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## The Silicone Gel-Filled Breast Implant Controversy: Testing the Bounds of Regulatory Intervention

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# **The Silicone Gel-Filled Breast Implant Controversy: Testing the Bounds of Regulatory Intervention**

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## Abstract

Silicone gel-filled breast implants were first introduced in the United States in the 1960s and immediately gained popularity among women seeking to augment or reconstruct their breasts. However, although the Food and Drug Administration (FDA) had the authority to regulate medical devices since the 1970s, breast implants were largely unregulated until concerns about a link between the devices and connective tissue diseases surfaced in the early 1980s. In the subsequent years, thousands of plaintiffs prevailed against implant manufacturers, leading to the bankruptcy of Dow Corning and a multi-million dollar class settlement. Ultimately, the controversy resulted in a FDA ban on silicone breast implants in 1992 that still survives today.

This paper examines the silicone breast implant controversy from the inception of silicone devices to the current regulatory status of breast implants in the United States. Part I describes the early uses of silicone and the introduction of silicone gel-filled breast implants in the United States. Part II examines the regulatory framework for medical devices that ultimately gave the FDA the authority to ban silicone breast implants. Part III depicts the responses to the FDA's decision from both proponents and opponents of the use of breast implants. Parts IV and V present the scientific research concerning the safety of the devices. Finally, Part VI examines the current developments regarding silicone implants, and Part VII provides some conclusions for the future.

## I.

### Introduction

One need only turn on a television set to see numerous images of the “ideal” female body. Until recently these images were just that – images of an ideal that was presumably obtained through genetics or celebrity wealth that was outside the grasp of the average woman. Television is changing, however, and at the forefront of this change is a new batch of reality makeover shows. Unlike the “old” makeover shows that changed an individual's hair, makeup and clothing to provide a new look or image, these shows are taking makeovers to extreme lengths. Instead of providing a trip to the local boutique and beauty parlor, the shows offer both men and women the chance to meet with the country's premier plastic surgeons to create a whole new body. And included in almost every woman's “makeover” experience is a breast augmentation procedure.

The American Society of Plastic Surgeons (ASPS) expressed concern recently that these reality programs may create unrealistic patient expectations.<sup>1</sup> Rod Rohrich, MD, ASPS president, noted that “some patients on these shows have unrealistic and, frankly, unhealthy expectations about what plastic surgery can do for them.”<sup>2</sup> It is not surprising that many individuals have unrealistic expectations regarding plastic surgery given the way that the shows describe the potential for physical change. On the *Extreme Makeover* website, the show purports to provide “a real life fairy tale in which [the show’s participants’] wishes come true, not just to change their looks, but their lives and destinies.”<sup>3</sup> Similarly, on the website for *The Swan*, a show in which sixteen women are given extensive plastic surgery so that they may ultimately compete in a beauty pageant, the website authors describe the show as offering “women the incredible opportunity to undergo physical, mental and emotional transformations with the help of a team of experts.”<sup>4</sup>

The popularity of these new shows is not surprising. Although the emergence of “reality” television shows offering cosmetic surgery is a recent phenomenon, the surgery itself (and the desire to change one’s appearance) has been around for decades. Many women have had breast implant surgery since silicone gel-filled breast implants were first introduced. Early reports estimated that at least 50,000 women received implants between 1962 and 1970, and, by 1992, the number had increased to approximately 150,000 women annually.<sup>5</sup> Recent estimates indicate that approximately 1-2 million women have had silicone gel-filled breast implants.<sup>6</sup> Moreover, despite the Food and Drug Administration’s (FDA) 1992 ban on silicone breast implants, breast

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<sup>1</sup>American Society of Plastic Surgeons, *New Reality TV Programs Create Unhealthy, Unrealistic Expectations of Plastic Surgery*, at [http://www.plasticsurgery.org/news\\_room/press\\_releases/New-Reality-TV-Programs-Create-Unhealthy-Unrealistic-Expectations](http://www.plasticsurgery.org/news_room/press_releases/New-Reality-TV-Programs-Create-Unhealthy-Unrealistic-Expectations) (March 30, 2004).

<sup>2</sup>*Id.*

<sup>3</sup>ABC Television, *Extreme Makeover*, show website, at <http://abc.go.com/primetime/extrememakeover/show.html> (last visited April 22, 2004).

<sup>4</sup>Fox Broadcasting Company, *The Swan*, show website, at <http://www.fox.com/swan/home.htm> (last visited April 22, 2004).

<sup>5</sup>Institute of Medicine Committee on the Safety of Silicone Breast Implants, *Safety of Silicone Breast Implants* 31 (Stuart Bondurant, Virginia Ernster & Roger Herdman eds., 1999) [hereinafter *Institute of Medicine*]; Marcia Angell, *Breast Implants—Protection or Paternalism?*, 326 *NEW ENG. J. MED.*, 1695-96 (June 18, 1992).

<sup>6</sup>Jack W. Snyder, *Silicone Breast Implants*, 18 *J. LEGAL MED.* 133, 133 (June 1997).

augmentation was still the third most common cosmetic operation in the US in [1994].<sup>7</sup> Members of the American Society of Plastic Surgeons performed 225,818 breast augmentation surgeries in 2002, compared with 37,607 in 1992.<sup>8</sup>

The majority of women who choose to undergo breast implant surgery do so for augmentation reasons. Some reports indicate that 34% of U.S. women are dissatisfied with their breasts, and more than half of breast augmentation patients reported having frequently checked the appearance of their breasts and camouflaging them.<sup>9</sup> When Dow Corning first introduced silicone breast implants to the US market in the 1960s, 98% of women who underwent breast implant surgery did so to increase the size of their breasts.<sup>10</sup> Recent studies report that approximately 70% of implants are placed for augmentation purposes.<sup>11</sup>

Although the majority of women obtain implants for breast augmentation, the number of women who receive implants for breast reconstruction is increasing. The number of women who received implants after mastectomy, which had previously been low and stable, began to increase in 1975 and continued to increase over the next two decades.<sup>12</sup> In 1983, 3% of women received breast implants for reconstruction after undergoing a mastectomy; by 1992, more than 25% received those implants.<sup>13</sup> Reconstruction after mastectomy for cancer, fibrocystic disease, or other reasons is believed to provide a sense of having overcome disease and may relieve or prevent a perception of loss, dissatisfaction, depression, and feelings of diminished sexual attractiveness.<sup>14</sup>

As the above statistics indicate, breast implant surgery is prevalent in this country for both augmentation

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<sup>7</sup>Marcia Angell, M.D., *Science on Trial: The Clash of Medical Evidence and the Law in the Breast Implant Case* 34 (W.W. Norton & Co. 1997) (1996).

<sup>8</sup>Anna Wilde Mathews, *A Second Chance for Silicone Implants: FDA Panel Recommends Approval for Cosmetic Breast Surgery, But Some Doctors Are Cautious*, WALL ST. J., Oct. 16, 2003, at D1.

<sup>9</sup>Institute of Medicine, *supra* note 5, at 20.

<sup>10</sup>*Id.* at 31.

<sup>11</sup>*Id.* at 32.

<sup>12</sup>Institute of Medicine, *supra* note 5, at 31.

<sup>13</sup>*Id.* at 31-32.

<sup>14</sup>*Id.* at 20.

and reconstruction patients. As a result, when the FDA imposed a ban on the marketing and manufacture of silicone gel-filled breast implants in 1992, its decision alarmed substantial numbers of potential and current implant recipients and added to growing wave of concern regarding the safety of breast implants. Although implants had been on the market for close to forty years by the time of the FDA's decision, very little regulatory action had been taken to require safety and efficacy data from implant manufacturers. Given the popularity of the procedure, it is not surprising that the FDA's ban on silicone gel-filled breast implants in 1992 created a strong reaction in both the regulatory and legal spheres. However, few could predict that the ban would result in Dow Corning's bankruptcy in 1995, several multi-million dollar settlement plans with implant manufacturers, thousands of product liability suits, and a moratorium on silicone breast implants that continues today.

## A.

### Early Uses of Silicone

Since the late 1800s, individuals have injected or implanted foreign substances into a woman's body to augment or reconstruct her breasts.<sup>15</sup> The first recorded breast augmentation procedure occurred in Germany in 1895 and involved the removal of fat from a non-cancerous tumor that was subsequently surgically re-inserted into a woman's breasts.<sup>16</sup> Experimentation with paraffin injections began in 1889 and in the early to mid-1900s, "surgeons" tried injecting a woman's breasts with a variety of other substances, including

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<sup>15</sup>Institute of Medicine, *supra* note 5, at 21.

<sup>16</sup>Julie M. Spanbauer, *Breast Implants as Beauty Ritual: Woman's Sceptre and Prison*, 9 YALE J.L. & FEMINISM 157, 172 (1997).

ivory, glass balls, ground rubber, and ox cartilage.<sup>17</sup> These early implants were unsuccessful, however, and were not pursued seriously.<sup>18</sup>

In the 1930s, scientists developed silicone, a synthetic polymer consisting of silicon, oxygen and carbon side chains.<sup>19</sup> The material remained inert after being placed in the body and patients easily tolerated the substance.<sup>20</sup> Further, silicone did not degrade after insertion into the human body and demonstrated a resistance to bacterial contamination.<sup>21</sup> Given these properties, surgeons recognized the potential uses of silicone in medical procedures and devices.<sup>22</sup> The FDA approved the injection of medical-grade silicone for soft-tissue (excluding breast) augmentation for experimental use in the United States under an FDA investigational new drug (IND) ten-year exemption for Dow Corning in 1965.<sup>23</sup> Although the FDA has never approved the marketing of liquid silicone injections for any cosmetic purpose, currently over 500 medical products contain measurable amounts of silicone (including facial implants, coating for needles and plastic syringes, and methods for the intravenous, intraarterial and gastrointestinal administration of nutrients or drugs).<sup>24</sup>

Despite the lack of FDA approval, however, doctors experimented with liquid silicone injections for breast augmentation. The first reported attempt occurred during World War II, when Japanese prostitutes injected silicone directly into their breast tissue in an attempt to satisfy American servicemen stationed in Japan.<sup>25</sup>

The silicone, however, often contained contaminants that generated a severe inflammatory reaction and in-

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<sup>17</sup>Institute of Medicine, *supra* note 5, at 21.

<sup>18</sup>*Id.*

<sup>19</sup>Debra L. Worthington, Merrie Jo Stallard & Joseph M. Price, *Clearing Away the Junk: Court-Appointed Experts, Scientifically Marginal Evidence, and the Silicone Breast Implant Litigation*, 56 FOOD & DRUG L.J. 227, 234 (2001); Snyder, *supra* note 6, at 135.

<sup>20</sup>Angell, *supra* note 7, at 36.

<sup>21</sup>*Id.*

<sup>22</sup>*Id.*

<sup>23</sup>Institute of Medicine, *supra* note 5, at 22.

<sup>24</sup>*Id.* at 23.

<sup>25</sup>Angell, *supra* note 7, at 36.



fected both the breast tissue and the surrounding tissues to which the gel migrated after injection.<sup>26</sup> The individuals who performed the procedure often used contaminated needles, further increasing the woman's risk of infection.<sup>27</sup> Furthermore, it became common practice to add irritants like olive oil to the silicone injection to minimize silicone migration to surrounding soft tissue areas.<sup>28</sup> Although the irritant localized the silicone in the breast by creating more scar tissue, the scarring could become severe enough to create painful tumor-like lumps around the breast.<sup>29</sup> The injection also handicapped breast cancer detection because injected breasts are full of lumpy silicone deposits that interfere with physical examination and mammography exams.<sup>30</sup> In spite of these problems, however, the use of silicone injections increased in popularity and by the 1960s had spread to the United States.<sup>31</sup>

## B.

### Introduction of Silicone Implants

Although early uses of silicone injections clearly generated significant safety concerns, scientists and doctors continued to experiment with new methods of silicone breast augmentation. In 1962, Dr. Fram Gerow and Dr. Thomas Cronin developed silicone gel-filled breast implants for Dow Corning.<sup>32</sup> The company marketed the implant, which consisted of a silicone envelope containing silicone gel, as an improvement over silicone injections because the envelope supposedly minimized inflammatory responses and reduced gel migration.<sup>33</sup>

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<sup>26</sup> *Id.* at 38.

<sup>27</sup> *Id.* at 36.

<sup>28</sup> *Id.* at 38.

<sup>29</sup> *Id.*

<sup>30</sup> Institute of Medicine, *supra* note 5, at 23.

<sup>31</sup> Angell, *supra* note 7, at 36.

<sup>32</sup> Snyder, *supra* note 6, at 136.

<sup>33</sup> Angell, *supra* note 7, at 39.

