

# INDEPENDENT JUSTICE

How Our Civil Justice System Protects Consumers and Patients in Ways the Regulatory System Does Not

# ALLIANCE FOR JUSTICE

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## EXECUTIVE SUMMARY

The right of Americans to go to court seeking compensation for damages is both basic and precious. While never perfect, our system has given millions of ordinary Americans their only chance to obtain justice from those who have harmed them.

Today, that right is threatened. Some policy-makers, including the current administration, want to limit access to the courts for people who have been injured. This campaign ignores decades of hard-learned lessons. Time and again, it was the civil justice system that brought to light the truth about dangerous products and allowed consumers to win appropriate compensation. Using the civil justice system, aggrieved plaintiffs peeled away layers of secrecy, obfuscation and outright dishonesty to reveal the real danger of devices and medicines allowed on the market. In many of those cases, the courts have been the sole mechanisms for retrieving that vital information, often doing so after the government has failed to prevent dangerous products from reaching or staying on the market. In short, the civil justice system has ensured that manufacturers are held accountable for their actions and protected the rights of people who have been harmed.

This report re-examines some of that history, focusing in particular on the extended saga of silicone-gel breast implants in the United States. These implants came on the market in the 1960s, without any government approval required and with no meaningful testing to guarantee their safety. Each year, thousands of women received such implants, either for cosmetic reasons or reconstructive purposes after surgery, assured by manufacturers and surgeons that the devices would safely last a lifetime.

However, many women developed problems from implants, and perhaps the first successful lawsuit against an implant manufacturer was decided in 1977. Over the next 15 years, many more women brought claims against the manufacturers, citing localized pain, loss of feeling, ruptured implants, rashes and a range of systemic problems such as chronic fatigue and joint pain. Through the litigation process—and despite the efforts of manufacturers—company documents emerged that revealed strong internal concerns about the implants and established a startling lack of research into implant safety.

As the civil justice system steadily uncovered information about implants, federal regulators moved slowly for more than a decade after Congress gave the Food and Drug Administration authority to regulate implants and other medical devices. In that time, the FDA took halting steps before finally forcing implant manufacturers to do research that demonstrated their products' safety. In the end, the manufacturers were unable to provide such proof. Shortly after the FDA received copies of internal documents gained through private litigation showing that a silicone breast manufacturer knew its implants could rupture and cause health problems, the agency pulled the implants from the general market. Since then, implant manufacturers have paid billions of dollars to settle claims from women with implant-related injuries.

In recent years, manufacturers and others are finally doing comprehensive research sought by advocates. New information has confirmed that nearly all silicone implants eventually rupture, while some research suggests possible links to higher cancer rates, suicides and connective-tissue disease. Even as such studies continue, the FDA appears poised to allow silicone-gel implants back on the market for cosmetic purposes, ending a moratorium now in its 15th year.

The implant story makes plain the danger inherent in relying only on manufacturers and government regulators to ensure the safety of consumer products. While the FDA plays a leading role in evaluating and approving drugs, medical devices and other consumer products, the courts provide a venue for ensuring that consumers are treated equitably and for enforcing appropriate rules of behavior on manufacturers.

Margaret Jane Porter, the agency's former chief counsel, framed the matter well in 1997: "FDA's view is that FDA product approval and state tort liability usually operate independently, each providing a significant, yet distinct, layer of consumer protection."<sup>1</sup>

History has made evident that without a significant threat from the civil justice system, manufacturers will take more risks with public safety in the race for higher profits. In the case of fen-phen—the popular diet drug regimen of the mid-1990s that killed and injured many consumers—legal action revealed that manufacturers had concealed important warning signs. These revelations came during rigorous discovery efforts by plaintiffs' lawyers, not through the efforts of federal regulators. More recently, consumers have been stunned by reports of major health risks associated with the pain drug Vioxx, risks that were downplayed for years by a manufacturer determined to capture a larger share of the market. These revelations are emerging, in part, from civil lawsuits against Merck & Co., the manufacturer of Vioxx.

Recently disclosed problems with Vioxx and other drugs have spurred significant debate over the FDA's ability to monitor product safety, with some leading authorities calling for a major overhaul. Among them is the Journal of the American Medical Association, which supports the creation of a new and independent "drug safety board" to monitor the medical devices and drugs already on the market.

President George W. Bush's administration resisted such calls until February 2005, when the FDA announced some changes in how the agency would monitor drugs that are on the market—changes some critics denounced as far too limited to address underlying problems with FDA oversight.

Meanwhile, the administration and some members of Congress are making it a far higher priority to push for legislation limiting the right of injured consumers to go to court to seek damages caused by drugs or devices that have won approval from federal regulators. This would be a profoundly anti-consumer step.

In a recent essay, former U.S. Labor Secretary Robert B. Reich noted the paradox inherent in the administration's position: "As a first step, [President Bush's] Republican allies in Congress are working on a bill to limit the liability of pharmaceutical companies from lawsuits brought by people injured by drugs or medical devices the FDA had okayed. But the administration can't have it both ways. Either it should move to strengthen regulatory agencies or it should maintain the present system of tort liability. Take away both, and consumers are in deep trouble."<sup>2</sup>

Aside from the legislative proposal, the Bush administration has entered several legal proceedings to assist manufacturers as they contest lawsuits from consumers injured by government-approved medicines and products. Such efforts serve to protect manufacturers and block consumers from their only means of pursuing justice.

As these debates continue, we must not forget the historical record, replete with cases in which consumers were injured by products that manufacturers claimed, inaccurately, to be safe and that had won government regulatory approval. From asbestos and silicone implants to diet drugs and the Ford Pinto, Americans injured by approved products have had nowhere to turn but the courts. Many won appropriate damages, and attorneys—not regulators—were able to ferret out the truth about dangerous products. In some cases, juries expressed the will of the people by imposing substantial awards against manufacturers who misled and harmed consumers. Those awards helped create a potent financial incentive for manufacturers to be sure about the safety of their products. It is no surprise that the pharmaceutical industry and others are pouring money into efforts to limit access to the civil justice system, and, as a result, their own financial liability for marketing unsafe products.

The pro-consumer success of the civil justice system appears to have been willfully ignored by some policy-makers, who now seek to limit the power of the courts. Given this sobering history, it is imperative that elected officials, judges and regulators protect the fundamental stature of the civil justice system.

<sup>1</sup> Margaret Jane Porter, "The Lohr Decision: FDA Perspective and Position," 52 Food and Drug Law Journal, 7 (1997).

<sup>2</sup> Robert B. Reich, "A Suitable Remedy: When the FDA Is Weak," Washington Post, Jan. 9, 2005, page B5.

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# 1. THE HISTORY OF SILICONE-GEL BREAST IMPLANTS ON THE MARKET AND IN THE COURTS

## Introduction

This report focuses on two intertwined subjects: the history of the silicone-gel breast implant controversy and the broader issue of protecting consumers' access to the civil justice system in a time when the regulatory system is not adequately protecting the public.

Implants were introduced in the early 1960s, many years before Congress had given the federal government authority to regulate implants and other medical devices. It would take the government 30 years to even question the safety of the implants and eventually take them off the general market, after finally concluding that implant makers could not prove their safety. In the meantime, litigation proceeded, often successfully, in courtrooms throughout the country, helping to shed light on both the adverse effects of implants and the malfeasance of implant-makers in trying to hide those effects.

Today the FDA is considering requests to return silicone-gel breast implants to the general market. At the same time, Congress and the courts are considering proposals to clamp down on the public's access to the civil justice system in product liability and other cases. As those efforts continue, the lessons of the breast implant story are worth reviewing.

The history of silicone-gel implants is a complicated one that played out in courtrooms, federal regulatory agencies and corporate offices, and in the lives of hundreds of thousands of women. Key developments in the litigation often had an impact on events in the regulatory arena; in other cases, the two efforts moved along independently. For the sake of clarity, this report summarizes the history of the regulatory effort, the efforts of litigants, and the attendant scientific research on implants in separate sections. However, a timeline that begins on page 23 offers a more concise overview of major developments in the implant saga.

## The FDA and Silicone-Gel Breast Implants

Silicone-gel breast implants came on the American market in 1962. However, the federal government had no regulatory authority over implants and other medical devices until 1976, when Congress passed the Medical Device Amendments to the Food, Drug and Cosmetic Act. The new law gave the FDA the authority to regulate most medical devices and the power to require manufacturers to submit data on their products' safety and effectiveness before putting them on the market.

Since silicone-gel implants were available for 14 years before the new law passed, they were grandfathered in and remained available to women. In the years following passage of the 1976 law, the agency faced a difficult challenge in deciding how to evaluate a product that had been on the market for more than a decade. But the record, summarized here, suggests the agency moved haltingly at best, even in the face of outside warnings, in assessing and finally ruling on the safety of implants.

In 1978, two years after the new law took effect, an FDA advisory panel of plastic surgeons and other doctors examined silicone-gel implants and recommended that they be categorized as Class II devices, meaning that manufacturers would not have to run tests to establish their safety. Around that time, some women were complaining about problems with their implants, and a number of lawsuits were moving through the courts, sometimes successfully.

Four years later, an FDA advisory panel again reviewed implants. This time, with a large number of problems emerging, the FDA announced it would move to place silicone-gel implants in Class III, which would force companies to do testing and conduct clinical trials to assess implant safety and effectiveness. However, it took the agency six years to make the move official. Finally, in June 1988, the FDA placed silicone-gel implants in the Class III category, a decision prompted in part by testimony from lawyers involved in litigation against implant manufacturers.<sup>3</sup> As part of the process, the FDA gave manufacturers an additional three years to conduct testing and clinical trials.

As the companies started their tests, a congressional House committee began examining implant safety after reports of serious implant-related problems. At a hearing in December 1990, Rep. Ted Weiss, D-NY, and others sharply criticized the FDA for ignoring warnings about implant safety. Among those who testified was Thomas D. Talcott, a former materials engineer for Dow Corning, who left the company in 1986 in a dispute over the implants' safety. "The manufacturers and surgeons have been performing experimental surgery on humans," he testified.

In July 1991, implant manufacturers submitted their final pre-market application information. Two months later, the FDA concluded that the information did not prove the devices were either safe or harmful. The studies done by manufacturers did not involve enough women, side effects were not adequately checked, and too few women were studied for more than two years; Dow Corning looked at records for thousands of women, but chose to study only a handful for more than two years.<sup>4</sup>

"Women need to be urged to strongly consider the risks of these implants," FDA Commissioner David A. Kessler said in a statement issued at that time. "The implants have been on the market a long time, and women have been lulled into thinking they are risk-free. They are not."

Plastic surgeons, who stood to lose a significant portion of their business if implants were banned, launched an aggressive, multimillion-dollar lobbying campaign. The surgeons recruited a large contingent of women to ask federal officials to keep implants on the market.<sup>5</sup>

<sup>3</sup> Joni Hersch, "Breast Implants: Regulation, Litigation, and Science," Chapter 5 of "Regulation through Litigation," edited by W. Kip Viscusi, AEI-Brookings Joint Center, 2002.

<sup>4</sup> Philip J. Hilts, "Under Pressure, U.S. Weighs Ban on Use of Breast Implants," New York Times, Oct. 21, 1991, page A1.

<sup>5</sup> Hilts.

Four months after the submissions, in November 1991, an FDA expert panel concluded that even though the manufacturers had not submitted enough information to establish the safety of silicone-gel implants, the implants should remain on the market, pending additional studies.

That position changed a few weeks later, when damaging internal documents that surfaced during a California lawsuit against an implant manufacturer were provided to Kessler. The documents acknowledged that implants could rupture and cause physical problems; in others, Dow Corning officials expressed concern about inadequate testing of the long-term safety of implants.

