Regulation through Litigation

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Silicone-gel-filled breast implants have been available in the United States since 1962. Yet until 1992, when the Food and Drug Administration (FDA) imposed a ban on silicone breast implants, sparking the largest class action settlement in history as well as widespread concern about health risks, no scientifically valid studies of the long-term health effects of breast implants had even begun. Although manufacturers knew since 1976 with the passage of the Medical Devices Amendments that the FDA could call on them to provide safety information at any time, the track record clearly shows they did only minimal research before 1992. It was not until 1994 that the first important epidemiological study providing evidence that silicone gel does not cause serious systemic health problems was published, and not until 1999 that the Institute of Medicine of the National Academy of Science analyzed all of the evidence and concurred.

Although current scientific evidence consistently and convincingly indicates that silicone breast implants do not cause serious systemic health problems, evidence produced during litigation suggested otherwise, leading to numerous multimillion dollar awards to individual plaintiffs, an FDA-imposed ban in 1992 on silicone breast implants, a multibillion dollar class action settlement, and the bankruptcy reorganization of the largest silicone

The author thanks Jessica Pishko and Jonathan Patchen for excellent research assistance.
manufacturer, Dow Corning. Because these outcomes now seem inconsistent with the scientific information indicating that implants are safe, many observers view the breast implant experience as a legendary example of legal and regulatory failure.\(^1\) Statements such as “recall the silicone-implant litigation fiasco” are commonplace.\(^2\) Critics complain that by failing to wait until reliable scientific evidence became available before making decisions, the FDA and the courts made mistakes of catastrophic magnitude.\(^3\)

Whether regulation and litigation erred and how they have erred requires an understanding of the informational context of their actions. In much the same way as the liability of companies should be assessed based on the state of information at the time of corporate decisions, similarly one should base assessments of the courts and regulatory interventions on the state of information at the time. This general principle includes, of course, the role that such institutions can play in generating requisite information, but it also includes recognition of the possibility that companies may withhold or fail to generate the key information. My evaluation based on this state of the information approach yields a quite different perspective than that of the standard critiques of the breast implants experience, many of which have taken advantage of the wisdom afforded by hindsight.

The practical consequence of awaiting the outcome of large-scale, long-term epidemiological studies is that regulatory bodies and the courts will fail to act even if a product is believed to be risky. How the courts and regulators should proceed with imperfect information is a complicated matter. The key concern is whether regulators and the courts acted properly based on the information available. The additional concern about the regulators is whether they exercised their authority to obtain information in a timely fashion.

The breast implants experience demonstrates how manufacturers control the flow of information and how litigation can provide information

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3. Marcia Angell, M.D., a highly vocal critic of the FDA and judicial system during the breast implant experience, summarized this viewpoint on Frontline, February 27, 1996, as “history is replete with instances of health scares based on claims, testimonials, and anecdotes, and we have to wait for the science.” Angell was the executive editor of the New England Journal of Medicine and is the author of the highly influential book Science on Trial: The Clash of Medical Evidence and the Law in the Breast Implant Case. (Video on file at Harvard Law School.)
that stimulates regulation. In the case of breast implants, the FDA did not initially require safety studies. Rather, the key information flow was in the opposite direction, as information revealed in the litigation about corporate behavior and product defects stimulated the FDA to take regulatory action. The possibility that exposure to silicone gel posed more serious risks failed to receive proper scrutiny until litigation pushed this issue to the forefront. Evidence produced during litigation demonstrated that not only did the manufacturers fail to perform safety tests, they also ignored warning alarms raised by their own employees and by surgeons who used the products, suppressed studies that may have indicated problems, and even destroyed evidence from negative studies. From the early days, Dow Corning and the other manufacturers knew of many product problems with breast implants, including bleeding of the silicone gel. Direct silicone injections were regulated as a drug and removed from the market in the early 1960s. Had the FDA known that silicone gel often leaked from the breast implant envelope, it could have classified implants immediately as a drug and so regulated silicone implants.4

The breast implants experience also demonstrates the hazards of regulatory agencies failing to exercise their authority in a timely fashion. Whether silicone implants caused systemic diseases was unknown when David Kessler, M.D., called for the moratorium in 1992. The available information mainly consisted of case reports without controls and research undertaken by the manufacturers for compliance purposes that was woefully inadequate by scientific standards. The transparent weaknesses of the studies that were submitted for marketing approval led the FDA to impose a moratorium on implant use while awaiting better information. By shirking its regulatory responsibilities until that time, the FDA set the stage for its authority to be usurped by litigation. Had the FDA exercised its authority in a more timely fashion, it is unlikely that breast implants would have joined the legion of mass toxic torts.

After discussing the history of breast augmentation procedures, I use a unique national survey of medical devices recipients to present new empirical evidence of the probability that a woman would have breast implants. This analysis helps reveal whether implant recipients were likely to be uninformed about the risks of implants. Women with implants tended to be more affluent, and education did not influence the implant decision, indicating that the women who received implants were not especially likely to

4. Indeed, Medical Engineering Corporation's Scientific Affairs Committee speculated in April 1977 that silicone oil bleeding through the shell and to the body tissue might cause the FDA to remove silicone gel implants from the market.
be misinformed or have few viable market alternatives. I also use this data set to provide an analysis of the types of localized defects commonly occurring in implants. The results show that defects and replacements were common. I discuss evidence from the literature on the localized and systemic health risks associated with breast implants. As this section shows, although localized risks were common among those with implants, the combination of relatively low implant usage among the population and low incidence of autoimmune diseases makes it difficult to either find strong evidence of enhanced risk or rule out this possibility, allowing both parties to litigation to use the science to support their position. I then describe the regulatory history of breast implants, followed by a description of the major litigations and the role of litigation in providing safety information. Table 5-1 provides a chronology of the key events in the breast implant experience.

The timeline demonstrates that the breast implant saga is not a tale of a tort system run amok as juries, ignorant of science, fell prey to the manipulations of greedy plaintiffs’ lawyers. The courts and regulatory agencies must make decisions at the time based on the available information. The cases presented to the jury had incomplete scientific evidence but did have plaintiffs with significant ailments. Jurors received convincing evidence that the manufacturers were guilty of fraud, negligence, and liability for failing to disclose information about the dangers of implants. There were also numerous case reports in the medical literature of serious autoimmune diseases occurring in women who had breast implants. Only in retrospect does the epidemiological evidence on longer-term hazards such as connective tissue disease exonerate the manufacturers.

**History of Breast Augmentation Procedures**

Efforts to enlarge breasts, either by surgically transferring fat to the breast from another part of the body or by injecting foreign substances into the breast area, began at least one hundred years ago. Some early examples include paraffin injections reported as early as 1889, followed by injection of other substances such as ivory, glass balls, ground rubber, and foam sponges. The Ivalon polyvinyl sponge was used in the early 1950s to enlarge breasts, although eventually this method was discontinued as the prosthesis tended to crush, reducing breast size and causing the breast to harden.5

5. Sarwer and others (2000, p. 845); and Bondurant and others (2000, p. 21).
Table 5-1. *Timeline of Critical Events*

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>1962</td>
<td>Silicone-gel-filled breast implants first used.</td>
</tr>
<tr>
<td>1965</td>
<td>Silicone injections classified as a drug and not approved for human use.</td>
</tr>
<tr>
<td>1976</td>
<td>Medical Devices Amendments give FDA authority to regulate breast implants. Implants grandfathered in.</td>
</tr>
<tr>
<td>1977</td>
<td><em>Mueller v. Corley.</em> Plaintiff is awarded $170,000 due to rupture.</td>
</tr>
<tr>
<td>1978</td>
<td>FDA General and Plastic Surgery Devices Panel recommends Class II status. FDA concerns in 1978 include gel leakage in intact implants.</td>
</tr>
<tr>
<td>1982</td>
<td>FDA proposes Class III status.</td>
</tr>
<tr>
<td>1984</td>
<td><em>Stern v. Dow Corning.</em> Plaintiff is awarded over $1.7 million for claim that ruptured implants caused connective tissue disease. Internal Dow Corning documents showed Dow had suppressed risk information. These documents were then sealed by court order.</td>
</tr>
<tr>
<td>1988</td>
<td>Silicone implants are classified as Class III requiring manufacturers to submit safety information. FDA concerns in 1988 include capsular contracture, breakage, bleeding outside the shell, migration of silicone to organs, interference with the accuracy of mammogram, calcification of the fibrous capsule, immune disorders, and cancer.</td>
</tr>
<tr>
<td>Nov. 1991</td>
<td>Manufacturers’ safety information deemed inadequate by FDA.</td>
</tr>
<tr>
<td>Dec. 1991</td>
<td><em>Hopkins v. Dow Corning.</em> Plaintiff is awarded $840,000 in compensatory damages and $6.5 million in punitive damages for claim that ruptured implants caused her connective tissue disease.</td>
</tr>
<tr>
<td>Jan. 1992</td>
<td>FDA imposes a moratorium on silicone implants.</td>
</tr>
<tr>
<td>Feb. 1992</td>
<td>First class action filed in wake of FDA moratorium. Eventually 440,000 women join.</td>
</tr>
<tr>
<td>April 1992</td>
<td>Silicone implants withdrawn from market except in limited cases.</td>
</tr>
<tr>
<td>1994</td>
<td>Mayo clinic study shows systemic health risks not likely.</td>
</tr>
<tr>
<td>1995</td>
<td>Federal settlement approved with Dow dropping out.</td>
</tr>
<tr>
<td>1995</td>
<td>Dow Corning files for Chapter 11 bankruptcy reorganization, citing 19,000 individual implant lawsuits and at least 45 putative class actions.</td>
</tr>
<tr>
<td>1996–98</td>
<td>Courts appoint science panels. All panels conclude implants do not cause systemic diseases. Various courts do not allow plaintiffs’ experts to testify under Daubert.</td>
</tr>
<tr>
<td>1999</td>
<td>Institute of Medicine concludes only localized risks of silicone implants including “overall reoperations, ruptures or deflations, contractures, infections, hematomas, and pain.”a</td>
</tr>
</tbody>
</table>


Silicone was an attractive alternative to such materials. Transformed from the natural element silicon, silicone is truly one of the most versatile and useful manmade materials. Developed in the 1930s by Dow Chemical, silicone is used as an insulator, coolant, and lubricator, and also is
widely used in products inserted in the body such as joint replacements and pacemaker covers. Jack W. Snyder surveys the use of silicone in medical products and the scientific evidence on safety. More than 500 medical products contain measurable amounts of silicone. The biologic effects of silicone have been tested in animals dating back at least to 1950. All scientific evidence indicates the substance is inert. The only adverse effect that has been detected in reaction to silicone implantation in animals is a tumor of soft tissue known as sarcomas or solid-state carcinogenesis. Animals who are implanted with any smooth object, including silicone, nylon, glass, and metals, are known to develop solid-state carcinogenesis. This is not a reaction to the chemical involved. This effect seems to be restricted to animals: there is no evidence that solid-state carcinogenesis also occurs in humans.

