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The Breast Implant Controversy: A Prism for Reform*

Benson Yang**

Introduction

The breast implant controversy is worthy of reflection because it probes and tests the connections between so many levels of contemporary American society. The debate is symbolic of a wave of technophobia that has infected the nation in the latter half of the twentieth century, especially with regard to modern medicine. Silicone, by virtue of being a foreign chemical, and autoimmune disease, by virtue of being a vaguely understood affliction, have combined to stir much public anxiety. Since the first clamors of unrest, the controversy has mushroomed to involve millions of women and billions of dollars. Yet, to this day, no valid research study has shown a positive correlation between silicone implants and any rare diseases.¹ But claiming that the breast implant controversy was merely about the safety of a small fluid-filled bag is oversimplistic. The central issue has drifted far from questioning the safety of the implants to what has contributed to the snowballing of this seemingly uncomplicated matter. This paper addresses the failures of existing regulatory and legal mechanisms as specifically applied to the breast implant debate, but also pertinent to a much wider spectrum of toxic tort cases which have become commonplace with the advent of novel materials and technologies. The breast implant controversy is, at its very core, about two uneasy relationships — one between the government and the people, the other between science and the courts.

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¹ Esther Janowsky, Lawrence Kupper, & Barbara Hulka, *Meta-Analyses of the Relation Between Silicone Breast Implants and the Risk of Connective-Tissue Diseases*, 342 *New Eng. J. Med.* 781 (2000).

The Government and the People

Despite their prevalence since the 1960s, silicone breast implants did not fall within the jurisdiction of the Food and Drug Administration (FDA) until Congress amended the federal food and drug statutes in 1976.² Since the amendment was not retroactive, breast implants were grandfathered, meaning that manufacturers of implants prior to 1976 were not required to furnish evidence of product safety and effectiveness.³ With questions about the safety and efficacy of implants slowly mounting, the FDA assembled an advisory panel to review existing data on silicone implants in 1991. David Kessler, then Commissioner of the FDA, proclaimed that, “the standard for implanted devices is not, Let the buyer beware,” and instituted a ban on breast implants.⁴ The availability of implants for reconstructive purposes following cancer or other deforming surgeries would not be hampered, but their availability for cosmetic purposes would be drastically limited.⁵ Since there had been no conclusive evidence to suggest that implants were harmful, women with existing implants were instructed to leave them in place. The FDA believed that the risk of surgical removal and the attendant anesthetic risk was far greater than the yet-undefined risk of leaving the devices intact. The legal basis for Kessler’s decision was incontrovertible: “the law requires a positive demonstration of safety and the burden of proof rests squarely with the manufacturer.”⁶ Nevertheless, legality rarely implies prudence; perhaps the FDA should have considered a range of alternatives before delivering such a shock to the American public.

In the face of uncertainty, the FDA thought it best to make a conservative decision that erred on the side of safety. The rationale was that if silicone breast implants were indeed found to be linked to autoimmune disease, a preemptive ban could potentially save many lives in the interim; alternatively, if implants were found to be safe, a

² Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-392 (1998).

³ David Kessler, *The Basis of the FDA’s Decision on Breast Implants*, 326 New Eng. J. Med. 1713 (1992).

⁴ W.S. Hein, Remarks at the Meeting of the Food and Drug Administration, General and Plastic Surgery Devices Panel (Feb. 18-20, 1992).

⁵ Kessler, *supra* note 3.

⁶ *Id.*

temporary ban would only delay an elective procedure. Had Kessler decided otherwise, he might have jeopardized lives and betrayed the mission of the FDA. Not surprisingly, the message that the FDA sent to the million or so women with existing implants was unsettling. For these women, the implication of the ban was that silicone implants were sufficiently dangerous enough to warrant a retraction from the market. Predictably, the FDA's reassurances that the implants had not been proven to be harmful were of no consolation. Mixed messages from agencies charged with the responsibility of protecting public health are generally not taken lightly by the public. Stephen Breyer notes, "the word uncertainty itself implies risk; the denial therefore carries a kind of self-refutation that does not alleviate public concern."⁷ The fact that silicone, an abstruse chemical in the public's eye, was at stake only compounded consternation. Many women, fearing the worst, fled to their plastic surgeons to have their implants immediately removed. Mass fear inspired mass litigation. In the first two years following the ban, Dow Corning was named in 20,000 lawsuits.⁸