On January 6, 1992, the 180th and final day under law for the FDA to consider the advisory panel's recommendation on the implant manufacturers' submissions, Kessler called for a voluntary moratorium on the use of silicone-gel implants until an independent panel could review the documents that had become available to the agency.

"Women considering breast implants deserve to know whether these products are safe enough for use," Kessler said in a statement. "I'm calling for a delay in the use of these products until our advisory panel can meet to consider new information which was not available when it met in November."<sup>6</sup>

Four months later, the FDA lifted the voluntary moratorium on the implants, but strictly restricted their use to three categories: in controlled clinical studies for reconstructions after mastectomy; for correction of congenital deformities; and for replacement of ruptured silicone and saline implants. The FDA also placed strict limits on the use of silicone-gel implants for breast augmentation, which accounted for roughly 80 percent of the implant market. This action was a tremendous blow to plastic surgeons and the implant manufacturers, but many advocates for women's health applauded the decision to remove a product that had not been adequately tested.

At the end of 1992, a House of Representatives subcommittee staff report was issued that was sharply critical of top FDA officials' handling of the implant issue over a long period. The report summarized the FDA's role:

"The subcommittee's investigation reveals that a great many scientists and other staff at FDA's Center for Devices and Radiological Health (CDRH) showed inspiring dedication and perseverance in their efforts to determine the safety and efficacy of breast implants since the late 1970's. Unfortunately, as the subcommittee staff has seen in many other investigations involving the FDA, the best efforts of those dedicated public servants were repeatedly undermined over a period of at least 15 years by decision-makers within the agency, who ignored and overruled the warnings and suggestions of the individuals most knowledgeable about the product. Despite unprecedented media attention since the subcommittee hearing 2 years ago, and the leadership shown by the current FDA Commissioner, that pattern continues to the present day."<sup>7</sup>

Over the next several years, several studies were launched and more facts were established about silicone-gel implants. In August 1995, Kessler testified in Congress that new studies showed that implants—once touted by the industry of being able to last a lifetime—had a rupture rate of as high as 51 percent.

Joni Hersch, an adjunct professor at Harvard Law School, studied the FDA's role monitoring silicone-gel breast implants and concluded the agency's performance was inadequate. "The message of the implant story is that the FDA dropped the ball and then overreacted when joining 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."<sup>8</sup>

The key question is whether the agency is equipped today to do a better job monitoring the safety of drugs and medical devices. As will be discussed in a subsequent section, many critics fear it is not.

### Seeking Justice through the Courts

During the 1970s and much of the 1980s, as the FDA did little to document the safety of implants, many women took matters into their own hands and went to court seeking compensation for problems they were having. By the early 1990s, certain documents that came out during some of the litigation directly influenced the FDA's decision.

More than a million women in the United States have received silicone-gel breast implants since their introduction to the market in the early 1960s. Manufacturers' surveys show that many women have been satisfied with their implants. But, thousands of others have suffered physical discomfort, pain, multiple surgeries and serious illnesses. Many of them chose implants with little understanding of what could go wrong, because information on rupture rates was unavailable or inaccurate, and warnings about possible problems were often overlooked or left unmentioned by doctors.

The women who turned to the courts had two goals in mind: to be compensated for their injuries and to hold the implant manufacturers accountable.

A breakthrough came in 1977 when a woman in Cleveland won a \$170,000 verdict against Dow Corning—the first such verdict noted in the public record.<sup>9</sup> Represented by Houston attorney Richard Mithoff, the woman said her ruptured implants caused everything from breast pain to mental anguish.<sup>10</sup> The case, though, drew little notice.

In subsequent years, Dow Corning and other implant manufacturers were hit with a small but steady number of lawsuits from women who claimed implant-related injuries. Lawyers for Dow Corning estimated that in the first part of the 1980s, the companies were facing about 15 or 20 such cases at a time, usually involving infections or ruptures. One lawyer said the cases "were no big deal" and usually settled for no more than \$20,000.<sup>11</sup>

The legal landscape began changing in 1983, when a woman in Idaho named Maria Stern filed suit against Dow Corning. She got implants after a double mastectomy and experienced serious health problems she believed were linked to the implants, including arthritis and debilitating fatigue. Stern's lawyers from the San Francisco firm of

<sup>8</sup> Joni Hersch, "Breast Implants: Regulation, Litigation, and Science," Chapter 5 of *Regulation through Litigation*, edited by W. Kip Viscusi, AEI-Brookings Joint Center, 2002.

<sup>9</sup> V. Mueller & Co. v. Corley, 570 S.W.2d 140 (Tex. Civ. App. 1978).

<sup>10</sup> Mimi Swartz, "Silicone City: The rise and fall of the implant—or how Houston went from an oil based economy to a breast based economy," *Texas Monthly*, August 1995, page 64.

<sup>11</sup> Alison Frankel, "The splendid past and muddled present of breast implant litigation," *The American Lawyer*, June 1992, page 82.

<sup>6</sup> U.S. Food and Drug Administration, press release P92-1, Jan. 6, 1992.

<sup>7</sup> "The FDA's Regulation of Silicone Breast Implants," Staff Report Prepared by the Human Resources and Intergovernmental Relations Subcommittee of the House Government Operations Committee, December 1992.

Hersh & Hersh produced evidence that silicone from the implants had moved into her lymphatic system. In court, the lawyers adopted an untested legal strategy of linking the silicone to the systemic autoimmune disease.<sup>12</sup>

In preparation for trial, attorney Dan Bolton went to Dow Corning's headquarters in Michigan to look through thousands of internal documents that the company was required to produce as part of the discovery process. Bolton was shocked by some of the documents he read.<sup>13</sup>

Among them was a memo written in 1983 that concluded: "As Product Steward...I must strongly urge that Bill's group be given an approval to design and conduct the necessary work to validate that these gels are safe.... only inferential data exists to substantiate the long-term safety of these gels for human implant applications."<sup>14</sup>

A second memo, which proved to be particularly damning, discussed a new, softer version of Dow Corning's implant. The memo was sent to the company's sales force in May 1975 and stated: "It has been observed that the new mammaries with responsive gel have a tendency to appear oily after being manipulated... 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 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 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 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."<sup>15</sup>

In addition, testimony at trial suggested that Dow Corning had misstated the results of a 1960s study of implants in dogs. The documents and testimony helped persuade the jury to award Stern a judgment of \$1.7 million in 1984, including \$1.5 million in punitive damages.<sup>16</sup>

Dow Corning appealed the judgment and eventually settled with Stern for an undisclosed sum. The judge in the case later wrote that the evidence in the case showed that Dow Corning's implant was inherently defective, adding that company studies "cast considerable doubt on the safety of the product"—doubt that was not disclosed to patients.<sup>17</sup>

As part of the settlement, the judgment was vacated and all documents in the case were sealed. Lawyers and expert witnesses who had seen the documents were bound by confidentiality agreements not to disclose their contents. The Stern verdict received little publicity, and the court seal slowed access by other plaintiffs to the documents.<sup>18</sup>

<sup>12</sup> Frankel.

<sup>13</sup> Frankel.

<sup>14</sup> Document cited by Joseph Nocera, "Fatal Litigation," *Fortune*, Oct. 16, 1995, page 60.

<sup>15</sup> Document cited by Marcia Angell, "Science on Trial: The clash of medical evidence and the law in the breast implant case," W.W. Norton, 1997, page 59.

<sup>16</sup> Frankel.

<sup>17</sup> U.S. District Judge Marilyn Hall Patel, quoted by Tim Smart, "Breast Implants: What Did the Industry Know and When?" *BusinessWeek*, June 10, 1991, page 94.

<sup>18</sup> Frankel.

That bar to disclosure proved particularly important when Bolton, Stern's lawyer, testified about the risks of breast implants at an FDA hearing in November 1988. Bolton told the panel of his concerns about silicone-gel implants as well as possible fraud by Dow Corning, but said he was prohibited by court order from producing the documents that would buttress his assertions.<sup>19</sup> In subsequent years, FDA officials requested that Dow Corning turn over some of the documents cited by Bolton, although the record suggests that FDA officials who saw them did not attach much significance to them.<sup>20</sup>

In late 1991, as the FDA was concluding its review of implant safety, another key case was heard in San Francisco. Mariann Hopkins had received Dow Corning silicone-gel implants in 1976 following a double mastectomy. Soon after the implant surgery, her health suffered drastically, and 10 years later, she discovered that her implants had ruptured. She hired Bolton, who once again used Dow Corning documents to sway the jury. A memo written in 1985 noted in passing that "a study of the effects on the human immune system of silicone gels, fluids, and elastomers particles should be undertaken." Another urged the company to "vigorously oppose" an "ominous" trend at the FDA to require lifetime carcinogenic testing of implants.<sup>21</sup> In December 1991, Hopkins won a \$7.3 million judgment, including \$6.5 million in punitive damages.

The judge upheld the punitive damages award with a strongly worded broadside against the company: "[G]iven the facts that Dow was aware of possible defects in its implants, that Dow knew long-term studies of the implants' safety were needed, that Dow concealed this information as well as the negative results of the few short-term laboratory tests performed, and that Dow continued for several years to market its implants as safe despite this knowledge, a substantial punitive damages award is justified."<sup>22</sup>

Concerned about the FDA's lack of action regarding breast implants, Bolton wrote Kessler to outline the evidence presented in the Hopkins case. He noted that Dow Corning "still has not performed valid studies on the long-term safety of silicone gel."<sup>23</sup> Once again, documents in the Hopkins case were sealed at the insistence of Dow Corning.

However, the court mistakenly released some internal company documents to a newspaper reporter, and the documents eventually reached Kessler near the end of 1991. Alarmed by their contents, the commissioner called for a moratorium on silicone-gel implants within days.<sup>24</sup> The agency announced that the FDA "recently learned that some relevant documents that could have a bearing may not have been submitted to the agency."<sup>25</sup>

These were documents the company had not been required to submit to the FDA but had been forced to provide during litigation. Not long after the FDA called for a moratorium, Dow Corning released hundreds of pages of internal documents; hours later, the company's board removed its chairman and demoted its chief executive.<sup>26</sup>

<sup>19</sup> Frankel.

<sup>20</sup> Frankel.

<sup>21</sup> Frankel.

<sup>22</sup> *Hopkins v. Dow Corning Corp.*, 33 F.3d 1116 (9th Cir. 1994). Cited by Joni Hersh, in "Breast Implants: Regulation, Litigation, and Science," Chapter 5 of *Regulation through Litigation*, edited by W. Kip Viscusi, AEI-Brookings Joint Center, 2002.

<sup>23</sup> Letter cited by Frankel.

<sup>24</sup> Glenn Kessler, "Dow Knew for Years of Implant Troubles," *Newsday*, Feb. 11, 1992, page 5.

<sup>25</sup> FDA press release, Jan. 6, 1992. [www.fda.gov/bbs/topics/NEWS/NEW00263.html](http://www.fda.gov/bbs/topics/NEWS/NEW00263.html).

<sup>26</sup> Kessler.

The FDA's moratorium prompted a flood of litigation. In Texas, prominent plaintiffs' attorneys John O'Quinn and Rick Laminack filed 78 lawsuits in the first week after the moratorium was announced.<sup>27</sup> A class action was eventually certified under the supervision of U.S. District Judge Sam W. Pointer, Jr. in Alabama.