The most recent silicone gel-filled breast implants have the same basic design as those introduced in the 1960s: a silicone rubber shell made of polysiloxane(s), such as polydimethylsiloxane and polydiphenylsiloxane, which is filled with a fixed amount of silicone gel.<sup>34</sup>

After the introduction of silicone gel-filled breast implants in the 1960s, silicone became the dominant implant filler for the next thirty years. Prior to the FDA's ban on silicone gel-filled implants in 1992, approximately 97% of women who underwent breast implant surgery chose to have silicone gel-filled implants.<sup>35</sup> Although manufacturers began to offer saline-filled breast implants as an alternative to silicone, the majority of women still preferred the silicone gel models. In addition to the relatively unnatural consistency of single-envelope saline implants, saline implants sometimes spontaneously emptied after surgery.<sup>36</sup> Moreover, unlike pre-filled silicone gel implants, the majority of saline implants are not pre-filled and have the potential to be either over-filled (and therefore too hard) or under-filled (and therefore crumple and cause wrinkles in the skin).<sup>37</sup> Thus, in countries where silicone implants have wider approval, manufacturers report that more than 90% of patients choose them over saline versions.<sup>38</sup>

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<sup>34</sup>Food and Drug Administration, *Guidance for Saline, Silicone Gel, and Alternative Breast Implants: Guidance for Industry and FDA*, 4 (Feb. 11, 2003) at <http://www.fda.gov/cdrh/ode/guidance/1354.html> [hereinafter FDA Guidance].

<sup>35</sup>Angell, *supra* note 7, at 44.

<sup>36</sup>Angell, *supra* note 7, at 44.

<sup>37</sup>*Id.* A saline-filled breast implant has a silicone rubber shell made of polysiloxane(s), such as polydimethylsiloxane and polydiphenylsiloxane, which is inflated to the desired size with sterile isotonic saline. There are three types of saline-filled breast implants. Type one is a fixed volume implant that is intraoperatively filled with the entire volume of saline via a valve. Type two is an adjustable volume implant that is intraoperatively filled with saline via a valve and has the potential for further postoperative adjustment of the saline. Type three is a pre-filled saline implant. FDA Guidance, *supra* note 34, at 3-4.

<sup>38</sup>Mathews, *supra* note 8.

## II.

### Regulation of Medical Devices

Although silicone gel-filled breast implants were introduced into the US market in the early 1960s, the FDA did not have a statutory basis to regulate silicone breast (or other) implants until Congress enacted the 1976 Medical Device Amendments (the 1976 Amendments) to the 1938 Food, Drug and Cosmetics Act (the 1938 Act).<sup>39</sup> Under the 1906 Federal Food and Drugs Act, Congress only granted the FDA authority to regulate food and drugs. The agency did not obtain jurisdiction over medical devices until 1938, and, because it only received limited authority over devices, the agency did not devote much resources to device regulation.<sup>40</sup>

Consequently, the FDA did not seriously begin to regulate medical devices until the 1976 Amendments to the 1938 Act. As a result, medical devices went virtually unregulated for close to forty years after Congress vested the FDA with the authority to regulate medical devices. It is therefore necessary to examine the silicone breast implant controversy within this regulatory context in order to better understand the FDA's delay in responding to concerns regarding silicone implants, and the corresponding litigation that emerged with the implants on the market.

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<sup>39</sup>21 U.S.C. §360(c) (1996).

<sup>40</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).

## A.

### 1976 Medical Device Amendments

Congress first granted the FDA authority over the regulation of medical devices under the 1938 Act. The 1938 Act, however, only provided the FDA with very limited regulatory power and the agency was restricted to monitoring adulterated and misbranded medical devices.<sup>41</sup> The 1938 Act did not authorize the FDA to require that a manufacturer demonstrate either the safety or the effectiveness of its devices.<sup>42</sup>

By the 1970s, increasingly complex medical devices began to dominate the market, and it became apparent to regulators, health care professionals and manufacturers that the existing framework for regulating medical devices was inadequate.<sup>43</sup> In 1976, in response to these growing concerns, Congress amended the 1938 Act to provide the FDA with greater authority to regulate the safety of medical devices. The 1938 Act, as further amended by the Safe Medical Device Act (SMDA) of 1990 and the FDA Modernization Act (FDAMA) of 1997, provides for the regulation and classification of medical devices intended for human use according to their relative degree of safety and effectiveness.<sup>44</sup>

The 1976 Amendments established three categories (classes) of medical devices depending on the regulatory controls needed to reasonably establish the device's safety and effectiveness. Class I devices must meet the requirements of general controls, such as premarket notification, listing of device types, and the registration of manufacturing facilities.<sup>45</sup> Class I devices are subject to the least burdensome restrictions. Class II devices

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<sup>41</sup>Merrill, *supra* note 40, at 1803.

<sup>42</sup>*Id.*

<sup>43</sup>*Id.* at 1806.

<sup>44</sup>21 U.S.C. §360(c) (1996).

<sup>45</sup>21 U.S.C. §360(c)(1)(A) (1996).

are those devices for which general controls are insufficient by themselves to provide reasonable safety and effectiveness assurances.<sup>46</sup> Thus, Class II devices are also subject to special controls, such as performance standards, postmarket surveillance, clinical data requirements, and labeling and tracking requirements.<sup>47</sup> Finally, Class III devices are those for which insufficient information exists to determine whether general and special controls are adequate to provide safety and effectiveness assurances.<sup>48</sup> These devices are regulated through well-controlled studies and case histories that are structured to provide valid scientific evidence of safety and effectiveness.<sup>49</sup>

On the advice of its Independent General and Plastic Surgery Devices Panel, the FDA placed implants in a category requiring general controls and performance standards. By grandfathering the implants under the new provisions of the 1938 Act, implant manufacturers were not required to test the implants or apply for marketing applications prior to selling their product.

## **B.**

### **FDA Regulation of Silicone Breast Implants**

Beginning in the 1980s, concerns surfaced that silicone might be associated with cancer, and reports of connective tissue diseases and less defined systemic complications in women with silicone injections and implants began to appear. The first major report of the possible link between silicone and connective tissue

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<sup>46</sup>21 U.S.C. §360(c)(1)(B) (1996).

<sup>47</sup>*Id.*

<sup>48</sup>21 U.S.C. §360(c)(1)(C) (1996).

<sup>49</sup>*Id.*

diseases originated in Japan and involved direct injections of liquid paraffin or silicone into the breasts.<sup>50</sup> Subsequently, in 1982, an Australian report identified connective tissue disease in three women who had silicone gel-filled breast implants.<sup>51</sup> During that same year, a plaintiff filed the first multimillion-dollar lawsuit alleging that implants caused systemic disease.<sup>52</sup>

The first multimillion-dollar award to a plaintiff in a breast implant product liability litigation suit occurred three years later in Stern v. Dow Corning Corp.<sup>53</sup> In Stern, the plaintiff received silicone breast implants as part of breast reconstruction surgery following a bilateral mastectomy.<sup>54</sup> The plaintiff developed rheumatoid arthritis and sued Dow Corning, the implant manufacturer, on strict liability and breach of warranty claims; the California jury awarded \$7 million in damages, including \$1.5 million in punitive damages.<sup>55</sup> After Dow Corning appealed the verdict, the plaintiff settled out of court for an undisclosed amount.<sup>56</sup>

In 1982, in response to mounting pressure regarding the safety of silicone implants, the FDA proposed and, on June 24, 1988, formally implemented a classification of silicone breast implants in a category (Class III) requiring stringent safety and effectiveness controls.<sup>57</sup> Under the 1976 Amendments, a Class III device may be lawfully marketed as long as the device is the subject of a premarket notification (PMN) to the FDA that demonstrates it is “substantially equivalent” to a preenactment device, a premarket approval application (PMA), or a reclassification petition.<sup>58</sup> Manufacturers of a preenactment Class III device (a device for which general controls are not sufficient to establish safety and effectiveness) are not required to obtain

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<sup>50</sup>Marcia Angell, *Shattuck Lecture—Evaluating the Health Risks of Breast Implants: The Interplay of Medical Science, the Law, and Public Opinion*, 334 NEW ENG. J. MED., 1513-18 (June 6, 1996).

<sup>51</sup>Angell, *supra* note 50, at 1513-18.

<sup>52</sup>*Id.*

<sup>53</sup>Snyder, *supra* note 6, at 165 (*citing* Stern v. Dow Corning Corp., No. C-83-2348-MMP (N.D. Cal. 1985)).

<sup>54</sup>*Id.*

<sup>55</sup>*Id.*

<sup>56</sup>*Id.*

<sup>57</sup>On June 24, 1988, FDA issued a final rule classifying the silicone gel-filled breast prosthesis into class III. 21 C.F.R. § 878.3540 (1988). The FDA issued a similar rule classifying silicone inflatable (saline-filled) breast implants into Class III. 21 C.F.R. § 878.3530 (1988).

<sup>58</sup>21 U.S.C. §360(c) (1996).

FDA approval of the device's safety and effectiveness until the FDA promulgates a regulation requiring such approval.<sup>59</sup> Thus, on January 6, 1989, the FDA published a notice of intent to require pre-market approval applications for silicone implants.<sup>60</sup> At approximately the same time, Public Citizen (Ralph Nader's consumer group) petitioned former FDA commissioner Frank Young to ban silicone breast implants and criticized the FDA's delay in formally implementing its safety and effectiveness data requirements.<sup>61</sup>

## 1.

### **Influence of Media**

In the midst of this heightened scrutiny, the news media began to focus its attention on the breast implant controversy and contributed to the general panic and paranoia surrounding the safety of breast implants. Although no large epidemiological studies demonstrating a link between breast implants and connective tissue or autoimmune diseases had been published, the media presented stories describing individual breast implant patients with diseases as though the link had been established. For example, in 1990, Connie Chung sensationalized the implant controversy on her show, *Face to Face with Connie Chung*; Chung interviewed women who claimed that their breast implants gave them autoimmune disorders and conveyed the message that implants were dangerous devices.<sup>62</sup> In her assessment of the silicone breast implant litigation, Marcia Angell, M.D. (Executive Editor of the *New England Journal of Medicine*) criticized Chung for “implicitly [blaming] the FDA for permitting such risky products to be sold.”<sup>63</sup> Angell argued that Chung terrified

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<sup>59</sup>Peter Barton Hutt & Richard A. Merrill, *Food and Drug Law: Cases and Materials* 753 (University Casebook Series ed., Foundation Press, 2<sup>nd</sup> ed. 1991).

<sup>60</sup>54 C.F.R. § 550 (1989).

<sup>61</sup>Angell, *supra* note 7, at 53.

<sup>62</sup>*Id.*

<sup>63</sup>Angell, *supra* note 7, at 54.

thousands of women into believing that their implants were walking time bombs.<sup>64</sup> After the broadcast aired, physicians reported an “avalanche” of calls from asymptomatic women who were concerned about the safety of their implants.<sup>65</sup>

In a review of all the news segments on ABC, NBC, and CBS from December 1990 to 1992, researchers identified a trend among the media of presenting stories that sensationalized the dangers of silicone breast implants.<sup>66</sup> The study revealed that 71% of the 60 television news segments examined had an overt negative bias against the implants and only 1 of the segments had a positive bias.<sup>67</sup> Moreover, the review indicated that the media tended to trivialize the benefits of undergoing implant surgery, while reporting safety claims less dramatically and less frequently than reports of implant dangers.<sup>68</sup>

The dramatic reporting of the dangers of breast implants and mounting concerns regarding the lack of FDA regulation of the devices undoubtedly contributed to general public perceptions about the safety of silicone breast implants. Given the nature of the overwhelming negative portrayal of the implants in the media, it is very likely that many people overestimated the possibility that the alleged link between breast implants and systemic disease was real.

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<sup>64</sup> *Id.*

<sup>65</sup> Debra L. Worthington, Merrie Jo Stallard, Joseph M. Price, Peter J. Gross, *Hindsight Bias, Daubert, and the Silicone Breast Implant Litigation*, 8 PSYCHOL. PUB. POL'Y & L. 154,165 (June 2002) [hereinafter Worthington] (citing M.L. Vanderford & D.H. Smith, *The silicone breast implant story: Communication and Uncertainty* (Erlbaum 1996)).

<sup>66</sup> *Id.*

<sup>67</sup> *Id.*

<sup>68</sup> *Id.*



2.

### FDA's Ban

Amidst this growing controversy, David Kessler took over as FDA commissioner in 1991, and, on April 10, 1991, the FDA required manufacturers to complete a PMA for silicone breast implant devices to be filed with the agency within ninety days.<sup>69</sup> To date, an approved PMA is still required for marketing breast implant devices.<sup>70</sup> By the time the deadline arrived, however, only four of the major manufacturers, Mentor Corporation, McGhan Medical Corporation, Dow Corning Corporation, and Bioplasty, Inc., had submitted the required PMA.<sup>71</sup> On August 22, 1991, the FDA determined that the PMA applications submitted by the manufacturers were insufficient, and on September 26, 1991, the FDA required the dissemination of information about the risks associated with breast implants to patients.<sup>72</sup> In November 1991, the FDA convened another advisory panel and the members concluded that the manufacturers had failed to provide adequate information regarding the safety and effectiveness of their implants; nevertheless, the panel unanimously recommended that the FDA permit the implants to remain on the market.<sup>73</sup>

One month later, on December 13, 1991, a jury awarded the largest verdict in a breast implant case (at the time). In Hopkins v. Dow Corning Corp., the plaintiff, Mariann Hopkins, underwent a bilateral subcutaneous mastectomy for severe fibrocystic disease in 1976 and, during reconstructive surgery, received silicone gel implants manufactured by Dow Corning.<sup>74</sup> In March 1979, Hopkins was diagnosed with mixed connective tissue disease, a rheumatological disorder characterized by symptoms such as arthritis, extreme fatigue

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<sup>69</sup>56 C.F.R. § 14620 (1991).