Silicone has been used to enlarge breasts since at least the 1940s. Initially, silicone oil was directly injected into the breasts. To prevent the silicone gel from migrating to other parts of the body, the silicone gel would be deliberately adulterated with other oils or other substances such as petroleum jelly, beeswax, or shellac to cause scarring in the breast area. Japanese prostitutes used silicone to enlarge their breasts, believing that American servicemen preferred large breasts. Direct injections were also widely used by showgirls in Las Vegas, where as many as 40,000 women had silicone injections by 1976. These direct injections of adulterated silicone caused serious medical problems as well as deaths. In 1965 the FDA classified silicone injections as a drug regulated under the Food, Drug and Cosmetic Act, and the FDA has not approved silicone injections for human use or any cosmetic purpose.

The modern era of breast implants began in the 1960s. Two plastic surgeons from Texas, Frank Gerow and Thomas Cronin, replaced direct injections with silicone gel inserted into a silicone envelope. In 1962 Timmie Jean Lindsey entered a hospital to have tattoos removed and became the first woman to receive silicone breast implants. Dow Corning began marketing these implants under the trade name “Silastic” in 1963. As the silicone was encased in an envelope, these implants were classified as a medical device rather than as a drug and so did not at that time fall under the FDA auspices. Saline-filled implants, in which saline is placed in the

envelope instead of silicone gel, have also been available since the late 1960s but are widely considered to produce an inferior cosmetic effect.

Dow Corning was the only supplier of silicone implants from 1962 to 1968, and remained the largest producer of implants through 1992 when the company opted to withdraw from the market rather than continue to seek FDA approval. A number of companies entered the market after 1968, with four manufacturers comprising 80 percent of the implant market: Dow Corning, Bristol-Myers Squibb, Mentor Corporation, and McGhan Medical Corporation. Although Dow Corning was the largest producer of implants at the time it withdrew from the market, the total value of its implants operations amounted to less than 1 percent of its business.

There are no exact data on the number of silicone implant procedures conducted before 1992. The most commonly cited value as of 1992 is that about 1 million American women had silicone breast implants, with most sold between 1980 and 1990. It was estimated that about 20 percent were for reconstruction after breast cancer or to correct abnormalities. The FDA revised its estimate of the number of implant patients in 1992, halving it to 1 million from 2 million, because the original estimate of 2 million seemed to be based on the number of implants sold.

Two national surveys that allow estimates of the number of implant recipients were conducted in the late 1980s. The Medical Device Implant Supplement to the 1988 National Health Interview Survey (NHIS) provided data on medical implants. The National Center for Health Statistics analysis of the data reports that 143 women within the sample had silicone breast implants, implying that as of 1988 there were an estimated 620,000 implants in 381,000 women. The second national survey was sponsored by Dow Corning. This mail survey of 40,000 households in 1989 reported 227 women with implants out of 27,538 women sampled. Extrapolated to the entire population, these values implied that an estimated 815,700 women in the United States had breast implants as of 1989. The Dow Corning survey did not limit their definition of breast implants to silicone only, which may in part account for the larger estimated number of

12. As this survey provides the primary data for my analysis, I discuss these data in detail in the next section.
implants. However, since the vast majority of implants through this period were silicone, only a small component of this disparity is likely to be accounted for by the difference in the types of breast implants reported in the respective surveys. The users of the NHIS data note that other sources suggest that their estimate may be an underestimate of the actual number.

The American Society of Plastic Surgeons (ASPS) has kept data on the number of plastic surgeries performed by member plastic surgeons since 1992. Their trend data show that cosmetic surgery procedures in general, and breast augmentation in particular, have increased dramatically through this decade. Overall, cosmetic surgery procedures increased by 175 percent between 1992 and 1999, with women far more likely to undertake cosmetic surgery than men. Of approximately 1 million cosmetic surgery procedures performed in 1999, 89 percent of the patients were women.

Despite the fallout over silicone implants beginning in 1992, breast augmentation procedures have become even more popular, increasing by 413 percent over the 1992–99 period. Breast augmentation is second only to liposuction, with 167,318 breast augmentations performed in 1999 alone. But breast surgery is not limited to augmentation procedures: another 82,975 patients had surgery for breast reconstruction, and almost as many—78,169—had breast reduction surgery. Of those with implants for reconstructive purposes, 13,009 had them removed, with about 73 percent replacing their implants.

**Empirical Profile**

To examine who gets breast implants and the characteristics of implants, I use data from the Medical Device Implant Supplement to the 1988 National Health Interview Survey. The National Health Interview Survey (NHIS) is an annual survey containing demographic and socioeconomic questions asked of all respondents in each year, such as sex, age, race, marital status, veteran status, education, family income, industry and occupation, limitations on activities, hospital stays, and doctor visits. Besides the annual core questions, the survey requests information on special topics that vary annually. To provide information for the FDA's regulation of medical devices, the FDA's Center for Devices and Radiological Health collaborated

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15. “Statistics and Costs.” www.plasticsurgery.org [March 2001]. These numbers represent a lower bound since some nonmember surgeons also perform these procedures.
with the National Center for Health Statistics to include questions about medical device implants in the 1988 NHIS. The Medical Device Implant Survey was the first nationally representative, population-based survey of prevalence and utilization experience of implanted medical devices.

All respondents to the NHIS (122,310 observations) were asked to report whether they had an implant of any kind. There were 5,592 sample respondents reporting a total of 7,600 implanted medical devices. (One reason that many respondents had more than one implant was that the survey would report breast implants in both breasts, or lenses implants in both eyes, as two devices.) The survey requested specific information for five of the more common implant types: artificial joints, fixation devices, artificial heart valves, intraocular lenses, and pacemakers. Respondents were not asked whether they had a breast implant. The survey also included a catch-all category for any other implanted medical device, and this information is used to perform the following analyses of breast implant usage and characteristics.

For each medical device, the respondent (or proxy) was asked a series of questions, including the number, type, and body part in which the implant was located, dates of insertion of original device and any replacements, frequency of replacement and reasons for the most recent replacement, length of time with the device, and any adverse effects or complications such as healing problems, pain, infections, or defect.

As I discussed earlier, two early analyses of these data reported that there were 143 women in the sample with silicone breast implants, based on the number of women who reported a silicone implant inserted into the breast. Since other types of implants were in use as of 1988, including saline and polyurethane implants, I performed an independent analysis of the NHIS data and determined the number of breast implants more broadly. First, one survey question asked the part of the body where the device is located. There were 170 women who responded that the device was located in the breast. Of these 170 women, one respondent reported that the implant in her breast was an infusion pump, and one respondent was an improbable seven years old. After eliminating these two observations, the sample is composed of 168 respondents with breast implants that are a silicone implant (143 respondents), other device (10 respondents), or unknown (15 respondents). Although there is some chance that my measure of implants is overinclusive, I note that other devices inserted in the chest or breast area such as heart valves, pacemakers, some fixation devices, infusion pumps, shunts, or catheters, and so forth, are asked about
separately and are therefore unlikely to be erroneously identified by my method as a breast implant.

Silicone implants accounted for the majority of implants during the pre-1992 period. Of the 168 women with implants, 143 (85.1 percent) reported silicone implants. The age of the implant recipients ranged from twenty-one to seventy-seven. The survey did not request information on the reason for implantation, so there is no way to know which of these individuals received implants for medical reasons (for example, reconstruction after mastectomy or prophylaxis) and how many received them for cosmetic reasons. To get a sense of the implant rate implied by this sample, there were 42,378 female respondents from twenty-one to seventy-seven years old to the full NHIS survey, indicating a breast implant rate of 0.40 percent.

To assess the probability that a woman has breast implants, I estimated a probit equation for the women in the NHIS sample. The results are presented in table 5-2. Breast implant use increases with age, but at a diminishing rate, peaking at age forty-one. In terms of the demographic profile, breast implant users are more likely to be white, divorced, and affluent. Breast implant use is more common in the South and the West, which reflects the historical origins of breast implant surgery in Texas and is consistent with the known high usage of silicone injections in California and Nevada.

A useful question to ask for any risky product is whether only groups who are likely to be misinformed or with few viable market alternatives will purchase it. There is no evidence of this form of market failure for breast implants. Education is not a significant determinant of implant status, and more affluent women with a greater choice of medical treatments are the ones most likely to obtain breast implants.