Individual cases continued to go to court in 1992 and 1993; plaintiffs won some, defendants won others. In one case that startled implant manufacturers, a woman in Houston who had received implants to augment the size of her breasts, not for reconstruction purposes, won \$25 million from Bristol-Myers Squibb, including \$20 million in punitive damages. The case was broadcast on Court TV, further increasing the visibility of breast implant litigation.<sup>28</sup>

Clearly, the large punitive damage awards helped spur manufacturers to negotiate a settlement in the class-action case. In March 1994, lawyers agreed on a global settlement totaling \$4.25 billion to be paid by four manufacturers. The settlement suggested that women would be eligible for payments of as much as \$2 million. However, it proved wildly unrealistic. Negotiators had estimated that as many as 60,000 women would eventually file claims in the case, but within a year, hundreds of thousands of women signed on, meaning claimants would receive far smaller amounts than the settlement had contemplated.<sup>29</sup>

The settlement terms became increasingly untenable, and the agreement was rendered moot in May 1995 when Dow Corning filed for protection under Chapter 11 of the U.S. bankruptcy code, thereby halting all litigation against the company. By the fall of 1995, three other manufacturers proposed a new settlement: Bristol-Myers Squibb Co., Baxter Healthcare Corp., a unit of Baxter International Inc., and 3M. Women would receive less than had been anticipated in the original settlement—from \$10,000 to \$250,000, depending on their injuries—and the total payout would reach about \$3 billion if all eligible women submitted claims.

Three years later, Dow Corning agreed to its own \$3.2 billion settlement, which would allow the company to move out of bankruptcy. However, that agreement also ran into trouble. In particular, plaintiffs' attorneys began filing cases against Dow Corning's parent company, Dow Chemical. With that litigation pending, Dow Corning refused to carry out the settlement plan until all cases against Dow Chemical were dropped. Finally, in March 2004, all the legal challenges were concluded, and Dow Corning began to execute the terms of the settlement. More than 12 years after the first request for a class-action lawsuit had been filed, Dow Corning began to make payments to women who had received its implants. By August 2004, more than 223,000 women had submitted claims for compensation.

Although the class-action lawsuit is now settled and payments are being made, other implant cases remain active in the courts, suits filed by women who opted not to join the class action. A firm count of the number of those cases is not available.

<sup>27</sup> Nocera.

<sup>28</sup> Nocera.

<sup>29</sup> Nocera.

## Getting to the Truth

Both litigation and FDA regulatory consideration helped prompt scientific research about the safety and durability of silicone-gel implants. The research has shown that beginning in the 1960s, hundreds of thousands of women received incomplete or misleading information. Contrary to the information they were given, the research has confirmed that a majority of, if not all, implants eventually rupture; that they can cause disfigurement, pain, loss of sensation, rashes and other problems; and that many women will require one or more additional surgeries because of implant problems. These are not minor concerns and have in many cases caused significant disruption—physical, emotional and financial—to women's lives.

The FDA and others have finally taken steps to inform the public about the risks of implants. Notably, the FDA Breast Implant Consumer Handbook now includes the following blunt statements:

“Breast implants will not last a lifetime. Either because of rupture or other complications, you will likely need to have the implants removed.

“You are likely to need additional doctor visits and reoperations because of one or more complications over the course of your life.

“You are likely to have the implants removed, with or without replacement, because of one or more complications over the course of your life.

“Many of the changes to your breast following implantation may be cosmetically undesirable, as well as irreversible (cannot be undone).”<sup>30</sup>

A large number of women have claimed that silicone-gel implants led to a wide range of other ailments, including chronic fatigue, muscle and joint pain, and connective-tissue diseases. The women spoke with intuitive confidence about their implants and the harm they were certain the implants had caused. Some scientists bolstered these cases with reports that sought to link silicone implants to a variety of health concerns.

In the late 1980s and early 1990s, critics branded some of this evidence about the systemic effects of implants (not the localized effects, which are now undisputed) as “junk science,” testimony based more on suppositions than empirical findings. Among the most prominent critics was Marcia Angell, a pathologist and former editor of the *New England Journal of Medicine*. Angell noted that during the key early stages of litigation, there were no scientific studies that showed a firm link between the silicone in implants and disease.<sup>31</sup>

On the other hand, the implant manufacturers were unable to show definitively that their products were safe. The companies had not tracked large numbers of women for the kind of long-term studies that would be needed to demonstrate implant safety. In plainest terms, the companies could not prove implants were completely safe, and that was borne out by damaging internal company documents.

<sup>30</sup> U.S. Food and Drug Administration “Breast Implant Consumer Handbook 2004, Local Complications & Reoperations.”

<sup>31</sup> Marcia Angell, “Science on Trial: The clash of medical evidence and the law in the breast implant case,” W.W. Norton, 1997, page 205.

Still, plaintiffs struggled to prove that their sometimes serious illnesses and injuries were caused by their implants.<sup>32</sup>

As reiterated during the most recent hearings on silicone-gel breast implants, the FDA and other groups have three areas of concern regarding the implants: the frequency of ruptures over the lifetime of the device; the migration of silicone gel outside the implant shell into the body; and the health consequences of ruptures and silicone gel migration.

In 1997, Congress asked the U.S. Department of Health and Human Services to sponsor a review by the Institute of Medicine, a branch of the National Academy of Sciences, of past research of silicone-gel implant safety. The IOM convened a panel of experts to review the existing evidence for any association of silicone-gel implants with health conditions. The IOM panel did not do independent research.

Issuing its findings in 1999, the panel concluded, “Reoperations and local and perioperative complications are frequent enough to be a cause for concern and to justify the conclusion that they are the primary safety issue with silicone breast implants.”<sup>33</sup> These local complications include painful contracture of the breasts, scarring and rupture of the implants. Information on such problems was necessary to allow women to give “informed consent” to the risks of implants. The panel also concluded, “Risks accumulate over the lifetime of the implant, but quantitative data on this point are lacking for modern implants and deficient historically.”

The panel reviewed 17 selected epidemiological studies of the many conducted that examined possible links between silicone-gel breast implants and a variety of classical connective tissue diseases. The panel found that the existing research did not demonstrate that silicone-gel implants posed an increased risk of such diseases. The panel also ruled that there was not sufficient evidence to associate the implants with a novel, unspecified connective tissue disorder.

An FDA study published in 2000 found that the median rupture age for silicone-gel implants was 10 years.<sup>34</sup> The study also noted that 21 percent of women who had ruptures experienced gel migration in the body outside the implant. In April 2005—one week before an FDA panel conducted hearings on Inamed’s and Mentor’s applications for pre-market approval of silicone gel-filled implants—the agency publicly released an estimate that up to 95 percent of the implants used for reconstructive surgery ruptured within 10 years. The FDA’s medical officers noted that it is impossible to accurately predict how many ruptures would occur.

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<sup>32</sup> One important point came in 1993, a year after silicone-gel implants were largely removed from the market, when the U.S. Supreme Court issued an opinion on the admissibility of expert testimony. The case, *Daubert v. Merrell Dow Pharmaceuticals*, involved a claim brought by the parents of two boys born with only rudimentary arms. The parents asserted that Benedectin, an antihistamine-like drug that the two mothers had taken to combat morning sickness during pregnancy, had caused boys’ malformed arms. In the case, the Supreme Court ruled that trial judges need to serve in a “gate keeping” role to bar the introduction of speculative, unscientific testimony. Rather, judges should allow only “pertinent evidence based on scientifically valid principles.” *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993).

The ruling did not offer clear rules for judges to follow when deciding what type of scientific testimony to allow at trial. But the ruling was seen as an attempt to force more rigor on judges as they screened scientific experts in court cases. It also led to cases in which judges prohibited some scientific testimony in lawsuits involving silicone-gel breast implants. In 1996, a federal judge in Oregon barred expert testimony linking silicone-gel implants to immune system diseases, such as lupus and rheumatoid arthritis. In that case, the judge relied on the guidance of a panel of outside experts that reviewed research on the subject. Ruling by U.S. District Judge Robert E. Jones, cited by John Schwartz, “Ruling Limits Testimony on Breast Implants: ‘Systemic’ Illness Link is Called Unscientific,” *Washington Post*, Dec. 19, 1996, page A1.

<sup>33</sup> Institute of Medicine, “Safety of Silicone Breast Implants,” National Academy Press, Washington, D.C., 2000, page 10.

<sup>34</sup> Brown, S.L., M.S. Middleton, W.A. Berg, M.S. Soo, G. Pennello. “Presence of rupture of silicone gel breast implants revealed on MR imaging in a population of women in Birmingham, Alabama,” *American Journal of Roentgenology*; 175: 1057-1064, 2000.

FDA medical experts note that while Inamed has three years of data on its gel-filled implant, the company screens patients in clinical trials only every other year so it had only two sets of complete screenings. Moreover, agency experts also determined that Mentor’s clinical trial data was of “limited value” and that the company provided less testing data than Inamed. One problem is that many ruptures do so “silently,” making women unaware that small amounts of silicone are leaking into their bodies from the implant.<sup>35</sup>

There are continuing concerns about what happens when the implants rupture or leak. A National Cancer Institute study released in 2001 tracked the health of 13,500 implant recipients over many years and found that implant recipients were somewhat more likely to die of brain and respiratory cancers than women without implants.<sup>36</sup> The increased risks were considered significant, although the researchers could not explain the association.

In 2001, a study by researchers from the National Institutes of Health and the FDA found that reports of fibromyalgia—a syndrome marked by pain in the muscles, ligaments and tendons—increased significantly in women who had ruptured implants, allowing silicone to spread outside the breast area.<sup>37</sup> Researchers called for additional studies of the matter to establish a stronger link. If this link exists, the researchers said implants should come with a clear warning to women about fibromyalgia.

That result was reinforced to an extent by research findings released in 2003 by implant manufacturer Inamed showing that women were significantly more likely to have a variety of problems, including muscle pain, joint pain and fatigue after receiving implants.<sup>38</sup>

A recent study published in the *American Journal of Surgical Pathology*, which was presented in April 2005 to the FDA advisory panels considering recent applications for new product approval by Inamed and Mentor Corp., reported that silicone gel migration may have an adverse effect on the immune system and concluded that “the possibility that silicone frequently migrates to regional lymph nodes of patients with silicone breast implants must be considered in assessing the safety of these devices.”<sup>39</sup>

Such results are inconclusive but amount to warning signs that the long-term implications of silicone implants are still not thoroughly understood.

Some observers have accused women’s health advocates of working to limit the choices of women who may choose to accept any risks associated with implants. However, many of these advocates are convinced that the federal government has yet to require manufacturers to perform the kind of long-term studies of significant numbers of women that would provide conclusive evidence of the risks of implants.

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<sup>35</sup> Marc Kaufman, “FDA Panel Opposes Silicone Gel Implants,” *Washington Post*, April 13, 2005, page A7.

<sup>36</sup> Brinton, L.A., J.H. Lubin, M.C. Burich, T. Colton, S.L. Brown, R.N. Hoover, “Cancer Risks at Sites Other than the Breast Following Augmentation Mammoplasty,” *AEP Vol. 11*, No. 4, May 2001, pp 248-256.

<sup>37</sup> Brown, S.L., G. Pennello, W.A. Berg, M.S. Soo, and M.S. Middleton, “Silicone Gel Breast Implant Rupture, Extracapsular Silicone, and Health Status in a Population of Women,” *The Journal of Rheumatology*, May 2001.

<sup>38</sup> U.S. Food and Drug Administration, General and Plastic Surgery Panel, Oct. 14, 2003. Slides summarizing Inamed Corp. research results.

<sup>39</sup> Katzin, W., et al, “Pathology of Lymph Nodes from Patients With Breast Implants,” *Am. Surg. Pathol.* 2005.

## Putting It in Perspective

Breast implant litigation is rarely in the news anymore. And the public may have long since concluded—inaccurately—that women who claimed injuries from implants uniformly received large payouts from manufacturers.

While there were many large jury awards, which often received wide publicity, judges sometimes reduced them on appeal. In some notable cases, the largest component of the jury awards was for punitive damages, a response by juries to what they considered fraudulent or improper behavior by manufacturers.