<sup>70</sup>FDA issued a proposed rule requiring a PMA for saline-filled implants on January 8, 1993. 58 C.F.R. § 3436 (1993). On August 19, 1999, FDA required a PMA for these devices to be filed with the Agency within 90 days. 64 C.F.R. § 45155 (1999). To date, an approved PMA is required for marketing. *Id.*

<sup>71</sup>Institute of Medicine, *supra* note 5, at 30-31.

<sup>72</sup>*Id.*

<sup>73</sup>Angell, *supra* note 7, at 55.

<sup>74</sup>Hopkins v. Dow Corning Corp., 33 F.3d 1116, 1118 (9<sup>th</sup> Cir. 1994).

and weakness.<sup>75</sup> In January 1986, Hopkins discovered that one of her implants had ruptured.<sup>76</sup> In 1988, Hopkins sued Dow Corning, alleging fraud, strict products liability and breach of expressed and implied warranty.<sup>77</sup> The jury found Dow Corning liable for \$840,000 in compensatory damages and \$6.5 million in punitive damages.<sup>78</sup> Dow appealed the verdict.

On appeal, the Ninth Circuit upheld the jury verdict and found that the scientific testimony submitted by Hopkins's experts was based on accepted scientific techniques and literature.<sup>79</sup> Further, the court found that "Dow's conduct in exposing thousands of women to a painful and debilitating disease, and the evidence that Dow gained financially from its conduct" might be considered in determining a punitive damage award.<sup>80</sup> The court also found a substantial award to be appropriate because Dow was aware of possible defects, knew that long-term studies of implant safety were needed and continued to market its implants as safe despite this knowledge.<sup>81</sup> At no point during the trial, however, did Hopkins present reliable epidemiological or toxicological data demonstrating an association between breast implants and connective tissue diseases.

In response to FDA pressure after the trial, Dow released several "incriminating" documents that had been submitted during the Hopkins litigation. The evidence indicated that Dow rushed the development of its implants and failed to adequately test their safety prior to marketing them to consumers.<sup>82</sup> A member of Dow's Mammary Task Force expressed concerns about possible gel bleed and Dow allegedly ignored proposed design modifications that may have reduced the likelihood of leakage.<sup>83</sup> Moreover, Dow instructed its salesmen to wash the implants with soap and water and to "dry with hand towels as the implants become

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<sup>75</sup> *Id.* at 1118.

<sup>76</sup> *Id.* at 1118-19.

<sup>77</sup> *Id.* at 1119.

<sup>78</sup> *Id.* at 1118.

<sup>79</sup> *Id.*

<sup>80</sup> *Id.* at 1127.

<sup>81</sup> *Id.*

<sup>82</sup> *Hopkins*, 33 F.3d 1116 at 1119.

<sup>83</sup> *Id.*

oily after being handled and [bleed] on the velvet in the showcase.”<sup>84</sup>

Subsequently, on January 6, 1992, the FDA announced a voluntary moratorium on silicone breast implants, requesting that surgeons stop inserting silicone implants and manufacturers stop supplying them.<sup>85</sup> Kessler also reconvened the advisory panel to consider the evidence submitted by Dow Corning regarding the implants’ safety. Although the evidence did not demonstrate any link between connective tissue disease and breast implants (the original basis for the Hopkins litigation), the FDA used the documents to bolster its concerns regarding implant safety. When the panel met on February 18, 1992, amidst even more intense political pressure and media publicity, the members recommended that silicone gel-filled implants be removed from the market in all but very highly limited conditions.<sup>86</sup>

On April 16, 1992, Kessler, citing the absence of safety and effectiveness data, followed the advice of his advisory panel and restricted the use of silicone gel-filled implants to clinical observation study participants, most of whom received implants for breast reconstruction.<sup>87</sup> Although the FDA was careful to acknowledge that the ban did not reflect any evidence of an associated risk between the devices and disease, the agency concluded that the implant manufacturers failed to provide sufficient positive safety evidence.<sup>88</sup> In approving the ban, Kessler noted, “caveat emptor has never been – and never will be – the philosophy at the FDA.”<sup>89</sup> The decision provided for three stages for implant availability. During the first stage, the implants would be available to patients with temporary breast tissue-expanders awaiting permanent reconstructive surgery, patients undergoing reconstructive surgery at the time of mastectomy, and patients with urgent medical

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<sup>84</sup> *Id.*

<sup>85</sup> Snyder, *supra* note 6, at 161.

<sup>86</sup> *Id.*

<sup>87</sup> David A. Kessler, *The Basis of the FDA’s Decision on Breast Implants*, 326 NEW ENG. J. MED., 1713-15 (June 18, 1992). By this time, all U.S. companies except Mentor Corporation and McGhan Medical Corporation had withdrawn from the market.

*Id.*

<sup>88</sup> *Id.*

<sup>89</sup> *Id.*

reasons (such as the rupture of a device already in place).<sup>90</sup> During the second stage, the implants would be available to those with a certified medical need under the extended-availability protocols of the public-health-need provisions of the 1938 Act.<sup>91</sup> Finally, during the third stage, the implants would be available in carefully controlled clinical trials (with the number of participants limited to the minimum number required by the study).<sup>92</sup>

### III.

## Responses to the FDA's Ban

The increasing litigation and media coverage surrounding the safety of silicone breast implants had already begun to influence, and possibly mislead, public perception regarding the riskiness of the devices. The FDA's decision to ban silicone breast implants exacerbated these safety concerns, even though no scientific studies had established a link between the implants and the alleged connective tissue diseases. The decision appeared to confirm the unsubstantiated belief held by many women that breast implants were likely to cause serious autoimmune disorders, despite the lack of strong supporting evidence. For example, a group of researchers measured women's attitudes toward their breast implants before and after the FDA's decision.<sup>93</sup> After the FDA moratorium, respondents' overall satisfaction with their augmentation dropped from 98% to 71% and the women were more likely to express concerns about autoimmune diseases.<sup>94</sup> Moreover, most participants

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<sup>90</sup> *Id.*

<sup>91</sup> *Id.*

<sup>92</sup> *Id.*

<sup>93</sup> M. Palcheff-Wiener, J.J. Concannon, V.S. Conn, & C.L. Puckett, *The Impact of the Media On Women With Breast Implants*, 92 *PLASTIC AND RECONSTRUCTIVE SURGERY*, 779-785 (1993).

<sup>94</sup> *Id.*

found media reports about the implants, the majority of which were negative, to be accurate.<sup>95</sup>

Similarly, a random telephone survey in New York City conducted in 1996 to determine potential jurors' opinions of breast implants revealed that 90% of the 235 respondents believed that the FDA imposed the ban because of evidence that silicone caused disease, despite the FDA's statement to the contrary.<sup>96</sup> Moreover, 85% of those interviewed believed that silicone is "somewhat likely" or "very likely" to cause illness or disease if it gets into a woman's system.<sup>97</sup>

## A.

### Breast Implant Opponents

In addition to increasing misperceptions about the inherent dangers and risks associated with silicone breast implants, the decision to ban silicone breast implants from the US market left the FDA open to criticism from both sides of the implant controversy. On the one hand, those who thought that no woman should have been exposed to the devices as long as their safety and effectiveness had not been demonstrated criticized the FDA for waiting close to twenty years to regulate breast implants under the 1976 Amendments. For example, a 1993 Congressional subcommittee criticized the FDA for ignoring warnings for more than twelve years about the need to regulate silicone implants, ignoring concerns among the scientific community since 1975 about the risk of connective tissue/autoimmune disorders, and allowing manufacturers to operate for

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<sup>95</sup> *Id.*

<sup>96</sup> Worthington et.al., *supra* note 19, at 236-237.

<sup>97</sup> *Id.*

years without providing proof of safety to the FDA.<sup>98</sup>

However, although the FDA did delay in promulgating regulations regarding breast implants in general (and silicone gel-filled breast implants in particular), broad criticisms of the FDA's failure to act earlier than 1992 are too sweeping and fail to consider the FDA's statutory constraints. As discussed earlier in this article, Congress restricted the FDA's ability to regulate medical devices under the 1938 Act to monitoring adulterated and misbranded devices; the agency did not have the authority to require implant manufacturers to submit safety and effectiveness data for more than fourteen years after implants were introduced in 1962.

Moreover, at the time of the 1976 Amendments, the FDA faced the overwhelming task of classifying pre- and post-enactment devices as either Class I, II or III devices while simultaneously developing regulations to implement and interpret the 1976 Amendments. The process took more time and resources than either Congress or the agency anticipated.<sup>99</sup> As a result, the FDA paid little attention to pre-market approval applications or pre-enactment devices that had been in use for years prior to the 1976 Amendments.<sup>100</sup> Although many devices on the market theoretically required classification as Class III devices, many backlogged devices remained on the market without further FDA review because the FDA focused its resources on classifying recently introduced medical devices. Once the FDA received reports of a link between implants and autoimmune diseases, the agency proposed classifying silicone implants as Class III devices and demanded safety data from manufacturers.<sup>101</sup>

Despite these actions, however, it is clear that the FDA did delay in regulating silicone breast implants. It

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<sup>98</sup>Snyder, *supra* note 6, at 133 n.152.

<sup>99</sup>Merrill, *supra* note 40, at 1812-13.

<sup>100</sup>*Id.*

<sup>101</sup>*See supra*, note 57.

took the agency more than six years to formally classify implants as Class III devices and to require manufacturers to conduct safety and effectiveness testing. Although the link between implants and connective tissue disease has been largely unsubstantiated, the FDA contributed to the mass litigation and hysteria surrounding the implants' safety by failing to require scientific testing of the implants sooner.

## B.

### Breast Implant Proponents

On the other side of the controversy, proponents of the use of silicone breast implants opposed the FDA's ban as an interference with a woman's ability to weigh the risks against the personal benefits of undergoing implantation.<sup>102</sup> For example, in her response to the FDA's decision, Marcia Angell argued that the decision would increase the fears of women who already had silicone breast implant surgery in a manner that would be disproportionate to the apparent risks of implantation; the decision would be "widely seen as official confirmation that breast implants are dangerous, despite Kessler's assertion that it simply reflects a lack of evidence."<sup>103</sup> Moreover, Angell argued that the decision ignored the background social context, which regularly allows individuals to take risks such as smoking and drinking to excess.<sup>104</sup> The ban affected thousands of women who would otherwise undergo breast implant surgery each year; individuals opposed to the ban, such as Angell, argued that the FDA's actions constrained the ability of these women to choose the surgery without identifying any substantiated risk of disease associated with the implants.

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<sup>102</sup> See Angell, *supra* note 5.

<sup>103</sup> *Id.*

<sup>104</sup> See Angell, *supra* note 5.

This argument has some merit because the FDA failed to explicitly examine the positive benefits associated with silicone breast implant surgery in its decision to ban the devices. Despite the high prevalence of silicone gel implants, neither the FDA nor the media made any substantial arguments discussing the perceived benefits of breast implants.<sup>105</sup> The FDA has never required that a drug or device be entirely risk-free (an impossibly high standard). Instead, the agency has always required that the benefits of a regulated device exceed the calculated risks of that device so that it is more desirable to have the device in the marketplace than not.<sup>106</sup>

It is unrealistic to presume that thousands of women undergo a potentially painful and risky procedure without anticipating somewhat substantial benefits. In many cases, it may be difficult to quantify or articulate the benefits of surgery because they are both personal and unique to each woman's situation.<sup>107</sup> Such difficulties, however, do not justify entirely dismissing the positive benefits of implantation. By refusing to recognize any positive benefits associated with silicone implants for breast augmentation, Kessler may be holding implants to an "impossibly high standard: since there are no benefits, there should be no risks."<sup>108</sup> This does not mean, however, that the perceived benefits of implantation should automatically trump legitimate safety concerns articulated by the FDA. As of 1991, a manufacturer is required to submit a pre-market approval application prior to marketing a breast implant device. Although the FDA gave implant manufacturers ninety days to submit safety data, even after the years of FDA regulatory delay the manufacturers still failed to meet this requirement. If the FDA had failed to take further regulatory action in the absence of adequate safety data, the agency would arguably have sent the message that manufacturers of grandfathered devices would be entirely free to market those devices without the FDA's approval absent evidence of con-

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<sup>105</sup> *Id.*

<sup>106</sup> *Id.*

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

<sup>108</sup> See Angell, *supra* note 5.



crete harms. As a policy matter, it would be imprudent to provide such a regulatory shield to manufacturers when the purpose of the FDA is to protect the average consumer. Moreover, although subsequent epidemiological data fails to establish a link between connective tissue diseases and silicone breast implants, there are still significant risks associated with breast implantation (such as implant rupture, capsular contracture, and other local complications).

