on the corset sufficiently. In addition, wearing such a constricting undergarment every day often caused the woman to experience severe pain and damaged her internal organs.<sup>36</sup> The Chinese culture, on the other hand, did not idealize women with tiny waists but rather those with tiny feet. In order to comport with this notion of beauty, Chinese women had their feet tightly bound at birth. Although the women with the smallest feet were considered the most beautiful, they were also unable to stand or walk without assistance as a result of the foot binding.<sup>37</sup> Although these examples represent two of the more extreme measures taken by women in the name of beauty, they demonstrate the lengths to which women have gone throughout history in pursuit of the feminine ideal and provide a historical background in which to understand modern cosmetic surgery.<sup>38</sup> As Spanbauer argues, when:

[s]ituated in this historical context, breast augmentation

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<sup>35</sup> See Julie M. Spanbauer, *Breast Implants as Beauty Ritual: Woman’s Sceptre and Prison*, 9 YALE J.L. & FEMINISM 157, \*163 (1997).

<sup>36</sup> See *id* at \*166-67.

<sup>37</sup> See *id* at \*164.

<sup>38</sup> See *id* at \*168.

surgery appears to be a natural technological evolution in feminine beauty practices. 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.<sup>39</sup>

She notes that for the past two decades, the ideal of the perfect woman has become progressively thinner and the ideal breast size has increased. These two factors, which are quite difficult to achieve individually, in combination become all but unattainable characteristics for the average woman.<sup>40</sup> As a result, more and more women have turned to artificial methods in their pursuit of the beauty ideal.

As Susan M. Zimmerman explains in her book, Silicone Survivors: Women’s Experience with Breast Implants, the decision to undergo breast augmentation surgery results from the interaction of a variety of cultural forces.<sup>41</sup> Zimmerman debates the assertion of many feminist theorists, such as Kathy Davis and Susan Bordo, that women undergoing plastic surgery often view the procedure as a liberating event.<sup>42</sup> Davis and Bordo have rejected the notion of women as “cultural dopes, who have been blinded by the promise of a new body.”<sup>43</sup> Davis has concluded from interviews with many women who have undergone cosmetic surgery that the women often had a full understanding of the cultural and interpersonal forces leading them to opt for cosmetic surgery. According to Davis, these women recognized the

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<sup>39</sup> *Id.*

<sup>40</sup> *See id.* at \*167.

<sup>41</sup> *See* SUSAN M. ZIMMERMAN, *SILICONE SURVIVORS: WOMEN’S EXPERIENCE WITH BREAST IMPLANTS* 55 (Temp. U. Press 1998).

<sup>42</sup> *See id.* at 44.

<sup>43</sup> *Id.*

interaction between their self-esteem and their outward appearance and viewed cosmetic surgery as a way to freedom from the suffering caused by an imperfect body image.<sup>44</sup> Bordo also has found that women feel liberated by the decision to undergo cosmetic surgery but has argued that Davis has placed too little emphasis on the cultural, historical, and social standards that cause women to believe that success comes from beauty.<sup>45</sup> Although each theorist has a somewhat different conception of the forces that lead a woman to alter her body, they agree that women, for the most part, are not blindly taken in by media images. However, as Zimmerman explains, women, when deciding to undergo breast augmentation surgery, may be simultaneously aware of the cultural forces that influence their decision and strongly pressured by those forces to achieve the feminine ideal.<sup>46</sup>

Other theorists have taken a more extreme view of the reasoning that leads a woman to undergo breast augmentation surgery. They portray women as nearly incapable of separating self-worth from body image.<sup>47</sup> For example, Stewart asserts that “[a]lthough American women are not likely to be killed by their husbands for not bringing in the promised dowry or bride price, the physical manipulation and interventions they endure – from liposuction to facelifts to waxes and peels – are a direct result of their relative economic powerlessness.”<sup>48</sup> That is, in this view, a woman’s sense of power and sense of self derive totally from her body. Moreover, her power and well being are directly related to her

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<sup>44</sup> See *id.*

<sup>45</sup> See *id.* at 44-5.

<sup>46</sup> See *id.* at 46.

<sup>47</sup> See STEWART, *supra* note 18, at 55-60 (discussing the work of Tseñlon, Wolf and others).

<sup>48</sup> *Id.* at 56-7.

attractiveness to men.<sup>49</sup> This group of theorists asserts that the connection between power and appearance is perpetuated by the fact that over 90% of plastic surgeons are male.<sup>50</sup> Thus, plastic surgeons inevitably bring to their practice the male perspective of what makes a woman attractive.<sup>51</sup>

Although interesting, the view discussed in Stewart's book is extreme. It seems a

rather large overstatement to suggest that, despite the advances made toward gender equality, women derive all of their power and self-worth from their outward appearance. However, what is evident from the above discussion is that women deciding to undergo any cosmetic procedure act under the influence of a variety of external pressures, most of which direct them toward having the procedure. Given the large amount of discussion both in academic settings and in the popular media regarding the pursuit of beauty, women are likely all the more aware of these forces and their influence on the decision making process. What is cause for concern is the possibility that these cultural influences exert so much pressure on women and are of such a systemic nature that they greatly compromise the decision making process. That is, cultural forces driving women to pursue the beauty ideal may cause otherwise rational and capable actors to give less weight than is reasonable to the risks of a given cosmetic procedure.<sup>52</sup>

The Australian author Loane Skene has suggested this theory in his article "In

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<sup>49</sup> See *id* at 54-5.

<sup>50</sup> See Spanbauer, *supra* note 35, at \*174.

<sup>51</sup> See ZIMMERMAN, *supra* note 41, at 56.

<sup>52</sup> See Loane Skene, *In Their Mind's Eye: A Different Direction for Cosmetic Surgery Consent Cases*, 1996 TLJ LEXIS 26, \*2.

Their Mind's Eye: A Different Direction for Cosmetic Surgery Consent Cases,” and it goes a long way in explaining why, even after the silicone breast implant disaster, cosmetic surgery, including breast augmentation, is more popular than ever.<sup>53</sup> It also is an important argument in favor of the FDA’s actions regarding silicone breast implants and in favor of requiring plastic surgeons to be specific in their description of the risks of a particular procedure.<sup>54</sup>

Cosmetic surgery has become glamorized in American society, and as a result, its risks have been de-emphasized. Although women should be able to and are capable of making decisions regarding cosmetic surgery, they are also entitled to complete information so that their decisions are truly *informed* decisions. The FDA, through its regulation of breast implants under the medical device provisions of the FDCA, played an important role in encouraging women to take a step back and truly consider the ramifications of their decision. In fact, although many critics of the FDA have cited the silicone breast implant controversy as evidence of the agency’s ineffectiveness, a closer look at the events leading up to the regulation of silicone implants reveals the dangers of allowing the medical device industry to self-regulate. If anything, the silicone breast implant controversy provides strong evidence to support efficient regulation.

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<sup>53</sup> See *id.*

<sup>54</sup> See *id.*

## II.

### The Road to Regulation

#### A.

##### The Medical Device Act of 1976

As Richard A. Merrill explains in his article, “The Architecture of Government

Regulation of Medical Products,” Congress vested the FDA with the authority to regulate the safety and marketing of food and drugs in the Food and Drug Act of 1906. However, it took another seventy years for Congress to expand fully the FDA’s authority to monitor medical devices.<sup>55</sup> It was through this expanded jurisdiction over medical devices that the FDA derived its authority to regulate silicone breast implants.

Congress first gave the FDA limited authority over medical devices in 1938, and the 1938 Act defined the word “device” expansively. According to the 1938 Amendments, the word “device” included “instruments, apparatus, and contrivances . . . intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals.”<sup>56</sup> Despite this expansive definition of device, the FDA’s authority to regulate medical devices was actually quite limited, and the agency did not spend much time or resources in this

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<sup>55</sup>See Richard A. Merrill, Symposium on Regulating Medical Innovation: The Architecture of Government Regulation of Medical Products, 82 Va. L. Rev. 1753, \*1800 (1996).

<sup>56</sup>*Id.* at \*1800 n.139.



area.<sup>57</sup> In fact, the 1938 Amendments only permitted the FDA to challenge “the sale of products that it believed were adulterated (unsanitary or unsafe) or misbranded (bearing false or misleading claims).”<sup>58</sup> At this stage in the development of medical device regulation, Congress did not permit the FDA to require proof of safety or effectiveness from the manufacturers of medical devices.<sup>59</sup> Thus, the FDA encountered some difficulty in its efforts to remove devices from the market and did not have the resources to spend on what often became time consuming enforcement actions.<sup>60</sup> However, in the early part of the twentieth century, the need for medical device regulation had not yet become imperative. Simple instruments used by doctors and hospitals made up the vast majority of devices during this time, and most medical devices in use during the 1920s and 1930s did not require surgical insertion into the body.<sup>61</sup>

The years following World War II, however, marked the advent of a new era of medical device development.<sup>62</sup> It was a time of great innovation in the medical field with the development of artificial joints, pacemakers, and cosmetic implants, but with this increased innovation, the FDA became more concerned with the need to test the safety and effectiveness of these devices prior to marketing.<sup>63</sup> This concern led the agency to attempt to circumvent its limited authority under the 1938 Amendments by classifying certain medical devices

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<sup>57</sup> *See id.*

<sup>58</sup> *Id.* at \*1802.

<sup>59</sup> *See id.* at \*1803.

<sup>60</sup> *See id.* \*1803 n. 154.

<sup>61</sup> *See id.* at \*1801-02.

<sup>62</sup> *See id.* at \*1803.

<sup>63</sup> *See id.*

as new drugs under the broad definition of the word “drug” provided in the 1938 Food and Drug Act. The classification of devices as “new drugs” rather than “devices” allowed the FDA to require manufacturers to test their safety and get FDA approval prior to marketing the product.<sup>64</sup> Despite some initial successes, the FDA’s regulation of devices in this way depended on a questionable reading of the definition of “drug,” and the agency was never quite sure how far it could proceed in its regulation of devices under this structure.<sup>65</sup> As the medical device industry developed more complex and intrusive products, it became apparent that Congress needed to develop specific provisions to enable the FDA to adequately serve its consumer protection function in the area of medical devices.

Congress developed these provisions in the 1976 Medical Device Amendments.<sup>66</sup> The 1976 Amendments gave the FDA expanded power to regulate medical devices by permitting the agency to establish good manufacturing requirements, to prohibit dangerous products, and to impose notification and replacement requirements on manufacturers of defective products.<sup>67</sup> The primary goals of the 1976 Amendments, as enumerated by Ashley W. Warren in, “Preemption of Claims Related to Class III Medical Devices: Are the Federal Objectives of Health and Safety Furthered or Hindered,” were to “(1) assure public protection against unsafe and ineffective devices; (2) ensure that health

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<sup>64</sup> *See id.*

<sup>65</sup> *See id.* at \*1806.

<sup>66</sup> *See id.* at \*1808.

<sup>67</sup> *See id.*

practitioners can be confident about the medical equipment they use or prescribe for their patients; and (3) provide market protection for pioneers of new medical technologies.”<sup>68</sup> Congress hoped this increased authority over medical devices would better enable the FDA to fulfill its role as a guardian of public health and safety, but also hoped to protect the competing interest of protecting medical science from unwarranted governmental intrusion.<sup>69</sup> These competing and important goals have often put the FDA in the difficult position of deciding how far it should intervene in the area of medical device innovation and were particularly apparent during the silicone breast implant controversy.