The record of the breast implant litigation is not unblemished. While the scientific evidence regarding the adverse, localized effects of implants is now beyond dispute, some of the scientific testimony put on during trials about the systemic effects, particularly in early litigation, did not stand up to scrutiny.<sup>40</sup> Even so, the civil justice system in this case produced well-deserved victories for many injured women. Many thousands have been compensated for their injuries; many more are now receiving disbursements.

The stories of the following women are typical of many who had silicone-gel breast implants. At the age of 25, Pam Noonan-Saraceni was diagnosed with breast cancer and had a radical mastectomy in 1978. More than five years later, she decided to have reconstruction surgery because she was unhappy with prosthetics.<sup>41</sup> The plastic surgeons she consulted urged her to have silicone-gel implants. Each assured her they would last a lifetime, and said there would be no complications.

Three months after that second surgery, she was back in the hospital because her implant had shifted toward her collarbone and a hard capsule had formed around it, causing searing pain in her shoulder area. She received a new implant, but again a capsule formed around it. And her health began to deteriorate, as she endured joint pain, fatigue, gastro-intestinal problems and sleep disorders. Ten years after the implant surgery, Noonan-Saraceni had it removed, convinced that the silicone-filled device was causing her health problems. After being tested repeatedly for other ailments, Noonan-Saraceni has concluded there is no other explanation for her poor health.

Noonan-Saraceni estimates she has spent \$40,000 on medical bills related to her implants and her search for explanations about her health problems. Those were out-of-pocket expenses, as her insurance policy explicitly did not cover any costs related to reconstructive surgery. She joined the class-action lawsuit filed against Dow Corning, which made her implant. Noonan-Saraceni does not expect a large settlement from the case, but that is not her goal. She is more concerned about ensuring that implant manufacturers do not repeat the mistakes of the past with more women in the future.

“It’s proven they do not last a lifetime. It’s proven there are local complications, but I was never told this,” she says. “I don’t care what a woman does to her body, but she needs to know that there are these major risks.”

Anne Stansell was also a cancer survivor. A real estate agent in New Mexico, Stansell was diagnosed in 1987 when she was 39. She underwent two mastectomies and radiation therapy. At her doctor’s suggestion, she also received two silicone-gel implants. The doctor did not mention possible problems with implants, nor did he inform her that there had been no long-term studies of implant safety. “You just follow along,” Stansell says. “You trust these doctors who just saved your life.”<sup>42</sup>

About five years after receiving her implants, Stansell’s health began to deteriorate. She developed Grave’s disease and fibromyalgia, and suffered from joint pain, dry eyes and muscle aches. She also had more surgery to deal with problems caused by the implants. Finally, roughly seven years after the implants were in, Stansell had them removed.

Over the next 10 years, Stansell’s health improved significantly. While she cannot prove that the implants caused her health problems, Stansell has no doubt. “I was fine until I had the implants put in; I was fine after they came out,” she says.

Stansell has devoted several years to holding implant manufacturers accountable. She joined the lawsuit against Dow Corning seeking some compensation for the years of health problems she has gone through. She has also worked on behalf of other women, going to Washington to lobby against allowing silicone-gel implants to go back on the market. If they do, she stresses the need for women to know the risks.

“When I got into this situation, I didn’t really do any checking,” she says. “Today, we have done our best to put the information out there. I hope that today women can learn more and completely check this out.”

Mary McDonough, the actress who portrayed Erin on “The Waltons,” received silicone-gel breast implants in 1984 when she was 24. Her health deteriorated almost immediately, with symptoms including rashes, headaches, muscle pain, chronic fatigue and aching breasts. After coping with the debilitating problems for a decade, McDonough had her implants removed; her surgeon discovered that the silicone implant envelope had disintegrated, leaving silicone surrounded by scar tissue. McDonough has no doubt that her physical problems were caused by her implants.

“I am well aware that some scientists believe that implants do not cause lupus, chronic fatigue, flu-like symptoms, or the aches and pains that I suffered from. I’m not a scientist, but I am an expert on me, so let me say it simply: I was healthy, I got implants, I got sick, I had them removed, and I got better. Maybe it’s just a coincidence, but since my implants were removed, I have become healthier every year, and now I can work as an actress again. And I know many women with implants who have had similar experiences.”<sup>43</sup>

In addition to the women who received compensation for their injuries, the public also won as the civil courts forced an ongoing regulatory re-examination of the safety of implants that many say is still inadequate. To accomplish those important victories, plaintiffs and their lawyers took strong advantage of the discovery process and unearthed important internal documents that shed light on the inner workings of implant manufacturers and the

<sup>40</sup> In 1996, U.S. District Judge Pointer in Alabama, who was overseeing the class-action proceedings against several implant manufacturers, appointed a four-member scientific panel to review the evidence linking implants to health problems. Two years later, the panel issued a report that concluded they had found no definite links between implants and a range of diseases.

<sup>41</sup> Pam Noonan-Saraceni, Author’s personal interview, Dec. 23, 2004.

<sup>42</sup> Anne Stansell, Author’s personal interview, Jan. 27, 2005.

<sup>43</sup> Statement of Mary McDonough, “One Woman’s Experience,” posted on the Web site of the National Research Center for Women and Families ([www.center4research.org/mary1.html](http://www.center4research.org/mary1.html)).

safety of the devices. In the case of Dow Corning, documents showed a manufacturer that was far less confident about the safety of its products than it publicly admitted. In one—the memo urging salespeople to clean off leaking implants—the company seemed intent on obscuring the truth from surgeons, the people who had the most sway with potential implant recipients.

These manufacturers were under no obligation to submit these documents to regulators at the FDA. Rather, the documents reached the public only through the civil justice system.

“This is a perfect example of how the regulatory system doesn’t work,” said Ralph Knowles Jr., a lawyer in Atlanta who successfully sued implant manufacturers. “It’s the tort system working. ... But for the lawsuits, the causation and documentary proof wouldn’t have come out.”<sup>44</sup>

The late Norman Anderson, a Johns Hopkins Medical School professor and one-time chairperson of the FDA’s advisory panel, also decried the agency’s handling of implants and credited the civil justice system with forcing the agency to act: “The courts knew more than the FDA. The lawyers knew more than the scientists.”<sup>45</sup> The record suggests that even when the companies did provide the FDA with some of the revealing internal documents, officials at the agency gave them little significance.

Interestingly, there is some evidence that FDA officials sometimes rely on the civil justice system as a backstop, one capable of holding drug and device manufacturers more accountable than the government can. The diet drug controversy of the late 1990s provides one example, recounted by writer Alicia Mundy, a fellow at the New America Foundation. “When one top FDA official declined to allow one of his doctors to testify for plaintiffs in the ‘fen-phen’ disaster in 1999, he explained his decision at an internal FDA meeting, saying, ‘Surely a smart plaintiffs’ attorney will figure out’ how to get company insider information into court.”<sup>46</sup> In other words, federal regulators do not always have the same ability to discern corporate behavior as plaintiffs and their lawyers do.

The documents that became known through implant litigation were extremely problematic for the companies, making clear that they had not been forthcoming about a product being implanted in women’s bodies. Contributing to the impression that Dow Corning was embarrassed by its behind-the-scenes behavior was the company’s determined effort to keep its internal documents secret. Using court orders, the company was successful for seven years.

The company’s own public relations advisors recognized the importance of the documents. They were, one advisor wrote in a memo at the time, “almost impossible to defend in court and certainly in the ‘court of public opinion.’”<sup>47</sup>

That Dow Corning found itself so besieged by litigation was attributable largely to the company’s long-term behavior, according to one expert who studied the controversy.

“From the standpoint of our interest in good risk communication practice, the silicone breast implant episode appears to be a story about two major failings by a company: first, the failure to disclose to its customers everything of material relevance that it knew about the risks associated with its product; and second, a failure to pursue thoroughly the full range of scientific studies that would have shed more light on those risks. In our opinion these failures turned out to be very serious.”<sup>48</sup>

### Epilogue—Renewed Efforts to Get FDA Approval for Silicone-Gel Breast Implants

Silicone-gel breast implants, which prompted hundreds of thousands of legal claims and led to one of the largest legal settlements in history, may soon be on the general market again for the first time since 1992. Two manufacturers of implants have requested FDA approval to market silicone-gel implants. In December 2002, Inamed Corp., parent company of long-time implant manufacturer McGhan Medical, filed a request to sell silicone gel-filled “third-generation” implants that are filled with a jelly-like silicone that is thicker than previous products.<sup>49</sup> In October 2003, the FDA’s General and Plastic Surgery Devices Panel convened to consider the application. Two months later, Mentor Corp. finished an application to market its version of a silicone gel-filled implant. And then a year later, Inamed submitted another request, to begin a review of its “fourth generation” Bio-Dimensional Cohesive Gel Matrix implant. The cohesive gel implant has been referred to as “the gummy bear” implant because the gel is thick enough to slice.

The advisory panel reviewing Inamed’s “third-generation” application in October 2003 voted nine to six in favor of allowing the implants to return to the market with conditions. But in January 2004, top FDA officials rejected the panel’s recommendation and declined, at least temporarily, to approve Inamed’s application. The FDA asked for more information on how soon and why implants rupture, and more data on complications that result from ruptures in surrounding tissues.<sup>50</sup>

An FDA advisory panel convened in early April 2005 to review new information submitted by Inamed and to consider Mentor’s request for approval. The panel approved Mentor’s application and rejected Inamed’s, by a vote of five to four.

The panel placed nine conditions on Mentor’s product, however, including that plastic surgeons receive “hands-on” training before using the implants and that the company continue to study rupture rates of the devices. One member, Dr. Michael Miller, announced that while the panel did not “have exhaustive knowledge about these devices,” it had “sufficient knowledge to justify their uses.”<sup>51</sup>

In the case of Inamed, the majority of the panel concluded that the scientific data was too insufficient to provide assurance that the implants were safe. Panel member Dr. Amy Newberger stated, “This hearing was premature. I don’t feel secure about the safety issues. I don’t see how we can get or give adequate informed consent for our patients based on the data we’ve seen.”<sup>52</sup>

<sup>44</sup> Frankel.

<sup>45</sup> Frankel.

<sup>46</sup> Alicia Mundy, “The Good Guys: Tort reformers complain about ‘frivolous’ lawsuits. But at a time when government has stopped protecting citizens, trial lawyers have become the regulators of last resort,” *The American Prospect*, November 2004, page 25.

<sup>47</sup> John Stauber and Sheldon Rampton, “Confidence Game: Burson-Marsteller’s PR Plan for Silicone Breast Implants,” *PR Watch*, Volume 3, number 1, First Quarter 1996.

<sup>48</sup> Conrad G. Brunk, with William Leiss, “Silicone Breasts: Dow Corning and the Implant Lawsuits,” Chapter 5, *Mad Cows and Mother’s Milk*, McGill-Queen’s University Press, 1997.

<sup>49</sup> Mary Duenwald, “Despite Ban, a Gray Market in Silicone Implants Thrives,” *New York Times*, April 21, 2005, page G1.

<sup>50</sup> Alice Dembner, “U.S. Keeps Limits on Implants,” *Boston Globe*, Jan. 9, 2004, page A1.

<sup>51</sup> Gardiner Harris, “FDA Panel Backs Breast Implants From One Maker,” *New York Times*, April 14, 2005, page A1.

<sup>52</sup> Marc Kaufman, “FDA Panel Opposes Silicone Gel Implants,” *Washington Post*, April 13, 2005, page A7.