The exception to the FDA's ban for reconstructive surgery patients who may be able to receive silicone implants as part of clinical trials, however, raises additional concerns. If the FDA is concerned about the safety and effectiveness of the devices, then it seems startling to allow the devices to be inserted in patients who are more susceptible to complications due to their weakened immune systems. A woman recovering from a mastectomy for breast cancer is more likely to be physically vulnerable than a woman merely seeking augmentation surgery. Instead of operating solely as a protective mechanism for women contemplating breast surgery, the ban seems to reflect a public policy preference against breast augmentation surgery. Kessler indicated that, "as a society, we are far from according cosmetic interventions the same importance as a matter of public health that we accord to cancer treatments."<sup>109</sup> Even if that is the case, it does not justify the FDA dismissing any discussion of the benefits of silicone breast augmentation. Kessler may dis-prefer breast implants for purely augmentation purposes; such a policy distinction, however, should not be couched as a safety concern justifying a FDA ban on a medical device. Without further safety information (presumably from manufacturers who have the greatest ability to test the devices and independent research groups who have no financial stake in the test results), it remains unclear whether the FDA should have banned silicone breast implants.

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<sup>109</sup>Kessler, *supra* note 87, at 1713.

C.

### Federal Multi-District Litigation

The FDA's decision to ban silicone gel-filled breast implants provided support to the growing momentum of claims by breast implant recipients of a link between silicone implants and disease. Although the decision did not identify any substantial risk associated with breast implants, it helped fuel the growing number of product liability lawsuits alleging a link between implants and connective tissue diseases. More than 400,000 cases were filed in federal and state courts after the FDA's decision in 1992, and Dow Corning claimed that 20,000 lawsuits were filed against the company alone in just the two years following the FDA's ban.<sup>110</sup>

In response to the overwhelming number of cases filed in federal courts throughout the country, in June of 1992 the Multi-District Litigation Panel referred all silicone breast implant cases on federal court dockets to Judge Samuel C. Pointer, III, in the Northern District of Alabama.<sup>111</sup> The Panel determined that centralization of the many cases awaiting litigation was appropriate to conserve party resources and avoid duplication.<sup>112</sup>

In December of 1993, Judge Pointer provisionally dismissed Dow Corning's parent companies, Dow Chemical Co. and Corning, Inc., as defendants in the multi-district litigation (MDL) because he could find no evidence that the contacts between the parent and subsidiary companies arose to a level of manipulation and control that would require piercing the corporate veil.<sup>113</sup> However, the court retained the right to return the defendants to the MDL if any of the parties introduced new evidence of the parent companies' involvement

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<sup>110</sup>Laura L. Hooper, Joe S. Cecil, Thomas E. Willging, *Assessing Causation in Breast Implant Litigation: The Role of Science Panels*, 64 AUT LAW & CONTEMP. PROBS. 139, 142 (Autumn 2001); *See also* Angell, *supra* note 50.

<sup>111</sup>*In re Silicone Gel Breast Implant Products Liability Litigation*, MDL-926, 793 F. Supp. 1098 (N.D. Ala. 1992).

<sup>112</sup>*Id.* at 1100

<sup>113</sup>*In re Silicone Gel Breast Implant Products Liability Litigation*, MDL-926, 837 F. Supp. 1128 (N.D. Ala. Dec. 2, 1993).

in the breast implant controversy.<sup>114</sup>

On September 1, 1994, Judge Pointer approved a proposed \$4.25 billion global class settlement, with Dow Corning, Bristol-Meyers Squibb Co., and Baxter International, Inc. underwriting more than \$3 billion of the settlement fund.<sup>115</sup> With almost 10,000 cases pending in federal court, and almost as many pending in state court, the proposed settlement reflected the parties' recognition of the limited resources of the defendants, the large costs of potential further litigation, and the limited resources of the judiciary to adjudicate individual claims.<sup>116</sup> The settlement included a program for receiving claims over a thirty-year period, a simplified claims procedure that did not involve adversarial proceedings or court-appointed physician exams, a method for adding additional diseases or medical conditions to the settlement terms, and procedures for incorporating additional opt-out rights when necessary.<sup>117</sup>

One month later, in November 1994, the MDL plaintiffs, alleging conspiracy and negligence claims, sought to reinstate Dow Chemical as a defendant in the litigation.<sup>118</sup> The plaintiffs argued that Dow Chemical marketed, sold, promoted and distributed implants worldwide through a foreign subsidiary and conducted research, testing and development of substances contained in Dow Corning's breast implants.<sup>119</sup> Furthermore, the plaintiffs argued that the parent company concealed its role in the research and development of Dow Corning's implants and information about the hazards of silicone.<sup>120</sup> In April 1995, Judge Pointer reinstated Dow Chemical Co. as a potential defendant in the MDL and found that a jury could find the company liable for the negligent research, testing and development of silicone.<sup>121</sup>

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<sup>114</sup> *Id.*

<sup>115</sup> *In re Silicone Gel Breast Implant Products Liability Litigation*, MDL-926, No. CV-92-P-10000-S, 1994 WL 578353 (N.D. Ala. Sept. 1, 1994). The class consisted of all persons who received an implant from a settling defendant prior to June 1, 1993 and their children, spouses, relatives and significant others who could have asserted claims against one of the defendants due to their relationship with the implant recipient. *Id.*

<sup>116</sup> MDL-926, 1994 WL 578353, at \*2.

<sup>117</sup> *Id.*

<sup>118</sup> *In re Silicone Gel Breast Implant Products Liability Litigation*, 887 F. Supp. 1455 (N.D. Ala. April 25, 1995).

<sup>119</sup> *Id.*

<sup>120</sup> *Id.*

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

By June 1995, more than 248,000 domestic compensation applications had been filed in the MDL, suggesting that the initial amounts available for individual plaintiffs under the \$4.25 global settlement agreement would be significantly decreased.<sup>122</sup> When Dow Corning filed for bankruptcy in May of 1995, the company limited its contribution to the \$2 billion it pledged toward the initial settlement agreement.<sup>123</sup> Thus, Dow Corning's announcement further exacerbated the concern that individual payments under the plan would be substantially decreased. In response, the court instructed the parties to restructure the fund, and when the parties failed to reach a new agreement by September 1995, the court set aside the \$4.25 billion settlement.<sup>124</sup>

Following its filing of a Chapter 11 bankruptcy petition, Dow Corning sought to remove all breast implant cases pending against Dow Corning, Dow Chemical, and Corning Inc. to federal court and to transfer the cases to the bankruptcy court in Michigan. In arguing for removal and transfer, the company argued that any judgment entered against it under the MDL would directly influence its assets in bankruptcy.<sup>125</sup> Both the district court and the bankruptcy court initially denied jurisdiction over the claims against Dow Chemical and other non-debtors as not related to Dow Corning's bankruptcy.<sup>126</sup> The Sixth Circuit Court of Appeals, however, held that the lawsuits in which Dow Corning was a codefendant may be transferred to the bankruptcy court in Michigan; the district court would still retain the right to abstain from the cases.<sup>127</sup> At the court's request, defendants Bristol-Meyers Squibb Co., Baxter International Healthcare Co., McGhan, Union Carbide and 3M proposed a revised settlement plan for domestic class members; the court approved the plan in December 1995.<sup>128</sup> Those claimants who submitted timely claims under the defunct \$4.25 billion settlement had two options under the revised plan. First, they could accept a fixed payment of \$10,000 to \$100,000 based on disease criteria and severity criteria outlined in the initial settlement. Alternatively, if,

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<sup>122</sup>In re Silicone Gel Breast Implant Products Liability Litigation, MDL-926, No. CV-92-P-10000-S (June 14, 1995)

<sup>123</sup>See In re Dow Corning Corp., 187 B.R. 919 (E.D. Mich. Sept. 12, 1995).

<sup>124</sup>See *id.*

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

<sup>126</sup>See *id.*

<sup>127</sup>See In re Dow Corning Corp., 86 F.3d 482 (6<sup>th</sup> Cir. 1996).

<sup>128</sup>Order 27: Approval of Revised Settlement Program and Injunctions, In re Silicone Gel Breast Implant Products Liability Litigation, MDL-926, Dec. 22, 1995, at <http://earth.fjc.gov/BREIMLIT/ORDERS/order27.rtf>.

within fifteen years, the claimants developed conditions meeting more restrictive criteria under the revised plan, they could potentially receive \$75,000 to \$250,000. Individuals who did not register under the initial settlement would only be eligible for the second option. Women who previously opted out of the global settlement would be allowed to rejoin the class to participate in the revised plan.<sup>129</sup>

On February 1, 1999, the court issued its final order approving and certifying the class settlement agreement between Inamed and its subsidiaries McGhan Medical Corporation/3M (“MMC”) and CUI Corporation (“CUI”) and the plaintiff class.<sup>130</sup> The class included all individuals who received an Inamed breast implant (either saline, silicone, silicone gel and/or elastomer made of silicone) prior to June 1, 1993 (whether or not they were removed) and all spouses, parents, children, relatives and “significant others” where warranted by law that may have had implant-related claims. The court further certified the action as a mandatory (“non-opt-out”) class because it found that the costs of the continued prosecution of separate claims by individual class members would greatly exceed Inamed’s limited resources. The court noted that the \$32 million settlement was substantially greater than the amount, if any, that Inamed would be able to pay in the absence of the settlement agreement. The court also found that Inamed was only able to borrow additional money to fund the agreement because of the existence of a negotiated settlement. The alternative of continued litigation, therefore, would bankrupt the company.<sup>131</sup>

As a result of its bankruptcy proceedings, Dow Corning did not participate in the class action settlement; instead, the company reached its own settlement agreement in conjunction with the bankruptcy proceedings. In the final agreement, approved in December 1999, the company provided \$3.2 billion for women suffering from implant-related illnesses.<sup>132</sup> The amount of compensation varied depending on the claimants’ level

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<sup>129</sup> *Id.*

<sup>130</sup> Order 47A: Order and Final Judgment Certifying Inamed Settlement Class, Approving Class Settlement, and Dismissing Claims Against Inamed and Released Parties, In re Silicone Gel Breast Implant Products Liability Litigation, MDL-926, Feb. 1, 1999, at <http://earth.fjc.gov/BREIMLIT/ORDERS/order47a.rtf>.

<sup>131</sup> Order 47A, *supra* note 130.

<sup>132</sup> *Closing the Implants File*, WASH POST, Dec. 9, 1999 at A44.

of injury; thus, women suffering from scarring could collect up to \$30,000 and women with more severe symptoms could collect up to \$300,000.<sup>133</sup>

## IV.

### Scientific Studies

The possibility that silicone gel-filled breast implants may lead to adverse autoimmune reactions had been a central allegation of the plaintiffs throughout the breast implant litigation. However, although the litigation involved a variety of woman with diagnosed or suspected connective tissue diseases who claimed that their breast implants were the cause of their disease, the plaintiffs' claims were largely unsubstantiated by any epidemiological evidence. The purely descriptive data of an association between implants and disease introduced by the plaintiffs was of limited value in the absence of data from a comparable group of women without implants. In order to gauge the relative risk of disease in women who have had silicone breast implants as compared to the general population, cohort and case-control epidemiological studies were needed.

Two main types of epidemiological studies were utilized to examine the risk of connective tissue diseases in women with silicone breast implants and the general population: cohort and case control studies. In a cohort study, the incidence and nature of diseases in women with silicone breast implants are obtained by following the group for a specified period of time; this data is then compared to the incidence rate with a randomly

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

identified control group of similarly situated women without breast implants.<sup>134</sup> In a case control study, researchers examine women who have already been diagnosed with connective tissue disease and women who have not been diagnosed, identify how many women in each group have silicone breast implants, and determine if there is a significantly higher prevalence of disease in women with implants.<sup>135</sup>

## A.

### Mayo Clinic Study

The first reliable epidemiological study to determine whether breast implants are associated with connective tissue disease was not published until June 16, 1994, two years after the FDA issued its ban on silicone breast implants. The study was a retrospective population-based cohort study that compared the risks of a variety of connective tissue diseases and disorders in women with and without breast implants.<sup>136</sup> The study examined all the women in Olmstead County, Minnesota who received a breast implant between January 1, 1964 and December 31, 1991. Of the 1840 devices implanted, 1441 (78.3%) were silicone, 95 (5.2%) were saline, 177 (9.6%) were polyurethane, and 123 (6.7%) were a combination of silicone and saline. All 749 case subjects were exposed to silicone because all the breast implants were contained within a silicone envelope.<sup>137</sup>

For each case subject, the control subjects were two women of the same age (within three years) from the same population who had not received a breast implant and who underwent a medical evaluation within two

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<sup>134</sup>Angell, *supra* note 7, at 99.

<sup>135</sup>*Id.*

<sup>136</sup>Sherine E. Gabriel, Michael W. O'Fallon, Leonard T. Kurland, Marcy C. Beard, John E. Woods, Joseph L. Melton III, *Risk of Connective-Tissue Diseases and Other Disorders After Breast Implantation*, 330 NEW ENG. J. MED. 1697-1702 (June 16, 1994).