The FDA has also been accused of harboring a double-standard by allowing silicone gel-filled implants for reconstructive purposes and prohibiting their use for cosmetic reasons. In his statement to *The New England Journal of Medicine*, Kessler stated that, "these restrictions on the use of silicone-gel implants for breast augmentation are not based on any judgment about values."⁹ Yet, an analysis of how the risk-benefit ratio was derived shows otherwise. There was generally little debate that the benefits of implants outweigh the risks for cancer patients; for many women, the availability of reconstructive surgery was the deciding factor in their choice to undergo cancer therapy. But the risk-benefit equation is more complicated concerning breast implants for purely augmentative purposes. The risks included the uncertain effects of silicone gels in the body and their potential to cause autoimmune diseases. For reconstructive cases, "women are using implants in diseased or deformed breasts as part of their treatment"; for augmentative cases, "women for cosmetic reasons alone are risking

⁷ Stephen Breyer, *Breaking the Vicious Circle: Toward Effective Risk Regulation* (1993).

⁸ Marcia Angell, Address at the Yale University School of Medicine Phyllis Bodell Memorial Lecture (Nov. 6, 1997).

⁹ Kessler, *supra* note 3.

healthy breasts.”¹⁰ The FDA took the position that there were no clear physical benefits to receiving implants and therefore the risks clearly outweigh the benefits. Yet the lack of physical benefits is not equivalent to the lack of health benefits; there are well documented psychological benefits for women who have had their breasts augmented. In effect, the FDA unwittingly placed itself in the awkward and paternalistic role of arbitrating the merits of women’s choices.

If silicone gel-filled breast implants had been fully proven to cause autoimmune disease or other harms, a ban would have been appropriate and necessary. This was not the case. The FDA’s decision to partially ban a device whose risk was largely uncharacterized was a mistake. Women who desired augmentation mammoplasty were not the only ones to question the logic of the FDA’s decision. Breast cancer patients, many of whom had compromised immune systems and were more prone to disease, must have wondered why implants were not safe for healthy women but were safe for them.

The FDA, whose decisions wield immense power over public reaction, must be definitive in its regulatory choices. In cases when partial bans are necessary, the FDA should assume the responsibility to fully educate the public about the rationale behind its decision. Furthermore, regulation should be a cooperative enterprise; granted that experts are more qualified to judge the technical merits of devices, they also must not ignore public sentiments and concerns. This is not to say that the FDA should never regulate substances and devices that have not been well studied; on the contrary, the FDA has the responsibility to act upon legitimate suspicions. But if the agency is to send the public into a frenzy, it must do so only if it believes that emerging evidence will support its conservative stance. The successful thirty-year history of breast implants should have commanded significantly more research before deciding to ban them.

One can argue that the cause of the entire silicone gel-filled breast implant controversy was not faulty logic on the side of the regulators but a lack of communication of this logic to the public. The mad rush to have implants removed after the FDA’s ban is a prime example of how a federal agency, in trying to reduce risk, actually increased risk.

¹⁰ Philip Hiltz, *F.D.A. Restricts Use of Implants Pending Studies*, N.Y. Times, April 17, 1992, at A1.

Had women with existing implants been properly informed, they could have weighed the relative risks themselves. As a regulatory agency, the FDA must make its data and its decision-making process transparent to the population that it hopes to protect. Kessler did not seem overly alarmed when he explained the basis of his decision in *The New England Journal of Medicine*; after all, breast implants had not been shown to cause systemic diseases, and there were many proven toxic substances which warranted more alarm. Why then did such a seemingly benign move send shockwaves across the nation? In his article, Kessler used words like “risk-benefit ratio” over and over again but never really explained how this calculation was made. Likewise, he referred to “unknown” risks but never presented existing evidence that may have dispelled some of the unwarranted fears that were worrying women with breast implants.

As Paul Slovic noted that: “[R]isk communication and risk management efforts are destined to fail unless they are structured as a two-way process. Each side, expert and public, has something valid to contribute. Each side must respect the insights and intelligence of the other.”¹¹ In the future, the FDA and other regulatory agencies must be more cognizant of underlying societal forces as well as public perceptions that may be perturbed by regulation. They must foster more comprehensive dialogue with the public; the ensuing relationship will enlighten each side as to the concerns of the other.