The advisory panel's split decision on Mentor's and Inamed's market approval applications was roundly criticized by advocates on both sides of the issue. The American Association of Cosmetic Surgeons complained about one of the panel's conditions for approval—that only board-certified plastic surgeons be permitted to use Mentor's silicone breast implant.<sup>53</sup> Inamed also blasted the panel's approval of Mentor's application after it rejected Inamed's application the previous day on the grounds that not enough data was presented about the safety of the implants, calling the decision “bizarre and strange.”<sup>54</sup> Noting that Mentor presented less data, Inamed Vice President Dan Cohen said, “Yesterday, they [the advisory panel] wanted more data and today they accepted less.”<sup>55</sup> Dr. Diana Zuckerman, president of the National Research Center for Women and Families, said that the decisions sent a mixed message that would make the decision hard for the FDA.<sup>56</sup>

Critics of the advisory panel's decision also note that the conditions the panel set out for Mentor to follow after the product was on the market are unenforceable by the FDA. When the same advisory panel approved Inamed's third-generation application in 2003, several members of Congress wrote to the FDA urging the agency to reject the panel's decision, expressing concern, among other things, that the “significant number of conditions for approval outlined by the panel will be unenforceable.”<sup>57</sup>

Critics also argue that these post-market conditions cannot be a substitute for the manufacturer's legal obligation to provide a reasonable assurance of a medical device's safety before going to market. In enacting the Federal Food Drug and Cosmetic Act, Congress placed a burden on a manufacturer to demonstrate a “reasonable assurance” that the medical device is safe.<sup>58</sup> Manufacturers have a poor record of following post-market conditions. FDA scientists have found that only 42 percent of post-market studies ordered in conditional product approvals from 1998 to 2000 were completed or on schedule.<sup>59</sup>

On July 28, 2005, a group of women U.S. senators, led by California Senator Dianne Feinstein and Maine Senator Olympia Snowe, urged the FDA to consider women's safety before the agency makes a final decision. The next day, on July 29, 2005, the FDA issued an “approvable letter” to Mentor for its application for silicone gel-filled breast implants. The contents of the letter were not disclosed, but the FDA noted that the letter “is one of several intermediate steps in the FDA review process.” The FDA further noted that its letter “does not mean that the device is approved for marketing in the United States at this time.”

<sup>53</sup> FDA Week, April 22, 2005, Vol. 11, No. 6.

<sup>54</sup> Gardiner Harris, “FDA Panel Backs Breast Implants From One Maker,” New York Times, April 14, 2005, page A1.

<sup>55</sup> Editorial, San Francisco Chronicle, April 15, 2005, page B8.

<sup>56</sup> Ricardo Alonso-Zaldivar, “A Silicone Implant Gets Panel's OK,” Los Angeles Times, April 14, 2005, page A1.

<sup>57</sup> Letter from Representatives Gene Green, Sherrod Brown, Stephanie Tubbs-Jones, Sam Farr, Janice Schakowsky, Neil Abercrombie, Maurice Hinchey, Dale Kildee and Carolyn Maloney to FDA Commissioner Mark McClellan, dated Dec. 15, 2003.

<sup>58</sup> 21 U.S.C. § 360e(d)(2)(A).

<sup>59</sup> Rita Ruben, “Conditions tied to implant decision,” USA Today, April 19, 2005, page 7D.

## Timeline of Silicone-Gel Breast Implants in the United States<sup>60</sup>

**1920s:** Doctors begin using fat from women's bodies to enlarge their breasts. The procedure causes complications and falls out of favor in the 1930s.

**1940s:** Japanese prostitutes use injected silicone to enlarge their breasts to attract U.S. military personnel.

**1950s-1960s:** Tens of thousands of women have liquid silicone injected to enlarge their breasts. Plastic surgeons experiment with injections of a variety of implant materials, including glass and ivory balls. Injections of liquid silicone produce a range of serious health problems, fall out of favor and are eventually outlawed.

**1962:** A Houston plastic surgeon, Frank Gerow, places the first silicone-gel breast implant in a woman, Timmie Jean Lindsey. Manufactured by Dow Corning, the “Silastic” implant is made of a rubbery silicone container holding silicone gel. The new implants become popular and replace the use of injected silicone. The federal government has no oversight authority of the devices, and little testing for safety is done.

**1965:** A French doctor, H.G. Arion, introduces the saline implant, a sterile saline solution inside a silicone pouch. Silicone-gel implants feel more natural and prove to be more popular with women.

**1967:** A federal indictment in Michigan charges Dow Corning with misbranding, mislabeling and transporting liquid silicone across state lines for illicit injection into women.

**1971:** Dow Corning pleads no contest and is found guilty of illegal interstate shipping of mislabeled silicone. In legal papers filed in connection with the criminal case, the company describes the use of silicone as a matter of “national concern” and pledges “whole-hearted cooperation” with the FDA on related matters.

**May 1976:** President Gerald R. Ford signs the Medical Device Amendments to the Food, Drug and Cosmetic Act, giving the FDA the authority to regulate most medical devices and requiring manufacturers to submit safety and effectiveness data before marketing products. Breast implants, having been on the market for 14 years, are “grandfathered” in; manufacturers are not required to show additional proof that the devices are safe.

**1977:** In perhaps the first successful legal challenge to implant manufacturers, a woman in Cleveland wins a lawsuit against Dow Corning, claiming that her ruptured implants had caused pain and suffering. The woman receives \$170,000 from Dow Corning.

**1978:** An FDA advisory panel recommends that breast implants be categorized as Class II devices, meaning manufacturers do not have to prove that the implants are safe.

<sup>60</sup> This timeline relies on interviews, Congressional records, newspaper and magazine articles, and other documents, including “Science on Trial,” by Marcia Angell, 1996, W.W. Norton & Co.; “Venus Envy: A History of Cosmetic Surgery,” by Elizabeth Haiken, 1997, Johns Hopkins University Press; a timeline prepared by the Command Trust Network ([www.commandtrust.org/moreinformation.shtml/timeline](http://www.commandtrust.org/moreinformation.shtml/timeline)); “Timeline of Breast Implant Activities,” U.S. Food and Drug Administration, consumer handbook, 2004; and the Chronology of Silicone Breast Implants prepared for PBS’ “Frontline,” 1998.

**1982:** An FDA advisory panel reviews safety of implants again. Medical literature includes reports of problems with breast implants. The FDA proposes to place implants in Class III of medical device categories, which would require additional controls for safety and effectiveness.

**1984:** Maria Stern wins a \$1.7 million judgment against Dow Corning in San Francisco. Her attorney, Dan Bolton, introduces testimony linking her systemic autoimmune disease to silicone-gel implants. Stern wins using internal Dow Corning documents that Bolton uncovered, some showing concerns at Dow Corning about the safety and durability of implants. Dow Corning drops its appeal and settles the case with a confidential payment but insists on sealing evidence.

The judge in the case later writes that the evidence showed that Dow Corning's implant was inherently defective, adding that company studies "cast considerable doubt on the safety of the product" that was not disclosed to patients.

**Late 1980s:** Public Citizen Health Research Group and other health organizations issue alerts about possible health risks of silicone implants.

**1987:** The Maryland legislature passes the first state law to require that patients considering breast implant surgery be given a brochure listing the potential risks and complications.

**June 1988:** After six years of consideration, the FDA classifies all breast implants in Class III, which carries more rigorous safety documentation standards.

**January 1989:** The FDA announces its intention to require manufacturers of silicone-gel and saline breast implants to submit Premarket Approval Applications, which are due by July 1991 and are to demonstrate safety and effectiveness of implants.

**December 1990:** Connie Chung's program on CBS highlights health problems of five women who have received implants, drawing national attention to the issue.

Rep. Ted Weiss, D-NY, holds hearing on implants, the first Congressional hearing on the subject. He and others sharply criticize the FDA for ignoring warnings about implant safety. "The manufacturers and surgeons have been performing experimental surgery on humans," testifies Thomas D. Talcott, a former materials engineer for Dow Corning, who left the company in 1986 in a dispute over the implants' safety. Witnesses discuss potential risks of polyurethane-covered implants.

**August 1991:** Implant recipient Brenda G. Toole wins a \$5.4 million verdict against manufacturer Baxter Health-care, including \$5 million in punitive damages.

**September 1991:** The FDA concludes that implant manufacturers' data does not prove the devices are safe or harmful. "Women need to be urged to strongly to consider the risks of these implants," announces FDA Commissioner David Kessler. "The implants have been on the market a long time and women have been lulled into thinking they are risk free. They are not."

**November 1991:** An FDA expert panel concludes that despite a lack of data establishing the safety of implants, the devices should remain on the market pending additional studies.

**December 1991:** A federal jury in California awards Mariann Hopkins \$7.3 million from Dow Corning, concluding that her ruptured implants caused her severe arthritis-like symptoms. The jury finds that Dow had "fraudulently and maliciously" failed to warn Hopkins that the implant might leak, with life-threatening results.

That same month, a newspaper reporter obtains copies of internal Dow documents under seal in the Hopkins litigation. The documents show Dow officials acknowledging that implants could rupture and cause possible health problems; in others Dow officials express concern that there was not enough testing of the long-term safety of implants. The documents are given by intermediaries to FDA Commissioner Kessler.

A public relations adviser to Dow notes that the company must do damage control over documents that are "almost impossible to defend in court and certainly in the 'court of public opinion.'"

**January 6, 1992:** The FDA asks for a voluntary moratorium on the use of breast implants while the agency considers reports on their safety.

**February 1992:** A federal judge in Ohio certifies implant recipients as a class for purposes of mass litigation against manufacturers. The class-action suit is later transferred to a federal judge in Alabama.

In the same month, an FDA panel reviews new material submitted by implant manufacturers, including information on cases of autoimmune diseases and evidence that some implants leaked excessively.

Dow releases 800 pages of internal documents. Among them are complaints from doctors of more ruptures with the softer implants introduced in the 1970s. Company officials say they are embarrassed by some of the documents but downplay any scientific importance. "We need to have more research," Dow Corning CEO Keith McKennon tells a national television audience. "We need to add to the body of knowledge about these products."

**March 1992:** Dow Corning, Bristol-Myers Squibb and Bioplasty quit the implant manufacturing business.

**April 1992:** The FDA lifts the voluntary moratorium on silicone-gel implants but imposes limits on their use. The agency allows the implants to be used only in controlled clinical studies for reconstructions after mastectomies, correction of congenital deformities or replacement of ruptured silicone implants. Breast augmentation, which makes up roughly 80 percent of the implant market, is strictly limited.

**December 1992:** A woman in Houston wins a \$25 million judgment, including \$20 million in punitive damages, from Bristol-Myers Squibb, for problems caused by ruptured silicone-gel implants. The award is reduced during settlement talks while the case is on appeal.

**1992-94:** Thousands of women file lawsuits against implant manufacturers.

**June 1993:** Dow Corning wins a case brought by a woman in Colorado after jurors conclude there is little evidence linking her health problems to silicone.

**March 1994:** Attorneys finalize the parameters of a \$4.25 billion settlement to the class-action lawsuit with Dow Corning, Baxter, Bristol-Myers Squibb/MEC and 3M.

**June 1994:** A Mayo Clinic study finds no increased risk of connective-tissue disease and other disorders in connection with silicone-gel implants.

**May 1995:** Dow Corning files for bankruptcy protection, facing 20,000 lawsuits and more than 170,000 claims. The filing halts all litigation against the company.

**August 1995:** In Congressional testimony, FDA Commissioner Kessler states that published studies suggest the rupture rate for implants falls between 5 percent and 51 percent.

**November 1995:** A new global settlement is devised without the participation of Dow Corning, which is in bankruptcy proceedings.

**1997:** The FDA asks the Institute of Medicine to review scientific research regarding the safety of implants, with a focus on links to systemic diseases.

**July 1998:** Dow Corning and plaintiffs agree to a \$3.2 billion settlement. Women with implant-related disease claims are entitled to receive between \$10,000 and more than \$250,000. Dow also agrees to pay for implant-removal surgery or to replace ruptured implants. Payments under the plan are held up due to other litigation against Dow Corning's parent company, Dow Chemical.

**November 1998:** A four-member scientific panel appointed by a federal judge concludes that research has not shown a definite link between implants and certain women's illnesses.