<sup>137</sup>Gabriel et al., *supra* note 136.

years of the date of implantation of the case subject.<sup>138</sup> Moreover, two additional county residents who had undergone mastectomies but did not receive breast implants were selected as controls for each woman who received an implant after a mastectomy. A total of 749 women who received a breast implant were followed for a mean of 7.8 years and 1498 community controls were followed for a mean of 8.3 years.

Among the various signs or symptoms examined, only morning stiffness was significantly increased among the women who had received a breast implant. The study concluded, therefore, that there was no association between breast implants and the connective tissue diseases and disorders studied.<sup>139</sup>

## B.

### Nurses' Health Study

At the same time as the authors of the Mayo Clinic study published their findings in the *New England Journal of Medicine*, the Nurses' Health Study Cohort was already underway. Researchers assembled the Nurses' Health Study Cohort in June 1976 and mailed questionnaires to all female, married registered nurses aged 30 to 44 years old living in California, Connecticut, Florida, Maryland, Massachusetts, Michigan, New Jersey, New York, Ohio, Pennsylvania, and Texas.<sup>140</sup>

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<sup>138</sup> *Id.*

<sup>139</sup> The study did have the following limitations: (1) very late outcomes (occurring more than 10 years after surgery) could not be adequately evaluated, (2) some racial and ethnic groups were underrepresented in the study population, (3) the data set was limited to conditions that would likely come to medical attention, and (4) the study had limited power to detect an increased risk of rare connective tissue diseases. *Id.*

<sup>140</sup> Jorge Sanchez-Guerrero, Graham A. Colditz, Elizabeth W. Karlson, David J. Hunter, Frank E. Speizer, Matthew H. Liang, *Silicone Breast Implants and the Risk of Connective-Tissue Diseases and Symptoms*, 332 *NEW ENG. J. MED.* 1666-70 (June 22, 1995).



The study followed women without connective-tissue diseases in June 1976 through May 31, 1990, before widespread media coverage of the possible association between implants and disease began. Researchers collected information on the study participants through biennial and supplemental mailed questionnaires and through blinded reviews of the participants' medical records. The study defined the relative risk of connective tissue disease as the incidence rate of connective tissue disease among women with breast implants divided by the corresponding incidence rate among women without breast implants.

Among 87,501 women who were eligible for follow-up, the researchers confirmed that 516 of the participants had definite connective-tissue diseases and 1183 had breast implants (of which 876 were silicone-gel, 170 saline). Three of the patients with definite connective tissue disease (all had rheumatoid arthritis) had implants (one silicone, one saline and one double lumen). Moreover, since 1976, 5087 women reported having a connective-tissue disease or rheumatic disorder on the biennial questionnaires. Of these women, thirty-two had some type of breast implant, including twenty-one women with silicone gel-filled implants. 1294 women reported signs or symptoms of a disease but did not meet the standard classification criteria. Of these women, seventeen had some type of breast implant and eleven had silicone gel-filled implants.

Based upon these findings, the study authors concluded that they could not find an association between silicone breast implants and connective-tissue diseases, as defined by a variety of standardized criteria and signs and symptoms of these diseases.<sup>141</sup>

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<sup>141</sup>Sanchez-Guerrero et al., *supra* note 140.

C.

## Expert Panels

1.

### Hall v. Baxter Healthcare

As the cases under the MDL became ready for trial, Judge Pointer returned several of them to their districts of origin with the expectation that early trials would set benchmarks to encourage later settlement negotiations. Among these cases was a group of approximately seventy cases returned to the District of Oregon that gave rise to Hall v. Baxter Healthcare Corp.<sup>142</sup>

Judge Jones presided over the consolidated cases and received twenty-five joint motions in limine seeking to exclude the testimony of the plaintiffs' expert witnesses at trial.<sup>143</sup> In an effort to resolve these motions, Jones appointed an expert panel with expertise in epidemiology, immunology, toxicology, rheumatology, and biochemistry to assist him in determining whether the experts' testimony rested on reliable scientific methodology.<sup>144</sup> After the panel assessed the scientific reliability of each expert's methods, the court sought further assistance in determining whether the expert's methodology and data supported his conclusions and applied to the particular disease at issue in the case.<sup>145</sup>

The panel received scientific information through a four-day pretrial hearing on the testimony's admissibility, articles and written materials provided by the parties, and videotaped summations prepared by the parties.<sup>146</sup> Approximately four months after their appointment, the panel submitted individual reports,

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<sup>142</sup>Hall v. Baxter Healthcare Corp., 947 F. Supp. 1387 (Or. 1996).

<sup>143</sup>*Id.* at 1392 n.7.

<sup>144</sup>*Id.* at 1393.

<sup>145</sup>*Id.*

<sup>146</sup>*Hall*, 947 F. Supp. at 1393.

in general suggesting that the scientific evidence used to demonstrate a causal link between implants and disease was unreliable.<sup>147</sup> Thus, the court found that the evidence submitted by the plaintiffs' experts was insufficient to defeat the defendant's summary judgment motion. The court stayed the order, however, until the MDL's National Science Panel completed its review.<sup>148</sup> The cases settled absent any additional court involvement.

## 2.

### National Science Panel under MDL

In June 1996, Judge Pointer approved a motion by the National Plaintiffs' Steering Committee (PSC) to nationally appoint a single set of scientific experts under Federal Rules of Evidence (FRE) 706 to evaluate the scientific evidence in the federal breast implant litigation.<sup>149</sup> At the time of the motion, over 21,000 cases had been transferred to the court under the MDL, and the panel (the National Science Panel) was designed to avoid potentially redundant or conflicting results that might arise from multiple FRE 706 appointments by different courts.<sup>150</sup> The primary function of the National Science Panel was to review, critique and evaluate the existing scientific literature on topics relevant to the breast implant litigation.<sup>151</sup> After making a report of its findings, each party would then be allowed to conduct a "discovery-type" non-videotaped deposition

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<sup>147</sup> *Id.* at 1461.

<sup>148</sup> *Id.*

<sup>149</sup> Order 31: Appointment of Rule 706 Expert Witnesses, In re Silicone Breast Implant Products Liability Litigation MDL 926, May 30, 1996, at [www.fjc.gov/BREIMLIT](http://www.fjc.gov/BREIMLIT) [hereinafter Order 31].

<sup>150</sup> *Id.*

<sup>151</sup> *Id.*

of the expert.<sup>152</sup> The experts' testimony would then be videotaped for presentation at subsequent trials.<sup>153</sup>

A selection panel of six experts provided the court with the names of neutral, impartial experts to serve on the National Science Panel (NSP) who would be able to communicate effectively with judges and juries.<sup>154</sup> Although the selection panel was not allowed to receive suggestions from the parties regarding the names of potential nominees, it was authorized to receive general suggestions regarding criteria, qualifications, and possible areas of bias or conflict.<sup>155</sup> The selection panel recommended four scientists, one each in the fields of immunology, epidemiology, toxicology, and rheumatology to form the NSP.

Despite the court's attempts to ensure a neutral selection process for the NSP, controversy still surrounded the final membership appointments. On April 13, 1999, the PSC moved to vacate the court's appointments of the four experts who had been serving on the NSP based on allegations of bias, conflict of interest, and improper conduct, primarily on the part of Dr. Tugwell (the panel's rheumatologist).<sup>156</sup> The PSC alleged that Dr. Tugwell received financial support from Bristol-Meyers Squibb and 3M Pharma Canada, silicone breast implant manufacturers, for research unrelated to breast implants or the litigation. Although the allegations were, for the most part, beyond factual dispute, the court concluded that a scientist may act neutrally and objectively, even when the outcome of his research may adversely affect a company that provides funding for his other projects.<sup>157</sup> The court therefore denied the motion and found that Dr. Tugwell did not have a conflict of interest or bias, and "acted neutrally, objectively and impartially" through his service.<sup>158</sup>

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<sup>152</sup>Order 31, *supra* note 149.

<sup>153</sup>*Id.*

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

<sup>155</sup>*Id.*

<sup>156</sup>Order 31L: Denying Plaintiffs' Motion for Relief from Prejudicial Bias, In re Silicone Breast Implant Products Liability Litigation MDL 926, April 25, 1999, at <http://earth.fjc.gov/BREIMLIT/ORDERS/order311.rtf> [hereinafter Order 31L].

<sup>157</sup>Order 31L, *supra* note 156.

<sup>158</sup>*Id.* In denying the PSC's motion with regard to Dr. Tugwell, the court found the challenges directed to the other panel experts to be clearly without merit. *Id.*

In October 1996 and July 1997, the NSP heard testimony from experts from both sides of the litigation and in November 1997 experts selected by the NSP presented their research to the panelists.<sup>159</sup> By spring of 1997, the panelists had received over 2,000 documents, which counsel for each side reduced to approximately forty of the most important documents for each side for each panel member.<sup>160</sup> The source of reference for the documents was not disclosed to the panelists.<sup>161</sup>

In preparing their report, the panel was asked to identify the extent to which, if any, existing studies and research provided a reliable and reasonable scientific basis to conclude that silicone gel-filled breast implants cause or exacerbate classic or atypical connective tissue diseases.<sup>162</sup> Further, the panelists were asked to note any contrary opinions by individuals generally qualified in the same area of expertise to those opinions presented in their final report.<sup>163</sup> In response, the panelists found that “it is our informed opinion that the large majority of scientists in our respective disciplines would find merit in our reviews and analyses. Nevertheless, as in every field of endeavor, a few individuals may find disagreements with our statements.”<sup>164</sup>

The completed report contained over 300 pages of scientific analysis and review and included nine cohort, nine case control, and two cross-sectional studies in its meta-analysis of the relationship between silicone breast implants and connective tissue diseases.<sup>165</sup> The only study to specifically address the relationship between undifferentiated connective tissue disease and breast implants found no association between the two.<sup>166</sup> The panel also noted that for each sign or symptom showing an association in a study, other studies

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<sup>159</sup>Barbara S. Hulka, Nancy L. Kerkvliet, Peter Tugwell, *Experience of a Scientific Panel Formed to Advise the Federal Judiciary on Silicone Breast Implants*, 342 NEW ENG. J. MED. 812-15 (March 16, 2000).

<sup>160</sup>Barbara S. Hulka, Nancy L. Kerkvliet, Peter Tugwell, *Silicone Breast Implants in Relation to Connective Tissue Diseases and Immunologic Dysfunction: A Report by a National Science Panel to the Honorable Sam C. Pointer Jr., Coordinating Judge for the Federal Breast Implant Multi-District Litigation* (November 30, 1998) at <http://www.fjc.gov/BREIMLIT/SCIENCE/summary.htm> [hereinafter MDL Report].

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

<sup>162</sup>*Id.*

<sup>163</sup>*Id.*

<sup>164</sup>MDL Report, *supra* note 160.

<sup>165</sup>Esther C. Janowsky, Lawrence L. Kupper, Barbara S. Hulka, *Meta-Analyses of the Relation between Silicone Breast Implants and the Risk of Connective-Tissue Diseases*, 342 NEW ENG. J. MED. 781-90 (March 16, 2000).

<sup>166</sup>MDL Report, *supra* note 160.

found no association. The panel found that the same complaint often appeared in more than one disease category and the studies did not verify self-reports of the disease.<sup>167</sup> Moreover, the reports did not indicate the timing of the disease in relation to the timing of implantation and the individual studies included only a small number of affected women.<sup>168</sup>

The results of the panel's extensive review found no association between breast implants in general, and silicone gel implants specifically, and any of the individual connective tissue diseases, all definite connective diseases combined, or any of the other autoimmune/rheumatic conditions examined.<sup>169</sup> Further, the NSP concluded that no consistent data demonstrated atypical systemic inflammation or autoreactive responses in women with silicone breast implants. The panel found that "the main conclusion that can be drawn from existing studies is that women with silicone breast implants do not display a silicone-induced systemic abnormality in the types or functions of cells of the immune system."<sup>170</sup>

Moreover, the report concluded that the preponderance of the data did not support claims that silicone implants alter the incidence or severity of autoimmune diseases.<sup>171</sup> Sjorgren's syndrome was a possible exception because a biopsy was not performed to identify definitive cases; because the symptoms were relatively common in any population group, the authors could not determine whether a definitive relationship existed between implants and the disease.<sup>172</sup> Nevertheless, the panel concluded that, from a public health perspective, "breast implants appear to have minimal effect on the number of women in whom connective tissue diseases develop and the elimination of implants would not be likely to reduce the incidence of connective-tissue diseases."<sup>173</sup>

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<sup>167</sup> *Id.*

<sup>168</sup> *Id.*

<sup>169</sup> *Id.*

<sup>170</sup> MDL Report, *supra* note 160.

<sup>171</sup> *Id.*

<sup>172</sup> *Id.*

<sup>173</sup> Janowsky et al., *supra* note 165.

D.

### **Independent Review Group**

In response to growing concerns regarding the safety of breast implants, the British Minister of Health requested that the country's Chief Medical Officer undertake a review of the use of silicone gel breast implants in the United Kingdom; the Chief Medical Officer established the Independent Review Group (IRG) to review the evidence relating to possible health risks associated with silicone gel breast implants.<sup>174</sup>

The IRG examined case control and cohort studies conducted between 1970 and 1988 and concluded that, if there is a risk of connective tissue disease in women with silicone breast implants, it is too small to be quantified.<sup>175</sup> The IRG found that the proportion of women with established connective tissue disease and silicone breast implants is small and the risk of developing such a disease is no higher in women with silicone breast implants than in women without implants.<sup>176</sup>

E.