The NHIS data also illuminate the extent to which patients with breast implants report problems with the device. The survey requested information only on product defects and localized characteristics such as pain and bleeding. The survey did not elicit information on any long-term or systemic health effects such as connective tissue disease (CTD) that have been the focus of litigation. The first columns of table 5-3 provide statistics on the problems recipients have with their current implants, and the second column reports statistics on the problems users had with their initial implant that led to a replacement. Of the women with breast implants, 22 percent reported problems with their current implants. The most frequently cited difficulties are pain, defects or malfunction, and infections.
Table 5-2. Probit Analysis of Breast Implant Use

<table>
<thead>
<tr>
<th>Explanatory variable</th>
<th>Coefficient (standard error in parentheses)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>0.057** (0.016)</td>
</tr>
<tr>
<td>Age squared x 100</td>
<td>-0.069** (0.017)</td>
</tr>
<tr>
<td>Education</td>
<td>0.012 (0.011)</td>
</tr>
<tr>
<td>White race</td>
<td>0.924** (0.203)</td>
</tr>
<tr>
<td>Married</td>
<td>0.230 (0.141)</td>
</tr>
<tr>
<td>Previously married</td>
<td>0.600** (0.147)</td>
</tr>
<tr>
<td>Family income</td>
<td>0.010** (0.002)</td>
</tr>
<tr>
<td>Family income missing</td>
<td>0.269* (0.114)</td>
</tr>
<tr>
<td>Employed</td>
<td>0.047 (0.064)</td>
</tr>
<tr>
<td>South</td>
<td>0.288** (0.077)</td>
</tr>
<tr>
<td>West</td>
<td>0.278** (0.083)</td>
</tr>
<tr>
<td>Northeast</td>
<td>-0.250* (0.115)</td>
</tr>
<tr>
<td>MSA over 1 million</td>
<td>-0.028 (0.070)</td>
</tr>
<tr>
<td>MSA 0.25–1 million</td>
<td>0.036 (0.074)</td>
</tr>
<tr>
<td>Constant</td>
<td>-5.550** (0.417)</td>
</tr>
<tr>
<td>Observations</td>
<td>42,399</td>
</tr>
</tbody>
</table>

Source: Author's calculations from the Medical Device Implant Supplement to the 1988 National Health Interview Survey.

a. Dependent variable: has breast implant. *Significant at 5 percent; **significant at 1 percent
More noteworthy is that 15 percent of the women with breast implants had their original implants replaced at least once. The reason for replacement resulted primarily from defects or malfunction, infections, and pain. The information from this survey on the high replacement rate was available by 1989, thus predating David Kessler’s moratorium and the extensive breast implant publicity.

**Localized Breast Implant Risks**

It has long been known that silicone breast implants may cause localized problems, such as hardening of the breast tissue. They have a high rate of rupture, releasing silicone gel into the body. Even without rupture, silicone gel can bleed outside the shells. They are not lifetime devices. Replacement involves additional surgery risk.

In humans, insertion of any foreign object into the body’s tissue leads to an inflammatory response. Scar tissue or a capsule frequently forms around all types of implants, squeezing the implant and making the breasts hard and painful. This effect is called capsular contracture. Studies indicate that capsular contracture is common. The degree of capsular contracture is graded by the Baker grading scale, where grade III indicates the breast is firm and looks abnormal, with visible distortion, and grade IV is more severe, with painful breasts and greater distortion. A 1984 study found a capsular contracture rate of grade III or grade IV of 54 percent among patients with silicone implants for reconstruction. Recent studies by Mentor and McGhan of the rate of capsular contracture of saline-filled breast implants of grade III or IV indicate a rate of 9 percent among augmentation patients and 25 or 30 percent among reconstruction patients.16

One treatment option for capsular contracture is to surgically remove the tissue capsule or replace the implant. The alternative is a technique called closed capsulotony. In this procedure, the surgeon would break the protective layer of scar tissue by hand. Not surprisingly, closed capsulotomy often caused the implant to rupture, as it involved manipulation of the breast tissue sufficiently forceful to break down scar tissue. Manufacturers recommended against using this procedure; despite their warnings, this technique was commonly used.

Implants also frequently ruptured for other reasons including damage

Table 5-3. Complications with Breast Implants, U.S. Women, 1988

<table>
<thead>
<tr>
<th>Complicationsa</th>
<th>Characteristics of current implant (N = 168)</th>
<th>Characteristics of original implant leading to replacement (N = 25)</th>
<th>Percentage of devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Defect or malfunction</td>
<td>5.5</td>
<td>32.0</td>
<td></td>
</tr>
<tr>
<td>Infection</td>
<td>3.6</td>
<td>16.0</td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td>6.1</td>
<td>16.0</td>
<td></td>
</tr>
<tr>
<td>Healing problem</td>
<td>2.4</td>
<td>4.0</td>
<td></td>
</tr>
<tr>
<td>Blood clots</td>
<td>Not asked</td>
<td>4.0</td>
<td></td>
</tr>
<tr>
<td>Bleeding</td>
<td>Not asked</td>
<td>4.0</td>
<td></td>
</tr>
<tr>
<td>Injury</td>
<td>Not asked</td>
<td>0.0</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>11.6</td>
<td>52.0</td>
<td></td>
</tr>
<tr>
<td>No complications</td>
<td>77.9</td>
<td>0.0</td>
<td></td>
</tr>
</tbody>
</table>

Source: Author's calculations from the Medical Device Implant Supplement to the 1988 National Health Interview Survey.

a. Complications are not mutually exclusive.

by surgical instruments during surgery, injury, or aging of the implant. A retrospective study performed by the FDA found that 69 percent of 344 women who had silicone implants inserted before 1988 had at least one ruptured implant, where the rupture was detected by an MRI examination.17 Of the total sample of 344 women, 21 percent had gel leakage in one or both breasts.

The earlier implants used a thick envelope and a thick gel. Their advantage was that they were probably less prone to rupture and gel bleed, and if ruptured, the silicone was less likely to disperse through the body.18 In an effort to reduce the extent of capsular contracture and to make the implants feel more natural, manufacturers switched to a thinner envelope and more fluid gel. The thinner envelopes seemed more prone to rupture, and even if intact, silicone leaked from the envelope and apparently migrated throughout the body. This phenomenon seemed to trigger the broad concern over health risks.

18. Indeed, Frank Gerow M.D., one of the inventors of the silicone gel implant, testified that he and other surgeons would purposely rupture the envelope after the implant was in place, as the gel in use before the mid-1970s was extremely cohesive and would stay as a gel mass within the pocket. See Henderson v. Heyer-Schulte Corp. Court of Civil Appeals of Texas, Houston (1st Dist.), No. 17627, March 27, 1980.
Besides the localized problems, implants or silicone gel outside the implant can interfere with mammography, making breast cancers more difficult to detect. As the silicone migrates to other parts of the body, granulomas (lumps) may also form around the free silicone. Other localized problems include infections and hematomas.

The Même implant, sold by Surgitek, a subsidiary of Bristol-Myers Squibb, was covered with polyurethane foam similar to that used for chair cushions or filters for air conditioners. This foam was known to break down into TDA, considered a known cancer risk. The polyurethane-covered breast implant was intended to reduce capsular contracture; however, when the polyurethane did break down, surgeons reported that it could not be removed without disfiguring surgery. Approximately 200,000 to 400,000 American women had polyurethane-covered implants, mostly inserted between 1985 and 1990. These implants were removed from the market in April 1991 by Bristol-Myers Squibb as a consequence of FDA pressure. Recent evidence indicates unambiguously that the cancer risk from these implants is trivial, and that women with such implants should not have them removed because of feared cancer risks.

Systemic Problems and Epidemiological Evidence

Although localized problems such as capsular contracture are certainly undesirable side effects of implantation, these localized problems alone did not lead to the FDA ban on silicone implants. The concern of the FDA and the contentious issue in the courts was that leakage of gel from silicone implants causes more debilitating systemic diseases.

The possibility that silicone gel outside the implant envelope causes serious systemic health problems gained momentum in the 1980s, with connective tissue diseases (CTD) and other diseases attributed to the presence of silicone outside of the implant. CTDs and related disorders pertain to the connective tissues of the body such as fibrous tissues and cartilage. The posited mechanism is that exposure to silicone causes the woman's immune system to attack her own cells (that is, an autoimmune reaction.) Defined autoimmune diseases include rheumatoid arthritis, systemic lupus erythematosus, scleroderma, Sjogren's syndrome, polymyositis, and dermatomyositis. A variety of other signs and symptoms that have been linked to silicone implants include joint pain, headaches, chronic
fatigue, dizziness, memory loss or problems with concentration, and so forth. Since the array of symptoms does not meet the criteria for a recognized disease, it has been proposed that exposure to silicone causes a new disease called by various names including “human adjuvant diseases,” “silicone related syndrome,” or “atypical disease.”

All of these conditions attributed to silicone occur to some proportion of the population without silicone implants. Table 5-4 presents estimates of the background risks of these diseases. As the table demonstrates, the background risk for the various connective tissue diseases that formed the focal point of the breast implant litigation, such as systemic lupus erythematosus and scleroderma, are quite small, ranging from incidence of 1 per 100,000 or less for dermatomyositis and an upper bound of the estimated range of 38 per 100,000 for rheumatoid arthritis.

The task for litigation is to distinguish whether breast implants significantly increased the risk. The key statistic in epidemiology is the measure of relative risk and the corresponding confidence interval. A relative risk of 1.0 indicates no increased risk. If the value of 1.0 is included in the confidence interval, breast implants do not cause a statistically significant change in risk. Some courts require a doubling of the risks, corresponding to a relative risk of 2.0, which is then interpreted by courts as making it more probable than not that breast implants caused the disease. When dealing with such low-probability events, it is difficult to distinguish whether such a doubling of a risk has occurred, even if an effect of that magnitude was present.