**June 1999:** The Institute of Medicine releases findings from its review of implant research. The institute's panel determines there is insufficient evidence to establish that implants cause systemic health effects such as autoimmune disease; the report notes that studies do show a high rate of local problems due to rupture, pain, capsular contracture, disfigurement and serious infections.

**March 2000:** An FDA panel meets to determine approval of saline breast implants.

**May 11, 2000:** The FDA announces approval of Inamed Inc.'s and Mentor's saline breast implants.

**December 2002:** Implant manufacturer Inamed Inc. requests FDA approval to bring silicone-gel implants to the market.

**October 2003:** An FDA panel votes nine to six in favor of allowing Inamed silicone-gel implants to return to the market with numerous post-market conditions.

**December 2003:** Mentor files its pre-market approval application for silicone gel-filled implants.

**January 2004:** The FDA rejects the panel's vote and declines to allow silicone-gel implants on the market, citing concerns about the rupture rate for the devices.

**March 2004:** With a final legal challenge dropped, Dow Corning begins to execute its 1998 settlement plan with implant recipients. Payments begin to be made. As of August 2005, more than 223,000 women have submitted claims.

**August 2004:** Mentor and Inamed file amendments to their existing gel-filled pre-market approval applications.

**December 2004:** Inamed files cohesive gel implant pre-market approval application, which is considered the "next generation" implant.

**April 2005:** FDA holds public hearing to review data submitted by two manufacturers seeking approval of silicone gel-filled breast implants.

**April 13, 2005:** FDA advisory panel denies Inamed pre-market approval for its silicone gel-filled breast implant.

**April 14, 2005:** FDA advisory panel gives Mentor pre-market approval for its silicone gel-filled breast implant.

**July 29, 2005:** FDA issues "approvable letter" to Mentor. The FDA notes the letter "is one of several intermediate steps in the FDA review process."

**September 21, 2005:** FDA issues "approvable letter" to Inamed. Mentor's and Inamed's silicone gel-filled breast implants are expected to be fully approved sometime in 2006.

## 2. EFFORTS TO LIMIT THE ROLE OF THE CIVIL JUSTICE SYSTEM

President George W. Bush's administration and some members of Congress are attempting to rewrite the laws that govern the nation's civil justice system. In some cases, these policy-makers cite the need to curb "frivolous" lawsuits or to rein in "ambulance-chasing" trial lawyers determined to get rich.

However, what is being proposed in Washington and pursued in courthouses around the country has far-reaching implications that could potentially affect every consumer. At stake is preserving a system that has repeatedly worked well for both injured parties and the public.

While the silicone-gel implant litigation did not proceed perfectly, it helped uncover the truth about manufacturers' concerns, won compensation for many women who suffered because of their implants, and spurred federal regulators to examine the safety of implants for the first time.

The implant litigation is far from unique in those regards. The civil justice system has repeatedly worked to protect consumers by forcing unsafe products off the market. In many cases, the courts have been forced to fulfill this crucial role after government regulators failed to identify harmful products. In some cases, the evidence that emerged in court cases so shocked juries that they awarded large punitive damages. Five brief case studies are summarized here.

### Fen-phen

The use of drugs to help patients lose weight exploded in the mid 1990s, thanks to a combination of drugs known as fen-phen. Some FDA officials had strong misgivings about approving one of the drugs when it came up for consideration in the fall of 1995. An advisory panel voted five to three against allowing another one called Redux to come to market, citing concerns about evidence that the drug caused brain damage in animals. The panel reversed itself later that year and approved the drug by a vote of six to five.<sup>61</sup>

New evidence quickly accumulated linking the fen-phen drugs to high rates of heart valve problems—a potentially deadly ailment. Soon, the FDA forced the drugs off the market.

As litigation unfolded, the true history of the diet drugs came to light. Attorneys for patients who had been injured or killed by the drugs unearthed a series of documents that outlined how the manufacturers had withheld safety information from FDA regulators and had worked desperately to stop the agency from ordering that a serious

warning label be placed on their drugs alerting doctors and patients to the risk of primary pulmonary hypertension. One in-house estimate from 1995 said such a "black box" warning would cut sales by an estimated \$800 million annually.<sup>62</sup> Remarkably, one memo that emerged during litigation showed that officials at one company were aware that the product had very little success at helping patients lose weight. "The efficacy of Redux is not impressive," the official wrote in 1995. Patients using Redux lost, on average, only 3 percent more weight than those taking a placebo.<sup>63</sup>

In many cases, juries were distressed enough by the company's behavior that they imposed significant punitive damage awards. After a series of legal setbacks, American Home Products, the maker of two of the drugs used in fen-phen negotiated a settlement in a class-action suit. By 2005, the company (now known as Wyeth) had set aside more than \$21 billion to cover litigation costs.

The fen-phen litigation produced a picture of a drug manufacturer that underplayed the known dangers of its products and overstated their effectiveness. It also became clear that the FDA had been unable to control the situation until many patients were injured and killed by the drugs.

### Dalkon Shield

The A.H. Robins Co. brought the Dalkon Shield intrauterine device to the American market in 1970 and eventually sold 2.2 million of them in the United States. Under federal law at the time, the FDA had no authority to regulate the IUD or other medical devices. (The law was changed in 1976, partly in response to the Dalkon Shield controversy.) Unlike other IUDs, the Dalkon Shield had a multi-filament, rather than monofilament, tail that women used to remove the device. The multi-filament tail increased the risk of infections and other potentially serious medical problems, including ectopic pregnancies and septic abortions.

Reports of such injuries mounted, and at least 20 deaths were linked to the device. In 1974, Robins pulled the Dalkon Shield from the market. Thousands of women who had been injured brought lawsuits against the company. During litigation, documents emerged showing that Robins had been aware that the IUD's tail could draw bacteria into the uterus and cause infection. The company also became aware that the IUD increased the risk of spontaneous abortions, but did not alert physicians and users.<sup>64</sup>

Robins was hit with a series of large judgments, including several awards for punitive damages. In June 1987, the Kansas Supreme Court upheld a \$7.5 million punitive damage award against Robins, concluding that the company "deliberately, intentionally and actively concealed the dangers of the Shield for year after year."<sup>65</sup>

Robins filed for bankruptcy protection in 1985. The company eventually paid nearly \$3 billion to more than 200,000 women for Dalkon Shield-related claims. In 1983, nearly a decade after Robins stopped selling the device, the FDA and the Centers for Disease Control recommended that women stop using the Dalkon Shield.

<sup>62</sup> Memo dated Feb. 23, 1995, outlining market research for America Cyanamid. Memo cited by Alicia Mundy, "Dispensing with the Truth: The Victims, the Drug Companies, and the Dramatic Story Behind the Battle over Fen-Phen," 2001, St. Martin's Press, page 156.

<sup>63</sup> Memo dated Nov. 21, 1995, from Carrie Smith Cox, vice president for women's health at Wyeth. Cited by Mundy, page 155.

<sup>64</sup> Barry Siegel, "The Right Question; One Man's Effort to Tell Dalkon Story," Los Angeles Times, Aug. 22, 1985, page 1.

<sup>65</sup> Tetuan v. A.H. Robins Co., 738 P.2d 1210, 1217-18 (Kan. 1987).

<sup>61</sup> Sheryl Gay Stolberg, "Questions for Drug Maker on Honesty of Test Results," New York Times, Sept. 10, 1999, page A18.

Some who followed the cases concluded that the truth about the Dalkon Shield emerged mainly through civil court action. Morton Mintz, a *Washington Post* reporter who covered the litigation and wrote a book about the Dalkon Shield, summarized the situation in a 1985 interview:

“It has to be pointed out that the FDA, after 1974, when the device was withdrawn from sale, effectively did nothing for nine years, until 1983. Meanwhile, trial lawyers had been digging out all this evidence of increasing risk of women still wearing the damned thing.”<sup>66</sup>

### Super-absorbent tampons

The early 1980s brought to the public’s attention a new medical problem: toxic shock syndrome or TSS. The rare, bacteria-caused illness causes chills, vomiting, fever, headache, sore throat and decreased urine output, and can lead to reduced blood pressure and renal failure. Scarcely noted before, the country saw hundreds of cases of TSS reported in 1980, including dozens of fatalities. Most of the victims were women who had seen the illness begin during a menstrual period.<sup>67</sup>

Research quickly led scientists to link the spike in TSS to super-absorbent tampons that had come on the market in recent years. More research showed a particular link to Rely tampons manufactured by Proctor & Gamble. These tampons were made of polyester foam and carboxymethylcellulose, while other tampons were made of cotton and rayon. Presented with the findings, Proctor & Gamble removed Rely tampons from the market in the fall of 1980.<sup>68</sup>

In 1983, a Kansas woman named Betty O’Gilvie died from toxic shock syndrome after using Playtex super-absorbent tampons that had remained on the market after the 1980 cases of TSS. Her family filed suit against Playtex. Although Playtex included a package warning that complied with FDA standards, experts testified at the trial that mere compliance was inadequate under the circumstances. The jury awarded the family \$1.5 million in actual damages and \$10 million in punitive damages.

The 10th Circuit Court of Appeals upheld the verdict and found that “Playtex deliberately disregarded studies and medical reports linking high-absorbency tampon fibers with increased risk of toxic shock at a time when other manufacturers were responding to this information by modifying or withdrawing their high-absorbency tampons.”<sup>69</sup> After the verdict, Playtex took the product off the market and modified the TSS warning statement on its tampon packaging.

<sup>66</sup> Morton Mintz interview, cited by Elizabeth Mehren, “IUD Controversy Begets Volumes,” *Los Angeles Times*, Oct. 8, 1985, page View 1.

<sup>67</sup> U.S. Food and Drug Administration report, “Tampon Safety.” [www.fda.gov/fdac/features/2000/200\\_tss.html](http://www.fda.gov/fdac/features/2000/200_tss.html).

<sup>68</sup> FDA report, “Tampon Safety.”

<sup>69</sup> O’Gilvie v. International Playtex Inc., 609 F. Supp. 817 (D. Kan. 1985), rev’d, 821 F.2d 1438 (10th Cir. 1987), cert. denied, 108 S.Ct. 2014 (1988).

<sup>70</sup> Environmental Working Group, “Asbestos: Think Again” report. [www.ewg.org/reports/asbestos/facts/fact1.php](http://www.ewg.org/reports/asbestos/facts/fact1.php). The EWG receives most of its funding from nonprofit foundations. For this report, the group received substantial financial assistance from the Association of Trial Lawyers of America.

### Asbestos

Efforts are under way on Capitol Hill to find a global legislative settlement in the ongoing multi-billion-dollar litigation related to asbestos. Asbestos, a fire-retardant material used widely in construction, shipbuilding and other fields, has been linked to several serious, sometimes deadly diseases. Such diseases led to nearly 10,000 deaths in 2002.<sup>70</sup>

Manufacturers, doctors and public health officials were well aware of the health risks of asbestos early in the 20th century.<sup>71</sup> However, the federal government did not begin to regulate the material until 1971. Eight years later, the government proposed a ban on the substance. But manufacturers and others managed to prevent the ban from becoming a reality, and products with asbestos remain on the market.<sup>72</sup>

Some observers have sharply criticized the asbestos litigation, focusing on the high fees lawyers have collected and a number of bankruptcies the litigation has helped generate. The record does include some excesses, including cases in which some plaintiffs received awards that dwarfed those that were due to others who were more deserving.