The delicate balance between promoting innovation and protecting consumers was evident in the mechanics of the 1976 Amendments, which established a detailed program for dealing with medical devices. The 1976 Amendments, in short, required the FDA to inventory and classify all medical devices as Class I, II, or III devices.<sup>70</sup> This classification system still governs medical device regulation today and is contained in §513 of the FDCA.<sup>71</sup> Class I devices require only as much control as is necessary to ensure the reasonable safety and effectiveness of the device.<sup>72</sup> They are subject to prohibitions against misbranding and adulteration and to requirements of pre-market notification and registration.<sup>73</sup>

Class I devices include, for example, elastic bandages and tongue depressors.<sup>74</sup>

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<sup>68</sup>Ashley W. Warren, *Preemption of Claims Related to Class III Medical Devices: Are the Federal Objectives of Public Health and Safety Furthered or Hindered*, 49 SMU L. REV. 619, \*624 (1996).

<sup>69</sup>*See id.*

<sup>70</sup>*See* Merrill, *supra* note 55, at \*1809.

<sup>71</sup>*See* Federal Food, Drug, & Cosmetic Act, 21 U.S.C. § 360c (1998).

<sup>72</sup>*See* Merrill, *supra* note 55, at \*1809.

<sup>73</sup>*See id.*

<sup>74</sup>*See* Warren, *supra* note 68, at \*625.

Class II devices are those for which the FDA requires safety performance standards. Manufacturers of Class II devices must provide sufficient information regarding the device to allow for the development of a safety and effectiveness standard. A standard for a Class II device generally establishes key features and characteristics of the device.<sup>75</sup> Once a standard for the device has been established, the FDA will block the entry to the market of any device that does not meet that standard.<sup>76</sup> For example, hearing aids and resuscitators are Class II devices.<sup>77</sup> Class III devices require the most regulation and include those devices with too little information to establish a performance standard or those that potentially pose great risk to the patient.<sup>78</sup> These devices are subject to a pre-market testing and approval scheme similar to that used for new drugs.<sup>79</sup> Silicone breast implants are considered Class III devices.

The importance of this structure to the silicone breast implant issue soon became evident. With the enactment of the 1976 Amendments, the FDA found itself facing the challenging task of classifying an enormous amount of devices, developing regulations to implement the amendments, and reviewing pre-market approval applications for devices without pre-1976 equivalents. This task took more time than either the drafters' of the amendments or the FDA itself likely had anticipated and forced the FDA to make certain decisions regarding the allocation of its limited resources.<sup>80</sup> In fact, the very structure of pre-market

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<sup>75</sup> See Merrill, *supra* note 55, at \*1809.

<sup>76</sup> See *id.*

<sup>77</sup> See Warren, *supra* note 68, at \*625.

<sup>78</sup> See Merrill, *supra* note 55, at \*1809; see also Warren, *supra* note 68, at \*625.

<sup>79</sup> See Merrill, *supra* note 55, at \*1809; see also Warren, *supra* note 68, at \*625.

<sup>80</sup> See Merrill, *supra* note 55, at \*1812-13.

review procedures established by the 1976 Amendments gave the FDA a way to allocate its resources to the task at hand in what, at the time, seemed an effective way. That is, the amendments only required *immediate* pre-market review for safety and effectiveness for “genuinely novel post-enactment devices and for marketed devices assigned to Class III.”<sup>81</sup> Although the medical devices structure established by the 1976 Amendments also required pre-market review for post-enactment devices substantially similar to pre-enactment Class III devices and for pre-enactment Class III devices, this pre-market review requirement only attached when the FDA formally requested pre-market approval applications from the manufacturers of such devices.<sup>82</sup> As Congress did not provide a timetable to govern the application process for these two types of Class III devices, the FDA could proceed at a pace it found appropriate.<sup>83</sup>

Although commentators have argued that the FDA did not make progress with regard to the regulation of these Class III devices at a sufficiently quick pace, there is also adequate support for the argument that the FDA did the best it could given the enormity of the task at hand.<sup>84</sup> Furthermore, Congress had established a strict timetable for regulation of new devices without pre-1976 equivalents and for completing the pre-market notification process. The pre-market notification process required a manufacturer of a new device to give the FDA ninety-day notification of its intent to sell the device so that the FDA could determine if the new device was actually substantially similar to an already

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<sup>81</sup> *Id.* at \*1812.

<sup>82</sup> *See id.* at \*1812-13.

<sup>83</sup> *See id.* at \*1813.

<sup>84</sup> *See id.*

marketed device.<sup>85</sup> Thus, the FDA made the decision to devote more attention to new devices and pre-market notification than to devices in existence prior to the enacting of the 1976 Amendments. Merrill sums up the FDA's dilemma and explains:

[u]nder the circumstances, it is perhaps not surprising that the Bureau [of Medical Devices] paid little attention to the premarket approval requirement for pre-enactment Class III devices and their post-1976 equivalents. Many had been in use for several years. Most had undergone some clinical testing, and patient experience in most instances had not given rise to doubts about safety or effectiveness. More than a decade passed without any determined effort by the FDA to 'clean up' the backlog of Class III devices for which

PMA applications were in theory required.<sup>86</sup>

Thus, the lack of attention paid to many Class III devices was likely the result of a combination of factors including flawed legislation and agency inefficiency. Even prior to the height of the breast implant controversy, the FDA was judged harshly for its perceived inattention to Class III devices. In enacting the 1990 Amendments to the medical device provisions of the FDCA, the Senate found that the FDA's track record regarding pre-1976 Class III devices had resulted in an unacceptable threat to public safety.<sup>87</sup> It certainly seemed that the Senate was correct in its assessment when the breast implant controversy rose to the level of mass hysteria in 1992.

## B.

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<sup>85</sup> See *id* at \*1810-11.

<sup>86</sup> *Id* at \*1814.

<sup>87</sup> See *id* at \*1813 n 192.

## The FDA's Action Regarding Silicone Breast Implants

**As discussed in earlier sections of this paper, there was evidence early on in the**

history of breast augmentation that women wishing to enlarge their breast size using silicone implants were placing themselves at some risk. However, as Sylvia A. Law describes in her article, "Tort Liability and the Availability of Contraceptive Drugs and Devices in the United States," by the mid 1980s and early 1990s thousands of women began to claim that their silicone implants caused a variety of systemic and even life threatening injuries.<sup>88</sup> In addition, statistics compiled by 1991 revealed that nearly two million women had received silicone breast implants during the thirty years since their development in the 1960s.<sup>89</sup> These statistics, coupled with the increasing number of women asserting problems with their implants, made evident the potential for a public health disaster and likely played a dominant role in the FDA's sudden interest in silicone breast implants in the late 1980s.

The FDA first showed some interest in examining the safety of silicone implants in 1982 when it proposed imposing a pre-market approval requirement on breast implant manufacturers.<sup>90</sup> This requirement, had it been finalized, would have required manufacturers to provide safety information for silicone implants to the FDA and may have avoided at least some of the hysteria that was to come.

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<sup>88</sup>See Sylvia A. Law, *Tort Liability and the Availability of Contraceptive Drugs and Devices in the United States*, 23 N.Y.U. REV. L. & SOC. CHANGE 339, \*44.

<sup>89</sup>See ZIMMERMAN, *supra* note 41, at 20.

<sup>90</sup>See ANGELL, *supra* note 4, at 51.

However, the FDA never finalized its proposal and did not address the issue of silicone implants again until 1988, when some preliminary studies of the products had revealed a possible connection between connective tissue disease and the implants.<sup>91</sup> In addition, in 1986, the first lawsuit brought by a woman alleging that ruptured silicone implants had caused her to suffer from chronic fatigue syndrome and joint pain had resulted in a \$1.7 million verdict for the plaintiff.<sup>92</sup> With these events swirling in the background and nearly 30 years and two million women after the first successful breast implant procedure, FDA Commissioner David Kessler requested that breast implant manufacturers provide safety information about their products. According to the statute, they had 30 months to gather the necessary safety information and present it to the FDA for review.<sup>93</sup>

In the ensuing 30 months, many more women filed claims against the manufacturers of silicone breast implants, particularly Dow Corning – the largest manufacturer of silicone implants. Consumer groups such as Ralph Nader’s Public Citizen Health Research Group became more involved in the controversy, and most of these groups became increasingly convinced that silicone implants posed a considerable health risk to women.<sup>94</sup> In fact, Dr. Sidney Wolfe, the president of the Health Research Group had called for an all out ban of silicone breast implants as early as 1988 citing insufficient safety information.<sup>95</sup> In his article, “The Breast Implant Fiasco,” David Bernstein asserts that Public Citizen ac-

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<sup>91</sup> *See id.*

<sup>92</sup> *See id*; *see also* Law, *supra* note 88, at 46.

<sup>93</sup> *See* ANGELL, *supra* note 4, at 52.

<sup>94</sup> *See* Law, *supra* note 88, at 46.

<sup>95</sup> *See* ANGELL, *supra* note 4, at 53.



tually played a critical role in fanning the fire of the breast implant controversy when the group released internal documents from Dow Corning demonstrating a link between silicone and cancer in animals.<sup>96</sup> These documents, as explained in the later sections of this paper, discussed the results of monkey and dog studies of the effects of silicone on the body and also played an important role in some of the silicone implant lawsuits.<sup>97</sup> In addition, Public Citizen obtained and released FDA documents that revealed that some members of an FDA panel convened in 1988 to study breast implants felt that the implants were dangerous enough to warrant a consumer warning.<sup>98</sup> In 1990, the group went even further than simply publicizing its beliefs and filed a lawsuit against the FDA under the Freedom of Information Act to compel the FDA to release the results of the animal tests.<sup>99</sup>

Although the Health Research Group's claims caused a panic among many women, the documents it cited for support did not quite stand for what it claimed.<sup>100</sup> Dow Corning's animal studies mostly tested the effect of liquid silicone on an animal when injected into different parts of the animal's body. Some of these studies showed that silicone could travel through the body, and those studies done on rats showed that the rats would develop sarcomas when injected with the silicone. However, the studies generally did not test silicone as

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<sup>96</sup> See David E. Bernstein, *The Breast Implant Fiasco*, 87 CALIF. L. REV. 457, \*465 (1999); see also ANGELL, *supra* note 4, at 53.

<sup>97</sup> See Bernstein, *supra* note 96, at \*465; see also ANGELL, *supra* note 4, at 53.

<sup>98</sup> See ANGELL, *supra* note 4, at 52; see also Law, *supra* note 88, at 46.

<sup>99</sup> See Law, *supra* note 88, at 46; see also *Teich v. FDA*, 751 F. Supp.243, \*20 (D.D.C. 1990).

<sup>100</sup> See ANGELL, *supra* note 4, at 57.

used as part of a breast implant, and the sarcomas developed by the rats almost never occur in human breast tissue. Moreover, rats regularly develop this type of sarcoma when injected with any type of irritant.<sup>101</sup> Thus, the relevance of the tests to the safety of breast implants in women was not as clear as the Health Research Group asserted.<sup>102</sup> In fact, over the course of its examination of the safety of silicone breast implants the FDA did consider the information brought to light by the animal tests and concluded that they did not demonstrate that the implants posed a significant cancer risk in humans.<sup>103</sup> Unfortunately, it proved much more difficult to reassure women that their implants posed little risk of cancer than it was to alarm them regarding the risk of a potentially incurable disease.

To make matters worse for those entrusted with the task of reaching an objective conclusion regarding the safety of silicone breast implants, Public Citizen Health Research Group was only one of many organizations and news sources to publicize the multitude of potential problems with silicone implants. A group called Command Trust Network boosted the litigation of the breast implant issue by referring women to attorneys.<sup>104</sup> In addition, the news media eventually noticed the firestorm surrounding silicone breast implants and began to print and televise regular coverage of the developments in the breast implant saga. A December 1990 segment of “Face to Face with Connie Chung” was a par-

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<sup>101</sup> See *id* at 58.

<sup>102</sup> See *id* at 60.

<sup>103</sup> See Bernstein, *supra* note 96, at \*466.