### **Institute of Medicine**

In House Report 104-659, which accompanied a 1997 appropriations bill, Congress expressed concerns about the fragmentation of research regarding the safety of silicone breast implants and their possible relationship

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<sup>174</sup>Independent Review Group, *Silicone Breast Implants: The Report of the Independent Review Group* 8 (July 1998).

<sup>175</sup>*Id.* at 23

<sup>176</sup>Independent Review Group, *supra* note 174, at 22.

with connective tissue or other autoimmune diseases.<sup>177</sup> The Appropriations Committee requested that the U.S. Department of Health and Human Services sponsor a study of the safety of silicone breast implants by the Institute of Medicine (IOM) of the National Academy of Sciences.

In response, the IOM formed a Committee on the Safety of Silicone Breast Implants (the “Committee”) to review the past and ongoing research regarding silicone implants. The Committee included experts in the fields of preventive and internal medicine, nursing, family and women’s health, rheumatology, clinical and basic research, epidemiology, immunology, neurology, silicone chemistry, toxicology, breast and other cancer, plastic surgery, and radiology or mammography.<sup>178</sup>

While preparing its report, the Committee relied on approximately 2,200-2,300 published, peer-reviewed scientific reports, 1,000-1,100 selected industry technical reports, books, letters, opinion pieces, written statements, and abstracts as secondary sources, and presentations by scientists, women with implants, and other interested parties.<sup>179</sup> Approximately 1,200 references are cited in the text of the IOM report.<sup>180</sup> In 1999, the IOM released its report, entitled *Safety of Silicone Breast Implants*.

The Committee concluded that no evidence supports an alleged association between silicone breast implants and connective tissue or other autoimmune diseases.<sup>181</sup> In its review of the epidemiological data, the Committee observed that some of the more than 1.5 million adult women in the United States with silicone breast implants would be expected to develop connective tissue or other systemic diseases.<sup>182</sup> However, the evidence reviewed in the report suggested that these diseases are no more common in women with breast

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<sup>177</sup>Institute of Medicine, *supra* note 5, at 1.

<sup>178</sup>*Id.* at 15.

<sup>179</sup>Institute of Medicine, *supra* note 5, at 508.

<sup>180</sup>*Id.*

<sup>181</sup>*Id.* at 6-7.

<sup>182</sup>*Id.* at 8.



implants than in the general population of women without implants.<sup>183</sup> In fact, the report found the studies remarkably consistent in finding no elevated risk of disease in women with silicone implants.<sup>184</sup> Moreover, the Committee found that there was no rigorous or convincing scientific evidence to support a link between atypical connective tissue disease, or any new disease in women, and breast implants.<sup>185</sup> To the contrary, the Committee found that the epidemiological evidence indicated that there is no novel syndrome associated with silicone breast implants.<sup>186</sup>

The IOM released its report after the Independent Review Group and the National Science Panel published their comprehensive reviews of the literature regarding the safety of silicone breast implants. Although the reports differ to some extent in emphasis and scope, the IOM acknowledged that the reports are in substantial agreement and together “form a mutually consistent body of current informed scientific work on the subject of health and silicone breast implants.”<sup>187</sup> Thus, taken together, the overwhelming body of scientific evidence has failed to find an association between silicone gel-filled breast implants and autoimmune disease.

## V.

### Additional Concerns Regarding Breast Implants

Although epidemiological studies have overwhelmingly been unable to demonstrate a link between silicone

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<sup>183</sup> *Id.*

<sup>184</sup> *Id.* at 6-7.

<sup>185</sup> *Id.* at 232.

<sup>186</sup> *Id.*

<sup>187</sup> Institute of Medicine, *supra* note 5, at 505.

breast implants and autoimmune diseases, there are still prevalent safety concerns associated with the devices. Concerns with local complications such as capsular contractures, implant leakage and rupture, and mammography difficulties still require further safety review.

For example, in a 1997 study published in the *New England Journal of Medicine*, researchers concluded that local complications that require additional surgical procedures, such as capsular contractures, implant rupture or leakage, hematoma or bleeding, infection, or chronic pain, are an important concern for women with breast implants.<sup>188</sup> The study examined 749 women living in Olmstead County, Minnesota who received an implant at the Mayo Clinic between 1964 and 1991. During a mean 7.8 years of follow-up, complications occurred in 178 (23.8%) of the women, with capsular contraction occurring in 131 women (the most frequent complication).<sup>189</sup>

Similarly, in its 1999 report, the IOM found that local complications are still a cause for concern for several reasons. First, complications (including reoperations, ruptures, contractures, infections and pain) occur frequently enough to be a cause for concern and are the primary safety issues with silicone gel-filled breast implants.<sup>190</sup> Second, the risks associated with breast implants increase over the lifetime of the implant. Therefore, it may be difficult to precisely ascertain the long-term effects of current implant models due to a lack of quantitative data about their effectiveness.<sup>191</sup> In order to address this lack of data, the IOM suggests that women contemplating breast implant surgery be properly informed about the risks associated with the operation prior to undergoing the procedure.

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<sup>188</sup>Sherine E. Gabriel, Michael W. O'Fallon, Leonard T. Kurland, Marcy C. Beard, John E. Woods, Joseph L. Melton III, *Complications Leading to Surgery After Breast Implantation*, 336 *NEW ENG. J. MED.* 677-82 (March 6, 1997).

<sup>189</sup>*Id.*

<sup>190</sup>Institute of Medicine, *supra* note 5, at 5.

<sup>191</sup>*Id.*

It is clear that local complications such as capsular contracture, rupture, and silicone migration may vary with implants from different manufacturers; the factors that account for this difference, however, remain unclear.<sup>192</sup> Characteristics such as different shell composition, different gel consistency and diffusion characteristics, and different gel chemical composition may be some of the factors accounting for this variability among manufacturers.<sup>193</sup>

In addition to the differences in the incidence rates of local complications in implants from different breast implant manufacturers, the implant's performance may also vary depending on when it was produced.<sup>194</sup> There have been at least three "generations" in breast implant manufacture.<sup>195</sup> In the first generation (1963-1972), dominated by Dow Corning products, the implants consisted of thick shells and gel, and exhibited low rupture rates, high contracture rates and moderate to high gel diffusion rates.<sup>196</sup> During the second generation (1972-mid 1980s), the implants had thinner shells, contained more compliant gel and exhibited high rupture, contracture and fluid diffusion rates.<sup>197</sup> Finally, the most recent silicone gel-filled breast implants on the market (late 1980s to date), third generation implants, have a stronger shell with a barrier layer, contain compliant gel, and presumably have lower rupture, gel diffusion and contracture rates.<sup>198</sup> Thus, first generation implants had no reported ruptures, 95% of second generation implants had ruptured at 12 years, and only 3.5% of third generation implants had ruptured by 1992.<sup>199</sup> Similarly, reported rates of noticeable capsular contracture dropped from approximately 40 to 60% in first and second generation implants to only about 10% in third generation implants.<sup>200</sup> Although the frequency of local complications has been substantial in both breast augmentation and reconstruction procedures with either saline or silicone gel implants,

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<sup>192</sup>*Id.* at 56.

<sup>193</sup>*Id.*

<sup>194</sup>*Id.* at 78.

<sup>195</sup>*Id.*

<sup>196</sup>*Id.*

<sup>197</sup>Institute of Medicine, *supra* note 5, at 78.

<sup>198</sup>*Id.*

<sup>199</sup>*Id.* at 139.

<sup>200</sup>Independent Review Group, *supra* note 174, at 15.

some of the more common complications, such as rupture and contracture, may be becoming less frequent as technology improves.<sup>201</sup>

## A.

### Capsular Contracture

Scarring is an inevitable result of the foreign-body reaction that occurs during breast implant surgery.<sup>202</sup> However, although the mere presence of scar tissue around each implant (the “capsule”) in itself is not problematic, capsular contracture can be a serious concern with breast implant surgery. Capsular contracture occurs when the fibrous scar tissue that normally forms around the implant contracts and squeezes the implant, making the breast hard, unnaturally round and painful.<sup>203</sup> The FDA has identified four different levels of capsular contracture, ranging from the breast appearing soft and natural to the breast appearing hard, painful and abnormal.<sup>204</sup> Although the percentage of women who suffer from both noticeable and unnoticeable contractures is unknown, it may be as high as 50%.<sup>205</sup>

The correction of capsular contracture ranges from the surgical removal of the implant capsule tissue to removal of the implant itself.<sup>206</sup> Surgeons used to perform “closed capsulotomies” to try to relieve excessive contracture by forcefully squeezing the breast to rupture the scar tissue.<sup>207</sup> However, the procedure often also ruptured the implant envelope, thereby releasing silicone gel into the surrounding tissues; white

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<sup>201</sup>Institute of Medicine, *supra* note 5, at 178.

<sup>202</sup>Angell, *supra* note 7, at 40.

<sup>203</sup>Food and Drug Administration, *Breast Implant Risks*, Nov. 2000, at [http://www.fda.gov/cdrh/breastimplants/breast\\_implant\\_risks\\_brochure](http://www.fda.gov/cdrh/breastimplants/breast_implant_risks_brochure) [hereinafter FDA brochure].

<sup>204</sup>*Id.*

<sup>205</sup>*Id.*

<sup>206</sup>*Id.*

<sup>207</sup>Angell, *supra* note 7, at 41.

blood cells subsequently carried the newly “freed” silicone gel through the lymphatic system into the entire body.<sup>208</sup> Most surgeons no longer perform the procedure and, beginning in 1980, Dow Corning included a warning against closed capsulotomy in its package inserts.<sup>209</sup>

## B.

### Leakage and Rupture

In addition to concerns surrounding capsular contracture, evidence of gel migration (gel “bleed”) began to appear during the 1970s.<sup>210</sup> Although the implant envelope remained intact, tiny molecules of the gel leaked through the pores of the surrounding envelope and escaped into the body.<sup>211</sup> The leakage is usually contained within the encasing capsule of scar tissue; however, tiny particles of silicone are sometimes discovered in nearby lymph glands.<sup>212</sup> The silicone may also cause lumps (“granulomas”) to form in the breast, chest wall, armpit, arm or abdomen.<sup>213</sup>

A variety of factors may cause breast implant leakage and rupture. The most common causes are the deterioration of the implant shell with time, undetected damage at the time of surgery, shell weakness due to a manufacturing flaw, and trauma to the breast.<sup>214</sup> Rupture may be accompanied by decreased breast size, uneven breast appearance, pain or tenderness, tingling, swelling, or other changes in sensation.<sup>215</sup> However,

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<sup>208</sup> *Id.*

<sup>209</sup> *Id.* at 42.

<sup>210</sup> *Id.* at 41.

<sup>211</sup> Angell, *supra* note 7, at 41.

<sup>212</sup> *Id.*

<sup>213</sup> FDA brochure, *supra* note 203.

<sup>214</sup> Independent Review Group, *supra* note 174, at 16.

<sup>215</sup> FDA brochure, *supra* note 203.

many women may unknowingly experience a rupture without any symptoms (“silent ruptures”). If only a small tear occurs, the escaping silicone gel may remain undetectable within the surrounding capsule.<sup>216</sup>

Although it is clear that some quantity of silicone breast implants rupture, the overall frequency or risk of rupture is not known. Intracapsular rupture may be especially difficult to detect; there will likely be no corresponding dramatic change in breast size or shape because the silicone remains within the surrounding breast capsule.<sup>217</sup> Magnetic resonance imaging (MRI) may be used to evaluate patients with suspected rupture or leakage of their silicone gel-filled implant, but often intracapsular rupture is only discovered when the rupture has become severe enough to require re-operation.<sup>218</sup> Estimates regarding the frequency of rupture range from 1% to as much as 5%; nevertheless, the exact incidence of rupture is unknown.<sup>219</sup> The frequency of implant rupture will depend on the manufacturer, type and model of implant; thus, organizations such as the IOM recommend controlling for these variables in any analysis of implant rupture resistance, shell strength or rupture prevalence.<sup>220</sup>

In a FDA-sponsored study presented at the Sixth World Biomaterials Congress on May 18, 2000, study participants (women who had their first implant prior to 1988) responded to a telephone questionnaire in which they described their past breast surgeries and whether their implants were found to be ruptured.<sup>221</sup> One third of the 907 women in the study (303 women) reported that they had at least one surgery in which their implant was removed or replaced; of these women, 171 reported that at least one of their implants was

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<sup>216</sup>Angell, *supra* note 7, at 42.

<sup>217</sup>Independent Review Group, *supra* note 174, at 16.

<sup>218</sup>FDA brochure, *supra* note 203.

<sup>219</sup>Angell, *supra* note 7, at 42.

<sup>220</sup>Institute of Medicine, *supra* note 5, at 134.