To provide information on the risks of implants as well as to demonstrate the difficulty in assessing risks of breast implants, it is useful to discuss three epidemiological studies using data from the Mayo Clinic Study, the Nurses Health Study, and the Harvard Women’s Health Cohort Study that received a great deal of media and legal attention. The study by Sherine E. Gabriel and others used medical records from the Mayo Clinic and affiliated hospitals in Olmstead County, Minnesota. The study compared the incidence of CTDs in 749 women with breast implants to a comparison group of 1,498 women without implants. Within this sample, five implanted women and ten comparison women had any CTD as determined by review of the medical records, which yielded an adjusted relative risk of 1.10 with a 95 percent confidence interval of (0.37, 3.23). This study thereby demonstrates no increased risk from implants; however, given the sample size, the test had little power to detect an effect for any rare

Table 5-4. *Background Risk of Connective Tissue Diseases (CTD)*
in Women

<table>
<thead>
<tr>
<th>Disease</th>
<th>Incidence per 100,000 women</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rheumatoid arthritis</td>
<td>27.9–38.0</td>
</tr>
<tr>
<td>Systemic lupus erythematosus</td>
<td>2.5–11.4</td>
</tr>
<tr>
<td>Systemic sclerosis/scleroderma</td>
<td>1.2–2.0</td>
</tr>
<tr>
<td>Sjögren's syndrome</td>
<td>4.0</td>
</tr>
<tr>
<td>Dermatomyositis/polymyositis</td>
<td>0.3–1.0</td>
</tr>
</tbody>
</table>


disease. The authors note that assuming a background risk of 1.6 per 100,000 women of scleroderma, they would require a sample of 62,000 women with implants, and 124,000 without implants, followed for an average of ten years each, for a doubling of the relative risk to be detectable.

Jorge Sanchez-Guerrero and others used data from the Nurses Health Study.20 The Nurses Health Study is a large cohort study started in 1976 with data on more than 120,000 individuals. The 1992 biennial questionnaires requested information on breast implants and injections. Based on self-reported prior information from the biennial questionnaires through 1990 about physician-diagnosed definite CTDs, rheumatic conditions, or other CTD, the authors calculated an adjusted relative risk for a definite CTD of 0.6 (95 percent confidence interval 0.2–2.0). Despite the large cohort, with 88,377 respondents in 1992, only 1,183 respondents had a breast implant of any type, and only 876 had silicone-gel-filled implants. By using medical information on CTDs reported only up to 1990, the authors avoided possible response bias arising from the vast media coverage that started in 1990. However, the study has been criticized for failing to capture other nonspecific complaints such as those arising in the litigation.

The largest study of the health risks of breast implants is based on data from the Harvard Women’s Health Cohort Study. This is a retrospective cohort study of female health professionals conducted by Charles H. Hennekens and others.21 The authors mailed a questionnaire to 1.75 million female health professionals between September 1992 and May 1995. This survey yielded 395,543 respondents who reported information on breast

implant status and year of implantation, and self-reported information on a diagnosis of five definite CTDs and any other CTD. The authors found statistically significant increases in the risk of “any CTD” and “other CTD” with relative risk values of 1.24 (95 percent confidence interval 1.08–1.41) and 1.30 (95 percent confidence interval 1.05–1.62) respectively. The relative risk for the individual CTDs were all above 1.0 but did not demonstrate a statistically significant increase in risk as the confidence intervals included 1.0. For example, the relative risk of rheumatoid arthritis was 1.18 (95 percent confidence interval 0.97–1.43). As the only major study to find an increase in relative risk, the results of this study have been widely used by plaintiffs to demonstrate the enhanced risk of breast implants. However, given the study design, the authors themselves interpret the study as demonstrating that any enhanced risks, if they exist, will be minor. Since the data were self-reported during a time of highly visible attention in the media, it is possible that women with implants and perceived illnesses were more likely to respond. Supporting this premise is the high reported implant rate that was at least twice the size reported elsewhere, as well as unusually high incidence rates of CTDs.

On balance, the science indicates that there are real and substantial localized problems with many implants, including rupture and capsular contracture. However, based on evidence that for the most part has been developed after the litigation emerged, there is little or no evidence of statistically significant increased risks of autoimmune diseases, and no evidence of risks sufficiently great to make it more probable than not that ailments such as CTDs are attributable to breast implants.

Yet despite the scientific consensus, those claiming that implants are indeed responsible for systemic diseases criticize these studies on two distinct grounds. One criticism that has some merit is that the sample sizes in existing epidemiological studies are too small to detect rarely occurring diseases—that is, the power of the tests is low. Judge Sam C. Pointer, who was appointed to oversee the consolidated federal class action cases, commissioned a Rule 706 National Science Panel to synthesize the emerging literature on breast implant risks. The panel performed a meta-analysis using the reliable available studies at the time, which allowed them to pool information from various smaller studies. Table 5-5 summarizes the

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22. Another criticism, that as directly or indirectly the studies have largely been funded by the manufacturers, they are automatically suspect, will not be discussed here.

estimates of the relative risks of breast implants for various CTD categories. The vast size of the Hennekens study means that it will be accorded great weight in a meta-analysis; for this reason the Rule 706 National Science Panel provided relative risk estimates calculated with and without the Hennekens study. For all of the studies excluding the Hennekens study, the 95 percent confidence intervals include 1.0. When the Hennekens study is included in the meta-analysis, breast implants appear to statistically increase the risk of CTD, but with a risk level far short of the 2.0 standard.

The other major criticism is that silicone implants cause a new disease. Proponents of this view have criticized the epidemiological studies for examining only recognized diseases, therefore failing to uncover evidence of a new condition. In cases involving new diseases, the epidemiological studies will be attacked for not asking the right questions. However, the Sanchez-Guerrero study based on the Nurses Health Study was careful to check not only for existing diseases but also to note any signs or symptoms of these diseases. This study again failed to detect any relation between implants and systemic diseases.

The Institute of Medicine report explains the circularity of any reasoning that generates the existence of a new disease: “The disease definition includes, as a precondition, the presence of silicone breast implants, so it cannot be studied as an independent health problem. The committee finds that the diagnosis of this condition could depend on the presence of a number of symptoms that are nonspecific and common in the general population. Thus there does not appear to be even suggestive evidence for the existence of a novel syndrome in women with breast implants.”

There is no evidence that implants cause lupus, scleroderma, or rheumatoid arthritis. Implants are not associated with recognized diseases, and there is no reliable scientific evidence that silicone gel leakage causes a new disease. The Institute of Medicine report stated that the primary safety issue with silicone breast implants is local and perioperative complications,

24. The quotation appears in Bondurant and others (2000, p. 7). The problem with defining the disease by the presence of implants was eloquently expressed in Kelley v. American Heyer-Schulte, 957 F.Supp. 873, March 11, 1997: “Dr. Espinoza has found that the Plaintiff possesses anomalous antibody levels in her blood chemistry; this anomaly leads him, based upon his observations with other women, to conclude that the Plaintiff’s condition is implant-related. However, the witness admits that if the Plaintiff did not have breast implants but had the exact same symptoms and blood chemistry, then his diagnosis would have been non-implant-caused Sjogren’s Syndrome. Essentially, this is a bit like saying that if a person has a scratchy throat, runny nose, and a nasty cough, that person has a cold; if, on the other hand, that person has a scratchy throat, runny nose, nasty cough, and wears a watch, they have a watch-induced cold.”
Table 5-5. Relative Risks of Connective Tissue Diseases (CTD) in Women Obtained from Adjusted Meta-Analysis

<table>
<thead>
<tr>
<th>Disease</th>
<th>Excluding Hennekens</th>
<th>Including Hennekens</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Relative risks (95% confidence interval)</td>
<td></td>
</tr>
<tr>
<td>Definite CTD combined</td>
<td>0.80 (0.62, 1.04)</td>
<td>1.14 (1.01, 1.28)</td>
</tr>
<tr>
<td>Rheumatoid arthritis</td>
<td>1.04 (0.72, 1.51)</td>
<td>1.15 (0.97, 1.36)</td>
</tr>
<tr>
<td>Systemic lupus erythematosus</td>
<td>0.65 (0.35, 1.23)</td>
<td>1.01 (0.74, 1.37)</td>
</tr>
<tr>
<td>Systemic sclerosis/scleroderma</td>
<td>1.01 (0.59, 1.73)</td>
<td>1.30 (0.86, 1.96)</td>
</tr>
<tr>
<td>Sjögren's syndrome</td>
<td>1.42 (0.65, 3.11)</td>
<td>1.47 (1.01, 2.14)</td>
</tr>
<tr>
<td>Dermatomyositis/polymyositis</td>
<td>. . .</td>
<td>1.52 (0.97, 2.37)</td>
</tr>
<tr>
<td>Other autoimmune/rheumatic conditions</td>
<td>0.96 (0.74, 1.25)</td>
<td>1.15 (0.97, 1.36)</td>
</tr>
</tbody>
</table>

Source: Adapted from table 6, III-42, Submission of Rule 706 National Science Panel Report.

including “overall reoperations, ruptures or deflations, contractures, infections, hematomas, and pain.”

The epidemiological evidence of the 1990s uniformly fails to find evidence supporting a causal link between implants and defined diseases. It is, however, difficult to estimate low-probability events such as these, so that these results should be viewed with caution. Clearly, there are no apparent large risks from breast implants. However, the inclusion of the Hennekens study indicates an increased risk of CTD in some categories. The plaintiffs’ successes in numerous cases do not imply that jurors overrode overwhelming epidemiological evidence. Rather, the weight given to scientific testimony, observable product defects, and identified plaintiffs with serious ailments is often greater than the weight given to epidemiology studies that are hampered by small sample sizes in comparison to the risk levels.

**FDA Regulation of Drugs and Medical Devices**

Understanding the failure of the FDA to ensure that breast implants were safe and to develop the informational base needed to assess breast implant risks requires an understanding of how the government regulates medical devices. Moreover, because silicone gel breast implants have been

in use since 1962, one must also understand how the different eras of reg-
ulation since the advent of breast implants affected the FDA’s authority
over the product. This regulatory effort also established the backdrop for
litigation in that it indicates the extent to which the government has or
has not certified the product as having met regulatory standards for safety.

The first legislation giving the FDA authority over safety testing was
the Food, Drug, and Cosmetic Act (FDC Act), which was signed into law
in 1938. The FDC Act of 1938 gave the FDA the power to require pre-
market approval (PMA) of new drugs. The PMA process obligated com-
panies to prove to the FDA that new drugs were safe before they were
allowed to be marketed, although proof of efficacy was not required until
1962 under the Kefauver-Harris Drug Amendments.