<sup>104</sup> See ANGELL, *supra* note 4, at 53.

ticularly memorable news story focusing on silicone breast implants. Millions of Americans viewed this program, which sent a definite message that silicone breast implants caused a variety of serious illnesses.<sup>105</sup> The program relied on two doctors to support the causal link between silicone implants and disease but did not reveal that the doctors were paid experts for the plaintiffs in silicone implant litigation. Chung also interviewed many women who claimed that their implants had caused them to become ill but did not present the other side of the issue.<sup>106</sup> As Bernstein states, “Chung’s tendentious coverage favoring the plaintiffs claims set the tone for media coverage of breast implants for the next five years” when a more balanced report would have been more useful for all involved.<sup>107</sup> While these citizens’ groups and news organizations undoubtedly served to increase awareness of a potential health problem, they did not foster the development of an unbiased account of the breast implant issue. Instead, they became instrumental in the creation of the mass hysteria that surrounded the breast implant controversy from beginning to end, impeded the fact-finders in their efforts to arrive at an objective resolution of the issue, and did little to reassure panicked women.

However, the manufacturers also did not do much to help their case. By 1991, they still had not provided the FDA with safety information regarding their products.<sup>108</sup> Commissioner Kessler, realized that the FDA had yet to resolve the issue of the safety of silicone implants and determined to speed the pro-

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<sup>105</sup> *See id.*

<sup>106</sup> *See* Bernstein, *supra* note 96, at \*468.

<sup>107</sup> *Id.*

<sup>108</sup> *See* ANGELL, *supra* note 4, at 54.

cess along. In April 1991, he informed the manufacturers that they had ninety days to provide the agency with completed pre-market approval applications for their products.<sup>109</sup> According to this deadline, manufacturers had until July 9, 1991 to complete their safety tests and compile the information necessary to permit the FDA to reach a decision regarding the status of silicone breast implants.<sup>110</sup> However, the July 9<sup>th</sup> deadline passed and only Mentor Corporation, McGhan Medical Corporation, Dow Corning and Bioplasty, Inc. had submitted pre-market approval applications to the FDA. Moreover, the FDA found the safety data provided by these manufacturers inadequate.<sup>111</sup> A few months after the July 9<sup>th</sup> deadline, Bristol Myers Squibb, another major manufacturer of breast implants, made public its decision to stop making the products citing an inability to comply with the FDA's requests.<sup>112</sup>

In an effort to draw out more information regarding the safety of silicone breast implants, Commissioner Kessler brought together members of the FDA General and Plastic Surgery Devices Advisory Panel. This panel contained experts in a variety of fields including plastic surgery, oncology, toxicology, immunology, psychology and epidemiology. Members of business and consumer groups also sat on the panel.<sup>113</sup> It is likely that Commissioner Kessler hoped this panel would be able to gather more information regarding the safety of the implants and would permit the FDA to wade through the hysteria surrounding the implant issue to find the facts necessary to make an informed decision.

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<sup>109</sup> See *id.*

<sup>110</sup> See Bernstein, *supra* note 96, at \*470.

<sup>111</sup> See ANGELL, *supra* note 4, at 54.

<sup>112</sup> See *id.*

<sup>113</sup> See Bernstein, *supra* note 96, at \*470.

The FDA had heard testimony regarding the safety of silicone breast implants when it first proposed reclassifying the implants as Class III devices in 1982, in 1988 when its Plastic Surgery Advisory Committee met to discuss the status of the implants, and in 1990 when Representative Ted Weiss held hearings to address silicone's safety. However, the 1991 hearings generated a far more comprehensive picture of the controversy.<sup>114</sup> The panel heard from representatives of the American Medical Association (AMA) and the American Cancer Society (ACS), both of which favored leaving the implants on the market.<sup>115</sup> The ASPRS also made known its position, which favored leaving the implants on the market. This position, of course, did not surprise those who had followed the breast implant story as the ASPRS had a significant monetary interest in the continued marketing of breast implants.<sup>116</sup> Ninety percent of plastic surgeons practicing in the United States consider themselves ASPRS members, and in 1983 the group invested \$4 million in an advertising campaign to publicize breast implants as “essential to women’s mental health...”<sup>117</sup> On the other hand, that the AMA and the ACS did not recommend banning the use of silicone implants shocked many of those who did favor a ban.

Although the proponents of silicone implants had some well-respected groups on their side, they also faced substantial opposition to their position from consumer advocacy groups and from the many women who testified as to the hardships caused them by their silicone implants.<sup>118</sup> As Dr. Frank B. Vasey and Josh Feld-

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<sup>114</sup> See ANGELL, *supra* note 4, at 54; see also Bernstein, *supra* note 96, at \*463-65.

<sup>115</sup> See ANGELL, *supra* note 4, at 55.

<sup>116</sup> See *id.*

<sup>117</sup> Spanbauer, *supra* note 35, at \*182.

<sup>118</sup> See ANGELL, *supra* note 4, at \*55.

stein recount in their book, The Silicone Breast Implant Controversy: What Women Need to Know,

22 groups and 60 women with implants explained their positions to the panel.<sup>119</sup>

At the conclusion of the testimony, the panel decided that the breast implant manufacturers had not provided sufficient data to demonstrate the safety of their product.<sup>120</sup> Specifically, the panel found a lack of data regarding “the chemical properties of implant materials, mechanical and physical properties of the implants, frequency of adverse effects such as rupture and contracture, the extent to which implants mask tumor detection in mammography, and risks of cancer or immune disorders.”<sup>121</sup> This list demonstrated a substantial lack of information and raises a question as to what relevant information, if any, the manufacturers actually did provide to the FDA in the pre-market approval applications. Despite these findings, the panel recommended that the FDA permit the continued availability of implants conditioned on the establishment of a National Implant Registry to track implant recipients, the development of an informed consent document for distribution to implant patients, and the establishment of timeline for the submission of safety data to the FDA.<sup>122</sup>

The FDA took some time to review the findings of the panel before making any announcement regarding the status of silicone implants. In the intervening months, litigation against the breast implant manufacturers continued, and this litigation, in particular *Hopkins v. Dow Corning*, 33 F.3d 1116 (9<sup>th</sup> Cir. 1994),

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<sup>119</sup>See FRANK B. VASEY, M.D. AND JOSH FELDSTEIN, *THE SILICONE BREAST IMPLANT CONTROVERSY: WHAT WOMEN NEED TO KNOW* 84 (The Crossing Press 1993).

<sup>120</sup>*See id.*

<sup>121</sup>*Id.*

<sup>122</sup>*See id.*

brought renewed emphasis to information, similar to that released by Public Citizen, that Dow Corning had withheld at least some information regarding potential hazards of silicone implants.<sup>123</sup> The documents in question had originally surfaced during discovery for the Stern case, which had resulted in the first major monetary award for a breast implant plaintiff.<sup>124</sup> Dan Bolton, a law clerk who did most of the work on the Stern case, had discovered internal documents at the Dow Corning Plant in Midland, Michigan during his preparations for the case.<sup>125</sup> Although the documents he relied on in Stern were placed under seal at the conclusion of that case, he relied on those same documents in his handling of the Hopkins case. As these documents had played such a large role in two major breast implant cases, it is no wonder that they were eventually leaked to the news media, specifically to Seth Rosenfeld, a reporter for the San Francisco Chronicle. Rosenfeld turned the documents over to Dr. Norman Anderson, the chair of the November FDA panel, and Dr. Anderson gave the documents to Commissioner Kessler.<sup>126</sup> Commissioner Kessler found the documents important because they provided some evidence that officials at Dow Corning knew that silicone tended to leak from the implants; however, the documents did not include any studies regarding the long term effects of this leakage on the body.<sup>127</sup> *Stern*, *Hopkins*, and the documents are discussed in more detail in the next section of this paper.

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<sup>123</sup>See Law, *supra* note 88, at 46 (discussing the Hopkins case).

<sup>124</sup>See ANGELL, *supra* note 4, at 52

<sup>125</sup>See *id.*

<sup>126</sup>See Bernstein, *supra* note 96, at \*473.

<sup>127</sup>See *id.*

The information contained in the Dow Corning documents spurred Commissioner Kessler to announce a 45-day moratorium on the use of silicone implants on January 6, 1992.<sup>128</sup> In February 1992, Commissioner Kessler reconvened the advisory panel that had examined the implant safety data in November 1991 and explained in his opening remarks that new cause for concern regarding the safety of silicone implants had surfaced.<sup>129</sup> Although the news media placed much emphasis on the Dow Corning documents, Commissioner Kessler listed three sources of new information:

[f]irst, documents from manufacturer – Dow Corning – raised questions about the adequacy of quality control, and product testing. Second, information from clinicians about issues involving rupture, leakage and bleeds. And third, additional information – including reports from rheumatologists – which have strengthened the possible connection between breast implants and inflammatory and

auto-immune disorders.<sup>130</sup>

The Commissioner tried to offset the additional panic that the moratorium had caused by emphasizing that the reconvening of the advisory panel did not signify that the FDA believed the implants were unsafe.<sup>131</sup> He clarified the task of the advisory panel by specifying two primary goals: to determine what advice to give women who have silicone implants and to determine whether or not to lift

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<sup>128</sup>See VASEY AND FELDSTEIN, *supra* note 119, at 85; *see also* Bernstein, *supra* note 96, at \*474.

<sup>129</sup>See FED. NEWS SERVICE, FDA ADVISORY PANEL MEETING ON BREAST IMPLANTS, REMARKS BY DAVID KESSLER, Feb. 18, 1992.

<sup>130</sup>*Id.*

<sup>131</sup>*See id.*



the moratorium on the use of silicone implants.<sup>132</sup> He further explained that:

[d]espite the emotions that this issue has aroused, the FDA has one fundamental task: to ensure that the implants are safe and effective. The law requires manufacturers to provide adequate evidence that a medical device is safe and effective. The standard for implanted devices is not ‘Let the buyer beware.’ The current standard carries the affirmative requirement that products must be shown to be safe. This is not the opinion of an individual commissioner, as some would have it. It is the law. The requirement that products must be shown to be safe is the basis of the FDA’s consumer protection mission. It is the standard that governs what

we do.<sup>133</sup>

The Commissioner also intended these comments to combat any suggestion that he had personal or political reasons for acting against silicone implants. He asserted that the FDA did not oppose implants but simply wanted to get the correct information to fully discharge its obligations under the law.<sup>134</sup> Despite these efforts to calm the public, the moratorium and subsequent hearings before the FDA panel turned an already emotional atmosphere into an explosive one in which reasonable voices were difficult to discern.<sup>135</sup>

Following the announcement of the moratorium and the FDA’s decision to reconvene the advisory panel, manufacturers and plastic surgeons immediately made their voices heard. Representatives of Dow Corning vociferously called for a return to science in evaluating the safety of silicone implants. In a news conference held shortly after Commissioner Kessler’s announcement of a mora-

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<sup>132</sup> See *id.*

<sup>133</sup> *Id.*

<sup>134</sup> See *id.*

<sup>135</sup> See Bernstein, *supra* note 96, at \*474.

torium on the sale and use of silicone gel implants, Robert T. Rylee II, then Vice President of Dow Corning Wright's Health Care Businesses, emphasized Dow Corning's concerns regarding the process through which the implants came under review.<sup>136</sup> On behalf of Dow Corning, Rylee stated "[a] major concern is that the debate over the safety and efficacy of breast implants be taken out of the political arena and returned to a discussion of the true science that supports the safety of this important medical device."<sup>137</sup> This news conference demonstrated that, by January 1992, Dow Corning legitimately feared that the hysteria surrounding silicone breast implants would overshadow science and result in a biased evaluation of the product. Rylee further emphasized Dow Corning's willingness to release all of the requested documents to the FDA and claimed that the corporation had given the FDA full access to its internal memoranda since it was first requested in 1988. However, he qualified these remarks by asserting that these old memoranda did not address genuine scientific and safety issues.<sup>138</sup> Thus, Dow Corning tried to demonstrate a cooperative attitude when faced with the FDA's investigation of its product and tried to assert its interest in drawing attention back to the issues important to implant recipients. However, as the consumer groups and lawsuits had suggested, there was some evidence that the corporation had not revealed the true extent of its knowledge regarding the leakage and rupture rates of its implants. As noted in the New York Law Journal article, "Concealment of Critical Information," Dow Corning did not issue ad-

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<sup>136</sup>See FED. NEWS SERVICE, FURTHER DEVELOPMENTS CONCERNING BREAST IMPLANTS, EXCERPTS OF NEWS CONF. BY ROBERT T. RYLEE II, V.P. DOW CORNING WRIGHT HEALTH CARE BUSINESSES, Jan. 22, 1992.