Effective risk communication, particularly with regard to uncertain risks, can be challenging. People have numerous sources of information, each with varying degrees of appeal and validity (often related in an inverse manner). Unfortunately, appeal is generally the decisive factor for public acceptance. The FDA’s choice to publish a bland statement in a scientific journal is not merely unappealing but aims at convincing only an elite subpopulation. There is no doubt that evaluating the risks associated with silicone gel-filled breast implants is a complex and controversial matter, but the FDA should not have summarily dismissed the lay majority as incapable of understanding the basis of its conclusions. Though the risks of breast implants were not established at the time of the FDA ban, experts could have reasonably compared their

¹¹ Paul Slovic, *Perception of Risk*, 236 *Science* 280 (1987).

potential risks to those of other products. Then, the agency should have made an attempt to publicly and firmly elucidate its position. If Kessler had arranged for adequate media exposure, his message would have been regarded by a much larger audience. Americans, as consumers, have good claim to be educated about products that are on the market. Cass Sunstein has stated, “we have tended to ... regulate first, educate only in exceptional cases.”¹² Not only is “command-and-control” regulation undemocratic, but it promotes public anxiety instead of public health.

The inability of the FDA to provide a clear statement is only an aspect of a much larger problem — random agenda selection. Although there was insufficient information to quantify the exact risk of contracting autoimmune disease from silicone gel-filled breast implants, the agency could have reasonably surmised that the risk would have been very low given the thirty-year history of implants in America. One may question the justification for banning implants when over 400,000 people a year die from cigarette smoking.¹³ Kessler fell prey to media pressures, and his good intentions needlessly caused widespread public hysteria. Regulatory agencies, including the FDA, have long been inclined to random agenda selection. Concerning environmental agencies, Breyer has written:

Agency priorities and agendas may more closely reflect public rankings, politics, history, or even chance ... one cannot find any detailed federal governmental list that prioritizes health or safety risk problems so as to create a rational, overall agenda — an agenda that would seek to maximize attainable safety or to minimize health-related problems.¹⁴

Regulatory agencies should consider devising a systematic index for risk that would apply universally in evaluating dangerous substances or devices. The most straightforward method would be to sequentially regulate those substances which have the largest risk population and which have been clearly characterized as harmful. Another method would be to sequentially regulate those substances which are the most

¹² Cass Sunstein, *Informing America: Risk, Disclosure, and the First Amendment*, 20 Fla. St. U. L. Rev. 21, 65 (1993).

¹³ Michael McGinnis & William H. Foege, *Actual Causes of Death in the United States*, 270 J. Am. Med. Ass’n 2207.

¹⁴ Breyer, *supra* note 7.

toxic and which threaten a significant risk population. Whatever methodology for prioritization is deemed appropriate, regulation must be executed from the top down. The list of goals cannot be dictated by media frenzy or special interests. Only with a clear and structured set of regulatory targets can the FDA attain the strict objectivity required to evaluate the most pressing needs of public health.

Science and the Courts

The federal government created regulatory agencies to monitor and prevent product-related injuries. As discussed above, the efficacy of these agencies has been compromised by politics and lobbying, especially by large corporations. Courts are better insulated from such corrupting influences and have played a significant role in regulation through product liability cases. Most dangerous products and toxic substances were first exposed in individual tort cases before attracting federal regulatory attention. Private litigation is particularly effective because a manufacturer guilty of designing and marketing an injurious product may be forced to pay substantial compensatory and punitive damages to the injured. The repercussions of losing weighty cases on profits and insurance premiums are reason enough for manufacturers to strive for higher safety standards. Even the mere threat of product-liability litigation has been sufficient to induce better product designs.¹⁵ In theory, civil litigation is a potent and effective stimulant for social change. In practice, however, this system is capricious at best and ineffective in general. Companies have struggled because “[t]he federal structure of the U.S. legal system operates to the disadvantage of manufacturer-defendants. A decision in a particular state benefits all plaintiffs attorneys in that state and harms manufacturers in all states since any manufacturer whose products are sold in a state may be sued there.”¹⁶ In many instances, well-meaning manufacturers have been brought to their knees and invested in defensive measures rather than safety innovations.¹⁷

¹⁵ Stephen Teret & Michael Jacobs, *Prevention and Torts: The Role of Litigation in Injury Control*, 17 *Law, Med., and Health Care* 17 (1989).

¹⁶ Paul Rubin & Martin Bailey, *The Role of Lawyers in Changing the Law*, 23 *J. Legal Stud.* 807 (1994).

¹⁷ Peter Huber, *Liability: The Legal Revolution and Its Consequences* (1988).