However, premarket approval of medical devices, including breast
implants, was not required. Manufacturers could introduce medical
devices such as breast implants at their discretion. The FDA did have some
authority over medical devices, but the mechanism of enforcement was lit-
igation, not regulation. The FDA had the authority to ask the courts to
discontinue sales or halt production of devices introduced into interstate
commerce that were adulterated (contaminated by filth) or misbranded
(falsely or misleadingly labeled.) In earlier years, this authority was broadly
exercised, with 3,848 separate court actions in 1945. However, use of lit-
igation dropped to 843 such actions in 1971.26

The failure to require premarket approval of medical devices in the
legislation enacted in 1938 was in part related to the state of medical sci-
ence at the time. Although many medical devices, such as tongue depres-
sors, bandages, and bed pans, were in wide use, the more complex devices
that worked by insertion into the body were still to come. Manufacturers
began to introduce increasingly complex medical devices after World War
II, such as cardiac pacemakers, renal catheters, surgical implants, artificial
vessels and heart valves, intrauterine contraception devices, and replace-
ment joints. However, extensions of the FDA’s regulatory authority to
address such products lagged behind their market role.

As more devices became marketed, the FDA sought expanded regula-
tory authority of medical devices commensurate with that provided for new
drugs. One method the FDA used to expand its authority in the absence of
new legislation was to use a broad definition of a drug. For example, the
FDA regulated interocular lenses, soft contact lenses, weight-reducing kits,
certain intrauterine devices, and some in vitro diagnostic products by classifying them as drugs.

Lacking direct authority to regulate, the FDA continued to use litigation to halt sales of adulterated or misbranded medical devices. Unsurprisingly, this was an expensive and inefficient process. Furthermore, simply removing from the market adulterated or misbranded devices did not touch the salient issue of safety, which is the concern with breast implants. Although hearings were held on the desirability of increasing FDA oversight on medical devices since the late 1960s, it took the Dalkon Shield intrauterine device catastrophe to push through legislation.\textsuperscript{27} The new Medical Device Amendments to the Food, Drug, and Cosmetic Act of 1938 were signed into law on May 28, 1976, giving the FDA authority to regulate medical devices fourteen years after silicone breast implants had been introduced.\textsuperscript{28} Responsibility for regulation of medical devices was assigned to the FDA Center for Devices and Radiological Health.

The objective of the MDA was to “provide reasonable assurance of the safety and effectiveness of the new device” while “weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.”\textsuperscript{29} The FDA’s authority was expanded to allow it to ban a device and require manufacturers to notify users of risks, repair or replace products, or give refunds. The FDA no longer had to pursue its mission through the courts.

The MDA required the FDA to classify all new medical devices into one of three classes: Class I (such as tongue depressors and elastic bandages), Class II (such as hearing aids), and Class III (such as heart valves and prosthetic hips). Class I devices are subject only to general controls on manufacturing. The MDA subjects Class II devices to performance standards, postmarket surveillance, guidelines for use, and other appropriate controls. Only Class III devices are required to submit proof of safety and effectiveness, and such devices cannot be marketed or sold until approved.

To obtain premarket approval for new devices, manufacturers are required to submit test data, including clinical studies showing that the

\textsuperscript{27} The Dalkon Shield intrauterine device, manufactured by A. H. Robins, was introduced in the United States in 1971. This unregulated device frequently caused pelvic inflammatory infections, which often caused infertility, spontaneous septic abortion, and other problems. Under pressure from the FDA, the manufacturer reluctantly removed this device from the market in 1974. But by then the damage was done. More than 3.6 million units had been sold, and the ensuing litigation resulted in 400,000 claimants, who received nearly $3 billion from the Dalkon Shield Claimants Trust.

\textsuperscript{28} 21 USC, sec. 360(e).

\textsuperscript{29} 90 U.S. Stat., p. 541.
device is safe and effective. When the MDA was passed in 1976, devices
deemed "substantially equivalent" to a preamendment device already on
the market were grandfathered into the market, implying that they could
remain on the market without further review. As silicone breast implants
had been in use since 1962, they were grandfathered in. Nevertheless,
breast implants were not explicitly guaranteed an exemption from such
regulatory scrutiny. The FDA could also require that preamendment
device manufacturers submit PMA applications. However, this authority
was rarely used, with makers of only 9 percent of preamendment Class III
devices required to submit PMA applications through 1991.\textsuperscript{30}

The Regulatory History of Breast Implants

Following the enactment of the Medical Devices Amendments in
1976, the FDA had the authority to classify breast implants, and if they
were classified as Class III, to require that manufacturers submit safety
information in their premarket approval (PMA) applications. Classifica-
tion of implants was slow.\textsuperscript{31} The FDA General and Plastic Surgery Devices
Panel recommended Class II status in 1978, despite evidence presented at
the meeting that even intact implants might leak.\textsuperscript{32} Ignoring this recom-
mandation, in 1982 the FDA published in the \textit{Federal Register} its proposed
rule to classify implants as Class III devices. This classification was finally

The impetus for finally classifying implants as Class III devices largely
arose from medical concerns. An increasing number of complications such
as rupture, gel bleed, and capsular contracture were reported in the med-
ical literature as well as to the FDA through the 1980s. Several concerns
about risks were raised during the FDA's General and Plastic Surgery
Devices Advisory Committee meeting in November 1988. The commit-
tee listed eight potential risks associated with breast implants: capsular
contracture, breakage, bleeding outside the shell, migration of silicone to
organs, interference with the accuracy of mammograms, calcification of
the fibrous capsule, immune disorders, and cancer. The last two risks have
not been borne out by the evidence, but the fact that the FDA noted these

\textsuperscript{30} U.S. House Committee on Energy and Commerce (1993, pp. 7–9).
\textsuperscript{31} The regulatory history is described in detail in U.S. House Committee on Human Resources
\textsuperscript{32} U.S. House Committee on Human Resources (1992, p. 5).
conditions as potential risks as recently as 1988 attests to the void in scientific information at the time.

With the Class III assignment, the FDA could now require PMA applications for all breast implants. But assigning Class III status is only the beginning of a long process. After issuing this final classification regulation, the manufacturers had thirty months to submit their PMA application, to allow time for research and data analysis.

But before requiring the PMA, the FDA had to first publish a 515(b) regulation in the *Federal Register*, which would describe known risks as well as the type of data required to demonstrate that the benefits exceed the risks. This final rule had to be available to the manufacturers at least ninety days before the deadline for their PMA. However, this final rule had not been written by December 1990, the end of the thirty-month period. The proposed regulations were issued in May 1990, the comment period ended in August 1990, and the final regulations were finally published in April 1991.

At this point, the manufacturers were given at least ninety days to respond. The due date was July 9, 1991. The FDA then had forty-five days after the submission to evaluate the applications to determine whether they should be granted a full review.

After evaluating the data submitted in July 1991, the FDA’s General and Plastic Surgery Devices Panel concluded in November 1991 that the manufacturers’ PMA applications did not adequately address the safety of implants. Three applications were rejected at this point, and these manufacturers were notified that they could no longer sell their products. Despite the recommendation of the FDA scientists to reject the seven remaining applications, the FDA informed the manufacturers that their applications were seriously flawed, and they were required to provide additional information by January 6, 1992. Their products could stay on the market until then but would have to be taken off the market on January 6, 1992, until the FDA completed its full review.

The subcommittee review of the PMAs documented certain shortcomings in all seven remaining applications. Criticisms of the applications were that most studied women for two years or less, so that information on long-term risks was not assessed; various biases owing to reporting and study design; inadequate pre-implant assessment; the majority of women were lost to the study after a few months; the samples of reconstruction patients were too small to allow separate reliable analysis; certain models of implants produced by manufacturers were not studied, as manufactur-
ers assumed that safety was the same among models; and in several studies women were not asked about symptoms of connective tissue or autoimmune disorders, cancer, or other medical problems. Medical records of plastic surgeons would not reveal these conditions as women would consult other physicians for these conditions. The women returned to their plastic surgeon for complications directly related to their surgery, so information on such risks generally, if present, could not be assessed.

For example, the reviewer of Dow Corning's application noted that physicians were instructed to note only complications at the implant site, thereby ignoring any potential systemic adverse effects and underestimating the types and rates of complications. The McGhan study had limited and incomplete follow-up of implant patients and studied only two of its four implants models listed in its PMA. The Bioplasty study assessed only 6 percent of its 860 patients with its MISTI implants at the two-year follow-up, yet the company reported safety and efficacy as though a larger sample had been used.

Although Dow submitted information on animal studies, none of these studies examined silicone placed in or beneath the breast tissue. There were no studies of what “energy” would be required to rupture an implant.

Citing inadequate information, on January 6, 1992, FDA Commissioner David Kessler called for a voluntary moratorium on sales of silicone breast implants until the FDA and the advisory panel were able to review newly available information. The moratorium rested on two bases. First, the manufacturers’ safety data were deemed inadequate, for reasons including those just noted. Second, the FDA wanted time to review new information. This included internal Dow documents that the FDA saw for the first time in December 1991, as well as new information from rheumatologists on a possible link between breast implants and connective tissue diseases.

Reconvening in February 1992 to review the new information, the General and Plastic Surgery Devices Panel concluded that no causal link had been established between implants and autoimmune diseases. Nonetheless, the panel recommended restricted use until more safety information was available, including information from epidemiology studies.

Kessler announced in April 1992 that the moratorium was lifted for women in urgent need of implants, which included women in three categories: replacement for rupture or contracture, reconstruction patients
who had started the reconstructive process, and reconstruction patients who were not suited for saline implants. Until additional information on safety was available, silicone implants would not be available for purely cosmetic purposes. By this point, only two manufacturers, McGhan and Mentor, remained on the market, as Dow Corning, Bristol-Myers Squibb, and Bioplasty withdrew from the market in March 1992.