<sup>137</sup>*Id.*

<sup>138</sup>See *id.*

visories against the massaging of silicone implants, a practice widely believed to reduce the formation of scar tissue but which also increased the likelihood that the implant would rupture, until 1992.<sup>139</sup> In addition, Dow Corning had conducted some animal studies, which revealed potential problems with its implants. As Sandra Blakeslee reported in the New York Times article, “Dow Found Silicone Danger in 1975 Study, Lawyers Say,” “[t]he study, had it been made public in 1975, could have prevented the marketing of silicone implants by being the first indication that an agent in silicone gel could harm cells of the immune system.”<sup>140</sup> The Dow Corning studies, at the very least, weighed in favor of the need for additional testing of silicone breast implants and revealed what little was actually known about their effects on the human body.<sup>141</sup> Moreover, adequate follow-up on the results of these early studies could have furthered the goal of informed consent much earlier on in the development of silicone implants. Instead, the emphasis placed on these documents by consumer groups and the litigation, whether warranted or not, left the corporation scrambling to justify its failure to take action regarding the documents at an earlier point in time. The ASPRS also had much to say between the time Commissioner Kessler first announced the moratorium on January 6, 1992 and the FDA’s next actions regarding silicone implants in April 1992. Dr. Norman Cole, then President of the ASPRS, expressed concern on behalf of the ASPRS about the progression

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<sup>139</sup>See Stuart A. Schlesinger, *Concealment of Critical Information*, N.Y.L. JOURN., Mar. 18, 1992, at 3.

<sup>140</sup>Sandra Blakeslee, *Dow Found Silicone Danger in 1975 Study, Lawyers Say*, N.Y. TIMES, Apr. 7, 1994, at A20.

<sup>141</sup>See *id.*

of events surrounding silicone implants.<sup>142</sup> He criticized the way in which the public got access to the information about implants and stated:

[f]or ten days, patients have been confused by bits and pieces of information that have leaked to the media. That's outrageous. The fact that I have to tell my patients that I can't tell you what your condition is because I haven't read the newspaper today. I have to get my information from the newspaper. That's my best source – bits and pieces of information that the agency seems able to leak to the press

and cannot provide to the physicians and to the patients.<sup>143</sup>

With this comment and sharp criticism of the FDA's review process regarding breast implants, Dr. Cole summed up a frustration shared by many implant recipients and undoubtedly by some doctors: the lack of authoritative information about the true risks associated with implants. The often-sensationalistic media coverage of the events in the breast implant saga made it quite difficult for women to discern the truth about their implants.

After conducting extensive hearings on the matter, the advisory panel recommended that the FDA severely limit access to silicone breast implants making them available only for mastectomy patients and potentially to a few women for breast augmentation studies.<sup>144</sup> All of these women would have to agree to participate in research studies. On April 16, 1992, Commissioner Kessler announced the FDA's decision to accept the advisory panel's recommendation, which essentially resulted in a ban on silicone implants.<sup>145</sup> The Commissioner announced

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<sup>142</sup>See FED. NEWS SERVICE, NEWS CONF. WITH NORMAN COLE, M.D., PRES. ASPRS, Jan 15, 1992.

<sup>143</sup>*Id.*

<sup>144</sup>See ANGELL, *supra* note 4, at 56-7.

<sup>145</sup>See *id.*

the decision in a press conference and stated that the decision to limit access to silicone implants reflected the existence of too many unanswered questions regarding their safety. Commissioner Kessler illustrated the lack safety information by quoting one member of the advisory panel who had stated “[w]e know more about the life span of automobile tires than we do about the longevity of breast implants.”<sup>146</sup> In particular, the FDA expressed concern about the varying data regarding rupture rates and about the composition of the gel that would leak into the body upon rupture. Commissioner Kessler cited the great discrepancy between the information provided by manufacturers which indicated a 2 to 1.1 percent rupture rate and that provided by certain medical studies which reported a four to six percent rupture rate as unacceptable.<sup>147</sup> He explained that the FDA could not approve the use of silicone breast implants without satisfactory answers to basic questions regarding their safety and that the FDA would pursue answers to those safety questions.<sup>148</sup>

In sum, the FDA lifted the total moratorium it had imposed on the use of silicone breast implants in January 1992 and allowed their use for two very limited cases: for those in urgent need and for use in long-term clinical studies.<sup>149</sup> The FDA developed three stages to facilitate the implementation of the April 1992 decision. Women in urgent need of the implants would have access to them first. This category included mastectomy patients who had already gone through the beginning stages of breast reconstruction surgery before the Jan-

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<sup>146</sup>FED. NEWS SERVICE, PRESS CONF. WITH FDA COMMISSIONER DAVID KESSLER, FDA DECISION ON AVAILABILITY OF BREAST IMPLANTS, Apr. 16, 1992.

<sup>147</sup>*See id.*

<sup>148</sup>*See id.*

<sup>149</sup>*See* VASEY AND FELDSTEIN, *supra* note 119, at 86.

uary 1992 moratorium. That is, they had already undergone surgery to receive a tissue expander in preparation for breast reconstruction. This group also included women who needed new silicone implants to replace implants that had ruptured. As a result of the total moratorium, these women had been forced to wait to continue their procedures.<sup>150</sup> The second stage of implementation of the April 1992 decision involved permitting access to silicone implants to certain women who would obtain the implants as part of a clinical study. This group included breast cancer patients, women who had suffered from a disease or trauma to the breast, and women with breast abnormalities resulting from congenital disorders. Strangely, the FDA, in these two categories, allowed women who were already sick either from breast cancer or from silicone leakage continued access to the implants.<sup>151</sup> The final stage of implementation of the FDA's decision involved allowing women who desired silicone implants either for cosmetic or for reconstructive purposes to obtain the implants as part of long-term research studies. The FDA hoped that these studies would provide a way to track silicone implant recipients and come to some definitive conclusions regarding their long-term safety.<sup>152</sup>

Thus, in April 1992, the FDA took long awaited action regarding silicone implants. The agency, as a matter of law, denied “pre-market approval applications for distribution and use of these devices for cosmetic purposes or for

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<sup>150</sup> *See id.*

<sup>151</sup> *See id.*

<sup>152</sup> *See id.* at 86-7.

augmentation of the healthy breast.”<sup>153</sup> As discussed above, it permitted the use of silicone implants in limited cases for reconstruction and for research studies “under the public health need extension of the application review period. . . .”<sup>154</sup> This exception allowed for the limited availability of a medical device to meet a public health need. The use of silicone implants for breast augmentation, which was permitted in the third stage of the implementation of the FDA’s decision, fell into the investigational device category contained in §215 of the FDCA.<sup>155</sup> Women obtaining silicone implants in this manner would have to enroll in an intensive approved research study.<sup>156</sup> Although the FDA likely hoped to put an end to the silicone gel implant issue with its decision, the litigation that had begun years before the FDA took any action would continue through the 1990s.

### III. The Litigation

Some important silicone implant cases such as *Stern* and *Hopkins* had already

come to trial before the FDA’s 1992 decision. However, after the FDA’s announcement in 1992 the number of cases filed against silicone breast implant manufacturers rose to enormous proportions. In the two years following the FDA’s decision, implant recipients filed more than 16,000 additional lawsuits against manufacturers.<sup>157</sup> As a result of the sheer number of lawsuits and the often large verdicts, the silicone breast implant litigation has amounted to one

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<sup>153</sup>FED. NEWS SERVICE, *supra* note 146.

<sup>154</sup>*Id.*

<sup>155</sup>*See* Federal Food, Drug, & Cosmetic Act 21 U.S.C. § 360j (1998).

<sup>156</sup>*See id.*

<sup>157</sup>*See* ANGELL, *supra* note 4, at 69.

of the most widely discussed and debated tort law issues in the U.S.

No discussion of silicone breast implants would be complete without a look at the litigation, although a comprehensive review of the litigation surrounding the silicone breast implant controversy is beyond the scope of this paper. However, because the early litigation played a role in drawing the attention of the FDA to the issue of silicone implants, the following sections discuss certain important aspects of the silicone breast implant litigation. The first section examines selected individual cases, and the second section examines the class action. The third section examines the litigation in light of past and recent scientific studies conducted to determine the safety of silicone implants.

## A.

### The Individual Lawsuits

#### 1. *Stern v. Dow Corning*

As briefly discussed earlier, Maria Stern won the first widely publicized favorable verdict for a silicone breast implant recipient in her lawsuit against Dow Corning.<sup>158</sup> John Byrne, author of Informed Consent, an account of a Dow Corning manager's personal experience with silicone implants, explains that the importance of the Stern verdict came as much from the publicity the case received as from the actual verdict itself.<sup>159</sup> Although other silicone implant recipients had sued Dow Corning before Maria Stern brought her case, the corporation had

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<sup>158</sup> See ANGELL, *supra* note 4, at 57.

<sup>159</sup> See JOHN A. BYRNE, *INFORMED CONSENT* 93 (McGraw-Hill 1996).



settled most of these cases without much publicity. In addition, the previous cases had alleged strict product liability claims and not that silicone implants caused systemic illnesses.<sup>160</sup>

Maria Stern, a mastectomy patient who had received silicone implants as part of a breast reconstruction procedure, was the first woman to allege that her implants had caused her to suffer from a disease of the autoimmune system. As Byrne elaborates in his book, “[s]hortly after the rupture of one of her implants, she began to suffer severe weight loss, hair loss, liver dysfunction, and swelling of her lymph nodes, as well as fatigue and weakness. Granulomas – noncancerous lumps or nodules of inflammatory cells – formed where silicone leaked into her body and combined with tissue.”<sup>161</sup> As a result of this leakage, silicone migrated to her thyroid gland, but once doctors removed the silicone from her body, her most severe symptoms lessened.<sup>162</sup> Stern, believing that the implants were the source of her problems, brought suit against Dow Corning, the manufacturer of her implants.

Her attorneys began preparing for trial and began the process of discovery. As mentioned earlier, it was during discovery for this case that the attorneys, specifically Dan Bolton who was still a law clerk at the time, came across internal memos that suggested that Dow Corning had some knowledge of problems with their silicone implants. These documents included letters from plastic surgeons reporting implant ruptures and adverse reactions by patients to the silicone that

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<sup>160</sup> *See id.*

<sup>161</sup> *Id.*

<sup>162</sup> *See id.* at 94.

leaked into the body when an implant ruptured.<sup>163</sup> In addition, the attorneys relied on documents, including those publicized in later years by Public Citizen, which relayed the results of studies on monkeys and dogs conducted by Dow Corning that suggested potential silicone leakage problems.<sup>164</sup>

Furthermore, Stern produced a pamphlet distributed by Dow Corning to potential breast implant patients entitled “Facts You Should Know About Your New Look.”<sup>165</sup> Although Dow Corning intended this pamphlet to inform patients about the particulars of silicone implant surgery, the corporation did not include in the pamphlet information about the possibility of silicone leakage, that the implants could rupture, or that some patients would experience enlarged lymph nodes, scar formation or inflammation as a result of leakage. It also omitted information about common side effects associated with silicone such as capsular contracture.<sup>166</sup> These omissions made it difficult for Dow Corning to rebut Stern’s claim that she had not agreed to the procedure in a situation of informed consent.