The plaintiffs' bar and consumer advocacy groups have called for an FDA ban on silicone gel-filled breast implants for some time. Even before the debate intensified, lawyers' groups actively solicited women as potential plaintiffs in lawsuits against implant manufacturers. Attorneys placed advertisements and sought to represent women who experienced even the slightest problems with their implants. The announcement of the FDA ban only spurred more frightened and angry women to sue for damages. Those who had only minor problems with their implants began to wonder whether they were plagued by something more serious. In the 30 years that silicone gel-filled breast implants were available before the FDA ban, Dow Corning was the target of approximately 200 lawsuits; in each of the two years after the ban, Dow Corning faced 10,000 cases.¹⁸ In 1994, a class action suit concluded with the largest settlement in history.¹⁹ Manufacturers were to contribute \$4.25 billion for implant recipients claiming to have autoimmune diseases, for implant recipients who develop symptoms for autoimmune diseases over the next 30 years, and for implant recipients claiming emotional distress. When Dow Corning, the largest contributor to the settlement, filed for Chapter 11 bankruptcy in May 1995, the settlement fizzled, and a revised settlement was drafted.

The plaintiffs' bar has greatly contributed to repeatedly inundated judicial systems and ruined industries. Particular to the American legal system is the use of contingency fees as a method of compensation, presumably to accommodate those who cannot afford attorneys' fees. As a result, plaintiffs' lawyers commonly receive one-third of each monetary award. The banning of silicone gel-filled breast implants represented a windfall for plaintiffs' attorneys in terms of lawsuits against implant manufacturers. Contingency compensation, coupled with unusually large awards, created strong incentives both for women with breast implants and for attorneys to sue. Manufacturers, knowing that losing just a few large cases in court could ruin them, were at the complete mercy of plaintiffs' lawyers and were often forced to settle even weak cases out of court. Instead of honest representation, the current system allows greed and corruption to reign. The elimination of

¹⁸ Angell, *supra* note 8.

¹⁹ Gina Kolata, *Details of Implant Settlement Announced by Federal Judge*, N.Y. Times, April 5, 1994, at A16.

contingency fees, as is the standard in other countries, might alleviate the problem at hand but has come across significant resistance in the past. Reduction of the contingency-fee percentage paid to attorneys is also likely to be ineffective, if not counterproductive, as lawyers could simply solicit more clients or demand greater damage awards in court.

Instead of reformulating the contingency fee system, reform should begin with the standardization of damage awards. At present, “[j]ury-determined damage awards are varied. Even when judges determine damage awards, results are varied. Results differ based on judge or jury makeup, based on who the parties are, and based on who the lawyers are.”²⁰ If the legal system were to institute a schedule of payments, much abuse would be avoided. Certainly, arguments can be made concerning the uniqueness of each case and the right for each person to be tried as an individual. But when a jury awards \$25 million to a woman whose claims were weak and unsubstantiated,²¹ there is need for reform. Categorization of damage awards does not disregard legitimate claims, but serves to ensure justice by protecting the defendant from conceivable excesses.

A second reform measure is the redirection of punitive damages away from the plaintiff, especially when it can be skimmed by contingency-fee lawyers. In breast implant litigation, these awards have been unusually large and, as such, have been virtual gold mines for profit-seeking attorneys. By definition, compensatory damages compensate for the losses experienced by the plaintiff. In the Western legal tradition, it has long been accepted that punishment should be exacted by a body of laws, not by individuals seeking to turn misfortune into windfall. From this, it follows that punitive damages should be awarded to the government, not to the plaintiff. Regulatory agencies could then use these awards to fund programs which would ensure the continued integrity of manufacturers and their products.

At a more ideological level, the breast implant controversy has again illuminated the ineptitude of courts to evaluate scientific theories and findings. In the current system, the plaintiff's burden is to convince the

²⁰ Katharine Baker, *Consorting with Forests: Rethinking Our Relationship to Natural Resources and How We Should Value Their Loss*, 22 *Ecology L. Q.* 677, 718 (1995).