Although silicone implants were withdrawn from the market in 1992, saline-filled implants remained available. Like silicone implants, saline implants had been grandfathered in 1976, and the FDA had not required manufacturers to go through the PMA process. The FDA started the PMA regulatory process for saline implants shortly after silicone implants were removed from the market, and both Mentor Corporation and McGhan Medical Corporation were granted approval to market their saline-filled breast implants by the FDA in May 2000. These implants were approved for reconstruction and for augmentation in patients age eighteen and older.

The Environment Leading to the 1992 FDA Ban

Kessler's decision to withdraw silicone implants from the market occurred in the context of active lobbying efforts and widespread media attention, for and against implants. Pressure for enhanced regulatory controls came from the Public Citizen's Health Research Group, the Boston Woman's Health Book Cooperative, the Command Trust Network, and the National Woman's Health Network.33 In contrast, other groups such as the Breast Implant Information Foundation and the National Organization of Women with Implants lobbied for continued availability of implants after mastectomy.

Ralph Nader's Public Citizen Health Research Group, under the leadership of Sidney Wolfe, began raising alarms over a possible connection of silicone breast implants to cancer in the 1980s. Wolfe's and Public Citizen's interest in breast implants was fairly obvious. Implants had not been regulated for years after the FDA had the authority to do so; if implants were indeed a public health problem, Public Citizen would have additional evidence to support a more activist regulatory regime.

There was a flurry of activity, with questions raised about the safety of

silicone implants on several fronts in December 1990. The television program “Face to Face with Connie Chung” featured an episode in which women claimed that their various health conditions, such as dizziness, swollen glands, fatigue, and so forth, were caused by their implants.\(^{34}\) Chung began this episode with the dramatic statement: “For almost 30 years, American women have been getting breast implants, [with] an astounding average of 350 implant operations each day. But what is shocking is that these devices haven’t been approved by the federal government. Only now is the government looking at the dangers. But, for some women, it may be too late.” Sybil Goldrich, co-founder of Command Trust Network, dramatically exposed her scarred and disfigured chest from operations to remove implants to Chung’s audience.

A week after Chung’s show aired in December 1990, Representative Ted Weiss headed a congressional hearing on implant safety. Weiss was highly critical of “the anti-regulatory attitude of the Reagan administration.” Only three scientific experts testified, and all were employed by plaintiffs in litigation.\(^{35}\) Among the concerns raised in this hearing was the unavailability of various Dow Corning documents that were sealed by court order in consequence of the Stern verdict in 1984 (discussed in the following pages).

As an example of efforts on the other side, in 1991 the American Society of Plastic and Reconstructive Surgeons (ASPRS) actively lobbied to keep breast implants on the market. An example of their efforts included paying for almost 400 women to fly to Washington to lobby about the importance of implants to their self-esteem. Their pro-breast implant arguments included the scare tactic that women would be less likely to seek medical attention for lumps if silicone implants were not an option.\(^{36}\)

Besides manufacturers’ information, other interest groups weighed in on the safety of implants. Much of the available information was misinformation or even intentionally misleading. For example, the American Society of Plastic and Reconstructive Surgeons (ASPRS) distributed information brochures on safety that were inconsistent with scientific research. They emphasized the low rate of capsular contracture, indicating it was 10 percent, rather than the 30–40 percent rate reported in the literature.

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34. This program was broadcast on December 10, 1990.
35. Nir Kossovsky and Frank Vasey testified in the 1991 Hopkins case; Pierre Blais in the Johnson trial as well as other consulting for plaintiffs.
of the time, and that implants are lifetime devices, again ignoring the high rate at which they were replaced. In retrospect, their statement that "loose silicone does not appear to be a health risk" has been confirmed, although at the time of their writing the validity of this assertion simply was not known.

Similarly misleading information was provided by Dow Corning. In response to the widespread negative media attention, Dow Corning initiated an 800 telephone hotline in late 1991 to answer questions. FDA staffers who called the hotline were told that "scientific data and research show that they are 100 percent safe. . . . We have done lengthy studies as have thousands of plastic surgeons to show they are safe." Other callers were told on December 30, 1991, that "there has been significant testing on arthritis, scleroderma, lupus, and other problems with the immune system. There is no link between this or cancer or silicone problems" and that "there is no detrimental effect to having silicone in the body." At the end of 1991, there simply were no lengthy studies or scientific evidence to support the claims of proven safety.

Opponents of breast implants also provided misleading information. Evidence that silicone gel caused cancer in rats and that it might do so in humans was discussed in the 1988 meeting, but FDA officials emphasized that the results were inconclusive. The impetus was internal documents from Dow describing rat studies and provided by Public Citizen, in which Dow Corning scientists had implanted a blob of silicone gel under the skin of 200 rats in 1985–87. Twenty to 25 percent of the rats developed fibrosarcoma. However, as discussed earlier, it was well known among scientists that rats often developed fibrosarcoma if any large smooth object was implanted under their skin, and that there was simply no evidence that this result also occurs in humans. Despite the known lack of cancer risk of this sort to humans, Sidney Wolfe, M.D., president of Public Citizen, made public statements, picked up by the media, that implants were dangerous and should be banned.

**Litigation and Safety Information**

The court system began to take action against breast implants long before serious FDA scrutiny began. Although there were a few isolated

suits in the 1970s based on ruptures, the real action in litigation did not begin until reports surfaced in the 1980s that silicone gel causes systemic diseases in humans. The first successful lawsuit against Dow occurred in 1977, awarding the plaintiff $170,000 for complications related to rupture. Richard Mithoff, a Houston attorney, successfully argued that his client’s ruptured implants and subsequent operations had caused pain and suffering. Patient information at the time claimed that leaks could occur only as a result of trauma. Although this case received little publicity, Dow then changed its package insert in 1978 to warn of potential nonpathogenic side effects such as rupture and scar tissue. The warnings about these potential side effects seemed to effectively prevent lawsuits against Dow on these grounds.

A turning point in litigation occurred with Stern v. Dow Corning. In 1984, after a month-long jury trial, the jury awarded Maria Stern $211,000 for compensatory damages and $1.5 million for punitive damages. For the first time, the silicone-immune disorder connection was introduced by experts into court. Attorney Dan Bolton successfully argued that her connective tissue disease was attributed to silicone implants. The case turned on many internal Dow Corning documents discovered by Bolton in a Dow storage area discussed in the following paragraphs. The punitive damages were imposed because Dow Corning was found guilty of fraud in misrepresenting animal studies. The Dow documents produced in trial were then sealed by court order. The success of this case turned not on the strength of the scientific evidence that implants caused Stern’s disease—there was none—but instead on the issues of corporate irresponsibility and fraud, including the jury’s belief that Dow had doctored a dog study.

Dow’s product warnings were changed in 1984 after this successful suit to acknowledge that there were “reports of suspected immunological responses to silicone mammary implants” but also that “convincing evidence does not exist to support a causal relationship between exposure to silicone materials and the acquisition or exacerbation of a variety of rheumatic and connective tissue disorders.”

In July 1991, Brenda Toole was awarded $5.4 million in her suit against Baxter/Heyer-Shulte. The jury found that although Toole had

42. See chronology on Frontline (www.pbs.org/wgbh/pages/frontline/implants/cron.html [April 24, 2002]).
only preliminary symptoms of systemic autoimmune problems, she faced an increased risk of an autoimmune disease according to the plaintiff’s experts, owing to the presence of silicone in her lymphatic system.

The trial of *Mariann Hopkins v. Dow Corning Corporation* is notable in that it brought to light the Dow Corning memos that had been sealed after the Stern trial.³³ Mariann Hopkins was awarded $7.3 million in December 1991, of which $6.5 million was for punitive damages, in her suit in California against Dow Corning. Hopkins claimed that her ruptured silicone implants had caused connective tissue disease. The suit alleged fraud, negligence, and product liability for Dow’s failure to disclose information about the dangers of implants, with many of the memos presented initially at the Stern trial also presented as evidence in the Hopkins trial.

This trial raised two important issues that were influential in shaping future regulation and litigation outcomes. Although the severity of Hopkins’s connective tissue disease was not disputed, Dow Corning denied that a causal link between silicone breast implants and CTD had not been established, and Hopkins’s expert testimony was not admissible. However, as of 1991 (and indeed until 1994) there simply was no epidemiological evidence that could provide such information. The court noted that “the record reflects that Hopkins’s experts based their opinions on the types of scientific data and utilized the types of scientific techniques relied upon by medical experts in making determinations regarding toxic causation when there is no solid body of epidemiological data to review.”⁴⁴

In affirming the punitive damages award, the court noted that “given the facts that Dow was aware of possible defects in its implants, that Dow knew long-term studies of the implants’ safety were needed, that Dow concealed this information as well as the negative results of the few short-term laboratory tests performed, and that Dow continued for several years to market its implants as safe despite this knowledge, a substantial punitive damages award is justified.”⁴⁵

What was in these incriminating memos that had such influence at trial? The memos included such information as the following.

A February 1975 memo noted concern about inflammatory reaction to implants in Dow Corning’s animal studies. Tom Talcott, a Dow engineer,

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⁴⁴ Indeed, as part of its defense, Dow Corning claimed that “a simple investigation would have revealed to Hopkins the possible connection between implants and MCTD [multiple connective tissue disease]” —a connection that Dow Corning denied existed! *Hopkins v. Dow Corning Corp.*

⁴⁵ *Hopkins v. Dow Corning Corp.*, 33 F.3d 1116 (9th Cir. 1994).
wrote a memo in May 1975 that in part reads, "We are hearing complaints from the field about the demonstration samples they are receiving. The general claim is that the units bleed profusely after they have been flexed vigorously. . . . Please run appropriate testing when you receive these samples to determine if a bleed rate problem exists."46

Dow senior clinical research specialist Art Rathjen wrote in a June 1976 memo, "I have proposed again and again that we must begin an in depth study of our gel, envelope, and bleed phenomenon. Capsule contracture isn't the only problem. Time is going to run out for us if we don't get underway."