The jury found in favor of Stern and awarded her \$211,000 in compensatory damages and \$1.5 million in punitive damages.<sup>167</sup> They found that Dow Corning had sold a defective product, that the product had caused Stern harm, and that Dow Corning had knowingly sold a harmful product.<sup>168</sup> Dow Corning appealed, lost its first appeal, appealed again, and eventually settled the case

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<sup>163</sup> *See id* at 98.

<sup>164</sup> *See id* at 99.

<sup>165</sup> *See id* at 101.

<sup>166</sup> *See id*.

<sup>167</sup> *See id* at 105.

<sup>168</sup> *See id*; *see also* ANGELL, *supra* note 4, at 112.

before the second appeal was decided. As part of the settlement, information regarding the case was placed under seal, and expert witnesses who had testified in the case were forbidden from discussing the case.<sup>169</sup> Despite these measures, the Stern verdict already had done its damage. Not only did the documents eventually fall into the hands of consumer groups and the FDA advisory panel, but also implant recipients had seen that they could pursue successful and profitable lawsuits against the implant manufacturers.<sup>170</sup>

## **2. *Hopkins v. Dow Corning Corp.***

The next important silicone breast implant case was *Hopkins v. Dow Corning*

*Corp.* and was decided shortly after the November 1991 FDA advisory panel began its work.<sup>171</sup> As Angell explains “[i]n its own way, this case was even more influential than the Stern case, because it was instrumental in the FDA ban.”<sup>172</sup> Like Stern, Mariann Hopkins was a mastectomy patient who had had her breasts removed because she suffered from fibrocystic disease of the breast. She obtained silicone implants manufactured by Dow Corning as part of a breast reconstruction procedure, but one of her implants ruptured a short time after the surgery. Following the rupture, she had both implants replaced to ensure that her breasts would continue to be symmetrical. Three years after the second procedure Hopkins developed mixed connective tissue disease, an

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<sup>169</sup> See ZIMMERMAN, *supra* note 41, at 32.

<sup>170</sup> See ZIMMERMAN, *supra* note 41, at 33; *see also* ANGELL, *supra* note 4, at 111.

<sup>171</sup> See ZIMMERMAN, *supra* note 41, at 35; *see also* *Hopkins v. Dow Corning Corp.*, 33 F. 3d 1116, \*1118 (9<sup>th</sup> Cir. 1994).

<sup>172</sup> ANGELL, *supra* note 4, at 118.

incurable autoimmune disorder that often produces debilitating symptoms such as systemic lupus, rheumatoid arthritis, and scleroderma.<sup>173</sup> Despite efforts to treat her disease, her symptoms remained severe, and Hopkins gave up her job seven years after the initial diagnosis.<sup>174</sup>

That same year, one of Hopkins implants ruptured, and she had them both replaced for the second time. Around this time, Hopkins saw a television report on the dangers of silicone implants and began to think that her implants had caused her illness.<sup>175</sup> She contacted Dan Bolton, who had been instrumental in winning the Stern case, to initiate a lawsuit against Dow Corning. As the case went to trial, it became clear that Bolton again had a sympathetic plaintiff. She had received silicone implants for reconstructive rather than cosmetic purposes and obviously had suffered from her illness. However, even more so than in the Stern case, the link between her implants and her illness remained tenuous throughout the trial.<sup>176</sup> The plaintiff called many experts to testify to a connection between her implants and her illness, but as Angell notes “[n]one of Bolton’s witnesses was an epidemiologist. Yet this is the only kind of specialist who could actively speak to the issue of a possible link between breast implants and connective tissue disease.”<sup>177</sup> Furthermore, two of Hopkins personal doctors testified that she had exhibited some symptoms of her illness before she ever had breast implant surgery.<sup>178</sup>

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<sup>173</sup>See ANGELL, *supra* note 4, at 117-18.

<sup>174</sup>See ANGELL, *supra* note 4, at 118.

<sup>175</sup>See *Hopkins*, 33 F.3d at \*1118-19.

<sup>176</sup>See BYRNE, *supra* note 159, at 167; *see also* ANGELL, *supra* note 4, at 120-21.

<sup>177</sup>ANGELL, *supra* note 4, at 122.

<sup>178</sup>See BYRNE, *supra* note 159, at 169.

In fact, a later case also questioned the Hopkins decision. *Hall v. Baxter Healthcare Corp.*, 947 F. Supp. 1387, \*1414 (Dist. Ct. Or. 1996), involved the admissibility of expert testimony in a breast implant case against Baxter Healthcare.<sup>179</sup> The evidence in question included testimony as to the scientific link between silicone implants and systemic disease. In holding the evidence regarding causation inadmissible, the court distinguished *Hopkins* by stating that the Ninth Circuit in *Hopkins* had not adequately investigated the methodology relied on by the plaintiff's experts. Furthermore, the court in *Hall* questioned exactly how the experts in *Hopkins* had established a causal connection between the silicone implants and the plaintiff's symptoms.<sup>180</sup>

Despite the questionable link between Hopkins' symptoms and her silicone gel implants, the jury found Dow Corning guilty of fraud and malice and awarded her \$7.3 million.<sup>181</sup> Dow Corning appealed arguing that Hopkins' lawsuit was barred by the statute of limitations and that the testimony at trial had not demonstrated that it was more likely than not that Hopkins' implants had caused her illness. The corporation challenged the qualifications of the plaintiff's experts and asserted that their studies had not shown a causal connection to the necessary level of certainty.<sup>182</sup> Nevertheless, in an opinion delivered by Judge Proctor Hug on August 24, 1994, the Court of Appeals for the Ninth Circuit affirmed the jury's verdict. The court concluded that the statute of

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<sup>179</sup> See *Hall v. Baxter Healthcare Corp.*, 947 F. Supp. 1387, \*1414 n. 50 (Dist. Ct. Or. 1996).

<sup>180</sup> See *id.*

<sup>181</sup> See *Hopkins*, 33 F.3d. at \*1126.

<sup>182</sup> See ANGELL, *supra* note 4, at 124.

limitations did not bar Hopkins' case as it only began to toll after 1987 when she knew or should have known that she had been harmed by the implants and that Hopkins' experts had met the requirements established in *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579, 597-8 (1993) for giving an expert opinion.<sup>183</sup> The ninth circuit interpreted *Daubert* as requiring only that an expert base his testimony on scientific knowledge that could assist the factfinder and not necessarily on a generally accepted methodology.<sup>184</sup> However, as discussed above, later cases such as *Hall* became more likely to exclude scientific evidence by relying on *Daubert's* discussion of the court's gatekeeping role.<sup>185</sup> As for the evidence presented by Hopkins' experts, Circuit Judge Hug wrote:

[t]he evidence presented at trial established that a large number of Dow silicone gel breast implants had been implanted in thousands of women. Each of these women was at risk of encountering the same fate from which Hopkins suffered. Therefore, Dow's conduct in exposing thousands of women to a painful and debilitating disease, and the evidence that Dow gained financially from its conduct, may properly be considered in imposing an award of punitive damages. Moreover, given the facts that Dow was aware of possible defects in its implants, that Dow knew long-term studies of the implants' safety were needed, that Dow concealed this information as well as the negative results of the few short-term laboratory tests performed, and that Dow continued for several years to market its implants as safe despite this knowledge, a

substantial punitive damages award is justified.<sup>186</sup>

Thus, the court emphasized the Dow Corning internal documents and studies

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<sup>183</sup> See *Hopkins*, 33 F.3d at \*1123-25 (citing *Daubert v. Merrell Dow Pharmaceuticals*, 33 F.3d 1116 (1993)).

<sup>184</sup> See *id* at \*1124-25.

<sup>185</sup> See *Hall*, 947 F. Supp. at \*1414.

<sup>186</sup> *Hopkins*, 33 F. 3d at \*1127.

in its decision to uphold the jury verdict. Despite the scarcity of long-term studies and the uncertain application of Dow Corning's animal studies to the use of silicone implants in humans, Dow Corning again found itself defeated in a breast implant case. In fact, as Circuit Judge Hug's opinion indicates, Dow Corning seemed to lose almost as much based on the studies it had conducted as based on the studies it had failed to conduct. That is, the jury and the court of appeals seemed to fault Dow Corning for marketing (and profiting from) a product without first conducting adequate safety tests.<sup>187</sup> Dow Corning stopped making silicone implants shortly after the Hopkins verdict.<sup>188</sup>

### **3. *Johnson v. Bristol Myers Squibb Co.***

The FDA's April 1992 announcement of its decision to allow the use of silicone implants only in strictly limited cases did nothing to stem the litigation tide. In fact, one of the first silicone implant cases decided after the announcement resulted in a \$25 million award to Pamela Johnson. Johnson, unlike Stern and Hopkins, received silicone implants as part of a breast augmentation procedure. She had no problems with her implants until nearly 13 years after the procedure when she began to experience hardening of her breasts.<sup>189</sup> Johnson visited her plastic surgeon to find relief from the hardening, and her surgeon performed a closed capsulotomy to reduce the hardening of the breast. As discussed earlier, many surgeons performed this procedure to break up hard scar

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<sup>187</sup> See *id.*

<sup>188</sup> See ANGELL, *supra* note 4, at 123.

<sup>189</sup> See *id.* at 134 (discussing *Johnson v. Bristol Myers Squibb Co.*, No. 91-21770 (S.D.Tex. 1992)).

tissue that often formed around the implant, but the practice fell out of favor in the 1980s because it tended to cause the implant to rupture.<sup>190</sup> Johnson's implants ruptured shortly after her surgeon performed the closed capsulotomy, and she had to return to her surgeon to have the implants replaced. She eventually consulted another plastic surgeon because she did not like the appearance of her new implants. The second surgeon replaced the implants again, but a few years later Johnson had these implants removed as well.<sup>191</sup>

Johnson had sought to have the second set of implants removed after she began to suffer from fatigue and flu like symptoms. She brought suit against Medical Engineering Corporation, a subsidiary of Bristol-Myers Squibb, alleging that her implants had caused her illness.<sup>192</sup> However, no doctor had diagnosed Johnson with any specific immune or connective tissue disorder, making her case even more difficult to demonstrate than Hopkins' case.<sup>193</sup> In addition, she was a less sympathetic plaintiff because she had received her implants for cosmetic reasons instead of for breast reconstruction, she smoked, and her plastic surgeon had performed a procedure known to increase rupture rates.<sup>194</sup> However, despite her plastic surgeons error, the manufacturer was still the most appealing defendant. It was a large corporation with deep pockets and so could meet any verdict or settlement, and like Dow Corning, it had its own set of incriminating internal documents. The plaintiff used these documents to portray the manufacturer as

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<sup>190</sup> See *id* at 135.

<sup>191</sup> See *id*.

<sup>192</sup> See *id*.

<sup>193</sup> See *id* at 134.

<sup>194</sup> See Bernstein, *supra* note 96, at \*478.



a corporation interested only in profits no matter what the costs.<sup>195</sup>

Johnson’s attorneys also made some use of her assorted symptoms and essentially rested the case on the possibility that Johnson could become sick in the future. Her attorneys focused on “all the other women with breast implants” and “suggested that Johnson was somehow a proxy for all these other women, all of whom shared fears engendered by the implants. . . .”<sup>196</sup> That is, because of the great panic surrounding silicone breast implants, Johnson would have to live in fear of developing a serious disease. In addition, the attorneys subtly shifted the burden of proof to the defendants by emphasizing that neither MEC nor Bristol Myers Squibb had bothered to conduct adequate safety tests of their products.<sup>197</sup> As Bernstein explains, the plaintiff’s attorneys “repeatedly asked the jury to hold the MEC and its parent Bristol Myers Squibb liable unless they could prove that they knew that breast implants were safe when they marketed them.”<sup>198</sup> Thus, as in *Hopkins*, the corporation in *Johnson* had to combat the notion that it had failed to fulfill its duty to ensure its product’s safety even though the scientific evidence did not provide a strong foundation for the plaintiff’s claim. Unfortunately for MEC and Bristol Myers Squibb, the jury awarded Johnson \$25 million despite the limited scientific support for her claim.<sup>199</sup>

#### 4. *Dow Chemical v. Mahlum*

Breast implant plaintiffs have also sued Dow Corning’s parent company, Dow

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<sup>195</sup> See *id.*

<sup>196</sup> ANGELL, *supra* note 4, at 135.