However, we now know the true history of asbestos in this country, and that’s largely because of the work of lawyers and plaintiffs within the civil justice system who brought to light a stunning litany of corporate neglect and dishonesty about the risks of asbestos. One manufacturer maintained that it discovered the dangers of asbestos only in 1964. But, company documents that came to light during litigation showed the company was actually aware of the dangers three decades earlier—decades in which untold numbers of people were injured by the company’s products. One company memo from 1988 summarized the situation:

“The documents...show corporate knowledge of the dangers associated with exposure to asbestos dating back to 1934. In addition, the plaintiffs’ bar will probably take the position—not unreasonably—that the documents are evidence of a corporate conspiracy to prevent asbestos workers from learning that their exposure to asbestos could kill them.”<sup>73</sup>

Today, some members of Congress look for ways to limit the legal rights of those injured by asbestos. As this debate unfolds, it is imperative that the demands of manufacturers not overshadow the history that led us to the current situation, which is summarized by the Environmental Working Group, a public interest advocacy organization:

“The companies aggressively fought requests for financial or medical aid and support; they callously, and notoriously, hid unambiguous scientific evidence of asbestos exposure, injury and death. Indeed, no meaningful proposals for help of any kind were forthcoming from asbestos industries and their insurers until a handful of people, out of hundreds of thousands whose lives had been destroyed by asbestos illness and death, went to court seeking justice because they had no other choice—and began to win.”

<sup>71</sup> Barry I. Castleman, “Asbestos: Medical and Legal Aspects,” Aspen Law & Business, Fourth Edition, 1996, page 781.

<sup>72</sup> Environmental Working Group, “Asbestos: Think Again” report. [www.ewg.org/reports/asbestos/facts/fact1.php](http://www.ewg.org/reports/asbestos/facts/fact1.php).

<sup>73</sup> Memo from David T. Austern to other trustees of the Manville Personal Injury Settlement Trust, Feb. 8, 1988.

## Ford Pinto

Introduced in 1970, the Ford Pinto was a popular, affordable alternative to foreign-made compact cars. Although the Pinto met federal regulatory standards, over time a flaw in the Pinto's gas tank placement became apparent, a flaw that increased the risk of fuel tank explosions. At least 27 people died in fires attributed to the Pinto's poor fuel tank design. Litigation produced startling evidence that Ford officials knew that the Pinto's design increased the risk of explosions and fires but did not make low-cost changes that would have reduced the danger.<sup>74</sup> As the injury toll mounted, the company was hit with lawsuits as well a large punitive damage award, after a jury concluded the company was well aware of the Pinto's dangers.<sup>75</sup> One prosecutor brought criminal charges against Ford officials, but all were acquitted.

Pressure from litigation and public interest groups eventually forced the federal government in 1977 to require safety testing for rear-end collisions. The following year Ford recalled Pintos built between 1971 and 1976 to make changes in the gas tank design.<sup>76</sup>

## Legislative Proposals to Limit Lawsuits

Our civil justice system, which has stood repeatedly as a bulwark against corporate abuse, is under attack. In 2005, Congress passed and President Bush signed legislation that forces plaintiffs to bring multi-state class-action lawsuits in federal, rather than state, courts. The bill is likely to cause many cases to be dismissed; in other cases, many deserving plaintiffs will find it logistically impossible to litigate their suits in federal courts. The net result: manufacturers will probably escape responsibility for illegal or improper activity on a large scale.

Congress is considering sweeping changes in the law that governs health-care lawsuits. Supporters of these measures contend that their goal is “to improve patient access to health care services and provide improved medical care by reducing the excessive burden the liability system places on the health-care delivery system.”<sup>77</sup>

But, the legislation would dramatically rewrite the rules on many health-related lawsuits. Under consideration are caps on punitive damages in all health-care lawsuits, a new standard of evidence for punitive damages, sharply reduced time limits for filing such suits and caps on the size of non-economic awards for “pain and suffering.” Congress is also considering a provision that would prevent a judge or jury from awarding punitive damages against manufacturers of devices or drugs that the FDA approved—or medical products that are “generally recognized among qualified experts as safe and effective.” This broad prohibition would not apply in cases in which the manufacturer withheld or misrepresented data required to be submitted to the FDA, or got FDA approval by bribing agency officials.

Those two exceptions notwithstanding, the language under consideration would essentially preclude punitive damage awards against drug companies and other medical-device manufacturers that have won FDA approval for their products.

Naturally, the pharmaceutical industry and medical device manufacturers strongly support such restrictions. However, this move to limit civil awards would be a major blow to consumers and public safety. Despite complaints from manufacturers and others, the fact is that punitive damages are rarely imposed in civil cases. In many cases, judges reduce such punitive damage awards to conform with the law and the evidence presented in the case.

Even though punitive damages rarely come into play, it is crucial to allow juries and judges to have the power to impose substantial damages on respondents whose behavior is egregiously wrong or dangerous. This threat of large awards—both punitive and non-economic—has served as a potent and appropriate check on the behavior of large corporations and manufacturers. Should Congress move forward with legislation described above, large manufacturers would no longer face the prospect of significant financial punishment in the courts. Without that threat, many manufacturers will surely be emboldened to act more cavalierly toward public health. The history cited in this section should give lawmakers grave concerns about rolling back the useful protections inherent in punitive damages.

## FDA Preemption Actions

Aside from the legislative efforts, the Bush administration has taken steps to support drug and device manufacturers that are being sued for damages. In the last three years, the FDA has filed statements of interest or *amicus curiae* briefs in five private lawsuits involving drugs or medical devices, four of which were product liability suits brought by injured consumers.<sup>78</sup> The thrust of the FDA's actions is to thwart consumers from bringing civil actions in state courts against manufacturers of drugs and devices that the FDA has approved.

The FDA's aggressive push into private court proceedings was led by then-chief counsel Daniel E. Troy, who resigned in late 2004. Troy came to the agency after doing some legal work for a drug company and working for a conservative legal foundation that went to court asserting that the FDA had limited ability to regulate drugs.<sup>79</sup>

In 2002, Troy made public his intention to have the FDA participate in product liability lawsuits on behalf of manufacturers that had products approved by the agency. The goal, he said, was to protect the agency's authority to regulate drugs on a national basis and not see state courts impose conflicting rulings on drug safety.

The following year, Troy took the unusual step of reaching out to attorneys who represented pharmaceutical companies and asking them to suggest cases in which the FDA should intervene. Troy advised the lawyers that the agency could not get involved in every case and urged the lawyers to make a strong case for FDA intervention, “make it sound like a Hollywood pitch.”<sup>80</sup>

<sup>74</sup> Mark Dowie, “Pinto Madness,” *Mother Jones*, September/October 1977.

<sup>75</sup> *Grimshaw et al v. Ford Motor Co.*; 119 Cal. App. 3d 757; 1981 Cal. App.

<sup>76</sup> Public Citizen, “Examples of Defective Products Meeting Federal Standards That Proved Inadequate to Protect Consumers from Death, Injuries,” April 14, 2003.

<sup>77</sup> Preamble, HR 534, the Help Efficient, Accessible, Low-cost, Timely Healthcare Act of 2005.

<sup>78</sup> Margaret H. Clune, “Stealth Tort Reform: How the Bush Administration's Aggressive Use of the Preemption Doctrine Hurts Consumers,” October 2004, Center for Progressive Regulation white paper, page 1.

<sup>79</sup> Anne C. Mulkern, “Watchdogs or Lap Dogs? When Advocates Become Regulators,” *Denver Post*, May 23, 2004, page A1.

<sup>80</sup> Affidavit of Jessica R. Dart, in *Dusek v. Pfizer Inc.*, No. H-02-3559 (S.D. Tex. Feb. 20, 2004), available on [www.house.gov/hinchey/issues/fda2.pdf](http://www.house.gov/hinchey/issues/fda2.pdf).

Among the cases in which the FDA has intervened is *Murphree v. Pacesetter*. In that case, Gary Murphree alleged that two pacemakers manufactured and later recalled by Pacesetter caused his third-degree heart block, which can lead to a heart attack. The FDA asserted in a brief that Murphree's claim was pre-empted by federal statute; FDA lawyers argued in the brief that private tort suits would create uncertainty and chaos "for both the regulated industry and FDA."<sup>81</sup> The trial court rejected the FDA's argument, although the matter will be considered again on appeal. The FDA's brief, however, was used successfully by the manufacturer of a heart pump that was sued by the widow of a man whose death was blamed on a malfunctioning pump. In that case, *Horn v. Thoratec*, a federal appeals court sided with the FDA and ruled the lawsuit was preempted under federal law.<sup>82</sup>

The legal issue of preemption is a complicated one. However, the FDA's new push to join lawsuits on behalf of manufacturers in support of preemption represents an important shift in policy. Margaret Jane Porter, a predecessor to Troy as chief counsel at the FDA, took a far more consumer-friendly position on preemption: "Given the harsh implications of foreclosing all judicial recourse for consumers injured by defective medical devices, FDA does not believe that Congress intended to effect so sweeping a change without even a comment. Rather, the agency believes that Congress intended to restrict preemption to positive enactments (for example, legislation or regulations) that apply to the marketing of medical devices within a state, and did not intend to preempt state tort remedies for injury to individual consumers."<sup>83</sup>

Although Troy has left the FDA, the agency's position on preemption has not changed. Lester M. Crawford, FDA's director, said in 2004 that it is "wrong and severely damaging to public health" to allow state courts to contest the judgment of the FDA.<sup>84</sup>

## Problems with the Regulators

While the FDA is going to court to challenge lawsuits against manufacturers that have received approval for their products, many experts both inside and outside the agency are questioning its ability to perform adequate oversight.

A recent case involves Vioxx, the widely used pain relief medication. The FDA approved Vioxx in 1999, and its manufacturer, Merck & Co., launched an expensive, aggressive marketing campaign that secured a huge market share for the painkiller.

In 2004, news came that Vioxx may have contributed to more than 27,000 heart attacks and deaths from 1999 to 2003. Shortly after those results were made public, in September 2004, Merck pulled Vioxx from the market.

As with so many other issues of product liability, the complete story of Vioxx will likely become known only through the civil justice system. Early indications from litigation against the company show that Merck had strong early concerns about its product that were not made public. Company documents suggest that Merck officials worked aggressively for years to prevent internal safety concerns from hurting sales of the popular drug.

<sup>81</sup> Statement of Interest of the United States of America, *Murphree v. Pacesetter Inc., et al*, Tennessee Circuit Court and Tennessee Court of Appeals.

<sup>82</sup> *Horn v. Thoratec Corp.*, 376 F.3d 163, 171 n. 13, 178 (3d Cir. 2004).

<sup>83</sup> See Porter, *supra*, n.1.

<sup>84</sup> Diedra Henderson, "Award limits eyed in suits involving FDA-approved drugs," *Boston Globe*, Dec. 17, 2004.

The Vioxx controversy has prompted stinging criticism of the FDA. Testifying before Congress in November 2004, David J. Graham, a longtime FDA drug-safety officer, said that problems with Vioxx "may be the single greatest drug safety catastrophe in the history of this country or the history of the world."<sup>85</sup>

Graham added that the FDA "has let the American people down, and sadly, betrayed a public trust.... I would argue that the FDA, as currently configured, is incapable of protecting America against another Vioxx. We are virtually defenseless."

He asserted that the FDA was unable to keep some unsafe drugs off the market, and that scientists who dissented about drug safety and effectiveness were sometimes pressured and intimidated.<sup>86</sup> A survey of FDA scientists in 2002 buttressed his claims. Almost 20 percent of scientists surveyed said they had been pressured to recommend approval of a new drug despite reservations about its safety, effectiveness or quality. A majority of those surveyed had doubts about the agency's ability to monitor drugs once they are on the market.<sup>87</sup>

Sidney M. Wolfe, director of Public Citizen's Health Research Group, has closely monitored the FDA's regulatory efforts for decades and is highly critical of the FDA. The FDA, he says, "is far from doing an adequate job protecting the public from [harmful] products."<sup>88</sup> A series of dangerous drugs have been allowed on the market in recent years, he notes. At the same time, the FDA has drastically scaled back its enforcement efforts to stop misleading advertising by drug manufacturers.