Plastic surgeons had also contacted the company over concerns about gel bleed and rupture. For example, plastic surgeon Charles Vinnik wrote to a Dow vice president in September 1981 about "considerable silicone reaction to the extruded material" to an implant that was "totally disrupted with the implant shell incorporated within the gel mass" and the presence of "an obvious siliconoma." Emphasizing the limited information made available to surgeons, Vinnik continued to voice his concerns about the high rupture rate and silicone gel bleed reaching the tissues. His September 1985 letter reads in part, "Inasmuch as this is not generally known by my colleagues, I feel that your company has both a moral and legal obligation to make this information available through your representatives and in your literature."

A 1983 Dow Corning memo presented by Dan Bolton at the Stern trial stated, "I want to emphasize that to my knowledge, we have no valid long-term implant data to substantiate the safety of gels for long-term implant use."

One of the memos that continued to haunt Dow Corning was directed to the salespeople:

> It has been observed that the new mammarys with responsive gel have a tendency to appear oily after being manipulated. This could prove to be a problem with your daily detailing activity where mammary manipulation is a must. Keep in mind that this is not a product problem; our technical people assure us that the doctor in the O.R. will not see any appreciable oiling on the product removed from the package. The oily phenomenon seems to appear the day following manipulation. You should make plans to change demonstration samples often. Also, be sure samples are clean and dry

46. The memos quoted in this section were publicly released by Dow Corning on February 10, 1992. These memos have been widely quoted in numerous sources including Angell (1996) and U.S. House Committee on Human Resources (1992).
before customer detailing. Two easy ways to clean demonstration samples while traveling, 1) wash with soap and water in nearest washroom, dry with hand towels, 2) carry a small bottle of IPA and rag. I have used both methods and the first is my choice. I will be interested to hear if any of you are seeing the oiling.

Memos produced in Johnson v. Medical Engineering Corporation (MEC) also showed that safety information had been suppressed or destroyed. MEC’s Scientific Affairs Committee speculated in April 1977 that silicone oil bleeding through the shell and to the body tissue might cause the FDA to remove silicone gel implants from the market. A 1978 document reported beagle studies demonstrating adverse reactions such as hemorrhage, possible pneumonia of the lung, and hyperplasia of lymphoid tissue in the large intestines. The company president said to “sacrifice dogs ASAP” and to keep “no organs of dogs in freezer.” In responding a year later to a letter about animal maintenance costs, this president wrote, “I thought we wiped out all dogs and had parts sent to W. L. [a company vice president]. My rec[ommendation]—kill dogs; forget organs; just dispose of them.”

Given what is now known about the safety of silicone implants, the memos serve not to provide evidence that implants are indeed risky but instead to demonstrate that the manufacturers had suppressed warning signs along the way and had not resolved or even researched the safety issue despite litigation that highlighted potential areas of concern. Keep in mind that to date there were no epidemiological studies that may have demonstrated the safety of implants. Thus these memos provide the informational context in which juries had to make decisions. They could not defer judgment to wait for more scientific evidence.

The most notable outcome of the Stern and Hopkins trials is that although the court records were sealed in the Stern case, the information revealed at trial eventually made its way to the FDA and was ultimately influential in shaping regulation. Notably, much of the information on what manufacturers knew or suspected about health risks before 1991 became available only as a result of litigation. At the November 1988 FDA meeting, a lawyer, a former Dow engineer, and other experts testified that they had seen information indicating that Dow Corning and other manufacturers had concealed safety information and verbally described this

47. U.S. House Committee on Human Resources (1992, p. 35).
information. The documents they described had been produced in the 1984 case of Stern v. Dow Corning. Dow Corning released these internal documents to the FDA in February 1992 as a result of the Hopkins trial.

**Litigation after the FDA Moratorium**

The public concern generated by these cases and the information that was obtained as part of the litigation contributed to the regulatory interest in breast implants. The moratorium announced by Kessler in 1992 on the distribution or implantation of implants in turn opened the floodgates for new litigation. There were thousands of lawsuits after the FDA required that silicone implants be removed from the market. For example, by December 1991, there were 137 individual lawsuits filed against Dow Corning. The number of suits surged after that, as more than 3,000 lawsuits were filed against Dow Corning in 1992, increasing to more than 8,000 new cases in 1993 and close to 7,000 new cases in 1994. The other manufacturers were also hit with lawsuits.

Perhaps the most consequential litigation outcome of the FDA’s moratorium imposed in January 1992 was a class action suit filed in February 1992 by Cincinnati lawyer Stan Chesley. Eventually all federal cases were transferred to Alabama federal judge the Honorable Sam C. Pointer. After two years of negotiation, a class action settlement was approved in which the four major breast implant manufacturers—Dow Corning, Baxter, Bristol-Myers Squibb/MEC, and 3M—would contribute $4.25 billion, with Dow Corning responsible for nearly half of the total. Women who presented medical evidence of a connective tissue disease or of symptoms of such diseases that began or worsened after their breast implants were inserted would receive payments based on age and type of disease. Potential class members were told they would each receive between $200,000 and $2 million, later reduced to $105,000 to $1.4 million. Class members would be able to opt out if the number of claims filed reduced the settlement amount below the original estimate.

The large number of claims filed—more than 440,000 women filed claims by spring of 1995—would result in individual claimants receiving only a small percentage of the original offer. More than 15,000 class members opted out of the proposed settlement, and the settlement fell apart by May 1995. By this time, Dow Corning was a defendant in more than 19,000 individual breast implants suits and at least forty-five class
actions, as well as in 470 more suits involving nonbreast implant medical products. Dow Corning filed for bankruptcy reorganization in 1995 in reaction to the flood of suits. The global settlement was reconfigured without Dow Corning, and Dow Corning also crafted its own settlement.

Juries awarded plaintiffs large damages throughout the early 1990s, as no new information on safety was yet available. In December 1992, Texas attorney John O’Quinn successfully argued that Pamela Jean Johnson’s ruptured implants were linked to her mixed connective tissue disease, autoimmune responses, chronic fatigue, muscle pain, joint pain, headaches, and dizziness. Even though her expert witnesses and lawyers described her symptoms as amounting to a bad flu, Pamela Jean Johnson was awarded $25 million in her Texas suit against Bristol-Myers Squibb, of which $20 million was for punitive damages.

In March 1994, a Houston jury awarded three women $27.9 million in a case against 3M. Once again John O’Quinn represented the plaintiffs. Of the total award, $15 million represented punitive damages, with the remainder compensation for illnesses identified as atypical lupus, neurological impairment, and a “silicone induced” autoimmune problem.

*Gladys Laas v. Dow Corning*, February 1995, was the first major trial after the Mayo Clinic study failed to show any causal effect of implants on systemic health conditions. This case indicated that the early scientific evidence apparently carried little weight in jury decisionmaking. Laas received implants for reconstruction. She claimed her surgeon told her the implants were harmless and would last a lifetime, and she was happy with her implants for thirteen years. Her health problems started around 1990. She reported that her shoulders would freeze up, her face would sting, and she had double vision, numbness in the tip of her tongue, memory loss, and spasms. When her suit against Dow Corning went to trial in 1995, the jury awarded her $5.2 million in compensation. Two jurors interviewed by Frontline after the trial stated that they gave little weight to the Mayo study. As my earlier discussion indicated, this study involved a small sample and had low power to detect an increase in risk. The jurors did not think silicone caused Laas’s disease, and that while there was no evidence that silicone was harmful, there was also no evidence that it was safe. They

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stated that they awarded so much money because Laas was sick and needed money for housework help and medical bills.\textsuperscript{50}

With Dow Corning under bankruptcy reorganization, the question arose whether Dow Chemical, the parent company, could be held liable. This question was answered affirmatively in \textit{Mahlum v. Dow Chemical} in Reno, October 1995.\textsuperscript{51} Charlotte Mahlum was awarded $3.9 million in compensatory damages and $10 million in punitive damages. In 1998 the Nevada Supreme Court upheld the compensatory damages but set aside the punitive damages award.\textsuperscript{52} At this time, there were about 13,000 pending implants suits against Dow Chemical. State appellate courts varied in whether they held Dow Chemical liable.

Plaintiffs have recently received large damages awards in breast implant cases, although some are overturned. Some recent examples are \textit{Meister v. MEC} in which a DC jury awarded $10 million in compensatory damages in 1999, and \textit{Barrow v. Bristol-Myers}, a 1998 nonjury case in Florida in which the plaintiff was awarded $357,000 in compensatory damages and $400,000 in punitive damages.\textsuperscript{53}

Litigation continues among the opt-out cases despite the scientific evidence, although it appears that the dramatic damages awards of the early 1990s are becoming more rare, and judges seem to be more inclined to dismiss cases for lack of scientific evidence of causality. For example, Oregon Federal Judge Robert E. Jones appointed a panel of masters similar to that appointed by Judge Sam Pointer and, based on their report determining that silicone breast implants did not cause the alleged diseases, declined to allow the plaintiffs’ experts to testify.\textsuperscript{54}

\section*{Concluding Remarks}

All of the attention directed to the safety of implants was not in vain. Moving on beyond the undeniably weak studies submitted by the manufacturers as part of the PMA process, society has had the benefit of rigorously

\textsuperscript{50} \textit{Frontline}, February 27, 1996.


\textsuperscript{52} \textit{Dow Chemical Co. v. Mahlum}, 970 P.2d 98 (Nea. 1998).


conducted studies that were scrutinized not only through the journal peer review process but also subjected to rigorous scrutiny by several appointed science advisory panels.