<sup>197</sup> See Bernstein, *supra* note 96, at \*479.

<sup>198</sup> *Id.* at \*479.

<sup>199</sup> See *id.*

Chemical Corporation. As explained by Michelle Kohlmeier her article, “Malpractice & Negligence: Negligent Undertaking Liability for Silicone Testing – Dow Chemical Co. v. Mahlum,” Charlotte Mahlum underwent silicone implant surgery as part of a breast reconstruction procedure.<sup>200</sup> A few years after the surgery, her implants began to leak silicone into her body, and she began to experience symptoms of atypical autoimmune disease. Alleging that the silicone implants produced by Dow Corning had caused her illness, she filed suit against Dow Corning and Dow Chemical for fraud and negligence in connection with the manufacture of silicone gel breast implants.<sup>201</sup> She based her claim against Dow Chemical on the fact that, as Dow Corning’s parent, Dow Chemical owned 50% of the subsidiary and had conducted studies on silicone for its subsidiary for thirty years. Thus, although Dow Chemical had delegated the manufacture of the implants to its subsidiary, Mahlum felt that the parent still bore some of the responsibility for her injuries.<sup>202</sup>

The claims against Dow Corning were severed, and a Nevada jury found in favor of the plaintiff in her case against Dow Chemical. Dow Chemical appealed.<sup>203</sup> In late 1998, the Nevada Supreme Court upheld the jury’s verdict, which awarded the plaintiff \$38,654 for past damages and \$3,915,000 for future damages. However, it vacated the jury’s award of \$10,000,000 for punitive damages citing inadequate evidence to support the allegations of fraud.<sup>204</sup> The

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<sup>200</sup>See Michelle Kohlmeier, *Malpractice & Negligence: Negligent Undertaking Liability for Silicone Testing – Dow Chemical Co. v. Mahlum*, 25 AM J.L. & MED. \*180 (1999).

<sup>201</sup>See Dow Chemical Co. v. Mahlum, 970 P.2d 98, \*103 (Sup. Ct. Nev. 1998).

<sup>202</sup>See Kohlmeier, *supra* note 200, at \*180.

<sup>203</sup>See *Mahlum*, 970 P.2d at \*106, \*124.

<sup>204</sup>See *id.*

court reasoned that the plaintiffs needed to present evidence to demonstrate that Dow Corning was negligent or marketed unsafe products and then needed to show that Dow Chemical was liable as well.<sup>205</sup> Once it upheld the jury's verdict for the plaintiff on the negligence claims, the court also found that the jury had properly held Dow Chemical liable for Mahlum's injuries because the parent had negligently performed services it had agreed to provide and which were necessary for the protection of third parties. The parent and its subsidiary had exchanged significant information regarding the safety of breast implants, and Dow Chemical had accepted a duty to completely test the safety of silicone.<sup>206</sup> Moreover, Dow Chemical owned 50% of Dow Corning and held seats on the subsidiary's Board of Directors. Thus, the parent exerted a significant amount of control over its subsidiary and could have influenced the subsidiary's marketing of the implants.<sup>207</sup> This corporate structure led the court to find that the parent had an obligation to consumers to adequately test the implants and to ensure that its subsidiary behaved responsibly. Dow Chemical failed to fulfill its responsibility to test the implants and failed to exert its influence to prevent Dow Corning's marketing of a potentially unsafe product. Therefore, the jury properly held it liable for negligence in marketing an inadequately tested product.<sup>208</sup>

However, before holding Dow Chemical liable, the plaintiff needed to demonstrate that Dow Corning had negligently marketed an unsafe product and estab-

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<sup>205</sup> See *id.* at \*107.

<sup>206</sup> See Kohlmeier, *supra* note 200, at \*180.

<sup>207</sup> See *id.*

<sup>208</sup> See *id.*

lish causation between that product and her illness.<sup>209</sup> In fact, the discussion of causation in *Mahlum v. Dow Chemical*, 970 P.2d 98, \*106 (Sup. Ct. Nev. 1998), is even more interesting than the issue of the liability of the parent corporation because the court in *Mahlum* clearly elaborated the standard for causation in breast implant cases. The court noted that *Mahlum* had presented evidence demonstrating a chronology of events that seemed to indicate that her illness had started and worsened from the time she received her implants to the time the implants ruptured. There was also expert testimony on whether the implants caused the injuries. Based on this evidence, the jury concluded that *Mahlum* not have become ill was it not for her silicone breast implants.<sup>210</sup> The Nevada Supreme Court upheld this finding and found that the plaintiffs had adequately established causation. The court further noted that *Mahlum*'s case "was not tried in the court of scientific opinion, but before a jury of her peers who considered the evidence and concluded that Dow Corning silicone gel breast implants caused her injuries. The jury in this case was properly instructed to consider the proof by a preponderance of the evidence."<sup>211</sup> That is, the court emphasized that consensus in the scientific community regarding causation was not necessary for the jurors to reach an appropriate verdict.<sup>212</sup> This discussion of causation is important to understanding the breast implant cases because the court made explicit the level of evidence necessary for a breast implant plaintiff to prove causation and in this way addressed those critics of

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<sup>209</sup> See *Mahlum*, 970 P.2d at \*106, \*124.

<sup>210</sup> See *id.*

<sup>211</sup> *Id.* at \*109

<sup>212</sup> See *id.*

the breast implant litigation who had questioned the scientific basis of the verdicts. A plaintiff need not show to scientific certainty that the implants caused the illness to prevail in a claim against a breast implant manufacturer. Rather, “[s]cience may properly require a higher standard of proof before declaring the truth,” but that higher standard is not necessary for a jury to find in favor of a breast implant plaintiff.<sup>213</sup> The plaintiff demonstrated causation to the legal standard of a preponderance of the evidence, though not necessarily to the level of scientific certainty. In addition, Dow Corning and Dow Chemical should have foreseen that the silicone could injure women and failed to adequately test the product’s safety.<sup>214</sup>

## **B. The Class Action**

Faced with an overwhelming number of claims against them and enormous potential liability, Dow Corning, Bristol Myers Squibb, Baxter International, and Minnesota Mining and Manufacturing Company (3M), the four major silicone breast implant manufacturers, agreed to a consolidated settlement of the federal class action in 1994.<sup>215</sup> This settlement followed the 1992 certification of a class action lawsuit against the silicone implant manufacturers by the Judicial Panel on Multidistrict Litigation.<sup>216</sup> The class action proceeded under the supervision of Alabama federal judge Samuel Pointer, who promptly appointed a 17-member committee to negotiate a settlement between the manufacturers

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<sup>213</sup> See *id.* at \*109.

<sup>214</sup> See *id.*

<sup>215</sup> See Bernstein, *supra* note 96, at \*479-80.

<sup>216</sup> See ANGELL, *supra* note 4, at 79.

and the thousands of women alleging injuries resulting from their silicone implants.<sup>217</sup>

According to the 1994 agreement, the manufacturers agreed to set aside \$4.25 billion for the settlement of the claims of all women who had received silicone implants. Implant recipients could qualify to take part in the settlement if they currently had or developed symptoms of connective tissue disease within 30 years of implant surgery that appeared or worsened after implant surgery. The settlement required women claiming a current disease to provide medical documentation of their illness, either in the form of medical records or a doctor's diagnosis. Once a woman qualified for the settlement, the type of disease, its severity, and the woman's age at the onset of the disease would determine the amount of money she would receive. Breast implant recipients could also receive money for emotional distress and uninsured medical expenses arising from silicone implants. Finally, spouses and children born before April 1994 could make emotional distress claims to receive compensation under the settlement.<sup>218</sup>

However, the settlement agreement permitted women to opt out to pursue individual lawsuits and provided a lower amount of compensation for each claimant as more women joined the settlement.<sup>219</sup> As more and more women came forward to take part in the settlement, the amount of money guaranteed to each woman declined significantly. These two aspects of the agreement combined with the precedents for large individual verdicts led many women to opt out of the agreement and pursue individual actions against the manufacturers. Fur-

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<sup>217</sup> *See id.*

<sup>218</sup> *See id.* at 80-1.

<sup>219</sup> *See id.* at 82.

thermore, in 1995, a year after the announcement of the agreement, the manufacturers declared that they could not meet the agreement's financial requirements. The final event to cause the settlement to fall apart was Dow Corning's declaration of bankruptcy in 1995.<sup>220</sup>

Despite these setbacks, Bristol Myers Squibb, Baxter International, and 3M arrived at another settlement agreement toward the end of 1995. As explained by Apryl A. Ference in her article, "Rushing to Judgment on Fen-Phen and Redux: Were the FDA, Drug Manufacturers, and Doctors too Quick to Respond to Americans' Infatuation with a Cure-All Diet Pill," this agreement provided breast implant recipients with a much lower amount of compensation than the earlier agreement.<sup>221</sup> It also provided that they could receive a fixed amount based on their current symptoms or a greater amount if they waited to see if they developed symptoms in the future. The first group of women would receive between \$10,000 and \$100,000, and the second group could qualify for \$75,000 to \$250,000 depending on the severity of the disease they developed.<sup>222</sup> As a result of its bankruptcy proceedings, Dow Corning did not participate in this settlement; however, it also reached a settlement with the breast implant recipients through proceedings in bankruptcy court.

Dow Corning's settlement, announced in 1997, set aside \$2.4 billion for those suffering from silicone-induced illnesses. According to the agreement, Dow Corn-

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<sup>220</sup>See *id.* at 192.

<sup>221</sup>See Apryl A. Ference, *Rushing to Judgment on Fen-Phen and Redux: Were the FDA, Drug Manufacturers, and Doctors too Quick to Respond to Americans' Infatuation with a Cure-All Diet Pill for Weight Loss*, 9 ALB. L.J. SCI. & TECH. 77, \*98-9 (1998).

<sup>222</sup>See *id.*

ing would provide between \$650 and \$250,000 to compensate breast implant recipients based on the severity of their symptoms and would provide up to \$8,000 to compensate women for expenses associated with the removal of ruptured implants.<sup>223</sup> As reported in “The Washington Post,” the final agreement, approved in December 1999, provided \$3.2 billion for women claiming to suffer illnesses because of their silicone implants. The terms of the settlement allowed silicone implant recipients to receive compensation depending on the level of their injury.<sup>224</sup> Those suffering from lumping and scarring could collect \$30,000, and those with more severe symptoms could collect up to \$300,000. Women could still opt out of the settlement to sue Dow Corning individually; however, the terms of the agreement prohibited women who opted out of the settlement from receiving punitive damages from Dow Corning and from suing Dow Corning’s parent company. In addition, Dow Corning could demand a separate trial in the individual lawsuits to establish the scientific connections between the implants and the illnesses.<sup>225</sup> Thus, the final settlement reflected the uncertainty of the causal link between silicone implants and disease that plaintiffs’ attorneys had previously glossed over during individual lawsuits.

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<sup>223</sup> *See id.*

<sup>224</sup> *See Closing the Implants File*, WASH POST, Dec. 9, 1999, at A44.