<sup>221</sup>Food and Drug Administration, *Study of Re-operations and Self-Reported Silicone-Gel Breast Implant Rupture*, May 22, 2000, at <http://www.fda.gov/cdrh/breastimplants/studies/biinterview.html>.

found to be ruptured or leaking. However, the study is seriously limited because researchers were unable to retrieve any medical records for nearly half of the 303 women. Moreover, surgical records were obtained for only 85 of the women who reported a ruptured implant and only 69 of those records indicated that the implant had actually ruptured. Finally, it is not clear what may have caused the implant ruptures that did occur, or whether the subset of participants is representative of the entire population of women with silicone gel-filled implants.<sup>222</sup>

Similarly, the FDA completed another questionnaire-based study of the health effects of ruptured silicone gel-filled breast implants that was published in the May 2001 *Journal of Rheumatology*.<sup>223</sup> 344 women with silicone gel implants responded to a FDA questionnaire asking them about persistent symptoms such as joint pain, swelling, stiffness, and fatigue and whether a doctor had diagnosed them with any of a list of connective tissue diseases. After the questionnaire, the women underwent a MRI exam of their breasts to detect whether their implants were ruptured. Women with MRI-diagnosed extracapsular silicone gel were 2.8 times more likely to report that they had the soft tissue syndrome, fibromyalgia. This study is also limited, however, because women did not receive a medical examination to confirm their self-reported diagnosis. Moreover, the study does not distinguish between women who developed fibromyalgia before implant surgery and women who developed the disease after surgery.<sup>224</sup>

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<sup>222</sup> *Id.*

<sup>223</sup> Food and Drug Administration, *Study of Silicone Gel Breast Implant Rupture, Extracapsular Silicone, and Health Status in a Population of Women*, May 2000, at <http://www.fda.gov/cdrh/breastimplants/extracapstudy.html>.

<sup>224</sup> *Id.*

C.

### Mammography difficulties

A necessary result of breast implants is that mammography examinations are more difficult to perform. During breast augmentation surgery, a surgeon squeezes the implant into a pocket created behind the breast tissue so that the implant lies behind the breast and in front of the underlying muscle.<sup>225</sup> As a result of this placement, the implants may delay or hinder the early detection of breast cancer by obscuring the underlying breast tissue and/or by compressing the overlying tissue.<sup>226</sup> Moreover, mammography requires breast compression (hard pressure) that may increase the risk of implant rupture.<sup>227</sup>

This increased difficulty in conducting mammography examinations has important consequences for the detection of breast cancer. If a mammogram is not performed properly, possibly due to the presence of breast implants, the potential for delayed breast cancer diagnoses increases.<sup>228</sup> Although there is no evidence that breast augmentation is associated with increasing the false-positive rate of breast cancer detection or increasing the risk of breast cancer itself, augmentation has been shown to decrease the sensitivity of mammography screening among asymptomatic women.<sup>229</sup> Therefore, it may be important to obtain multiple views of the breast and manipulate the implant so that the breast tissue may be viewed more effectively.<sup>230</sup> Mammograms are more difficult to obtain in breast augmentation patients because the breast implant obstructs the passage of x-rays through the breast tissue.<sup>231</sup> This is less of a concern for mastectomy patients

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<sup>225</sup> Angell, *supra* note 7, at 39.

<sup>226</sup> FDA brochure, *supra* note 203.

<sup>227</sup> FDA brochure, *supra* note 203.

<sup>228</sup> See Heather Bryant & Penny Brasher, *Breast Implants and Breast Cancer—Reanalysis of a Linkage Study*, 332 NEW ENG. J. MED. 1535-39 (June 8, 1995) (cohort study finding that the incidence of breast cancer among women who underwent breast augmentation surgery was neither significantly higher nor lower than that among the general population during the period of time in which the cohort was followed).

<sup>229</sup> Diana L. Miglioretti, Carolyn M. Rutter, Berta M. Geller, *Effect of Breast Augmentation on the Accuracy of Mammography and Cancer Characteristics*, 291 JAMA 442-50 (Jan. 28, 2004).

<sup>230</sup> Angell, *supra* note 7, at 40.

<sup>231</sup> *Id.* at 42.



because the breast tissue is no longer present. In contrast to breast augmentation patients, where the implant is inserted behind the breast tissue, the implant is placed either behind the muscle, against the ribs, or between layers of the muscle in women undergoing implantation after a mastectomy for breast cancer.<sup>232</sup> As part of the FDA's justification for limiting the continued use of silicone implants to reconstructive surgery patients in its 1992 ban, the agency pointed to this discrepancy in mammography effectiveness between augmentation and reconstruction patients.<sup>233</sup> Although breast cancer may be more readily detectable in implant patients who no longer have breast tissue remaining, detection remains a concern for augmentation patients.

## D.

### Toxicity

Toxicology studies of silicone are helpful in assessing the safety of silicone breast implants for several reasons. First, given the potentially high incidence of gel bleed and implant rupture, it is useful to gauge the relative toxicity of silicone in the body; since it is neither ethically nor practically feasible to test a potentially dangerous toxin in human subjects, toxicology studies in animals may be used to identify possible adverse health effects of silicone.<sup>234</sup> Second, the studies may assist researchers in clarifying dose response variations.<sup>235</sup> Similarly, given the ethical constraints limiting testing on human research participants, researchers are free to experiment with varying doses in animals to determine potential effects at very high or very low exposure

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<sup>232</sup> *Id.* at 40.

<sup>233</sup> Kessler, *supra* note 87.

<sup>234</sup> Institute of Medicine, *supra* note 5, at 82.

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

levels. Finally, the studies may help to identify how and under what conditions a specific substance produces an effect.<sup>236</sup>

The majority of animal studies examining the toxicity of silicone have failed to identify an adverse toxicologic response. For example, the NSP found that toxicologic testing with silicone has occurred for almost fifty years and the majority of recent studies reaffirm the low systemic toxicity of silicone.<sup>237</sup> Some animal studies have suggested the possibility that silicone may promote systemic disease by altering the normal regulating mechanisms of the immune system or by inducing systemic inflammation.<sup>238</sup> The preponderance of the data from specialized animal models, however, indicates that silicone implants do not alter the incidence or severity of autoimmune disease.<sup>239</sup>

The IOM also examined the toxicity of silicone in its 1999 report. The Committee examined studies evaluating the carcinogenic, reproductive, mutagenic, teratologic, immunotoxic and general toxicity of silicone compounds.<sup>240</sup> The IOM concluded that, in its review of over fifty years of toxicology studies and industry reports, the studies of individual substances found in breast implants demonstrated no significant substance toxicity.<sup>241</sup> The report noted that, although the design and methodology of some of the older toxicity studies was somewhat deficient according to current standards, the toxicological information, as a whole, is “substantial and improving.”<sup>242</sup> Moreover, several studies have shown that the majority of silicones remain localized where they are deposited and do not move freely throughout the body.<sup>243</sup> Further, low molecular

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<sup>236</sup> *Id.*

<sup>237</sup> MDL Report, *supra* note 160. The panel also noted that toxicologic testing is useful because confounding variables, such as age, sex, and environmental factors, can be controlled experimentally. *Id.*

<sup>238</sup> *Id.*

<sup>239</sup> MDL Report, *supra* note 160.

<sup>240</sup> Institute of Medicine, *supra* note 5, at 112.

<sup>241</sup> *Id.*

<sup>242</sup> *Id.*

<sup>243</sup> *Id.*

weight silicones, which may be slightly more mobile, are cleared from the body relatively quickly because they have short half-lives.<sup>244</sup> Thus, the report concluded that the “accumulating qualitative and quantitative data on the general toxicity of silicones [. . .] allow a reasonable degree of confidence that silicone compounds in breast implants are not hazardous.”<sup>245</sup>

Similarly, the IRG determined that the information regarding the local and systemic toxicity, genetic and reproductive toxicity, and carcinogenicity of silicones indicated that silicone is a “relatively bland substance.”<sup>246</sup> The overall pattern of toxicity findings, both with regard to systemic and local actions, was consistent with conventional responses to foreign materials and indicated no unusual or unique type of reaction.<sup>247</sup>

## VI.

### Current Developments

#### A.

##### INAMED Application

In the years following the FDA’s ban, McGhan Medical (now Inamed Corp.) developed a breast implant device composed of silicone gel encased in a silicone elastomer envelope (shell). The shell consisted of

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<sup>244</sup> *Id.*.

<sup>245</sup> *Id.* at 82.

<sup>246</sup> Independent Review Group, *supra* note 174, at 24.

<sup>247</sup> *Id.* at 28.

an inner and outer layer sandwiched around a barrier layer that was designed to impede the diffusion of gel through the shell.<sup>248</sup> By June 1998, Inamed had received FDA approval for a study of these silicone implants in augmentation, reconstruction and revision patients.<sup>249</sup> The prospective study, which began in 1999, involved 940 silicone breast implant patients (494 augmentation, 221 reconstruction, and 225 revision patients). The study collected detailed local complication and effectiveness data yearly and a subset of approximately 34% of the patients underwent serial MRI screenings for silent ruptures. Consistent with FDA guidance at the time, Inamed collected at least two years of follow-up data prior to submitting a PMA. The study revealed a low frequency of implant rupture, low silicone toxicity rates, and relatively high levels of patient satisfaction.<sup>250</sup>

In October 2003, an FDA advisory committee evaluated Inamed's request to reintroduce silicone gel-filled breast implants to the US market.<sup>251</sup> Although Inamed's study revealed few implant ruptures, some committee members felt that there was not enough data to accurately gauge the risks of rupture because the study only covered a couple of years and not all participants received MRI exams.<sup>252</sup> Nevertheless, the panel recommended in a nine to six vote that silicone implants be allowed back into the market, but required that Inamed meet an array of conditions, including improved patient information, doctor-education programs, and further research into outstanding safety issues.<sup>253</sup> In response, Inamed agreed to create new educational materials for women who use implants, develop detailed informed consent procedures in cooperation with the FDA, and develop physician-training programs. Further, Inamed agreed to keep a registry of women who receive implants to provide long-term information about the status of the implants and assist women

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<sup>248</sup>Clinical Summary Memorandum, *Summary of Prospective Clinical Data contained in PMA #P020056*, September 12, 2003, <http://www.fda.gov/ohrms/dockets/ac/03/briefing/3989b1.clinical-summary-memo.pdf> [hereinafter Inamed PMA]

<sup>249</sup>*Id.*

<sup>250</sup>*Id.*

<sup>251</sup>Mathews, *supra* note 8. Similarly, in 2000 FDA re-evaluated saline-filled implants and declared that two companies' versions were safe enough to continue selling if women are warned about high breakage and replacement risks. *Id.*

<sup>252</sup>*Id.*

<sup>253</sup>*Id.*

in tracking their health.<sup>254</sup>

However, the advisory committee's decision was not without controversy. Just one month after the panel announced its recommendations, its chairman, Thomas V. Whalen, a professor of surgery at the Robert Wood Johnson Medical School, urged the FDA to override the panel's recommendation because of lingering long-term safety concerns.<sup>255</sup> In a letter to FDA Commissioner Mark McClellan, Whalen concluded that approval of Inamed's device would pose "threats to women that are clearly unknown" and argued that it is "incumbent upon the FDA to demand that the manufacturer establish in a rigorous, prospective, controlled study that these devices, despite their established breakage and leakage rates, are safe in the long term."<sup>256</sup> The FDA declined to comment on Whalen's letter. However, on January 8, 2004, the FDA deferred a final decision on the marketing of silicone breast implants and left the current ban in place, overriding its own advisory panel's recommendations.<sup>257</sup> The FDA cited a need for further information about the likelihood of leaks and their complications and unveiled new, tougher guidelines for PMA applications.<sup>258</sup> The decision is clearly a setback for Inamed; although its CEO, Nick Teti, said that the company did not believe it would be required to repeat its clinical trial, it was not apparent how the company would satisfy the FDA's new guidelines.<sup>259</sup> Teti expressed concern that the whole process had become highly politicized, even though the science supporting the marketing of implants is substantial.<sup>260</sup> Similarly, critics of the FDA's decision argued that "instead of going with the science here, the FDA has sided with the fears, holding silicone implants to ever higher and shifting standards."<sup>261</sup>

At the same time as the US continues to place limitations on the reintroduction of silicone breast implants into the market, the European Union has reached a different conclusion regarding the device's safety. In

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<sup>254</sup> *Id.*

<sup>255</sup> Ceci Connolly, *Panel Chair Opposes Advice on Breast Implants*, THE WASH POST, Nov. 6, 2003, at A10.

<sup>256</sup> Connolly, *supra* note 255, at A10.

<sup>257</sup> *Breast Beating at the FDA*, THE WALL ST. J., Jan. 13, 2004 [hereinafter *Breast Beating*]

<sup>258</sup> *Id.*

<sup>259</sup> Anna Wilde Mathews, *FDA Reaffirms Tight Restraints on Silicone Implant Sales*, THE WALL ST. J., Jan. 9, 2004, at A7.

<sup>260</sup> Clarke Thomas, *Inamed Pursues Its Silicone Future*, FIN. TIMES, Feb. 27, 2004.

<sup>261</sup> *Breast Beating*, *supra* note 257.