"Reducing the 'regulation' of drug and device companies by lessening their liability for injuries and deaths to patients is all the more onerous in the face of such lax FDA activities," Wolfe added.

Given such warnings from Graham, Wolfe and others, it would be shameful to rely even more heavily on the FDA's ability to assess product safety, while rolling back access to the courts and appropriate tort verdicts. Yet Congress is considering doing so. The litigation reform bill pending in Congress would likely prohibit plaintiffs, for example, from collecting any punitive damages against Merck for its handling of Vioxx, because the drug was approved by the FDA. Likewise, the bill appears to limit any non-economic damage awards in such cases to \$250,000 or twice the amount of economic damages.

In other words, the administration is placing enormous faith in the agency's ability to ensure the safety of drugs and medical products. This faith is misplaced.

Many experts are calling for major changes in how the FDA monitors the safety of drugs and other products. The FDA, many assert, is mired in conflicts of interest with drug manufacturers and has become dependent on industry funding. Many of the members of a panel convened in February 2005 to consider whether to recommend allowing Vioxx and other pain pills to stay on the market had previously consulted for the drugs' manufacturers.<sup>89</sup> Ten of the 32 scientific advisers on the panel had such ties to the manufacturers; nine out of the 10 voted to

<sup>85</sup> Testimony of David Graham, associate director for science, Office of Drug Safety, Center for Drug Evaluation and Research, Food and Drug Administration, Washington, D.C., before the Committee on Finance, United States Senate, Nov. 18, 2004.

<sup>86</sup> Marc Kaufman, "Many FDA Scientists Had Drug Concerns, 2002 Survey Shows," *Washington Post*, Dec. 16, 2004, page A1.

<sup>87</sup> Kaufman.

<sup>88</sup> Testimony of Sidney M. Wolfe, M.D., before the Health Subcommittee of the House Energy and Commerce Committee, Feb. 10, 2005.

<sup>89</sup> Gardiner Harris and Alex Berenson, "10 Voters on Panel Backing Pain Pills Had Industry Ties," *New York Times*, Feb. 25, 2005.

recommend that two of the drugs be allowed to remain on the market. Their votes were particularly crucial since a majority of the remaining panel members voted not to allow the drugs to remain on the market.

Avoiding such conflicts will prove difficult under the current regulatory scheme as pharmaceutical firms pay for a large segment of the research into drugs. The pharmaceutical industry also ranks as one of the largest contributors to political campaigns. During the 2002 and 2004 campaign cycles, the pharmaceutical industry made more than \$45 million in federal contributions.<sup>90</sup>

The industry has proven adept at winning favorable legislation, including a 1992 bill that increased the agency's reliance on pharmaceutical industry funding and that led the FDA to devote far more of its budget to approving new drugs, rather than monitoring those already approved.<sup>91</sup>

In 2004, Marcia Angell—the prominent critic of breast implant litigation—wrote: “This [pharmaceutical] industry uses its wealth and power to co-opt every institution that might stand in its way, including the U.S. Congress, the Food and Drug Administration, academic medical centers, and the medical profession itself.”<sup>92</sup>

Given the history of drug manufacturers, Angell said the government needs a new, independent agency within the National Institutes of Health—not part of the FDA—to test prescription drugs against each other independently of manufacturers.

Some lawmakers, including Sen. Charles Grassley, a Republican from Iowa, support the creation of an office of drug safety that is independent of the FDA. Sen. Edward M. Kennedy, D-Mass., is working on legislation to strengthen the FDA's drug-safety efforts.

Despite such concerns both within and outside the agency, the Bush administration initially resisted major reforms at the FDA. In December 2004, then White House Chief of Staff Andrew Card said the FDA was doing a “spectacular” job and should “continue to do the job they do.”<sup>93</sup>

However, in February 2005 the administration responded to the growing criticism by announcing several changes in the FDA's operations.<sup>94</sup> First, the FDA created an independent Drug Safety Oversight Board that will examine research that involves drugs already on the market. The panel is made up of FDA officials, as well as scientists from other government agencies. The FDA also announced it would begin using large databases maintained by managed care organizations to better monitor the effects of drugs in the market—a step that experts outside of the FDA have long advocated.

While some observers said these moves represent progress, others were skeptical. One vocal critic of the FDA, Rep. Maurice Hinchey, Democrat from New York, called the new oversight board a farce because it would remain within the FDA's drug safety office and would include officials from the FDA, the same agency that will have approved all drugs on the market.

“The real problem with the FDA is that it remains far too closely tied to the pharmaceutical industry,” he said. “The entire culture at the FDA needs to change and that is not something a fake ‘independent’ panel can fix. It would be an absolute shame if the FDA uses the cover of this new oversight board as an excuse to avoid making fundamental reforms that would create real, independent oversight at the agency.”<sup>95</sup>

It will require considerable time to carry out the changes, and it will take far longer to assess whether they will lead to more effective scrutiny of drugs and medical products, either before or after they receive initial approval. Even if these changes do lead to more effective scrutiny of drugs and medical devices, they would remain only part of the answer.

The civil justice system will continue to play a vital role in both obtaining compensation from those who are injured and in forcing manufacturers to provide a full accounting of their products. Policy-makers must ensure that nothing is done to limit the courts' ability to monitor and enforce appropriate behavior on powerful and well-connected industries.

Alicia Mundy, who has written extensively about the civil justice system, concludes: “The average American needs the chance to bring civil suits because government—systematically over the last decade—has stopped protecting us. When corporate front groups complain about ‘regulation by lawsuit,’ they are right: Without lawsuits, the government's weakened rules do a poor job of guarding against bad drugs, bad doctors, corporations that shortchange their shareholders and pension funds, rollover cars, exploding tires, unstable buildings, poisonous waste, and undrinkable water. So it's true: Trial lawyers have become the regulators of last resort. They are the only sheriffs left in town.”<sup>96</sup>

<sup>90</sup> The Center for Responsive Politics, [www.opensecrets.org](http://www.opensecrets.org).

<sup>91</sup> Gardiner Harris with John Schwartz, “Strong Drug Ties and Less Monitoring,” *New York Times*, Dec. 6, 2004, page 1.

<sup>92</sup> Marcia Angell, “The Truth About the Drug Companies: How They Deceive Us and What to Do About It,” Random House, 2004.

<sup>93</sup> Quoted by Marc Kaufman, “White House Defends FDA as Drug Safety Debate Looms,” *Washington Post*, Dec. 20, 2004, page A2.

<sup>94</sup> FDA Fact Sheet, Feb. 15, 2005, “FDA Improvements in Drug Safety Monitoring.”

<sup>95</sup> Statement by Rep. Hinchey, Feb. 15, 2005. [www.house.gov/hinchey/](http://www.house.gov/hinchey/).

<sup>96</sup> Alicia Mundy, “The Good Guys: Tort reformers complain about ‘frivolous’ lawsuits. But at a time when government has stopped protecting citizens, trial lawyers have become the regulators of last resort,” *The American Prospect*, November 2004, page 25.

## 3. CONCLUSION

The silicone-gel breast implant saga was a painful one for many women. While some things remain in dispute about the long-term risks of implants, some key facts have become clear.

- A product that has never been established as safe was brought to market and sold to more than a million women.
- Manufacturers repeatedly expressed doubts—privately—about implant safety, but assured the public that they were safe.
- Despite mounting complaints from women and physicians, federal regulators took nearly 30 years to require implant manufacturers to provide research showing the safety of their products, something the manufacturers were unable to do.
- Silicone-gel implants cause a significant number of localized, often serious complications.
- A significant number of implant recipients must have second or third surgeries to deal with problems. Many more women experience painful scarring, disfigurement and other symptoms from their implants.
- The risk of implant rupture increases over time.
- A significant number of women have developed a range of serious connective-tissue disorders, some of them debilitating. Some research has suggested that the ailments are associated with silicone from leaky implants; other research shows no connection. Long-term studies are ongoing.

It was through the civil justice system that the public—and, in turn, federal regulators—finally came to know the full story of implants and how their manufacturers dealt cavalierly with women’s health. While observers have raised important questions about some of the scientific evidence used in breast implant litigation, the overall record in the matter constitutes a victory for consumers and public safety.

### Maintaining Access to the Courts

The breast implant case is one of many in which the civil justice system has taken the lead in exposing the risks and dangers of consumer products—everything from diet pills to defibrillators—that were on the market legally but were harming consumers. Civil courts remain the primary avenue for protecting the rights of ordinary consumers who have been harmed and for holding manufacturers and others accountable for the damage they inflict on the public.

As efforts continue in Congress, state capitals and courthouses to limit access to the courts, policy-makers must bear this history in mind. The products cited previously in this report and elsewhere met federal regulatory standards; however, each also caused grave harm or deaths to consumers. In some cases, manufacturers failed to follow up on in-house concerns; in others, companies ignored such warnings and misled the public. We can say with certainty that, despite the efforts of federal regulators, unsafe products do make it onto the market. Recent news about Vioxx and other medical products confirms this.

Consider the history of a defibrillator sold by Access Cardiosystems of Concord, Mass. In early 2004, a former official of the company alerted the FDA that the company had been shipping potentially defective units. FDA inspectors toured the manufacturing site but found no major defects and cleared the company of serious problems. However, later in the year, complaints about the devices mounted, including deaths possibly associated with them. In one, a fisherman suffered a heart attack while on a boat in the Pacific Ocean. The defibrillator on board the boat, manufactured by Access Cardiosystems, malfunctioned and the man died. The company eventually forwarded information about that death and other serious complaints regarding the devices to the FDA, but the agency did not re-open its investigation. In November, the company recalled all of the defibrillators it had manufactured.<sup>97</sup>

Ideally, the FDA would have spotted the problems with the defibrillators and removed them from the market at the first sign of trouble. In this case, the agency did not, and consumers have apparently suffered significant injuries.

Despite the FDA’s record dealing with the types of defective products noted in this report, some elected officials seek now to limit the public’s access to the courts, citing the need to protect manufacturers from excessive litigation. One key focus would be to prohibit some suits or limit damages in cases in which a product has won federal regulatory approval—cases that conceivably could include Vioxx and Cardiosystems’ defibrillator.

Limiting access to the courts for people injured by dangerous products violates the nation’s fundamental sense of equity. More broadly, limiting civil litigation may well encourage a cold-hearted corporate calculus, in which manufacturers sacrifice a degree of public safety for higher profits, confident that litigation costs can be managed and profits maintained. This is not a cynical indictment of private enterprise, merely a reflection of documented cases of corporate decision-making.

Whatever the excesses of the civil justice system, the nation must not lose sight of the crucial role it plays ensuring that the public has a place to take its claims. This is a fundamental notion that has served the nation well and deserves to be protected, not eviscerated.

Daniel Swartzman, a lawyer and public health professor at the University of Illinois-Chicago, framed the issue this way:

“If I had to choose, I’d prefer to have a court system that every once in a while costs us a god-awful amount of money that we shouldn’t have had to pay but which overall might keep us from dying. Tort liability acts as a safeguard. And over time, the system self-corrects.”<sup>98</sup>

<sup>97</sup> Barry Meier, “Flawed Device Places F.D.A. Under Scrutiny,” *New York Times*, Dec. 15, 2004.

<sup>98</sup> Quoted by Mike Tolson, “Implants Left Bitter Legacy of Health vs. Money; Silicone Legal War Lingers,” *Houston Chronicle*, Nov. 2, 2003, page A29.

## **About the Report**

This report was prepared as a project of Alliance for Justice. Tom Waldron, a writer in Baltimore and the former State House bureau chief for The (Baltimore) Sun, wrote the report. At Alliance for Justice, Sandra Benson Brantley, legislative counsel, provided editorial supervision.

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