<sup>225</sup> *See id.*



### C. A Look at the Scientific Studies of Silicone Implants

Although most studies conducted by both manufacturers and independent research groups have not found a significant connection between silicone implants and the most severe symptoms experienced by implant recipients, consumer groups and women's advocates continue to question the validity of these studies. As a result of this constant speculation about the results of the studies, it is difficult to discern which studies provide the most valid result, and it is unlikely that the public will ever clearly know the extent of the actual link between silicone implants and disease.

The first two major studies of the long-term effects of silicone implants on women's health published in 1994 and 1995 in the *New England Journal of Medicine* showed no link between the implants and disease.<sup>226</sup> As explained in the FDA Consumer, the study published in 1994 and conducted by the prestigious Mayo Clinic compared the health of 749 residents of Olmsted County, Minnesota with silicone implants with a comparable group of women without implants. The study published in 1995, known as the Harvard Nurses' Study, tracked the health of over 87,000 nurses, some without implants and some with implants, from 1976 through 1990. Although some of the participants in these studies did develop connective tissue diseases, the researchers concluded that there was not a significant connection between silicone implants and the diseases.<sup>227</sup>

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<sup>226</sup> See Law, *supra* note 88, at 48.

<sup>227</sup> See Marian Segal, *A Status Report on Breast Implant Safety* (visited Feb. 26, 2000) <[http://www.fda.gov/fdac/features/995\\_implants.html](http://www.fda.gov/fdac/features/995_implants.html)>.

Consumer advocates immediately criticized these studies as unreliable based on the number of participants in the study and the inclusion of women who had received their implants only a few years prior to participating in the study. They emphasized that many of the autoimmune symptoms would not even surface for eight to fifteen years after the insertion of the implants and that the studies should have allowed more time to elapse before following up on the participants. In addition, critics of the studies questioned their impartiality because they had relied on plastic surgeons for part of their funding.<sup>228</sup> Thus, despite initial scientific results that should have reassured women about their implants, immediate and well-publicized criticism of the studies served to eliminate any reassurance that the results may have generated.<sup>229</sup>

Subsequent studies conducted by SBI Laboratories and by a Harvard University

doctor in 1995 and 1996 respectively showed a small link between silicone implants and a distinct autoimmune profile. As reported in the PR Newswire, the SBI study followed 600 women and found that women with silicone implants exhibited a distinct autoimmune profile previously undetectable using traditional rheumatological tests.<sup>230</sup> The study used a new test called the “Detecsil” test to identify antibodies, which form in response to proteins developed by the human body in response to silicone exposure.<sup>231</sup> However, silicone implant manufac-

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<sup>228</sup> See Law, *supra* note 88, at 48.

<sup>229</sup> See *id.*

<sup>230</sup> See *SBI Laboratories: Silicone Breast Implants Cause Autoimmune Disease*, PR NEWswire, May 15, 1995.

<sup>231</sup> See *id.*

turers and supporters quickly emphasized problems with the accuracy of this study. Most of the criticism surrounding the study focused on the fact that Dr. Nir Kossovsky had funded the study and developed the test. Dr. Kossovsky had founded SBI to facilitate the development and use of the Detecsil test. In addition, he had advertised his test in lawyers' magazines as a way to diagnosis diseases caused by silicone. In fact, his test could identify certain antibodies but could not diagnosis silicone related illnesses. These misstatements caused the FDA to inform Dr. Kossovsky that he had failed to comply with federal regulations by misbranding his test.<sup>232</sup> Thus, questions about the reliability of the study ensured that its results did little to settle the issue of silicone's causation of disease.

Despite questionable early studies, later and more comprehensive studies provided more support for the manufacturers contention that there was no significant link between silicone implants and disease. First, in July 1998, The Lancet, one of the most prestigious British medical journals, reported the results of a study conducted by the UK Independent Review Group on Silicone Gel Breast Implants (IRG).<sup>233</sup> This study found no "epidemiological evidence of a link between silicone gel breast implants and abnormal immune responses or connective-tissue disease."<sup>234</sup> The IRG enumerated its findings in The Lancet and explained that:

silicone breast implants are not associated with any greater health risk than other surgical implants; if there is

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<sup>232</sup> See ANGELL, *supra* note 4, at 152.

<sup>233</sup> See Marie-Clare McMenemy, *UK Review Group Gives Silicone Implants All Clear*, THE LANCET, July 18, 1998.

<sup>234</sup> *Id.*

any risk of connective tissue disease it is too small to be quantified; further epidemiological studies are not justified; the incidence of ill health in women implanted with silicone gel is no greater than the general population; and children of these women are not at increased risk of connective-tissue

disease.<sup>235</sup>

These findings seemed to address many of the concerns expressed by the FDA about earlier studies. As the IRG explained in its report on silicone breast implants, it sorted through an enormous amount of old and new information and was made up of a group of experts chosen for their independence. It also addressed the issues of rupture and leakage.<sup>236</sup> Thus, the study was not open to many of the criticisms leveled at earlier studies. Moreover, its findings, when considered in light of the thousands of claims alleging that silicone implants had caused a variety of diseases, were quite startling.

The second major study of silicone implants was released less than a year after that of the IRG. As reported in the Mass Tort Litigation Reporter, in June 1999 the Institute of Medicine (IOM) released a study that revealed no connection between silicone breast implants and disease.<sup>237</sup> The IOM panelists had examined the claims of more than a thousand women and reviewed thousands of publications dealing with silicone implants before arriving their conclusion. In addition, the IOM report confirmed the results of the study conducted by the panel appointed by Judge Pointer during the multi-district settlement negotia-

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<sup>235</sup> *Id.*

<sup>236</sup> See *Silicone Gel Breast Implants*, THE REPORT OF THE INDEPENDENT REVIEW GROUP (July 1998) (The study's results are accessible on the internet at [www.silicone-review.gov.uk](http://www.silicone-review.gov.uk)).

<sup>237</sup> See *IOM is Bearer of More Bad News for Breast Implant Plaintiffs*, MASS TORT LIT. REP., at 6 (July 1999).

tions and the findings of the study conducted by the IRG's British scientists.<sup>238</sup>

Although the IOM is a branch of the National Academy of Sciences, which is the most prestigious scientific organization in the United States, consumer advocates still found fault with the results.<sup>239</sup>

In fact, it is possible to find fault with almost any study, and critics may be correct in asserting that the studies did not follow enough implant recipients to come to a totally certain conclusion. It is also possible to argue that despite the lack of scientific studies supporting their claims the plaintiffs in the silicone implant cases made an adequate case for holding the manufacturers at least partially liable for their injuries. The plaintiffs had provided some evidence to support their claims such as testimony from reputable doctors who had observed a correlation between illness and implants, testimony that the manufacturers had not adequately tested their products, and testimony that the manufacturers also intentionally concealed the fact that their implants could leak.<sup>240</sup> However, this evidence may not have warranted the amount of damages assessed to the defendants, and the verdicts certainly should not have been viewed as resting on studies that demonstrated causation to any *scientific* certainty. Moreover, later studies, despite being subject to criticism and despite the verdicts in the litigation, have at least shown that any potential correlation between silicone implants and the most severe symptoms claimed by implant recipients is not as common as the events of silicone implant controversy would suggest.<sup>241</sup> In fact,

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<sup>238</sup> See *id.*

<sup>239</sup> See *Institute of Medicine Report on Silicone Breast Implants Affirms Lack of Connection between Implants and Disease*, PR NEWswire, June 21, 1999.

<sup>240</sup> See Law, *supra* note 88, at 49.

<sup>241</sup> See McMenemy, *supra* note 233.

some more recent cases against breast implant manufacturers such as *Allison v. McGhan Medical Corp.*, 184 F.3d 1300, \*1315 (11<sup>th</sup> Cir. 1999), have relied on the results of these studies finding no causal link between silicone implants and systemic disease to exclude expert testimony seeking to demonstrate otherwise.<sup>242</sup>

#### IV.

##### **An Assessment of the Silicone Implant Regulation**

Throughout the silicone implant saga, the manufacturers and the plastic surgeons performing the breast implant surgery stood in a relatively similar position with respect to the women deciding to undergo the procedures. That is, they both had a direct financial interest in encouraging women to choose silicone breast augmentation surgery.<sup>243</sup> Although Dow Corning, and some of the other manufacturers had conducted limited testing of their product, they failed to follow up on those studies with larger studies of the effects of silicone implants as used in the human body.<sup>244</sup> The manufacturers may not have wanted to invest resources in further study, may have feared the results of further studies would force them to halt their manufacture of a very profitable product, or may have feared the studies would indicate a need for additional warnings to prospective patients and reduce the number of women choosing implants. Regardless of their motives for not conducting more tests on the safety of their

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<sup>242</sup> See *Allison v. McGhan Medical Corp.*, 184 F.3d 1300, \*1315 (11<sup>th</sup> Cir. 1999).

<sup>243</sup> See Spanbauer, *supra* note 35, \*191.

<sup>244</sup> See Bernstein, *supra* note 96, at \*485.

product, the fact remains that they profited immensely from the manufacture and sale of silicone breast implants for over thirty years and ignored some indications that further study of their product was needed. Moreover, there is some evidence that manufacturers, prior to 1992, did not indicate in their advertisements a complete list of the risks associated with silicone implants nor did they include a statement that they had not conducted long-term studies regarding the implants' safety.<sup>245</sup> As Spanbauer argues, "[a]t 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."<sup>246</sup> Thus, as argued by Rebecca Weisman in her article, "Reforms in Medical Device Regulation: An Examination of the Silicone Gel Breast Implant Debacle," the manufacturers played a large part in creating the illusion that breast augmentation procedures had few risks.<sup>247</sup>

Many plastic surgeons, also largely interested in the bottom line, did little to correct this illusion. As discussed earlier, the ASPRS, a group to which 90% of the plastic surgeons in America belong, conducted a costly publicity campaign to promote breast augmentation procedures and to suggest that an increase in breast size would also increase a woman's self-esteem.<sup>248</sup> Moreover, plastic surgeons also often occupy a fundamentally different position with respect to their patients than do other types of physicians. That is, the plastic surgeon's prof-

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<sup>245</sup> See Spanbauer, *supra* note 35, at \*193.

<sup>246</sup> *Id.*

<sup>247</sup> See Rebecca Weisman, *Reforms in Medical Device Regulation: An Examination of the Silicone Gel Breast Implant Debacle*, 23 GOLDEN GATE U.L. REV. 973, \*988.

<sup>248</sup> See Spanbauer, *supra* note 35, at \*182.

its depend largely on treating patients who have no real medical need for the surgeon's services. As a result of this relationship between the plastic surgeon and the patient, the surgeon's interests may not always coincide with the best interest of the patient. Unlike an internist or a cardiologist who must provide complete information so that a patient can choose between competing medical procedures, a plastic surgeon may not have an incentive to provide a patient with the worst case scenario as that information may cause the patient to decide against the procedure.<sup>249</sup> Furthermore, as Loane Skene explains, "many people seeking cosmetic surgery have such a picture 'in their mind's eye' of how they will appear after the surgery" and "this may override the caution of a 'reasonable person' in considering risks associated with the surgery."<sup>250</sup> Thus, although plastic surgeons may have needed to confront patients with the worst case scenario in order to ensure that the patient appreciated the true risks of the procedure, they did not necessarily have a financial interest in providing this information.<sup>251</sup> This is not to say that all plastic surgeons performing silicone breast implant surgery encouraged their patients to undergo a risky procedure without any concern for the patients' health. Moreover, the surgeons themselves may not have had complete information from the manufacturer regarding the risks of the silicone implants.<sup>252</sup> However, the nature of plastic surgery and the actions of the ASPRS do suggest that the plastic surgeons played a large role in selling women on the benefits of breast augmentation without including a

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<sup>249</sup> See *id* at \*194.

<sup>250</sup> See Skene, *supra* note 52, at \*2.