²¹ See, e.g., *Johnson v. Bristol-Myers Squibb Co.*, No. 91-021770 (Tex. Dist. Ct., Harris County Dec. 23, 1992) (jury verdict for plaintiff who claimed silicone from ruptured implant caused wide array of illnesses).

jury that the defendant's product caused or was a substantial factor contributing to her harm. Exactly how this is done, with respect to admissibility of scientific evidence or expert testimony, has been the target of much speculation. In 1923, *Frye v. United States* established that "the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs."²² This decision set forth "general acceptance" as a standard for expert testimony and effectively barred unsubstantiated claims from juries. It shifted the responsibility of judging scientific methods and results from the jury to the scientific community. By requiring a consensus, *Frye* protected the legal system from admission of any expert, particularly adherents of "junk science," to the courtroom. Critics claimed that *Frye* barred novel and groundbreaking theories and unnecessarily withheld deserved compensation for those who have been harmed until a consensus developed. In 1975, the Federal Rules of Evidence established that admissibility of evidence into federal courts did not require a general consensus among the scientific community. Rule 702 authorized scientific testimony when "it will assist the trier of fact to understand the evidence or to determine a fact in issue."²³ In effect, the Federal Rules of Evidence facilitated the return of junk science. In breast implant litigation, plaintiffs' attorneys were able to call experts who propounded wild theories that implicated silicone gel as the cause of a wide array of systemic diseases.

In 1993, the Supreme Court's ruling in *Daubert v. Merrell Dow Pharmaceuticals* offered an important interpretation of Rule 702.²⁴ The decision authorized judges to act as evidentiary gatekeepers by deciding the reliability and relevance of experts' testimonies. Judges were to examine only the "scientific validity" of an expert's "principles and methodology," not the persuasiveness of his conclusions. In essence, the quality of evidence was to be assessed as the primary determinant of admissibility. *Daubert* offered a more conservative interpretation of the Federal Rules of Evidence, but still evades the fundamental

²² *Frye v. United States*, 293 F. 1013, 1014 (1923).

²³ Fed. R. Evid. 702.

²⁴ *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993).

dilemma of requiring lay juries and lay judges to make judgments on technical issues. In traditional tort cases, jurors are as effective in evaluating evidence as any expert. Their role is to determine whether there was or was not a wrong inflicted upon the plaintiff by the defendant; usually a straightforward evaluation of the evidence yields an answer. But when technical issues are involved, evaluation can be confounded by inexperience or ignorance. Years of training are required to fully understand the implications and limitations of even a simple epidemiological study; a lay juror cannot make an informed judgment when the results of such studies are briefly presented to him. If the American tort system is to be effective in judging technical matters, it cannot subject science to lay persons who often are easily swept by passions as opposed to scientific evidence. Foster et al. have suggested that legal professionals become more informed about current consensus in science and about technical issues involved in risk research.²⁵ However, these improvements would still leave scientific evidence to non-expert intermediaries.

Consulting an expert panel in lieu of a jury for cases revolving around technical issues, though not an infallible solution, will represent a great step towards remedying the present travesty. The notion of a "science court" has arisen with regard to several toxic tort cases and, more recently, with regard to breast implant litigation. The difficulty with evaluating technical evidence in the courtroom concerns the incongruity between scientific and legal discovery. Whereas research treads incrementally, critically, and consensually, trials move rapidly, capriciously, and adversarially. Lay jurors struggle with understanding scientific evidence, let alone perceiving its relevance after courtroom contortions. The main shortcoming of *Daubert* is that it views judges as informed gatekeepers when, in fact, they are often no more qualified than their juries in matters of science. Shifting the burden of competence from juries to judges does not ameliorate the situation; rather, it beckons the return of junk science. A scientific panel composed of representatives from specialties pertinent to the case at hand, as well as experts who can contribute a broader viewpoint, is essential to arrive at a critically reasoned judgment. In cases concerning

²⁵ Kenneth Foster, David Bernstein, & Peter Huber, *Science and the Toxic Tort*, 261 *Science* 1509 (1993).

claims that have not been well appraised by the scientific community, as was true of breast implant litigation, epidemiologists are vitally needed to evaluate any existing data. Their universal absence from breast implant trials reaffirms the current system's inability to distinguish and pursue relevant testimony. As is true of any set of individuals, personal biases are likely to preclude purely objective conclusions. Nevertheless, judgments made by those who can appreciate the complexities of the issues involved are certain to be worthier than those which are made by a lay jury.

Conclusion

The notion that a breast implant, a bag weighing but a few ounces, could cause turmoil in so many contexts is ironic if not sobering. Nevertheless, the silicone gel-filled breast implant controversy is representative of the influence of science and medicine on late 20th century America. The introduction of novel substances and advanced devices will likely continue with an ever-expanding pool of scientific knowledge. More and more, we will have to rely on others who have the expertise to evaluate such products. Undoubtedly, we will also hear from those who are less qualified. As we move forward, we must remember the lessons from the breast implant controversy, as well as a dozen other similar experiences that have already been forgotten. The breast implant controversy has truly been a prism for reform, if only we have eyes to see.