February 2003, amid safety concerns, Inamed's silicone implants were upgraded from a Class II to a Class III device, the E.U.'s most rigorously controlled device class.<sup>262</sup> The change triggered an approval and recertification process requiring a safety and efficacy demonstration for all Class III products to be marketed after March 1, 2004. Inamed received E.U. Class III CE Mark Approval and recertification in February 2004.<sup>263</sup>

## B.

### FDA Guidance Revisions

Since 1991, the FDA has required manufacturers to demonstrate the safety and effectiveness of their breast implants prior to marketing them to consumers. However, until recent guidelines, the FDA has not clearly specified the type, quality and quantity of data required to meet this standard. Although developing scientific studies (primarily the epidemiological studies discussed above) do not substantiate allegations of an association between silicone implants and connective tissue disease, concerns regarding implant rupture and gel bleed, capsular contracture, and overall safety and efficacy remain. Given the FDA's current policies curtailing the manufacture and distribution of silicone breast implants, further clarification of the FDA's expectations regarding safety and efficacy requirements is necessary for manufacturers seeking to market updated silicone implant models.

On January 13, 2004, the FDA issued a draft guidance document for breast implant marketing applications for industry and the FDA staff that would modify existing guidance (published in February 2003) in several

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<sup>262</sup>*Inamed Breast Implants Win E.U. Class III Approval*, 31 Device & Diagnostic Letter, Feb. 23, 2004 [hereinafter *E.U. Approval*].

<sup>263</sup>*E.U. Approval*, *supra* note 262.

ways. The presumable goal of the modifications is to clarify the FDA's expectations regarding the type and quantity of scientific data that will be required of manufacturers seeking to obtain PMA for their implants.<sup>264</sup> The new recommendations, included in the areas of mechanical testing, modes and causes of rupture, clinical study information, postapproval requirements, and labeling, seek to provide further guidance about the FDA's PMA screening process to implant manufacturers.<sup>265</sup>

In the area of mechanical testing, the FDA is concerned about the frequency and prevalence of rupture and gel bleed in silicone implants. At this time, as discussed earlier in this article, very little information is available about the risk of implant rupture. Thus, the updated guidelines reflect a concerted effort to develop mechanical testing strategies that more accurately predict rupture rates, causes and frequencies over time.<sup>266</sup> Similarly, the FDA introduced a new section, *Modes and Causes of Rupture*, in its guidance to explicitly recommend that a manufacturer characterize the modes and causes of implant rupture over time through retrieval studies, manufacturing processes assessments, surgical technique assessments, and comprehensive literature reviews.<sup>267</sup> Further, the FDA recommends the development of more accurate gel bleed tests that mimic body conditions.<sup>268</sup> The recommendations for both rupture and gel bleed testing echo the safety concerns the FDA voiced in its 1992 ban of silicone implants regarding the chemical composition of silicone and its unknown long-term effects on the body.

In the area of clinical studies, the FDA allows itself fairly broad discretion to evaluate manufacturer PMAs. For example, although the guidelines allow a manufacturer to submit a PMA after collecting and evaluating

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<sup>264</sup> See Food and Drug Administration, *Draft Guidance for Industry and FDA Staff—Saline, Silicone Gel, and Alternative Breast Implants*, Jan. 13, 2004 at <http://www.fda.gov/cdrh/ode/guidance/1239.html>.

<sup>265</sup> Compare Draft Guidance for Industry and FDA Staff – Saline, Silicone Gel, and Alternative Breast Implants, Jan. 13, 2004, at <http://www.fda.gov/cdrh/ode/guidance/1239.html> with Guidance for Industry and FDA Staff – Saline, Silicone Gel, and Alternative Breast Implants, Feb. 11, 2003, at <http://www.fda.gov/cdrh/ode/guidance/1354.html>.

<sup>266</sup> See generally, Food and Drug Administration, *Draft Guidance for Industry and FDA Staff – Saline, Silicone Gel, and Alternative Breast Implants, Part 6: Mechanical Testing*, Jan, 13, 2004 at <http://www.fda.gov/cdrh/ode/guidance/1239.html>

<sup>267</sup> See *id.*

<sup>268</sup> See *id.*

two years of clinical data, the FDA may, at its discretion, require additional submissions and testing to evaluate the device's safety and effectiveness (particularly with regard to gel-bleed and rupture concerns).<sup>269</sup> Moreover, in keeping with its new focus on implant rupture, the FDA recommends that a manufacturer include the rate, frequency, and local health consequences of intracapsular, extracapsular and migrated gel ruptures in a PMA, and provide relevant information from the published literature on issues relating to implant rupture.<sup>270</sup>

The FDA's goal of maintaining broad discretion over the PMA process is also apparent in its modifications to the *Postapproval Requirements* section. The section clarifies that the FDA may exercise its statutory authority to require post approval studies (i.e., physician follow-up), continued data collection (i.e., rupture rates and causes), physician certification and training programs, implant complication management, and patient registries to continually monitor device safety and efficacy.<sup>271</sup>

Finally, the *Labeling* section ties the modifications to the preceding sections together. In general, the agency wants far more information about the frequency and effects of implant rupture. Thus, the FDA now recommends that a manufacturer include the method and frequency of rupture screening, clinical management of ruptures, gel bleed results, and other supplemental information based on a literature review on patient and physician labels.<sup>272</sup>

The proposed changes also reflect a growing awareness within the agency of the increased scientific research and publication that has occurred in the field of silicone gel breast implants since the 1992 ban. For example, the guidance regarding data collection on connective tissue diseases and symptoms has been modified to indicate the agency's recognition of the substantial scientific research that has been done over the last decade.<sup>273</sup>

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<sup>269</sup> See Food and Drug Administration, *Draft Guidance for Industry and FDA Staff – Saline, Silicone Gel, and Alternative Breast Implants, Part 9.1: Clinical Studies*, Jan. 13, 2004, at <http://www.fda.gov/cdrh/ode/guidance/1239.html>.

<sup>270</sup> See Food and Drug Administration, *Draft Guidance for Industry and FDA Staff – Saline, Silicone Gel, and Alternative Breast Implants, Part 9.3: Safety Assessments*, Jan. 13, 2004, at <http://www.fda.gov/cdrh/ode/guidance/1239.html>.

<sup>271</sup> See Food and Drug Administration, *Draft Guidance for Industry and FDA Staff – Saline, Silicone Gel, and Alternative Breast Implants, Part 9.7: Postapproval Requirements*, Jan. 13, 2004, at <http://www.fda.gov/cdrh/ode/guidance/1239.html>.  
<sup>272</sup> *Id.*

<sup>273</sup> See Draft Guidance Part 9.3, *supra* note 270.



Thus, the FDA recognizes that the core study of a PMA does not need to examine a potential link between breast implants and connective tissue diseases; the agency still recommends, however, that a manufacturer collect information on the diagnosis of such diseases as part of the overall device safety assessment.<sup>274</sup> The extent to which this recognition will affect the agency's review of PMAs, however, remains unclear.

Despite the agency's recognition of scientific developments in the area of the connective tissue diseases, the new guidelines still create a higher bar for approving future PMA requests. The modifications impose tougher research requirements, including substantial new tests and studies regarding the risks, frequency and effects of implant rupture.

## VII.

### Conclusions

Silicone gel-filled breast implants entered the US market in the 1960s and were quickly embraced by both surgeons and breast surgery patients as an effective way to augment or reconstruct the breasts. However, although the introduction of silicone implants was relatively uncontroversial, by the early 1980s reports of potential links between the implants and connective tissue diseases began to surface. This purported association between the implants and disease spurred thousands of lawsuits and a multi-million dollar class settlement agreement, despite the absence of any epidemiological data to support such an association. In the midst of this heightened controversy, the FDA faced a dilemma. If the agency chose to allow the implants

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<sup>274</sup> See *id.*

to remain on the market, it would exacerbate criticisms by opponents of the use of silicone breast implants that the agency was unnecessarily delaying in acting to protect the average consumer. On the other hand, if the agency chose to ban the implants, breast implant proponents would criticize the FDA for banning a procedure that thousands of women might seek to undergo, without any evidence of a link between implants and disease. The FDA chose the latter option, thereby instituting a ban on silicone breast implants that still exists today.

It is not clear whether the FDA made the appropriate decision to ban silicone breast implants in 1992; it is clear, however, that the decision helped stimulate both manufacturers and independent research facilities to conduct further investigations regarding the safety of the devices. Since the FDA announced its decision, countless epidemiological studies have determined that there is no demonstrable association between the implants and connective tissue diseases. Moreover, groups like the IRG, the NSP, and the IOM have also examined the risks of local complications from silicone breast implants. Although many questions regarding the safety of the devices remain unanswered (such as rupture and leakage rates), the primary justification for the FDA's ban (that silicone implants are associated with connective tissue diseases) no longer exists. Given the changing information surrounding the implants' safety, it no longer makes sense to maintain a complete ban on silicone implants. Instead, the FDA should encourage further research and testing by allowing manufacturers to re-enter the market.

Although implants have been shown to cause significant local complications, these complications are not unique to silicone gel-filled implants; instead, as the IRG concluded, "the risks to patients associated with the use of silicone gel breast implants are no greater than for other implants."<sup>275</sup> The FDA has concluded that saline breast implants do not impose a significant enough risk to justify excluding the devices from

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<sup>275</sup>Independent Review Group, *supra* note 174, at 27.

the marketplace. Thus, given that no connection between autoimmune disease (or any new disorder) and silicone implants has been established, the FDA's justification for the implant ban no longer serves the purpose of protecting women's health when the risks associated with those devices are no greater than freely available saline implants. As an alternative to maintaining a complete ban on silicone implants, the FDA should establish comprehensive informed consent procedures to reintroduce the devices into the market. Such procedures would acknowledge both the perceived benefits of breast implantation and the significant risks associated with the surgery.

The FDA has already made some modifications to its policies for reviewing silicone breast implant PMAs; these changes are evident in the FDA's recent proposals updating guidelines for manufacturers. The new guidelines require further testing of implant rupture and gel bleed rates to obtain more comprehensive information about the risks and local complications associated with silicone implants. Moreover, as discussed earlier in this article, in its review of Inamed's recent PMA the FDA's advisory committee recommended instituting a compulsory national breast implant registry to identify short-term complications and provide data for future long-term research studies. It is not clear, however, whether these changes will serve as a further impediment to implant manufacturers by creating additional hurdles for regulatory approval. Such a result would be unfortunate; instead of imposing greater restrictions on implant manufacturers, the FDA should promote incentives for further research to properly identify implant risks.

The IRG made several proposals and recommendations for the future provision of breast implants that recognize the competing tensions between the physical and psychological benefits of breast implants and the significant physiological concerns associated with implantation. In addition to the changes the FDA has already made, these proposals may serve as a guideline for further FDA reforms. First, the IRG recommended that women contemplating breast implant surgery should have access to adequate information to make an

informed decision about whether to undergo the risks inherent in implant surgery.<sup>276</sup> Advertisements that promote breast implant surgery should also be required to include a statement that indicates that the procedure necessarily has some risks and discloses resources where potential patients can obtain comprehensive information about those risks.<sup>277</sup> In addition to the risks associated with the surgery, surgeons should also communicate the likely financial implications of both the surgery itself and the potential follow-up treatments and expenses that may be required. Prior to initiating the procedure, the woman should be required to sign a consent form that details the risks discussed and different implant options available.<sup>278</sup>

Second, the IRG proposed that surgeons should provide more systemic follow-up services for women who choose to undergo silicone breast implant surgery.<sup>279</sup> The women should be followed for a minimum of one year, with the option of longer follow-up periods, in order to identify potential complications that women would otherwise not choose to bring to their doctors' attention. Moreover, in connection with the more comprehensive provision of information discussed above, women should be given advice about how to identify potential implant rupture and signs of capsular contracture.<sup>280</sup>

These provisions for comprehensive risk disclosure provide a mechanism to address the FDA's concerns regarding the local complications of silicone implants, while avoiding the draconian measure of removing the implants entirely from the market. Most importantly, the measures offer a concrete way to confirm that the woman has in fact given knowing, voluntary consent upon full disclosure of the inherent risks of the procedure. At the time of the 1992 ban, the FDA found that many women were not adequately informed

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<sup>276</sup>Independent Review Group, *supra* note 174, at 27.

<sup>277</sup>*Id.*

<sup>278</sup>*Id.*

<sup>279</sup>Independent Review Group, *supra* note 174, at 28.

<sup>280</sup>*Id.*

about the risks associated with breast implant surgery prior to having the surgery performed.<sup>281</sup> In order to make sure that women are making informed decisions, therefore, it is necessary for both surgeons and manufacturers to provide more detailed information about the risks of local complications and the potential costs of further surgeries. As the IOM noted in its report, informed consent will not be adequate unless women are given information regarding the nature and relatively high frequency of local complications and reoperations.<sup>282</sup>

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<sup>281</sup>Rebecca S. Dresser, Wendy E. Wagner, Paul C. Giannelli, *Breast Implants Revisited: Beyond Science on Trial*, 1997 WIS. L. REV. 705 (1997).

<sup>282</sup>See Institute of Medicine, *supra* note 5, at 12.