The story of breast implants is like a roller coaster ride. After emergence of substantial and increasing fears of health risks, concerns tied to scientific evidence have subsided. In the simplest terms, breast implants were faulty products, as they often ruptured and hardened, causing breasts to be painful or even unsightly. The manufacturers knew of these product problems from at least the early 1970s—indeed the problem of capsular contracture prompted most of the product innovations. As a result of litigation that found companies liable for such problems, manufacturers provided hazard warnings to alert physicians and consumers to these risks. Whether implants caused only localized problems or also caused serious systemic health problems was unknown until recently. The manufacturers clearly had information from the early 1970s that raised alarms over health risks, but they suppressed such information. However, with the new scientific studies that followed the litigation explosion, we know that the unique risks of silicone implants are restricted to localized problems.

In the breast implant situation, litigation did not lead to new regulations. The regulations granting the FDA authority to regulate implants as a medical device were passed in 1976. However, as implants had been in use since 1962, they were grandfathered in, and the FDA did not require the manufacturers to go through the premarket approval process for another fifteen years, until murmurs of possibly serious health problems caused by implants turned into shouts.

Litigation played an important role in spurring FDA action. Information about suppressed safety information discovered in the 1984 Stern trial was reported at the FDA advisory meeting in 1988. This information, which was new to the FDA, generated the impetus for the FDA to require that the manufacturers submit information on safety and efficacy. When the manufacturers ultimately submitted information, their submitted information was too inadequate to meet scientific standards, and the FDA reacted by imposing a moratorium on silicone implants. In turn, the FDA ban on implants sparked large-scale litigation beginning in 1992.

As a consequence of the costly litigation, Dow Corning and other manufacturers withdrew from the implant market entirely rather than continue to seek FDA approval to market implants. Also in consequence
of the litigation, judges convened scientific panels to study the health risks of silicone implants. Together with the study by the Institute of Medicine, the conclusion of this careful scrutiny is a consensus that silicone breast implants do not cause systemic or autoimmune diseases.

The message of the breast implant story is that the FDA dropped the ball and then overreacted when rejoining the game. Had the FDA requested information from the manufacturers in a more timely fashion, the risks, or lack of risks, would have been known, and the litigation crisis would have been avoided. Breast augmentation is a highly popular cosmetic surgery, as saline-filled implants remained on the market while going through the premarket approval process after silicone implants were banned. Silicone implants had been overwhelmingly preferred to saline when both types were marketed. In the light of the increasingly compelling scientific information, perhaps silicone implants will be granted broad marketing approval.

The principal lesson of the breast implant experience is that the FDA has the power to create substantial public alarm and drive mass litigation. Obtaining scientific information in a timely manner, and giving appropriate weight to the scientific evidence as opposed to worst-case fears, would have eliminated the breast implant debacle. Whether the FDA has learned this lesson is unclear. The current experience with phenylpropanolamine (PPA) is so far following the breast implant paradigm. PPA was grandfathered in when the Food, Drug, and Cosmetic Act was passed in 1938, and it was used annually by millions of Americans in popular over-the-counter cold remedies and appetite suppressants. Only one epidemiological study demonstrates an increased risk of hemorrhagic stroke and then only among women using appetite suppressants.55 Legitimate questions exist about whether these results would be replicated in a larger study. Nevertheless, the FDA successfully requested a voluntary recall of products containing PPA. Fortunately, it is much easier for people to give up their favorite cold remedy than to have breast implants removed out of fear of life-threatening illnesses. However, the FDA's action has launched a deluge of class action and individual lawsuits that have yet to be resolved.

55. Kernan and others (2000, p. 1830). The relative risk is 16.58, with the 95 percent confidence interval of (1.51-182.21). These values are based on six cases with stroke and one control. Statistically significant effects were not present for any men or any other subgroup of women.
COMMENT BY

Peter Schuck

I would like to comment on Joni Hersch's interesting chapter by identifying some facts in it and then giving them a somewhat different interpretation than Hersch did.

The first is that a breast implant is a very valuable product. One million women purchased these implants. Hersch says that she thinks it costs about $2,000 to do so, so that's a $2 billion value that women evidently placed on this product. I also understand from Hersch that the breast implants have been restored to the market in most or all European countries. So the demand is there, and this demand must be weighed in the balance.

Second, by 1992, when the Food and Drug Administration imposed this ban, the product had been on the market for thirty years. That is a long time. That is a very large body of data on the effectiveness and safety of the product. Now, it is not clear to me from the science whether long-term, latent effects are alleged to result from exposure to this product, or whether, if the causal pattern is as alleged, the damage happens quickly. My understanding is that damage is evident more quickly. We are not dealing with a latency period of thirty or forty years, as happens with exposure to asbestos.

A third fact is that very little systematic, long-term research had been conducted by 1992. Again, this product had been on the market for thirty years, so a very large number of women had used the product and quite satisfactorily so.

Four, the FDA had grandfathered this product until 1988. The manufacturers believed this product was going to be regulated on a Class II basis, which meant that they would not have to conduct the kinds of studies for which they were subsequently criticized as not having conducted. And manufacturers only learned in 1988 that the implants were going to be classified as a Class III device, and therefore the companies had to conduct these studies. Hersch also tells us that the FDA's advisory panel recommended that the product be classified as a Class II device, not a Class III device, thereby fortifying any belief that the companies might have had that they would not be required to produce this kind of research.

A fifth fact that certainly is incontrovertible is that plaintiffs won huge compensatory awards by any standards. The plaintiffs did not die because
of these products. They suffered terribly, no question about that. But given the norms of personal injury verdicts, the compensatory awards mentioned in this chapter, at least, were very high. And these awards were rendered, in some cases, even after the epidemiological evidence had, as far as such evidence can, exonerated the product.

It seems to me that silicone gel breast implants have a good deal in common with Bendectin, in which, again, juries rendered very large verdicts even after the epidemiological evidence, virtually unanimously, had exonerated the product. Hersch mentions a trial court in Washington, D.C., that rendered one of these large verdicts after data failing to show causation had come in. The same thing happened to Bendectin, in the Oxendine case (Oxendine v. Merrill Dow Pharmaceuticals). Well after Bendectin had been proved a very useful product and one that created no untoward effects, the jury gave the plaintiff a large award.

These punitive damage awards, which by Hersch's account seem to have been routine in these cases, were also enormous, presumably because of the perception by the juries of corporate wrongdoing. Recall that these punitive damage awards were rendered even though the product had been grandfathered until 1988. As I understand the regulatory scheme, therefore, the manufacturers were under no obligation to have conducted systematic, long-term research. Again, the product had been in use, at that point, for twenty-six years, without any evidence that it caused systemic harms of the kinds alleged by the plaintiffs.

Now, maybe there was evidence of a cover-up by companies. But the evidence presented in the chapter of a cover-up does not seem very clear-cut. There are two examples. Perhaps if one looked at them closely, they would constitute a cover-up, but one of them is based on a memorandum to the sales force urging salespeople to move oil before showing the product to potential buyers, which seems to me an innocuous and perhaps even sensible precaution. I do not know the context well enough to judge for sure. And the second is a memo connected with the sacrificing of dogs that apparently had evidence of some pathological symptoms. Again, it is hard to know, without knowing more about the context, whether or not sacrificing the dogs was a cost-saving move. Something in Hersch's account suggests that this decision was part of an effort by the management to reduce the cost of animal maintenance. This may have been a pretext. I have absolutely no idea. But the evidence of a cover-up is at least ambiguous.

The last interesting fact, which Richard A. Epstein and David Rosenberg will certainly debate, is that the class action courts in Alabama and
Oregon handled these disputes in a much more systematic way than other courts. In Alabama and Oregon, courts kept complex scientific disputes away from the jury until the scientific disputes were resolved in the sense that, according to the courts, no reasonable juror could find causation.

Given the nature of epidemiological evidence, which deals with large populations, and given that the class contained 400,000 or more women—maybe it was even the more than one million women who had purchased implants—the isomorphism between the size of the class and the size of the population studied epidemiologically strengthens the no-causation inference that the court could draw from this evidence. A class action facilitates this inference.

I am left with a few broader questions that grow out of this episode. The first—and I really am agnostic about the answer—is whether the industry's initial decision not to conduct long-term research before the late 1980s was a prudent one. Certainly, given what we know now, it was a sensible decision.

But given the facts I've emphasized from Hersch's account—that is, the long period of usage without much evidence of harm, a disease pattern without long latency periods, and that the product had been grandfathered until the late 1980s—it is plausible to think that the industry's decision not to conduct the research for which they are now being faulted was, at least at the time, a prudent one.

Another question is, what incentives does this create for the FDA? The FDA banned a product, which sparked massive litigation that brought the manufacturer into bankruptcy and produced claims and large judgments that were based on spurious scientific claims. I think that the FDA, in retrospect, would conclude that it ought not to have acted decisively in the way that it did. In the future the FDA may, other things being equal, be somewhat less energetic in pursuit of its statutory responsibilities.

Another question is whether punitive damages are appropriate when an agency regulates an industry closely, and the industry complies with the agency's orders. I raise this question even though there is evidence from Hersch's account, which I am prepared to believe, that the FDA did not regulate and monitor implants as vigilantly as it should have, particularly after the public commitment it made in 1992.

I am also concerned about the perversity of public policy that allows twelve people, or maybe it was six people, selected at random to impose huge punitive damage awards. These juries had no legal guidance about which criteria, other than their own sense of indignation, to apply to their
judgments. After all, in the case of breast implants, the industry was regulated, compensatory damages were substantial, the reputational costs imposed on drug companies were enormous, and a number of other important factors came into play.

Finally, Hersch says that the lesson she draws from this episode is that the FDA should have acted sooner. She may be right, but I want to know what the regulatory opportunity costs of the FDA would have been. The FDA is a fairly small agency monitoring a very large set of industries. If the FDA had acted more vigilantly and vigorously, there are presumably other regulatory activities that it could not have conducted. I think that regulatory trade-off is especially poignant in the case of the FDA, because it is egregiously underfunded in light of its responsibilities. Until we know what the opportunity costs of the agency were, it is difficult to say, even in retrospect, that the agency should have acted sooner.

References