<sup>251</sup> See *id* at \*27.

<sup>252</sup> See VASEY AND FELDSTEIN, *supra* note 119, at 93.



corresponding emphasis on the risks.<sup>253</sup>

As the above discussions indicate, it is a matter of economic reality that in a competitive society concern for profits will play a critical role in determining corporate and individual behavior. For this reason, government regulatory agencies, in this case the FDA, play a critical role in ensuring that concern for profit does not overcome consumer safety. In the case of silicone implants, powerful forces such as manufacturers' interest in profits, physicians' disincentive to portray the worst case scenario, and the media's pervasive portrayal of an unrealistic body image combined to heighten the need for regulation.<sup>254</sup> Nevertheless, the FDA did not use the power given it under the Medical Device Amendments in 1976 to request safety information from the manufacturers of silicone implants for over ten years. Angell asserts that this lax regulation is evidence of the difficult balance the FDA must maintain between permitting choice and protecting consumers and questions the rationality of the FDA's 1992 decision to strictly limit the use of silicone implants.<sup>255</sup> She argues that the FDA primarily exists to fill in the information gap between consumers and manufacturers so that the consumer is in a better position to make a choice. As the FDA did not know much more about the risks of silicone implants than did consumers, Angell questions the basis of the FDA's 1992 decision. She explains the decision as based on the judgement that the FDA should tolerate very little risk in products where the benefits are merely cosmetic and asserts that "[i]n

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<sup>253</sup> See Spanbauer, *supra* note 32, at \*182.

<sup>254</sup> See Weisman, *supra* note 247, at \*987.

<sup>255</sup> See ANGELL, *supra* note 4, at 62-4.

waving aside the benefits of breast implants for most women who had them, Kessler seemed to be introducing an impossible high standard for the devices: since there were no benefits, there should be no risks.”<sup>256</sup>

However, the FDA’s 1992 decision is open to another interpretation, one advanced by Commissioner Kessler in his April 1992 press conference. That is the interpretation that the FDA’s regulation of silicone implants would draw out much needed information about their effects on the body. Even if the evidence linking silicone implants to the more serious diseases alleged by the implant recipients was weak, there was still a substantial lack of information regarding rupture rates, leakage, and the less chronic effects of silicone when released into the body.<sup>257</sup> Studies were necessary to answer these questions, and at the time of the 1992 decision, more studies regarding the correlation between systemic diseases and silicone implants were still needed. Thus, although the FDA did not have much more information than consumers did on which to base its decision, it was in the best position to ensure that more information came to light. After all, the 1976 Medical Device Amendments required manufacturers to provide evidence of the safety of their products so that the FDA could properly evaluate that product. These amendments responded to serious concerns regarding the safety of medical devices, and the FDA simply fulfilled its role as a consumer protection agency by limiting access to silicone implants until manufacturers complied with the information requirement. Any fault assessed to the FDA should be that it waited too long before taking action with regard

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<sup>256</sup> *Id* at 63.

<sup>257</sup> *See* FED. NEWS SERVICE, *supra* note 146.

to a medical device used by millions of women. As a result of the delay, the FDA's decision seemed more like a response to popular pressure than a result of a desire to properly carry out its mandate under the MDA.

## V.

### Lessons for the Future

As the above analysis of the silicone implant controversy reveals, the interaction

of three groups largely controlled the direction of the debate leading to regulation: those responsible for promoting the devices (manufacturers and plastic surgeons), the tort system and the FDA. All three groups can learn lessons from the silicone implant story.

The IRG, in its report on silicone gel breast implants, made sensible suggestions to counteract the possibly biased influences of those promoting breast implants. As summarized in The Lancet, the IRG suggested providing all patients undergoing cosmetic breast surgery with full access to information detailing the benefits and risks of surgery and having a waiting period between consultation and operation.<sup>258</sup> A group designated to providing this information would do so free of charge, and all advertisements encouraging breast augmentation would direct women to this group to obtain more information. However, manufacturers would not be permitted to contact women considering implant surgery

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<sup>258</sup>See McMenemy, *supra* note 233.

directly.<sup>259</sup> Moreover, plastic surgeons would provide women considering breast augmentation surgery with an opportunity to fully discuss the risks of the procedure and the financial implications of any future procedures that may be necessary. They would also refund any deposits if the potential implant recipient had a change of heart.<sup>260</sup> To ensure that the plastic surgeons provided the women with full information, a woman deciding to undergo breast augmentation would have to sign a consent form certifying that the surgeon has addressed all of her concerns. In addition, the private plastic surgeons would have to adhere to proper standards of care for follow up procedures and report all adverse effects associated with the implants to the appropriate agency. A national breast implant registry would keep track of breast implant procedures and a steering group would be established to monitor further research in the area.<sup>261</sup>

Some of these suggestions such as the national registry and the use of consent forms have already been implemented. The suggestions generally would require that manufacturers and physicians take some responsibility for ensuring that the woman considering the implant procedure appreciates the seriousness of her decision and is not swayed by other forces into thinking that cosmetic surgery is a low-risk procedure. In this way, they address the concerns of some commentators that women may develop an idealized vision of what the procedure will accomplish for their appearance and may not fully weigh the associated risks unless presented with a worst case scenario.<sup>262</sup> However, given the number of

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<sup>259</sup> See IRG REPORT, *supra* note 236.

<sup>260</sup> See *id.*

<sup>261</sup> See *id.*

<sup>262</sup> See Skene, *supra* note 52, at \*27.

surgeons performing cosmetic surgery and the number of breast augmentation procedures performed each year, it may be difficult to enforce some of these requirements, particularly the monitoring of information conveyed in office consultations. It seems that plastic surgeons would have to be convinced that following these suggestions would benefit them individually in order to reach a high level of compliance.

The precedent for enormous jury verdicts established by some of the breast implant cases has demonstrated the power of the tort system to compel behavior from otherwise non-compliant actors. As profits likely drove manufacturers and plastic surgeons to behave in a less than prudent way when it came to selling implant surgery, the threat of large monetary liability is also a way to encourage responsible corporate and individual behavior. Some commentators, such as Angell, have strongly criticized the breast implant verdicts as not founded on science. They suggest various reforms such as expanded use of court appointed experts and scientific panels to help courts decide the issue of causation.<sup>263</sup> However, although at the time of many of the breast implant trials the scientific evidence supporting the plaintiffs was weak, there was stronger evidence that manufacturers had not done what they should have to investigate the safety of their product. In addition, as the Nevada Supreme Court explained in *Mahlum*, the legal standard applicable to the breast implant cases required only a preponderance of the evidence and not a showing of causation to a scientific cer-

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<sup>263</sup>See Law, *supra* note 88, at 73.

tainty.<sup>264</sup> In fact, it may not be wise to require such a high burden of plaintiffs who bring claims such as those brought by the breast implant recipients. A requirement of scientific certainty would impose an incredibly high standard on plaintiffs who might not have the resources to pursue such claims. Such a high standard would likely greatly reduce an important role of the tort system – deterrence. That is, regardless of the standard required to establish causation, the lesson manufacturers can take away from the breast implant story is that even if they escape regulation, the tort system is an equally important deterrent to corporate misbehavior.<sup>265</sup>

Perhaps the largest lesson revealed by the breast implant story is that the FDA plays a vital role in assuring public safety and responsible corporate behavior. This lesson is particularly important in light of the sharp criticisms that followed the breast implant decision. These criticisms included fears that, in the wake of the breast implant debacle, companies, fearing immense liability, would cease to create new products. For example, the Chicago Tribune reported on March 13, 1995 that “[t]he safety debate over breast implants has spawned a legal controversy that could derail new medical advances and lead to a shortage of medical implants of all types, including pacemakers, heart valves, and plastic shunts used to drain fluids from the brain.”<sup>266</sup> A similar article in the Los Angeles Times reported, on October 25, 1995, that “[s]ooner than we imagine, the supply of silicone for such medical devices – and for heart pace-

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<sup>264</sup> See *Mahlum*, 970 P.2d at \*109.

<sup>265</sup> See Law, *supra* note 88, at 53.

<sup>266</sup> Trisha Gura, *Implant Debate to Cripple Innovation; Liability Fears May Impede Testing, Limit Supplies*, CHI. TRIB., Mar. 13, 1995, at 1.

makers, intraocular lenses, artificial fingers and wrist joints and implantable drug-delivery pumps – may be severely threatened.”<sup>267</sup> On the other hand, a New York Times article blamed increased FDA caution in approving new drugs and devices in the wake of debacles such as the breast implant controversy for the movement of biomedical firms abroad.<sup>268</sup> Thus, these articles clearly demonstrate the FDA’s difficult task of promoting safety without overly deterring innovation or limiting choice. Moreover, the FDA, as administrative agency may be slow to respond to new public health problems, has limited staff to monitor a large amount of products, has a limited budget, and largely depends on the manufacturers to provide the necessary safety information.<sup>269</sup>

Nevertheless, the final responsibility for regulation in the area of medical devices should remain with the FDA, and some changes could improve FDA’s regulation in this area. As Larry R. Pilot and Daniel R. Waldmann note in their article, “Food and Drug Administration Modernization Act of 1997: Medical Device Provisions,” expanded use of a third party review system to evaluate the effectiveness of devices could improve efficiency.<sup>270</sup> This type of review system, used successfully by European Union countries for some time, calls on accredited third party experts to review pre-market review applications and to certify compliance with quality regulations. Proper use of this system could free up

<sup>267</sup>Katherine Dowling, *A Class Action Nightmare; Wide-Ranging Suits Against Manufacturers May Keep Lifesaving Medical Devices on the Shelf and Out of Reach*, L.A. TIMES, Oct. 25, 1995, at 9.

<sup>268</sup>See Lawrence M. Fisher, *Frustration for Medical Innovators*, N.Y. TIMES, June 30, 1993, at D1.

<sup>269</sup>See Bernstein, *supra* note 96, at \*507.

<sup>270</sup>See Larry R. Pilot and Daniel R. Waldmann, *Food and Drug Administration Modernization Act of 1997: Medical Device Provisions*, 53 FOOD DRUG COSM. L.J. 267, \*272-3 (1998).

FDA resources to deal with more serious safety issues without sacrificing consumer health.<sup>271</sup> In addition, in the case of medical device and drug regulation, those prescribing the devices and drugs, must also take more responsibility for ensuring that manufacturers adequately test their products. As suggested by Rebecca Dresser, Wendy Wagner, and Paul Giannelli in their article, “Breast Implants Revisited: Beyond Science on Trial,” especially in the case of elective procedures such as cosmetic surgery, the medical community must not permit concern for profits to overshadow concern for the patient.<sup>272</sup> Thus, while the final checkpoint for product safety should rest with the FDA, ideally the agency should not have to prod manufacturers into conducting adequate safety tests of their products.

## **VI. Conclusion**

An article published in the Houston Chronicle on December 5, 1999 reported that

silicone implants may soon return to the market. Both Mentor Corporation and McGhan Medical Corporation have expressed confidence that the FDA will soon lift its limitation on the use of silicone implants, and McGhan’s CEO has projected that silicone implant sales will quickly rise to overtake sales of saline implants. The article further reported that McGhan will have submitted all the

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<sup>271</sup> See *id.* at \*273.

<sup>272</sup> See Rebecca S. Dresser et. al., *Breast Implants Revisited: Beyond Science on Trial*, 1997 Wis. L. REV. 705, \*772 (1997).



necessary safety information to the FDA by 2002.<sup>273</sup> Considering the extent of the silicone implant debacle of the late 1980s and early 1990s, it is amazing to think that silicone implants could again become popular. Hopefully, these new silicone implants will not suffer the same fate as their predecessors.

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<sup>273</sup>See Eric Rosenberg, *Silicone Breast Implants May be Back on the Market Soon*, HOUS. CHRON., Dec. 5, 1999, at 25.